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THE WHITE HOUSE

WASHINGTON

December 29, 1982

MEMORANDUM FOR FRED F. FIELDING

FROM: JOHN G. ROBERTS *JGR*

SUBJECT: Enrolled Bill S. 1364 - Relief of
Jose Ramon Beltron Aiveda Ostler

Richard Darman has requested comments by close of business today, December 29, on Enrolled Bill S. 1364, a private relief bill sponsored by Senator Hatch. S. 1364 would deem Jose Ostler to be a child within the meaning of § 101(b)(1)(E) of the Immigration and Nationality Act, in effect granting him permanent residence status. He was adopted at age 15 in 1978 by the Ostlers, but the Act sets a maximum adoption age of 14 for purposes of being classified as an immediate relative for immigration purposes. The bill also specifies that no natural relatives of Jose can derive "piggyback" benefits from his special legislation. OMB recommends approval; INS and State interpose no objection.

I have reviewed the memorandum to the President from James Frey, Assistant Director of OMB for Legislative Reference, and the bill itself. I see no legal objection, and have prepared a memorandum to Darman to that effect for your signature.

Attachment

THE WHITE HOUSE

WASHINGTON

December 29, 1982

MEMORANDUM FOR RICHARD G. DARMAN
ASSISTANT TO THE PRESIDENT

FROM: FRED F. FIELDING *Orig. signed by FFF*
COUNSEL TO THE PRESIDENT

SUBJECT: Enrolled Bill S. 1364 - Relief of
Jose Ramon Beltron Aivenda Ostler

Counsel's Office finds no objection from a legal perspective
to the above-referenced enrolled bill.

FFF:JGR:dgh 12/29/82

cc: FFFielding
VGRoberts
Chron
Subj

THE WHITE HOUSE

WASHINGTON

December 29, 1982

MEMORANDUM FOR RICHARD G. DARMAN
ASSISTANT TO THE PRESIDENT

FROM: FRED F. FIELDING
COUNSEL TO THE PRESIDENT

SUBJECT: Enrolled Bill S. 1364 - Relief of
Jose Ramon Beltron Aiveda Ostler

Counsel's Office finds no objection from a legal perspective to the above-referenced enrolled bill.

THE WHITE HOUSE

WASHINGTON

December 29, 1982

MEMORANDUM FOR RICHARD G. DARMAN
ASSISTANT TO THE PRESIDENT

FROM: FRED F. FIELDING
COUNSEL TO THE PRESIDENT

SUBJECT: Enrolled Bill S. 1364 - Relief of
Jose Ramon Beltron Aiveda Ostler

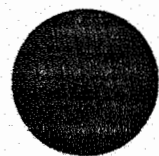
Counsel's Office finds no objection from a legal perspective
to the above-referenced enrolled bill.

FFF:JGR:aw 12/29/82

cc: FFFielding
JGRoberts
Subj.
Chron

WHITE HOUSE CORRESPONDENCE TRACKING WORKSHEET

- O - OUTGOING
- H - INTERNAL
- I - INCOMING



Date Correspondence Received (YY/MM/DD) 1 1

Name of Correspondent: Richard G. Warman

MI Mail Report User Codes: (A) _____ (B) _____ (C) _____

Subject: S. 1364 - Relief of Jose Ramon Beltrán
Aiveda Ostler

ROUTE TO:

ACTION

DISPOSITION

Office/Agency (Staff Name)	Action Code	Tracking Date YY/MM/DD	Type of Response	Completion Date YY/MM/DD
<u>CU Holland</u>	ORIGINATOR	<u>82/12/28</u>		<u>1 1</u>
<u>CUAT 18</u>	Referral Note: <u>D</u>	<u>82/12/28</u>		<u>S 82/12/29</u>
	Referral Note:	<u>1 1</u>		<u>1 1</u>
	Referral Note:	<u>1 1</u>		<u>1 1</u>
	Referral Note:	<u>1 1</u>		<u>1 1</u>
	Referral Note:	<u>1 1</u>		<u>1 1</u>

ACTION CODES:

- | | |
|---|--|
| A - Appropriate Action | I - Info Copy Only/No Action Necessary |
| C - Comment/Recommendation | R - Direct Reply w/Copy |
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to be used as Enclosure | X - Interim Reply |

DISPOSITION CODES:

- | | |
|--------------------------|---------------|
| A - Answered | C - Completed |
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FOR OUTGOING CORRESPONDENCE:

- Type of Response = Initials of Signer
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Comments: _____

Keep this worksheet attached to the original incoming letter.
 Send all routing updates to Central Reference (Room 75, OEOB).
 Always return completed correspondence record to Central Files.
 Refer questions about the correspondence tracking system to Central Reference, ext. 2590.

WHITE HOUSE STAFFING MEMORANDUM

DATE: 12/28/82 ACTION/CONCURRENCE/COMMENT DUE BY: c.o.b. 12/29/82

SUBJECT: S. 1364 - RELIEF OF JOSE RAMON BELTRON AIVEDA OSTLER

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input type="checkbox"/>	<input type="checkbox"/>	FULLER	<input type="checkbox"/>	<input type="checkbox"/>
MEESE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	GERGEN	<input type="checkbox"/>	<input type="checkbox"/>
BAKER	<input type="checkbox"/>	<input checked="" type="checkbox"/>	HARPER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DEAVER	<input type="checkbox"/>	<input type="checkbox"/>	JENKINS	<input type="checkbox"/>	<input type="checkbox"/>
STOCKMAN	<input type="checkbox"/>	<input type="checkbox"/>	MURPHY	<input type="checkbox"/>	<input type="checkbox"/>
CLARK	<input checked="" type="checkbox"/>	<input type="checkbox"/>	ROLLINS	<input type="checkbox"/>	<input type="checkbox"/>
DARMAN	<input type="checkbox"/> P	<input checked="" type="checkbox"/> SS	WILLIAMSON	<input type="checkbox"/>	<input type="checkbox"/>
DOLE	<input type="checkbox"/>	<input type="checkbox"/>	VON DAMM	<input type="checkbox"/>	<input type="checkbox"/>
DUBERSTEIN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	BRADY/SPEAKES	<input type="checkbox"/>	<input type="checkbox"/>
FELDSTEIN	<input type="checkbox"/>	<input type="checkbox"/>	ROGERS	<input type="checkbox"/>	<input type="checkbox"/>
FIELDING	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

Remarks:

Please provide any comments/recommendations by c.o.b. tomorrow, 12/29.

Thank you.

Richard G. Darman
Assistant to the President
(x2702)

Response:



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

DEC 28 1982

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill S. 1364 - Relief of Jose Ramon Beltron
Aivenda Ostler
Sponsor - Sen. Hatch (D) Utah

Last Day for Action

January 3, 1983 - Monday

Purpose

Grants permanent residence status to the adopted son of citizens of the United States.

Agency Recommendations

Office of Management and Budget	Approval
Immigration and Naturalization Service	No objection
Department of State	No objection

Discussion

Jose Ramon Beltron Aivenda Ostler is a 19-year-old native of Mexico. He was legally adopted in 1978, when he was 15 years old, by Mr. and Mrs. Ray Ostler of Orem, Utah, where he now resides.

Jose Ostler was born in Pajarito, Nayarit, Mexico, and was abandoned by his natural father when he was three years old. He was orphaned in 1975, upon the death of his mother, and entered the United States from Mexico without inspection in 1977. Jose's current illegal status makes him deportable and, because he was adopted when he was over 14, he cannot be classified as an immediate relative for immigration purposes.

S. 1364, which passed both Houses by voice vote, would deem Jose Ostler to be a "child" for purposes of legal admission as an immediate relative, upon petition of his adoptive parents, thus granting him permanent residence status as an adopted child of U.S. citizens. The bill also would specify that no natural

parent or sibling of Jose Ostler shall be accorded any right, privilege, or status under the Immigration and Nationality Act by reason of the special relief the bill provides for him.

(Signed) James M. Frey
Assistant Director for
Legislative Reference

Enclosures

Ninety-seventh Congress of the United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday, the twenty-fifth day of January,
one thousand nine hundred and eighty-two*

An Act

For the relief of Jose Ramon Beltron Aivenda Ostler.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That in the administration of the Immigration and Nationality Act, Jose Ramon Beltron Aivenda Ostler of Orem, Utah, shall be classified as a child within the meaning of section 101(b)(1)(E) of such Act upon approval of a petition filed in his behalf by Mr. and Mrs. M. Ray Ostler of Orem, Utah, citizens of the United States, pursuant to section 204 of such Act. No natural parent, brother, or sister, if any, of Jose Ramon Beltron Aivenda Ostler shall, by virtue of such relationship, be accorded any right, privilege, or status under the Immigration and Nationality Act.

Speaker of the House of Representatives.

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

THE WHITE HOUSE

WASHINGTON

December 30, 1982

MEMORANDUM FOR FRED F. FIELDING

FROM: JOHN G. ROBERTS *JGR*

SUBJECT: Enrolled Bill H.R. 6254 - Protection
of Certain Foreign Diplomatic Missions

Richard Darman has requested comments by close of business Monday, January 3, on Enrolled Bill H.R. 6254, which would increase appropriations to reimburse New York City for protective services it provides for foreign diplomats, and permit reimbursement for the cost of motorcades for foreign diplomats. The Administration opposed H.R. 6254, on the grounds that motorcades are ceremonial and not protective, and that New York City is already being adequately reimbursed. OMB and Treasury recommend approval, noting that the Continuing Resolution already authorizes increased funds for reimbursement to New York City, and covers motorcades. Reimbursement is much less costly than replacing local security with Federal officers, which Mayor Koch has threatened will be necessary if the bill fails. State recommends disapproval, essentially for the reasons the Administration initially opposed the bill. Signing and disapproval statements have been prepared by Treasury and State, respectively.

I have reviewed the memorandum to the President from David Stockman, the bill itself, and the draft statements. I see no legal objections to the bill, nor do I think the policy dispute between Treasury and State holds any particular significance for this office. I therefore recommend a simple "no legal objection" memorandum to Darman. I also have no legal objection to either the signing or disapproval statement.

THE WHITE HOUSE

WASHINGTON

December 30, 1982

MEMORANDUM FOR RICHARD G. DARMAN
ASSISTANT TO THE PRESIDENT

FROM: FRED F. FIELDING *Orig. signed by FFF*
COUNSEL TO THE PRESIDENT

SUBJECT: Enrolled Bill H.R. 6254 - Protection
of Certain Foreign Diplomatic Missions

Counsel's Office finds no objection from a legal perspective to the above-referenced enrolled bill. We also have no legal objection to either the proposed signing statement or the memorandum of disapproval.

JGR
FFF:HPG:aw 12/30/82

cc: FFFielding
~~HPGoldfield~~
Subj.
Chron

JGRoberts

THE WHITE HOUSE

WASHINGTON

December 30, 1982

MEMORANDUM FOR RICHARD G. DARMAN
ASSISTANT TO THE PRESIDENT

FROM: FRED F. FIELDING
COUNSEL TO THE PRESIDENT

SUBJECT: Enrolled Bill H.R. 6254 - Protection
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~~HPGoldfield~~
Subj.
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Roberts

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Date Correspondence Received (YY/MM/DD) 1 1

Name of Correspondent: Richard G. Narman

MI Mail Report User Codes: (A) _____ (B) _____ (C) _____

Subject: Enrolled Bill H.R. 6254 - Secret Service Protection of Certain Foreign Diplomatic Missions

ROUTE TO:	ACTION	DISPOSITION	
Office/Agency (Staff Name)	Action Code	Tracking Date YY/MM/DD	Type of Response Code Completion Date YY/MM/DD
<u>CU Holland</u>	ORIGINATOR	<u>82/12/29</u>	<u>1 1</u>
<u>CU AT 18</u>	Referral Note: <u>D</u>	<u>82/12/29</u>	<u>583,01,03</u>
	Referral Note:	<u>1 1</u>	<u>1 1</u>
	Referral Note:	<u>1 1</u>	<u>1 1</u>
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WHITE HOUSE STAFFING MEMORANDUM

DATE: 12/29/82 ACTION/CONCURRENCE/COMMENT DUE BY: c.o.b. MONDAY, 1/3/83

SUBJECT: ENROLLED BILL H.R. 6254 - SECRET SERVICE PROTECTION OF CERTAIN FOREIGN DIPLOMATIC MISSIONS

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input type="checkbox"/>	<input type="checkbox"/>	FULLER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
MEESE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	GERGEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BAKER	<input type="checkbox"/>	<input checked="" type="checkbox"/>	HARPER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DEAVER	<input type="checkbox"/>	<input checked="" type="checkbox"/>	JENKINS	<input type="checkbox"/>	<input type="checkbox"/>
STOCKMAN	<input type="checkbox"/>	<input type="checkbox"/>	MURPHY	<input type="checkbox"/>	<input type="checkbox"/>
CLARK	<input checked="" type="checkbox"/>	<input type="checkbox"/>	ROLLINS	<input type="checkbox"/>	<input type="checkbox"/>
DARMAN	<input type="checkbox"/> P	<input checked="" type="checkbox"/> SS	WILLIAMSON	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DOLE	<input type="checkbox"/>	<input type="checkbox"/>	VON DAMM	<input type="checkbox"/>	<input type="checkbox"/>
DUBERSTEIN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	BRADY/SPEAKES	<input type="checkbox"/>	<input type="checkbox"/>
FELDSTEIN	<input type="checkbox"/>	<input type="checkbox"/>	ROGERS	<input type="checkbox"/>	<input type="checkbox"/>
FIELDING	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

Remarks:

May we have your comments on the attached Bill and Draft Statements by close of business Monday, January 3.

Note: Draft Signing Statement prepared by Treasury and
 Draft Disapproval Statement prepared by the Department of State

Richard G. Darman
 Assistant to the President
 (x2702)

Response:



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

DEC 29 1982

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill H.R. 6254 - Secret Service Protection of --
Certain Foreign Diplomatic Missions
Sponsor - Rep. Ferraro (D) New York

Last Day for Action

January 4, 1983 - Tuesday

Purpose

(1) Authorizes increased appropriations to cover reimbursements to New York City (NYC) for protective services it provides to foreign diplomatic facilities and visitors and (2) expands the circumstances under which such reimbursements may be made.

Agency Recommendations

Office of Management and Budget

Approval

Department of the Treasury

Approval (Signing
Statement attached)

Department of Defense

No objection

Department of State

Disapproval (Memorandum
of Disapproval
attached)

Discussion

Background

Current law authorizes the appropriation of not more than \$3.5 million in any fiscal year to reimburse NYC for protective services it provides to foreign diplomatic facilities and visitors. H.R. 6254 increases this amount to \$7 million annually beginning after September 30, 1982. In addition, the enrolled bill authorizes the appropriation of an additional \$17.7 million to cover obligations entered into before October 1, 1982, but only recently submitted by NYC for reimbursement. The enrolled bill also expands the circumstances under which reimbursement may be made to add protection of motorcades and other places visited by them. Similar language has been included in recent Secret Service appropriations. In fact, the fiscal year 1983 continuing resolution provides \$7 million for FY 1983 claims and \$8 million for past claims, including continued reimbursement for motorcades. Finally, H.R. 6254 directs the Secretaries of State and

the Treasury (1) to consult with the Secretary of the Navy regarding the placement of Marine security guard services at the United States Mission to the United Nations to promote effective and cost-efficient security and (2) to report their findings to Congress within sixty days.

The Administration had opposed enactment of H.R. 6254 and similar legislation for the following reasons. First, under our Federal system, protecting foreign establishments and official visitors in the United States has historically been a responsibility of the States and localities. In this regard, expenses for the extraordinary protection of foreign dignitaries' motorcades, which are largely ceremonial rather than protective in nature, and for other places visited by them, are the principal responsibility of the States and localities which should absorb the costs of their own security measures. Second, the current statutory ceiling of \$3.5 million has been deemed to be a sufficient Federal contribution toward a primarily local responsibility. Third, NYC itself has completed a study which concludes that the presence of the United Nations, foreign missions accredited to it, and foreign consulates, results in a \$600 million net gain for the NYC economy. The Administration position has been that such a gain further obviates the need to increase the \$3.5 million reimbursement limit.

Agency Recommendations

State, in its enrolled bill views letter, recommends that you veto H.R. 6254 because it provides for the reimbursement of motorcades which "...are usually mounted for local political reasons not associated with protection of dignitaries. Indeed, motorcades and the attendant publicity often increase the risk." While NYC and Washington, D.C. are unique because of their large diplomatic communities, State continues, "They are not unique when it comes to visiting dignitaries who are given motorcades. If the change in criteria to include motorcades is accepted for New York City, the pressure will be irresistible to apply it to other cities."

Treasury, on the other hand, recommends that you sign H.R. 6254, notwithstanding the fact that the Administration earlier opposed its passage. Treasury feels that a veto would be "...a futile gesture causing gratuitous provocation of New York City and its Congressional delegation...." Furthermore, Treasury points out that:

- enactment of this legislation would not substantially change current practices for reimbursing NYC because the fiscal year 1983 continuing resolution authorizes funds above the current \$3.5 million ceiling for diplomatic protection, including motorcades;

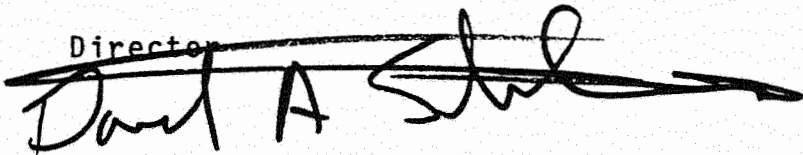
- in the absence of increased funding, Mayor Koch has threatened to terminate NYC's diplomatic security role; and
- if Federal personnel and resources have to take over the protective functions in NYC, the cost will be at least double that of the NYC Police Department for fixed guard posts.

In addition to the concerns cited above, we have been advised by Ambassador Kirkpatrick's Washington Office that, notwithstanding the Executive branch's opposition to the bill, she has pledged her personal support for H.R. 6254 in testimony, and directly to various Senators and Mayor Koch. Accordingly, she recommends that you approve H.R. 6254.

While we share State's view that the reimbursement for motorcade protection is inappropriate and costly, we find Treasury's arguments persuasive and, accordingly, recommend that you approve the enrolled bill. Treasury has prepared a draft signing statement which describes the unique circumstances in NYC which set it apart from other cities which could make similar requests for assistance. We feel it is unwise, however, to highlight this bill which could be viewed as a precedent by other communities seeking comparable treatment. Should you decide to veto H.R. 6254, a draft Memorandum of Disapproval, prepared by the Department of State, is attached for your consideration.

The enrolled bill passed the House by a vote of 218 to 177 and by voice vote in the Senate.

Enclosures

Director


PROPOSED REMARKS FOR PRESIDENT REAGAN
UPON SIGNING H.R. 6254, THE DIPLOMATIC
PROTECTION REIMBURSEMENT BILL

Under our system of federalism the protection of foreign missions and officials in the United States is a responsibility shared by Federal, State and local authorities.

The bill I have just signed into law recognizes that the presence of the United Nations in New York City creates unique demands on the resources of the New York City Police Department and that the Federal government must now, in this age of terrorism, bear a greater share of the City's costs. In addition to the United Nations itself, there are nearly 250 foreign missions in New York City and the world's most populous diplomatic community. New York must also deal with a constant flow to the United Nations of distinguished foreign officials who require police protection. Together, these facts create an exceptional situation in New York City for which additional Federal contributions are justified.

DEPARTMENT OF STATE DRAFT
DISAPPROVAL STATEMENT

MEMORANDUM OF DISAPPROVAL

I am withholding approval of HR 6254 because adequate provision already exists to reimburse New York City for protection of foreign missions to the UN. In addition, this legislation would change the criteria for reimbursement to include motorcades for visiting dignitaries, which would significantly increase Federal costs associated with protecting foreign dignitaries. Although New York City has a large diplomatic establishment requiring protection, it is not unique in having motorcades for visiting dignitaries. Motorcades are not essential to provide protection and including them would shift to the Federal Government costs traditionally handled by local governments. Especially in light of the fact that adequate resources are provided in the continuing Resolution to reimburse New York City under existing criteria, I cannot approve HR 6254.

Ninety-seventh Congress of the United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday, the twenty-fifth day of January,
one thousand nine hundred and eighty-two*

An Act

To amend title 3, United States Code, to clarify the function of the United States Secret Service Uniformed Division with respect to certain foreign diplomatic missions in the United States, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That (a) section 202(7)(C) of title 3, United States Code, is amended by inserting "may be provided for motorcades and at other places associated with such a visit and" after "protection".

(b) Section 208(b) of title 3, United States Code, is amended to read as follows:

"(b) There is authorized to be appropriated, in addition to such sums as have been heretofore appropriated under this section—

"(1) \$7,000,000 for each fiscal year beginning after September 30, 1982, for the payment of reimbursement obligations entered into under subsection (a) after such date; and

"(2) \$17,700,000 for the payment of reimbursement obligations entered into under subsection (a) before October 1, 1982.

Amounts appropriated under this subsection shall remain available until expended."

SEC. 2. The amendments made by the first section of this Act shall take effect on the date of enactment of this Act, except that no amount authorized to be appropriated by the amendment made by subsection (b) of the first section of this Act may be made available for use or obligation prior to October 1, 1982.

SEC. 3. In order to assure effective security at the United States mission to the United Nations, and to promote efficient use of

H. R. 6254—2

Federal security resources, the Secretary of the Treasury and the Secretary of State shall consult with the Secretary of the Navy with regard to placement of Marine security guard services within such mission and shall report thereon to the Congress not later than sixty days after the date of enactment of this Act.

Speaker of the House of Representatives.

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

THE WHITE HOUSE

WASHINGTON

December 30, 1982

MEMORANDUM FOR FRED F. FIELDING

FROM: JOHN G. ROBERTS *JGR*

SUBJECT: Enrolled Bill S.J. Res. 264 - National
Children and Television Week

Richard Darman has requested comments by close of business Tuesday, January 4, on Enrolled Bill S.J. Res. 264, which would designate the week of March 13-19, 1983, as "National Children and Television Week." The resolution authorizes and requests the President to issue an appropriate proclamation calling for appropriate observances of the week. OMB recommends approval.

I have reviewed the memorandum for the President from James Frey, Assistant Director of OMB for Legislative Reference, and the resolution itself. I see no legal objections, and recommend that you sign the attached memorandum to Darman.

Attachment

THE WHITE HOUSE

WASHINGTON

December 30, 1982

MEMORANDUM FOR RICHARD G. DARMAN
ASSISTANT TO THE PRESIDENT

FROM: FRED F. FIELDING *Orig. signed by FFF*
COUNSEL TO THE PRESIDENT

SUBJECT: Enrolled Bill S.J. Res. 264 - National
Children and Television Week

Counsel's Office finds no objection from a legal perspective to the above-referenced enrolled bill.

FFF:JGR:aw 12/30/82

cc: FFFielding
JGRoberts
Subj.
Chron

THE WHITE HOUSE

WASHINGTON

December 30, 1982

MEMORANDUM FOR RICHARD G. DARMAN
ASSISTANT TO THE PRESIDENT

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SUBJECT: Enrolled Bill S.J. Res. 264 - National
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- O - OUTGOING
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Date Correspondence Received (YY/MM/DD) 1 1

Name of Correspondent: Richard G. Daiman

MI Mail Report User Codes: (A) _____ (B) _____ (C) _____

Subject: Enrolled Bill S.F. Res. 264 - National Children and Television

ROUTE TO:	ACTION	Tracking Date	Disposition	Completion Date
Office/Agency (Staff Name)	Action Code	YY/MM/DD	Type of Response Code	YY/MM/DD
<u>W Holland</u>	ORIGINATOR	<u>82112129</u>		<u>1 1</u>
<u>WAT18</u>	Referral Note: <u>D</u>	<u>82112129</u>	<u>S</u>	<u>83101104</u>
	Referral Note:	<u>1 1</u>		<u>1 1</u>
	Referral Note:	<u>1 1</u>		<u>1 1</u>
	Referral Note:	<u>1 1</u>		<u>1 1</u>

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| <p>ACTION CODES:</p> <ul style="list-style-type: none"> A - Appropriate Action C - Comment/Recommendation D - Draft Response F - Furnish Fact Sheet to be used as Enclosure I - Info Copy Only/No Action Necessary R - Direct Reply w/Copy S - For Signature X - Interim Reply | <p>DISPOSITION CODES:</p> <ul style="list-style-type: none"> A - Answered B - Non-Special Referral C - Completed S - Suspended |
|---|---|
- FOR OUTGOING CORRESPONDENCE:**
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Comments: _____


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 Refer questions about the correspondence tracking system to Central Reference, ext. 2590.

WHITE HOUSE STAFFING MEMORANDUM

GR

DATE: 12/29/82 ACTION/CONCURRENCE/COMMENT DUE BY: c.o.b. Tuesday, 1/4

SUBJECT: ENROLLED BILL S.J.RES. 264 - NATIONAL CHILDREN AND TELEVISION WEEK

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input type="checkbox"/>	<input type="checkbox"/>	FULLER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
MEESE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	GERGEN	<input type="checkbox"/>	<input type="checkbox"/>
BAKER	<input type="checkbox"/>	<input checked="" type="checkbox"/>	HARPER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DEAVER	<input type="checkbox"/>	<input checked="" type="checkbox"/>	JENKINS	<input type="checkbox"/>	<input type="checkbox"/>
STOCKMAN	<input type="checkbox"/>	<input type="checkbox"/>	MURPHY	<input type="checkbox"/>	<input type="checkbox"/>
CLARK	<input type="checkbox"/>	<input type="checkbox"/>	ROLLINS	<input type="checkbox"/>	<input type="checkbox"/>
DARMAN	<input type="checkbox"/> P	<input checked="" type="checkbox"/> SS	WILLIAMSON	<input type="checkbox"/>	<input type="checkbox"/>
DOLE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	VON DAMM	<input type="checkbox"/>	<input type="checkbox"/>
DUBERSTEIN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	BRADY/SPEAKES	<input type="checkbox"/>	<input type="checkbox"/>
FELDSTEIN	<input type="checkbox"/>	<input type="checkbox"/>	ROGERS	<input type="checkbox"/>	<input type="checkbox"/>
FIELDING 	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

Remarks:

May we have your comments on the attached Bill by close of business Tuesday, January 4.

Richard G. Darman
Assistant to the President
(x2702)

Response:



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

DEC 29 1982

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Resolution S.J. Res. 264 - National Children
and Television Week
Sponsor - Sen. Heinz (R) Pennsylvania and 30 others

Last Day for Action

Purpose

Designates the week of March 13, 1983, through March 19, 1983,
as "National Children and Television Week".

Agency Recommendations

Office of Management and Budget

Approval

Discussion

S.J. Res. 264 designates the week beginning March 13, 1983, as
"National Children and Television Week", and requests the
President to issue a proclamation calling upon government
agencies and the public to observe the week with appropriate
activities supporting television programs which are attentive to
the needs and interests of children. The resolution passed both
Houses by voice vote.

The preamble to the resolution notes that television can create
an intellectual and emotional environment which can play a
decisive role in shaping individual development and perception.
It further points out that America has a continuing responsibil-
ity to provide appropriate stimulating programing for children
and adolescents. According to Rep. Wirth, sponsor of the
companion measure in the House, the designated week will help to
spotlight our quest for excellence in children's programing, and
call attention to the best that television has to offer our
young citizens.

An appropriate proclamation will be forwarded for your consideration and issuance in a timely manner.

James M. Fry
Assistant Director for
Legislative Reference

Enclosures

Ninety-seventh Congress of the United States of America

AT THE SECOND SESSION

*Begun and held at the City of Washington on Monday, the twenty-fifth day of January,
one thousand nine hundred and eighty-two*

Joint Resolution

To designate the week of March 13, 1983, through March 19, 1983, as "National Children and Television Week".

Whereas television can create an intellectual and emotional environment which can play a decisive role in shaping individual development and perception;

Whereas parents and other adults should be able to look to television to provide children with true pictures of the world and positive models for behavior;

Whereas many dedicated groups and individuals strive to improve the quality of television programing viewed by children and their families; and

Whereas this Nation has a continuing responsibility to provide appropriate, stimulating programing for children and adolescents:
Now, therefore, be it

Resolved by the Senate and House of Representatives of the United States of America in Congress assembled, That the week of March 13, 1983, through March 19, 1983, is designated as "National Children and Television Week" and the President of the United States is authorized and requested to issue a proclamation calling upon all government agencies and the people of the United States to observe the week with appropriate activities supporting television programs which are attentive to the needs and interests of children.

Speaker of the House of Representatives.

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

THE WHITE HOUSE

Office of the Press Secretary
(Palm Springs, California)

For Immediate Release

December 31, 1982

The President today signed the following legislation:

S. 1340, which authorizes the distribution and use of funds already awarded and appropriated to the Clallam Tribe of Indians in Washington.

S. 187, which directs the Secretary of the Interior to convey the interests of the United States in certain lands in and around Miles City, Montana, to the appropriate units of local government.

S. 1735, which authorizes the distribution and use of funds already awarded and appropriated to the Pembina Chippewa Indians.

S. 3113, which makes technical amendments and one minor substantive amendment to the recently enacted Job Training Partnership Act.

H.R. 1952, which (1) extends the authorization of appropriations for certain conservation programs on Federal lands; (2) authorizes the Secretaries of the Interior and Commerce to make certain financial transactions in conducting undercover operations in the enforcement of fish and wildlife laws; and (3) modifies the boundaries of the Coastal Barrier Resources System.

H.R. 6946, which establishes penalties for certain crimes involving the use of false identification documents.

H.R. 7155, which provides Congressional ratification of an agreement between the State of Florida and the Miccosukee Indian Tribe of Florida settling certain land claims of the Tribe within the State.

H.R. 7377, which designates the Lakeview Lake project on Mountain Creek in Texas as the "Joe Pool Lake".

H.R. 5204, which directs the Secretary of the Interior to accept in trust certain lands in San Diego County, California, for the benefit of the Sycuan Band of Mission Indians.

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THE WHITE HOUSE

WASHINGTON

January 3, 1983

MEMORANDUM FOR FRED F. FIELDING

FROM: JOHN G. ROBERTS *JGR*

SUBJECT: Enrolled Bill H.R. 5238 - Orphan Drug Act

Richard Darman has requested comments by 5:00 p.m. today on Enrolled Bill H.R. 5238, known as the Orphan Drug Act. The main provision of this bill would authorize tax credits, direct grants, and exclusive marketing rights for drug manufacturers to develop and market drugs for rare diseases -- so-called (for no apparent reason) "orphan drugs." The companies have argued that it is economically unprofitable for them to devote time and resources to such drugs, because there are so few buyers or potential buyers, even though the availability of the drugs is a matter of life and death for those few. Treasury opposes the orphan drug provisions, on the ground that the tax system should generally not be used to distribute subsidies.

The main opposition to the bill within the Executive Branch, however, focuses on section 7, a rider attached by Senator Hatch. Section 7 would require HHS to devise and publish charts demonstrating the probability that persons of different ages, sex, etc. are likely to develop cancer as a result of varying degrees of exposure to radiation fallout from nuclear bomb testing. The Department of Justice recommends a veto, on the ground that this provision would cripple the government's defense of radiation suits. That defense has focused on lack of evidence of causation, and the tables contemplated by the bill could fill this void in the typical plaintiff's case. The resulting exposure of the United States would be in the billions of dollars. HHS, urging approval, argues that the tables would clearly state their limitations and would simply convey scientific information, not predetermine legal questions. The bill contains a number of other objectionable riders, specifying funding of a categorical home health grant program, sickle cell centers, and EPA investigation of a particular reservoir.

OMB, Justice, Treasury, Energy, and OSTP recommend disapproval, primarily due to the radiation tables provision. Defense joins HHS in recommending approval, apparently

because a number of people with orphan drug diseases are associated with Defense. The bill is a high-profile one, the subject of an open letter to the President and Post editorial (attached). The legal objections raised by Justice are serious ones, and the tables could potentially be very costly to the United States. That depends, however, on what the tables say, and how they are used by courts. In essence the tables would simply provide more factual information on what is a mixed factual and legal question. While that may harm Justice's defense, it does not in itself change existing legal rules. The tables should not therefore be portrayed as determinative of the liability question.

I recommend that the memorandum to Darman reiterate the legal objections to the bill, but also correct the possible misimpression that signing the bill would be tantamount to conceding the radiation fallout cases.

Two draft memoranda of disapproval, prepared by OMB, are attached. The longer one notes that disapproval is based primarily on section 7, but also objects to the other riders and the tax credit aspects of the orphan drug provisions. The shorter memorandum simply objects to section 7 and indicates support for the orphan drug provisions. OMB and Treasury prefer the longer version. I favor the shorter version, since Congressional and popular support for the orphan drug provisions is so strong that the President's opposition to this bill must be seen as completely unrelated to those provisions.

I have attached a proposed memorandum to Darman.

Attachments

MR. PRESIDENT— PLEASE DO NOT VETO THE ORPHAN DRUG ACT

Dear Mr. President:

We represent millions of Americans who suffer from over 2000 rare diseases.

Our *only* hope is the ORPHAN DRUG ACT now sitting on your desk. That bill would give tax credits to drug companies that develop treatments for diseases that occur so infrequently that no company can expect to profit from the new drugs.

Just two weeks ago we rejoiced at the news that the ORPHAN DRUG ACT had passed both the Senate and the House of Representatives by *unanimous* vote.

Shortly before Christmas we were shocked to learn that you have been advised to veto the ORPHAN DRUG ACT. This news turned our holidays from a time of joy to one of deep despair.

Without the ORPHAN DRUG ACT some of us are doomed to an early death. Some of us will be forced to face painful and disabling sicknesses with *no hope* of recovery or even relief.

Your signature before January 4 will bring America's great pharmaceutical industry into partnership with the Federal government on our behalf. It is incomprehensible to us and to our families that you would reject this opportunity to alleviate so much human suffering.

PLEASE SIGN THE ORPHAN DRUG ACT TODAY!

Ruby Horansky
National Huntington's
Disease Assn.

Abbey Meyers
Tourette Syndrome Assn.

Melvin Van Woert, M.D.
Mt. Sinai School of
Medicine

Sharon Dobkin
Myoclonus Families United

Charlotte Drake
Parkinson's Educ. Program

Rita Kasky
National Neurofibromatosis
Foun.

Judy Roser
United Parkinson Disease
Foun.

Arlene Pessar
Dystrophic Epidermolysis
Bullosa Research Assn.

John Chung
Wilson's Disease Assn.

Anne Kone
Paget's Disease Foun.

George Brewer, M.D.
Jess Thoene, M.D.
University of Michigan

Marjorie Guthrie
Comm. to Combat
Huntington's Disease

Dennis Smur
Paralyzed Veterans of
America

Dick Vodra
Cystic Fibrosis Foun.

Butt Diamond
National Myoclonus Foun.

Eames Bishop
Amyotrophic Lateral Sclerosis
Soc. of America

Rubin Bakin
Gaucher's Disease
International Registry

Thor Hanson
National Multiple Sclerosis
Soc.

Barbara Landwehr
National Ichthyosis Foun.

Bill Baird
American Narcolepsy Assn.

Rose Marie Silva
International Joseph's
Disease Assn.

*Organizational Affiliation listed for identification purposes only.

**TO OUR FRIENDS: PLEASE TELEPHONE THE
WHITE HOUSE IMMEDIATELY AT (202) 456-1414.
THERE IS NOT ENOUGH TIME FOR LETTERS.
WITHOUT THE PRESIDENT'S SIGNATURE THE
ORPHAN DRUG ACT WILL DIE JANUARY 4, 1983.**

FOR MORE INFORMATION ABOUT ORPHAN DISEASES, CONTACT:
National Organization for Rare Disorders
c/o National Huntington's Disease Association

Orphan Drugs

THE PRESIDENT must decide by tomorrow whether to sign the Orphan Drug Act, and some of the advice he's getting is bad.

There are dozens of rare diseases that could be relieved by drugs that are uneconomical for pharmaceutical companies to produce because of the small number of people who need them. Or there may be a problem in finding companies to do the research necessary to develop drugs to treat rare diseases—an unprofitable exercise unless there are likely to be benefits for other areas of the companies' business. Some companies will test or even produce an uneconomical drug just out of the goodness of their hearts or for public relations purposes. But they can hardly be counted on to do this as a routine matter. Is there a role for government here?

By unanimous votes, the House and Senate have said yes. The Orphan Drug Act would give tax credits to subsidize production of these so-called orphan drugs, at a projected annual cost of \$15 million, and would create a small discretionary grant program totaling \$12 million to help finance preliminary testing. It would also streamline Food and Drug Administration procedures and grant limited patent-like rights when a drug is orphaned because it would be unpatentable. The legislation is carefully constructed to make maximum use of market incentives, rather than to create an elaborate regulatory scheme or a system of government controls over research and production decisions by drug companies. But there is strong opposition within the administration.

Put aside the usual objections based on cost, because the price tag is too small to treat it as a budget threat. And put aside the objection to a grant program for private research, because there is

certainly a public purpose here and there are plenty of other examples of research subsidies for profit-making enterprises. And how seriously can one take Treasury's objection to using the tax code to provide economic incentives? The incentive approach employed by the legislation is quite consistent with the administration's own general approach to government intervention.

In fact, the problem seems to be that Sen. Orrin Hatch attached a rider to the bill instructing the secretary of health and human services to conduct a study on the relationship between exposure to radiation and the incidence of certain cancers. This revives the old argument over the exposure of residents of Utah and Nevada to nuclear testing radiation years ago. The government has argued that any health effects were minimal and has tried to avoid liability, so a study might complicate matters. And some scientists believe the kind of study the Hatch amendment would force them to produce would be scientifically spurious.

This amendment, however, is not a good reason to veto an important bill. The proposed study would have no legal or regulatory effect. Nothing would be banned, no one would receive a court judgment, no workplaces would be regulated as a result of it. Sen. Hatch just wants to force the government to state as best it can the current scientific consensus on radiation hazards—or at least document the extent of the ignorance.

Medical science could give hundreds of thousands of people productive and relatively comfortable lives if the economics of the pharmaceutical industry did not work against them. Congress has given the president a way to help, and he should sign the legislation.

THE WHITE HOUSE

WASHINGTON

January 3, 1983

MEMORANDUM FOR RICHARD G. DARMAN
ASSISTANT TO THE PRESIDENT

FROM: FRED F. FIELDING *Orig. signed by FFF*
COUNSEL TO THE PRESIDENT

SUBJECT: Enrolled Bill H.R. 5238 - Orphan Drug Act

Counsel's Office has reviewed the above-referenced enrolled bill. We share the concerns expressed by the Department of Justice on section 7 of the bill. That section mandates the preparation of probability tables that could undermine the government's defense of radiation fallout cases. The exposure of the government in such cases runs into the billions of dollars.

The tables, however, would not be determinative of the government's liability. They would provide factual information of relevance to the question of causation. The significance of the tables to the ultimate resolution of radiation litigation will depend on what the tables say (unknown at this point) and how they are used by the courts. Government lawyers will be able to advance arguments limiting the use of the tables, and -- unless the tables reveal an overwhelming causative link between exposure to radioactive fallout and cancer -- the tables will be simply one of several factors for judges to consider in assessing the mixed factual and legal question of causation.

We do not, therefore, view the objections to section 7 of the bill -- while serious -- as an absolute bar to Executive approval, particularly in light of the strong support for the orphan drug provisions of the bill in Congress and among the public.

Counsel's Office has no legal objection to either of the draft memoranda of disapproval. In light of the strong support for the orphan drug provisions, however, we prefer the shorter memorandum. That memorandum limits the basis for disapproval to section 7, and expresses support for the orphan drug provisions. It avoids the danger -- present with the longer memorandum -- that the President may be perceived as opposed to government support for orphan drug development.

Legal positions aside, I recommend approval of this bill.

FFF:JGR:aw 1/3/82

cc: FFFielding/JGRoberts/Subj./Chron

THE WHITE HOUSE

WASHINGTON

January 3, 1983

MEMORANDUM FOR RICHARD G. DARMAN
ASSISTANT TO THE PRESIDENT

FROM: FRED F. FIELDING
COUNSEL TO THE PRESIDENT

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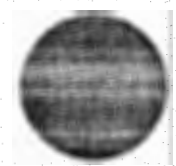
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FFF:JGR:aw 1/3/82
cc: FFFielding/JGRoberts/Subj./Chron

**WHITE HOUSE
CORRESPONDENCE TRACKING WORKSHEET**



- O - OUTGOING
- H - INTERNAL
- I - INCOMING
Date Correspondence Received (YY/MM/DD) 1/1

Name of Correspondent: Richard G. Darman

MI Mail Report User Codes: (A) _____ (B) _____ (C) _____

Subject: H.R. 5238 - Orphan Drug Act

ROUTE TO:

ACTION

DISPOSITION

Office/Agency (Staff Name)	Action Code	Tracking Date YY/MM/DD	Type of Response Code	Completion Date YY/MM/DD
<u>W Holland</u>	ORIGINATOR	<u>82/12/30</u>		<u>1/1</u>
<u>CUAT 18</u>	<u>D</u>	<u>82/12/30</u>	<u>S</u>	<u>83/01/03</u>
		<u>1/1</u>		<u>1/1</u>
		<u>1/1</u>		<u>1/1</u>
		<u>1/1</u>		<u>1/1</u>

- ACTION CODES:**
- A - Appropriate Action
 - C - Comment/Recommendation
 - D - Draft Response
 - F - Furnish Fact Sheet to be used as Enclosure
 - I - Info Copy Only/No Action Necessary
 - R - Direct Reply w/Copy
 - S - For Signature
 - X - Interim Reply

- DISPOSITION CODES:**
- A - Answered
 - B - Non-Special Referral
 - C - Completed
 - S - Suspended

FOR OUTGOING CORRESPONDENCE:
 Type of Response = Initials of Signer
 Code = "A"
 Completion Date = Date of Outgoing

Comments: _____

Keep this worksheet attached to the original incoming letter.
 Send all routing updates to Central Reference (Room 75, OEOB).
 Always return completed correspondence record to Central Files.
 Refer questions about the correspondence tracking system to Central Reference, ext. 2590.

WHITE HOUSE STAFFING MEMORANDUM

DATE: 12/30/82 ACTION/CONCURRENCE/COMMENT DUE BY: 5:00 p.m. MONDAY
January 3, 1983

SUBJECT: H.R. 5238 - ORPHAN DRUG ACT

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input type="checkbox"/>	<input type="checkbox"/>	FULLER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
MEESE	<input type="checkbox"/>	<input checked="" type="checkbox"/>	GERGEN	<input checked="" type="checkbox"/>	<input type="checkbox"/>
BAKER	<input type="checkbox"/>	<input checked="" type="checkbox"/>	HARPER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DEAVER	<input type="checkbox"/>	<input checked="" type="checkbox"/>	JENKINS	<input type="checkbox"/>	<input type="checkbox"/>
STOCKMAN	<input type="checkbox"/>	<input type="checkbox"/>	MURPHY	<input type="checkbox"/>	<input type="checkbox"/>
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DARMAN	<input type="checkbox"/> P	<input checked="" type="checkbox"/> SS	WILLIAMSON	<input checked="" type="checkbox"/>	<input type="checkbox"/>
DOLE	<input checked="" type="checkbox"/>	<input type="checkbox"/>	VON DAMM	<input type="checkbox"/>	<input type="checkbox"/>
DUBERSTEIN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	BRADY/SPEAKES	<input type="checkbox"/>	<input type="checkbox"/>
FELDSTEIN	<input type="checkbox"/>	<input type="checkbox"/>	ROGERS	<input type="checkbox"/>	<input type="checkbox"/>
<u>FIELDING</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

Remarks:

Please provide any comments/recommendations by 5:00 on Monday, January 3rd.

NOTE: There two draft disapproval memos attached. Both were prepared by OMB with the concurrence of Treasury. Both Treasury and OMB prefer the longer (3 page) draft. Please note your preference and edit appropriately.

Thank you.

Richard G. Darman
 Assistant to the President
 (x2702)

Response:



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

DEC 30 1982

MEMORANDUM FOR THE PRESIDENT

Subject: Enrolled Bill H.R. 5238 - Orphan Drug Act
Sponsor - Rep. Waxman (D) California and 171 others

Last Day for Action

January 4, 1983 - Tuesday

Purpose

(a) Authorizes tax credits and grants to drug manufacturers for the development of drugs for rare diseases or conditions and offers exclusive marketing rights for sponsors of such "orphan" drugs; (b) requires the development of radioepidemiological tables to estimate the probabilities of cancer caused by various levels of radiation exposure; (c) authorizes grants and loans for home health care services; (d) mandates funding requirements for sickle cell disease centers and an EPA study of Quabbin Reservoir; and (e) makes various technical amendments to the Public Health Service Act.

Agency Recommendations

Office of Management and Budget	Disapproval (Memorandum of Disapproval attached)
Department of the Treasury	Disapproval (Memorandum of Disapproval attached)
Department of Energy	Disapproval (Memorandum of Disapproval attached)
Department of Justice	Disapproval
Office of Science and Technology Policy	Disapproval
Environmental Protection Agency	Cites serious objection to section 10
Department of Commerce	No objection to sections 2 and 11
Nuclear Regulatory Commission	No objection
Department of Health and Human Services	Approval
Department of Defense	Approval
Office of Consumer Affairs	Approval
Veterans Administration	No recommendation (informally)

Discussion

H.R. 5238, although entitled the "Orphan Drug Act", contains many provisions not germane to orphan drugs; indeed, one of the other provisions -- relating to cancer causation due to radiation exposure -- forms the principal basis for recommending that the bill be vetoed.

I. Radiation Exposure and Cancer Causation

Section 7 of H.R. 5238 is a far-reaching provision. It would require the Secretary of Health and Human Services (HHS), within one year of enactment, to devise and publish radioepidemiological tables that estimate the probabilities that persons exposed to radiation are likely to develop cancer as a result. The tables would have to "show a probability of causation of developing each radiation related cancer associated with receipt of doses... in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary... determines to be relevant." Section 7 of the bill would also require the Secretary to publish an evaluation of the credibility, validity, and degree of certainty associated with such tables, as well as the formulas used to calculate the probabilities. These formulas could presumably be used by individuals with cancer to determine the probability of their cancer having been caused by radiation exposure.

The Department of Justice recommends a veto of H.R. 5238 because of the grave implications should section 7 become law. The Justice position is based upon:

-- Existing Litigation. Justice's position in existing litigation against the Federal Government arising from atmospheric testing of nuclear weapons could be severely undermined by section 7. Several law suits are pending in the courts against the United States involving thousands of plaintiffs seeking damages for cancers allegedly caused by radiation exposure. While it is difficult to estimate the exact level of potential liability of the Federal Government, Justice believes it ranges in the billions of dollars. The recently tried, but yet to be decided, Utah downwind radiation case, Allen v. United States, alone involves potential liability in excess of \$1 billion.

One of the Federal Government's key defenses in the pending law suits -- and one Justice is confident will severely limit the Federal Government's ultimate liability -- is the element of causation. That is, plaintiffs must prove that the cancer allegedly caused by radiation from atmospheric testing was, in fact, caused by the testing. Senior litigating attorneys in the Allen case are convinced that there is no credible evidence of causation before the court, and that if the radiation tables are published, the Federal Government's causation defense could be severely undercut. They are concerned that the Federal

Government will be forced to accept, at a minimum, these "officially endorsed" probabilities. Justice also is extremely concerned that such tables will be used by the courts to shift the burden of proving causation. That is, once the Government concedes, in tables published by a Federal agency and mandated in Federal law, that certain levels of low radiation may cause cancer, it is possible that the Government will be required to prove that its testing did not cause the cancer in question. Although a shift of the burden of proof as to causation would seem extraordinary, there is increasing pressure for such a shift.

-- Encouraging Additional Suits Against the United States.

Publication of these tables and accompanying formulas by the Federal Government will encourage additional radiation exposure litigation against the United States. Justice estimates that there are in excess of 500,000 potential plaintiffs who have or have had cancer and who at some time were exposed to radiation traceable to direct activities of the Federal Government. Once HHS promulgates the probability tables and formulas that would be mandated in Federal law, it would be a relatively simple matter for each such potential plaintiff to plug in the necessary data and determine the applicable probability. Moreover, publication of these tables and formulas certainly will be viewed by many as an implicit concession of "fault" on the part of the United States. The incentive to file a lawsuit thus will be extremely strong, particularly if the United States should lose a well publicized lawsuit based on the probabilities contained in tables mandated by Federal statute.

-- Prelude to Radiation Compensation Legislation. The tables mandated by section 7 would be the first critical step in enacting radiation compensation legislation -- like S. 1483 (introduced by Senator Hatch) that the Administration threatened to veto earlier this year. S. 1483, because of the veto threat, did not reach the floor. Crucial to that legislation was the promulgation of causation tables that section 7 of H.R. 5238 would now mandate. Justice estimates that the potential liability of the Federal Government, should a radiation compensation program be enacted, is at least \$25 billion.

In its views letter, HHS states that "the Justice Department's opposition is misguided, and ...it would be a serious mistake to veto this bill because it contains this provision." HHS bases this position on three factors:

-- development of the tables is not contingent upon enactment of this legislation. HHS has authority to develop the tables and has already made a commitment to do so, if scientifically feasible;

-- Justice's concern that such tables would be misused seems excessive. The tables themselves would clearly state their limitations and the degree of confidence that could be placed in

their accuracy. Inclusion of this information would, in any case, be the normal scientific practice, but, in addition, the bill expressly requires that the limitations of the tables be made clear; and

-- consideration of the entire question of compensation of radiation victims can proceed in "a more informed fashion" if the tables are produced.

II. Orphan Drugs

A House Commerce Subcommittee on Health and the Environment survey concluded, among other things, that developing and marketing drugs for rare diseases are not profitable. In response to this finding, H.R. 5238 would:

-- give the FDA broad latitude to designate rare diseases or conditions in the United States;

-- offer exclusive marketing rights on unpatentable orphan drugs. The Secretary of HHS would be prohibited from approving another drug application for the same disease for a period of seven years from the time of the initial drug approval; and

-- provide a tax credit to drug manufacturers as an economic incentive to develop orphan drugs. The tax credit would be 50% of a manufacturer's costs of conducting clinical testing required for FDA approval for commercial sale for a rare disease or condition. This tax credit would expire after December 31, 1987.

The Treasury Department is recommending a veto of H.R. 5238 because of the tax credit provision contained in section 4 of the bill. The Treasury Department believes that the tax system is not an appropriate means of providing Federal aid for orphan drug development. A tax credit for testing expenses would not allow appropriate evaluation of the relative value and effectiveness of funding testing of various drugs under consideration. The tax system is not capable of making such value comparisons and thus is a poor method for allocating funds for testing orphan drugs. In fact, tax credits would be granted before the effectiveness of a drug for a rare disease is demonstrated.

Treasury believes that the tax system is an inefficient method for distributing subsidies for orphan drug testing and that an orphan drug tax credit would greatly increase the complexity of the tax laws relating to research expenditures, thereby creating administrative problems for the government and confusion for taxpayers.

Section 3 of the enrolled bill would mandate the establishment of an Orphan Products Board in HHS to promote the development of drugs and devices for rare diseases and conditions, and

coordinate Federal, other public, and private agencies activities in orphan drug development. Such a board already exists in HHS, and H.R. 5238 would add nothing to this existing capability. Although HHS opposed a statutory Board in testimony before Congress and acknowledges that the creation of this Board is not necessary, HHS does not object to this provision.

Section 5 of H.R. 5238 would authorize \$4 million for each fiscal year from 1983 through 1985 for grants and contracts to drug manufacturers in order to pay for clinical testing to develop orphan drugs. This new grant program -- to be administered by FDA -- is inappropriate; it places FDA in a conflict of interest position. FDA would be making grants for drug clinical testing to develop new drugs at the same time the law requires FDA to regulate those clinical tests to assure patient safety and informed consent. FDA would be required to approve the scientific validity of sponsors' testing for the grants FDA approved. Thus, FDA would lose the arms length review of testing data it has traditionally had as a dispassionate reviewer.

In its views letter, HHS does not oppose any of the orphan drugs sections and states that these provisions are consistent with the Department's goals.

III. Other Provisions

The enrolled bill contains additional provisions which would:

-- re-create the narrow, categorical home health grant and loan program (section 6) with authorizations of \$7 million for fiscal years 1983 and 1984. This would duplicate current authority and funding already included in the Preventive Health and Health Services Block Grant. This provision would hamper State and local efforts to implement the Preventive Health Block Grant by creating additional administrative burdens for grantees. HHS's views letter points out that if this section were a free-standing bill, the Department would recommend that it not be approved;

-- require that \$800,000 of EPA research funds be used to study the effects of acid deposition on the Quabbin Reservoir in Massachusetts (section 10). EPA states in its views letter that if this section were a free-standing bill, it would recommend a veto;

-- direct HHS to fund at least 10 sickle cell centers in fiscal year 1983 (section 8). HHS and OSTP strongly object to this provision on the grounds that the number of such centers should be determined by program priorities and scientific merit, not congressional mandate;

-- single out, from all other regulated products, G. D. Searle's food additive, aspartame, for patent term extension; and

-- make numerous non-controversial technical and miscellaneous amendments to the Public Health Service Act and others.

H.R. 5238 was passed in both Houses by voice vote, both initially and in its final version.

Recommendations

H.R. 5238 is a highly visible piece of legislation; it enjoys considerable support in the Congress. Except in the case of Senator Hatch, however, that support seems predicated largely on the orphan drug provisions. A press conference was held after congressional passage by the bill's key sponsors (Senators Kassebaum, Dole, and Kennedy, and Representatives Waxman and Madigan, among others) to generate additional public support.

HHS recommends approval, but notes in its views letter that should "the President... decide to veto the bill, we urge that the veto message make clear that the reason for this decision is not objection to the orphan drug amendments, but rather to other unrelated provisions contained in the bill." Virginia Knauer's Office also recommends approval.

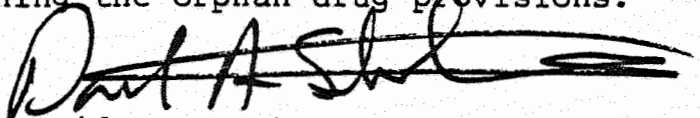
The Department of Defense (DOD) recommends approval because there are a number of people associated with DOD with the diseases that orphan drugs would assist. DOD is very concerned, however, with section 7, largely because of the scientific problems involved in the mandated epidemiological tables. DOD recommends that, should H.R. 5238 be approved, a Cabinet Council working group be established to coordinate Executive Branch review of these tables prepared by HHS.

Justice, OSTP, Energy, and Treasury recommend disapproval, and we concur.

To veto this bill and at the same time respond to the support for orphan drug development, we recommend that your Memorandum of Disapproval indicate that you are directing the Secretary of HHS to report to you by March 31, 1983, on a comprehensive set of administrative actions to promote additional orphan drug research and development. Such steps can include FDA's allowing sponsors of experimental orphan drugs to charge for the costs of the drugs in order to permit them to recoup part of their development costs. FDA can also be asked to consider fewer tests and less voluminous data collection for orphan drugs, thereby reducing the cost of development and licensing. These approaches already apply to FDA's regulation of medical devices, and FDA is currently reviewing steps along these lines for drugs. Most importantly, NIH, which does an extensive amount

of drug development, can use more of its grant money for orphan drug research and development. NIH already has ten drug development programs of relevance to orphan drugs.

A draft memorandum of disapproval, announcing the policy cited above, is attached for your consideration. In accordance with agreement reached at a White House meeting on this bill last week, an alternative draft memorandum is also attached that bases your disapproval on section 7 and indicates that you would have signed legislation containing the orphan drug provisions.



David A. Stockman
Director

Enclosures

MEMORANDUM OF DISAPPROVAL

I am withholding my signature from H.R. 5238, the Orphan Drug Act.

I am taking this action reluctantly, since I totally support the goal of encouraging the development of drugs or other treatments for those afflicted with rare diseases and conditions. Unfortunately, H.R. 5238 contains a number of highly objectionable features that cause me to withhold approval of this piece of legislation in its current form.

I am especially concerned about a provision in H.R. 5238 that would require the Secretary of HHS to assess the possible relationship between radiation exposure and cancer. Section 7 of H.R. 5238 would require the Federal Government to publish radioepidemiological tables within one year after approval of the bill. The one-year timetable proposed in H.R. 5238 is unrealistically short because the scientific validation process alone will take considerably more than one year to complete. The hurried result could yield questionable figures and could be construed in misleading and perhaps harmful ways. The provision also fails to recognize that both the national and international organizations of experts involved in radiation protection have not completed work critical to the development of scientifically valid tables; nor have they reached consensus on the probability of causation approach to cancer risk. Section 7 of this bill would cast aside the very substantial doubts as to the wisdom of a tabular approach, thereby truncating the debate as to whether such tables should be the focus of further research. This important issue needs considerably more discussion and consensus within the scientific community before such probability relationships are adopted under Federal law.

H.R. 5238 would also re-create the narrow categorical home health grant and loan program that would duplicate and conflict with authorities already included in the Preventive Health and Health Services Block Grant authorized by Congress in 1981. The

implementation of block grants by my Administration has been a major step in reducing administrative burdens on State and local governments and in improving the delivery of federally funded services. Proposals to undo the block grants are unacceptable and will only undermine State and local efforts to manage the delivery of services.

I fully support the intent of the orphan drug provisions of H.R. 5238. The bill would, however, inappropriately subsidize the development of orphan drugs through tax credits and grants and it would establish a statutory Orphan Products Board.

The use of tax credits to spur private investment has merit in certain limited circumstances. Nevertheless, our tax system is not an appropriate means of providing Federal subsidies for orphan drug development. A tax credit for drug testing expenses does not allow appropriate evaluation of the relative value and effectiveness of various drugs under development. The tax system is not capable of making such value comparisons and thus is a poor method for allocating Federal dollars for private testing of drug products.

H.R. 5238 is also defective in that the proposed tax credits would increase the complexities of the tax laws, thus creating administrative problems for the Government and confusion for taxpayers. Neither of these outcomes is desirable. Moreover, it is not clear from H.R. 5238 what standards would be applied in granting orphan drug status and tax subsidy credits. It would appear that orphan drug status and tax subsidies would be granted before the effectiveness of the drug for a rare disease was documented. Many currently marketed drugs for rare diseases, for example, are already used to treat common diseases.

The bill would also unnecessarily mandate an Orphan Products Board. Such a board already exists administratively within the Department of Health and Human Services. H.R. 5238 would add nothing to this existing administrative capability.

Indeed, various agencies within HHS are already taking steps administratively to foster the development of orphan drugs. For instance, the National Institutes of Health has a total of 10 drug development programs of relevance to orphan drugs, conducted in seven of its Institutes; the Centers for Disease Control has a program for distributing approximately 30 special immunobiologic agents and drugs; the Alcohol Drug Abuse and Mental Health Administration has an orphan drug development program; and the Food and Drug Administration (FDA) accords priority review to orphan drugs and tailors data requirements to the circumstances in which the orphan drug will be used. FDA also facilitates the development and marketing of orphan drugs by seeking commercial sponsors and providing technical assistance and support.

More can and will be done administratively to encourage the development of orphan drugs and eliminate, to the extent that they exist, barriers to such development. I am directing the Secretary of HHS to report to me by March 31, 1983, on a comprehensive set of administrative actions to facilitate the development of orphan drugs within current research grant and contract funding levels and to reduce unnecessary regulatory barriers that may discourage the development of orphan drugs.

In addition, I will be pleased to support legislation in the next Congress that will supplement these actions with appropriate incentives for the commercial development of orphan drugs. Accomplishing this objective will be a high priority of my Administration during the coming year.

MEMORANDUM OF DISAPPROVAL

I am withholding my signature from H.R. 5238, the Orphan Drug Act.

I am taking this action reluctantly, since I fully support the goal of encouraging the development of drugs or other treatments for those afflicted with rare diseases and conditions. Unfortunately, H.R. 5238 contains a highly objectionable provision, totally unrelated to the orphan drug issue, that causes me to withhold approval of this piece of legislation in its current form.

Section 7 of H.R. 5238 would require the Secretary of HHS to assess the possible relationship between radiation exposure and cancer, and to publish radioepidemiological tables within one year after approval of the bill. The one-year timetable proposed in H.R. 5238 is unrealistically short because the scientific validation process alone will take considerably more than one year to complete. The hurried result could yield questionable figures and could be construed in misleading and perhaps harmful ways. The provision also fails to recognize that both the national and international organizations of experts involved in radiation protection have not completed work critical to the development of scientifically valid tables; nor have they reached consensus on the probability of causation approach to cancer risk. Section 7 of this bill would cast aside the very substantial doubts as to the wisdom of a tabular approach, thereby truncating the debate as to whether such tables should be the focus of further research. This important issue needs considerably more discussion and consensus within the scientific community before such probability relationships are adopted under Federal law.

I totally support the intent of the orphan drug provisions of H.R. 5238 -- to offer economic and other incentives for the development of these drugs. Indeed, the Department of Health and Human Services has a number of activities already underway

to encourage orphan drug development. I will be happy to work with the Congress in its coming session to obtain enactment of legislation similar in all major respects to the orphan drug features of H.R. 5238.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release

January 3, 1983

The President has signed the following legislation:

H.R. 2520, which grants permanent resident status to Emanuel F. Lenkersdorf, a citizen of both Mexico and Germany;

S. 625, which (1) modifies the boundaries of the Voyageurs National Park in Minnesota; (2) increases the authorization of appropriations for land acquisition at the Park; (3) requires studies of the Park's road access and visitor facilities; and (4) requires the President to submit his recommendations regarding the Park's suitability as wilderness by June 1, 1983;

S. 717, which grants permanent resident status to the Maxfield-Raynor family.

S. 835, which requires the Secretary of the Interior to (1) sell Jerry Crow certain land in Alaska, and offer to lease him other land and (2) sell Ralph and Connie Hubbell certain land in Colorado;

? S. 1364, which grants permanent resident status to the adopted son of citizens of the United States;

S. 1501, which conveys certain lands in Alaska to the University of Alaska to be used by mining and geology students;

S. 1838, which facilitates issuance of an immigrant visa to Cesar Noel Jump, the adopted son of U.S. citizens;

S. 1965, which designates a 6,888-acre area in the Mark Twain National Forest, Missouri, known as the Paddy Creek Wilderness, as part of the National Wilderness Preservation System;

S. 1986, which authorizes the distribution and use of funds already awarded and appropriated to the Blackfeet and Gros Ventre Tribes of Indians, the Assiniboine Tribe of the Fort Belknap Indian Community, and the Papago Tribe of Arizona;

S. 2059, which amends the Ethics in Government Act to extend and revise the coverage of the Act;

S. 2955, which establishes the Cheaha Wilderness in the Talladega National Forest, Alabama;

S. 3103, which permits the President's Commission on Executive Exchange (PCEE) to impose participation fees for private sector participants in its Executive Exchange program; allows the fees collected to be spent for education and related travel of exchanged executives, and for other purposes related to the PCEE's work;

S.J. Res. 270, which designates 1983 as the "Bicentennial of Air and Space Flight".

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