

July 30, 1994

MEMORANDUM

TO: Carol Rasco

FR: Sara Rosenbaum

RE: Immunizations

This memorandum summarizes where we stand as of the end of the week. It assesses the status of the HHS negotiations with the manufacturers, warehouse issues, and the compromise suggested by Waxman's office and where it stands.

1. HHS negotiations

According to Bill Corr on Thursday, 10 out of 15 necessary contracts are signed. We will know by next week which contracts are signed and which are not. However, I do know that the two products for which there are no signatures are MMR (Merck) and OPV (Lederle). This is still closely held information. However, the Department is considering the strategic ways in which pressure can be mounted on Merck and Lederle to "cease and desist" in light of the fact that other manufacturers are coming into line.

2. GSA warehouse and warehouse bid

Bill reports that if the Bumpers committee amendment is allowed to prevail, there will be a minimum 4.5 month delay from October 1 in being able to implement the program. This is how long it would take the Department to develop the warehouse bid, collect and evaluate all of the bids, and award the contracts. If GSA is permitted to go ahead, HHS remains convinced that it can make a 10/1/94 effective date.

3. Senator Bumpers and further amendments

We assume that Senator Bumpers still is planning further amendments as part of either the appropriations or NHI bills. It may be that Senator Bumpers still will mount a full effort on the Senate floor to eliminate the VFC program this week when the appropriations bill is considered. It may also be that nothing will arise until the NHI floor debate in the Senate.

4. Senator Riegle's compromise

Senator Riegle has worked out compromise language to be inserted in the NHI bill. They are now clearing the language with Bumpers and Danforth, Mitchell's staff indicates that he is ready to accept it at that point. Debbie is meeting with Bumpers today to determine if he will accept the Reigle package.

5. Waxman compromise

The Waxman staff has outlined a compromise that calls for a slight delay in the mandate to permit warehouse development, no cutback in children, modification of the universal purchase option, and inclusion of the proposal to mandate employer coverage of immunization and well child care. They will try to get the measure included in the Gephardt package.

It is unclear whether Bumpers will wait for NHI or whether we will face a repeal of the program this week in the appropriations bill. Apparently there is reason to believe that Bumpers intends to move faster than NHI, although his staff may have relented somewhat. Discussions with Riegle's office today hopefully will bear some fruit. Bill Corr also expects to see Bumpers' staff today, although it is unclear to me how much Senator Bumpers will disclose about plans to speed up his amendments.

BUMPERS
KAR5AB

COMMITTEE
APPROPRIATIONS
ENERGY AND
NATURAL RESOURCES
SMALL BUSINESS

United States Senate
WASHINGTON, DC 20510-0401

July 25, 1994

David Satcher M.D.
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, Georgia 30333

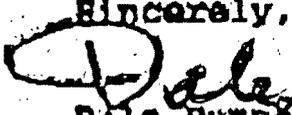
Dear Dr. Satcher:

Thank you for appearing at the July 21 hearing of the Committee on Appropriations. As I mentioned during the hearing, the subcommittee members have some additional questions to be answered for the record. A copy of those questions is attached.

Please send your completed document to Richard Larson, Committee on Appropriations, Room SD-126, Dirksen Senate Office Building, United States Senate, Washington, D.C., 20510, on or before August 1, 1994. In addition, please supply a disk of the document and specify if ASCII, or WordPerfect 5.1.

If you have any questions, please call Mary Ann Chaffee at 202/224-6439.

Thank you so much for your cooperation.

Sincerely,

Dale Bumpers

1. Please indicate the amount of funds that have been obligated to date to implement the VFC program. Please include: all obligations by the General Services Administration and the Department of Health and Human Services, and specifically: all costs associated with development of software and information and training sessions for state officials; all costs associated with purchasing prevailing charge data from American Association of Pediatricians; all costs associated with purchasing, developing, testing and validating packaging materials, warehouse equipment and the distribution information system; all personnel costs (both DHHS and GSA); and any other spending associated with implementation of the program by activity. Additionally, please identify all sources of funding for each activity and the authority used to allocate funds from those sources.

2. The General Accounting Office has told us that DHHS did not compute actual costs to physicians for administering vaccine because the Department had no way of computing actual costs. Please review the microcosting study completed by the Health Care Financing Administration regarding the costs of 500 outpatient services and provide to the subcommittee those data that are relevant to the actual cost of administering vaccines.

3. Please provide detailed specifics on Dr. Orenstein's testimony regarding a "6-month transition period" for Federal Financial participation in the Medicaid program. We understand the Department's policy is not to require Medicaid providers to enroll in the VFC program. Does Dr. Orenstein's testimony relate to that policy? After the transition period, what will the Department's policy be regarding the Federal share of vaccine costs for Medicaid children who receive vaccine from a provider who is not enrolled in the VFC program?

4. Please provide for the record a copy of the contract the General Services Administration has executed with Action Pak and any other entity for developing, testing, and validating packaging materials. Please include all specifications related to the contract, as well as cost estimates for all materials to be developed and validated, and, particularly for containers that will be used to distribute frozen and unfrozen vaccine in a single shipment.

5. Dr. Orenstein indicated that the only activity CDC and GSA will undertake related to returns and recalls, is to record the excise tax credit. Please elaborate on that policy. Does this mean that CDC and GSA will not participate in a recall effort?

Does this mean that GSA will not accept returns? Are you aware of the FDA regulations regarding the quarantine and disposal of vaccine products? Does GSA plan to accept returns of damaged goods, mis-shipments, overorders? If not, how will they be handled? Who will dispose of the vaccine? Who will handle phone and written inquiries from providers who have problems with their shipments? If GSA does plan to accept returns, please provide the cost estimates (both funding and FTEs) for handling inquiries, retrieving vaccine and disposing of vaccine. Won't these costs have to be added to GSA's current estimate, since that cost estimate has no provisions for handling inquiries, returns, and recalls, or for disposing of vaccine consistent with FDA requirements?

6. At a press conference on the VFC program last week, DHHS officials indicated they have already given the states \$18 million for distribution of vaccine to VFC providers. What is the source of these funds and under what authority were they obligated? Please provide a General Counsel opinion on authority for allocating funds to states for this purpose. As you know, the CBO estimate of the VFC program costs assumed that states would absorb delivery costs beyond any delivery costs included in the capped price for vaccines. Please provide a detailed cost estimate of total delivery costs (state and federal) that will be incurred annually beyond the capped price of vaccine. Within the estimate of federal costs, please include all personnel costs.

7. Dr. Orenstein indicated in his testimony that CDC officials have many years of experience in distributing vaccine. Please provide the names of CDC personnel who have had prior experience with the following activities: designing, developing, testing and validating of containers and packaging materials to ship vaccines to private physicians' offices in the U.S.; designing, developing, testing and validating automated information systems for ordering and billing related to vaccine shipments in the U.S.; designing, developing, testing and validating automated information systems for distribution of vaccine in the U.S.; designing, testing, equipping and validating all aspects of warehouse storage for vaccine in the U.S. For each employee you identify, please indicate his assigned responsibilities regarding the VFC program and the funding source from which his salary is currently derived.

8. What is the number and cost of FTEs that have worked on the VFC program at CDC? What is the funding source for these FTEs? What tasks were these individuals working on before the VFC program implementation began?

9. Dr. Orenstein indicated in his testimony that he "has been told that many uninsured children of the working poor receive well-child care from private providers." What is the source of that information? Please provide any research findings or other documentation to support that contention.

10. Please provide detailed cost estimates of CDC/GSA distribution system if the number of annual shipments are 700,000; 1,400,000; 3,000,000; rather than GSA's current estimated number of shipments (336,000) .

11. DHHS and GSA officials have said there is no legal requirement for GSA to comply with FDA regulations, but that GSA will voluntarily comply. Please provide the General Counsel's opinion that supports the assertion that GSA is exempt from FDA requirements.

12. What is the policy regarding physicians in universal purchase states who do not enroll in the VFC program? Will physicians in universal purchase states who do not enroll be eligible to receive vaccine purchased with VFC funds? With 117 funds? With state option funds?

13. Dr. Satcher noted that a goal of the VFC program is to get children out of the public system and into private medical offices. CDC recently released diagnostic studies which look at factors in underimmunization. One factor identified is missed opportunities by providers. Does CDC have any data to indicate that private providers have fewer missed opportunities than public clinics? Didn't the diagnostic studies show that public clinics actually had higher coverage rates of high-risk children than private doctors did?

14. Please provide the actuarial studies conducted by HCFA and mentioned in Dr. Orenstein's testimony.

DALE BUMPERS
ARKANSAS

COMMITTEE
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SMALL BUSINESS

United States Senate

WASHINGTON, DC 20510-0401

July 25, 1994

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07-25-94 12:20PM FROM SENATOR BUMPERS D.C. TO 314046398626

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July 26, 1994

**MEMORANDUM TO HARRIET RABB
GENERAL COUNSEL
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

From: Walter Dellinger *WED*
Assistant Attorney General

Re: HHS Appropriations Bill

I am writing to express grave concerns about a provision in the proposed Department of Health and Human Services ("HHS") appropriations bill that would prevent the Secretary of HHS from expending funds for storage or distribution of publicly purchased pediatric vaccine through a warehouse and distribution facility operated by the General Services Administration, unless such expenditures are approved by the Appropriations Committees of both houses of Congress. We believe that this provision is plainly unconstitutional under the Supreme Court's decisions in INS v. Chadha, 462 U.S. 919 (1983), and Metropolitan Washington Airports Authority v. Citizens for the Abatement of Aircraft Noise, 501 U.S. 252 (1991).

When exercising its legislative power, Congress must act in accordance with "the single, finely wrought and exhaustively considered, procedures" established in Article I of the Constitution: passage by both houses of Congress and presentment to the President. Chadha, 462 U.S. at 951. See Metropolitan Washington Airports Authority, 501 U.S. at 274-75. Thus, in Chadha, the Supreme Court struck down a statute that authorized either house of Congress, by resolution and without presentment to the President, to veto particular decisions by the Attorney General. The Court held that while Congress had the authority to achieve that same result through the proper exercise of its legislative power, the statute was unconstitutional because Congress was exercising that authority without following the bicameral passage and presentment procedures set forth in Article I.

Like the one-house legislative veto invalidated in Chadha and the congressional action invalidated in Metropolitan Washington Airports Authority, the provision of the HHS appropriations bill by which Congress would exercise legislative authority solely through its Appropriations Committees, without passage by both houses of Congress and without presentment to the President, clearly violates the requirements of Article I. While Congress

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07/26/94 10:58

TO

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has broad authority to grant, limit, or withhold appropriations, that power may not be used — as it would be here — to circumvent the restrictions that the Constitution places on the form of legislative action.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Brunel

Washington D.C. 20201

FACSIMILE

JUL 26 1991

DATE _____

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Carol Rasco
Assistant to the President
for Domestic Policy

456-2216

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Kevin Thurm
Chief of Staff

690-6133

RECIPIENT'S FAX NUMBER: () 456-2878

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 4

COMMENTS:



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

JUL 26 1994

MEMORANDUM

TO: Carol Rasco
Nancy Ann Min

FROM: Kevin Thurm *KT*

SUBJECT: Immunization Amendment

Attached please find a letter from Walter Dellinger at the Department of Justice to Harriet Rabb concerning the constitutionality of the immunization amendment on the HHS Appropriations Bill.

If desired, DOJ is prepared to turn this into a letter to Senator Byrd and Congressman Obey. Please call as soon as possible and let me know how you want to proceed.

Attachments

cc: Barbara Silby

07/26/94 10:57

0002



U. S. Department of Justice

Office of Legal Counsel

Office of the
Assistant Attorney General

Washington, D. C. 20530

July 26, 1994

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has broad authority to grant, limit, or withhold appropriations, that power may not be used -- as it would be here -- to circumvent the restrictions that the Constitution places on the form of legislative action.

Wampouth - Laura
Riegle - Susan

Walter
Dellinger
sent

Finance - Jane Horvath

to obey
with
McDonald

Mary Ann - rejected Lederle

country cc
Bumpus even tho she Patu

Byrd
Harfield
Harlow
Specter

said sd. policy
but they are
going their own way

Lawson of Smith's staff

Justice the after conference
announced & after mtg
to instruct

AUG 10 REC'D



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION
WASHINGTON, D.C. 20201**

PHONE: (202) 690-7627

FAX: (202) 690-7380

TO: _____

FROM: _____

NAME: Carol Rascoe

NAME: Jerry D. Klepner

OFFICE: _____

OFFICE: _____

ROOM NO.: _____

ROOM NO.: _____

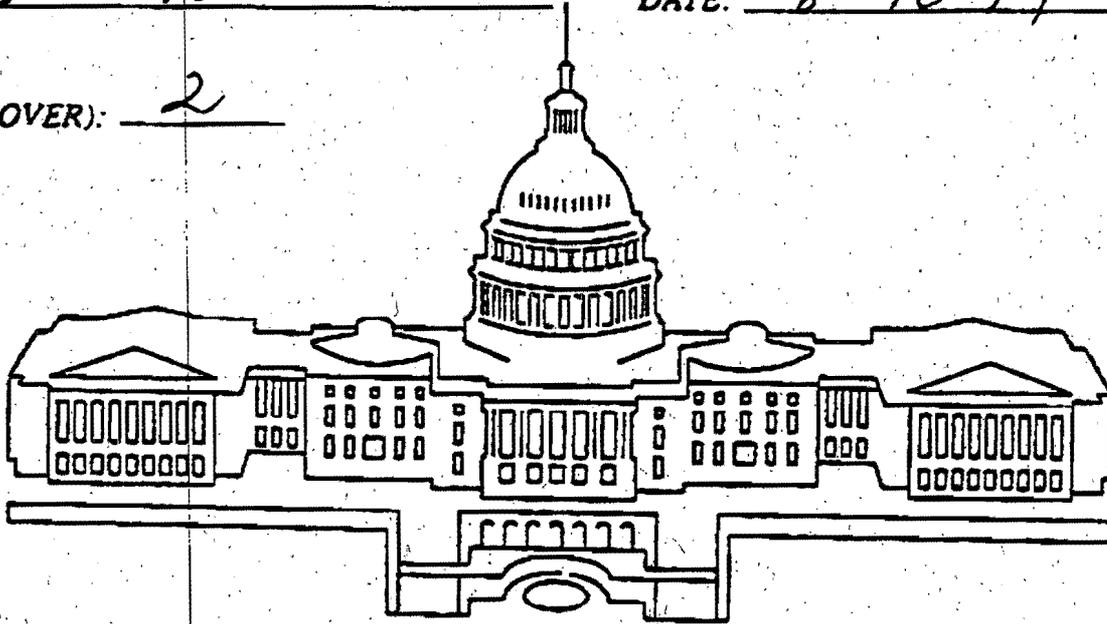
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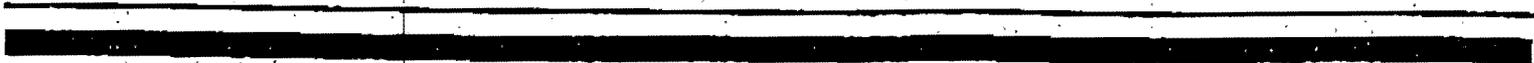
FAX NO.: 456-2878

DATE: 8-10-94

**TOTAL PAGES
(INCLUDING COVER):** 2



REMARKS:



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PAGE.002

PROPOSAL -- 8/9/94

- (1) Delete the "parenthetical" --

1928(d)(3)(B): delete the phrase "(including delivery costs and any applicable excise tax established under section 4131 of the Internal Revenue Code of 1986)" and make conforming amendments throughout.

- (2) In 1928(d)(4)(B), limit State optional purchase to universal purchase states or those ready to become universal immediately (includes any State, as previously discussed, which, as of 10/1/94, is prepared to provide all of the required vaccines, as well as States that manufacture their own vaccines).

- (3) Add the following language: "In carrying out section 1928 of the Social Security Act, the Secretary may not expend funds for storage or distribution of qualified pediatric vaccines for Federally vaccine-eligible children through a warehouse and distribution facility operated by the General Services Administration."
[Language taken directly from Bumpers amendment.]

- (4) Amend language to allow current Medicaid replacement programs (at State-Federal match) to continue during transition period --

1902(a)(32)(D): change "before October 1, 1994" to "January 1, 1995".



AUG 11 11:22 AM

CENTER FOR HEALTH POLICY RESEARCH

8/11

Carol -

Sara



CENTER FOR HEALTH POLICY RESEARCH

August 11, 1994

MEMORANDUM

TO: Carol H. Rasco

FR: Sara Rosenbaum

RE: VFC compromise proposals

This is an update on the status of the VFC compromise proposals as they now stand..

Senator Bumpers

I am told that the attached pages may have changed slightly, but they remain essentially the same. The Bumpers proposal would basically eviscerate the VFC program and would go far beyond any complaints raised by the manufacturers. It would be bad for children, bad for state health agencies, and bad for private physicians. It basically will leave the President with most of his initiative gone and in a position of having seriously backtracked for low income children.

Under the amendment:

1. The VFC program would be repealed insofar as it makes free vaccine available to Indian children, children served at rural health clinics, and children served at health centers. No manufacturer has ever asked for this.
2. County public health clinics would no longer be able to get VFC vaccines. They would instead have to get all of their vaccine through the §317 appropriation. This means that if the health clinics run out of vaccine (because appropriations are too low) they are barred from receiving any of the VFC supplies. Already there are certain key vaccines that simply are not stocked at local health clinics because there simply is not enough money to purchase what is needed. I simply cannot imagine how the states will react. To the extent that this is being done so that local health agencies do not have to make the VFC eligibility determination, we could waive that requirement without depriving them of the vaccines they need.
3. Doctors who do not participate in Medicaid would get no free vaccine from VFC and would not qualify for payment of the administration fee. This will make the AAP furious.

The Waxman Dingell proposal

They have communicated a bottom line position to both the Department and to the Senate. Under their position:

1. All VFC-eligible children would remain eligible. There would be no elimination of any group of children. State health agencies would remain eligible to participate in the program, as well.
2. The language restricting the delivery price (which led to a big portion of our problems to begin with) would be stricken, thereby permitting private delivery contracts.
3. The Medicaid replacement program, which is scheduled to expire, would continue for several months more so that the new delivery system would have time to get set up.
4. The optional use clause would be limited to states already running universal programs or who are about to begin one by 10/1/94.
5. Doctors could participate in VFC and not in Medicaid, thereby broadening access options for uninsured children.

In essence, the position preserves the program until such time as children are insured.

Since there is so little time left for the VFC problems to be resolved (especially if the House adjourns next Friday as is now anticipated), I wanted to be sure that you know the substance of both proposals at this point.

Waxman / Dingell

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[Language taken directly from Bumpers amendment.]

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1902(a)(32)(D): change "before October 1, 1994" to "January 1, 1995".

Bumpers

Summary Bumpers

- 1) MAINTAIN INTENT OF VFC PROGRAM BY PROVIDING FREE VACCINE TO UNINSURED CHILDREN IN PRIVATE PROVIDERS' OFFICES.

- 2) PROVIDE VACCINE (AT CAPPED PRICE) FOR MEDICAID-ELIGIBLE CHILDREN AND UNINSURED CHILDREN IN PRIVATE SETTINGS THROUGH A REPLACEMENT PROGRAM, ADMINISTERED THROUGH MEDICAID AND PAID FOR WITH 100% FEDERAL SHARE. REPLACEMENT MUST BE DONE BY MANUFACTURERS OR DISTRIBUTORS AT COST. STATES CAN OPT FOR ALTERNATIVE DISTRIBUTION SYSTEM, PROVIDED IT DOES NOT COST MORE THAN REPLACEMENT AND DOES NOT RESULT IN MORE VACCINE BEING PURCHASED. (FEDS PAY 100% SHARE OF DISTRIBUTION COSTS). ELIMINATE NEED FOR FEDERAL GOVERNMENT TO STORE AND DISTRIBUTE VACCINE. (IN LEGISLATION OR LETTER FROM PANETTA)

- 3) ELIMINATE VFC ELIGIBILITY FOR CHILDREN TREATED AT STATE AND COUNTY HEALTH CLINICS. CONTINUE 317 PROGRAM FOR THAT POPULATION.

- 4) PROVIDE FREE VACCINE TO MEDICAID PROVIDERS (FOR MEDICAID CHILDREN) WITHOUT REQUIRING THEM TO ENROLL.

- 5) ENSURE FEE SCHEDULE FOR ADMINISTRATION OF VFC VACCINE BY PRIVATE PROVIDERS IS TIED TO COST, AS OBRA REQUIRES. NO LIMIT ON OFFICE VISIT FEES.

- 6) REQUIRE ACCOUNTABILITY BY PRIVATE PROVIDERS. ALLOW PATIENTS TO SELF-DECLARE WITH NO REQUIREMENT TO DOCUMENT LACK OF INSURANCE BUT REQUIRE PHYSICIANS TO REPORT ADMINISTRATION OF VACCINE BY CHILD'S NAME. BUILD IN QUALITY CONTROL MECHANISMS FOR FRAUD AND ABUSE PURPOSES.

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This
is out
of
state

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- 7) IMPLEMENT OCTOBER 1, BUT PROVIDE 100% FEDERAL SHARE FOR VACCINE COSTS FOR MEDICAID CHILDREN UNTIL REPLACEMENT PROGRAMS ARE ALL IN PLACE (REPLACEMENT PROGRAMS WILL NOT BE IN PLACE BY OCTOBER 1 IN ALL STATES). ALLOW "ROLLING ADMISSIONS" FOR OTHER PROVIDERS WHO MAY WANT TO TAKE UNINSURED CHILDREN, BUT NOT MEDICAID CHILDREN.
- 8) ADMINISTER PROGRAM THROUGH HCFA. CDC WILL CONTINUE TO NEGOTIATE FOR CONTRACTS WITH MANUFACTURERS AND DISTRIBUTORS, BUT UNINSURED/PRIVATE PROVIDER ASPECT OF THE PROGRAM WILL BE ADMINISTERED THROUGH HCFA. (LETTER FROM PANETTA)
- 9) STATES' ABILITY TO DO UNIVERSAL PURCHASE --SAME AS YOUR PROVISIONS.
- 10) SUNSET PROVISION -- SAME AS YOUR PROVISIONS

we think
Swingers means
"10 # listed
on the attached
rule proposal
(we are checking)

8/12

Waxman - mark day def.
yesterday

Bumpers thus far has
refused to accept
Waxman

Rigle
Fin.
Kennedy

Will these
go beyond
Wax?

Bumpers wants which

- ① doesn't want PH ^{Waxman} wants
 - ② clinics to be eligible ^{Waxman} wants
- XIX prov. should only serve ^{but} instead 317
XIX & not uninsured

Lederle
said yesterday
Bumpers
interested

Core

Spoke to M.A.

" to Sim, Ruth

Justice ltr > Tuesday

Greg Jones in Sheila's
office

8/8

Walter Dellinger

Byrd

Harkin

Hart

Specter

Summers



Ready
to go
late Thurs.



Ober

Smith

McDade

Porter



Justice
Dept.

8/10
Opens del; to private

Univ. purchase
provision w/in
Schedule
Born on GSA

XIX replacement
until Jan. '95

Waxman ↑

Being on street w/
manuf. —

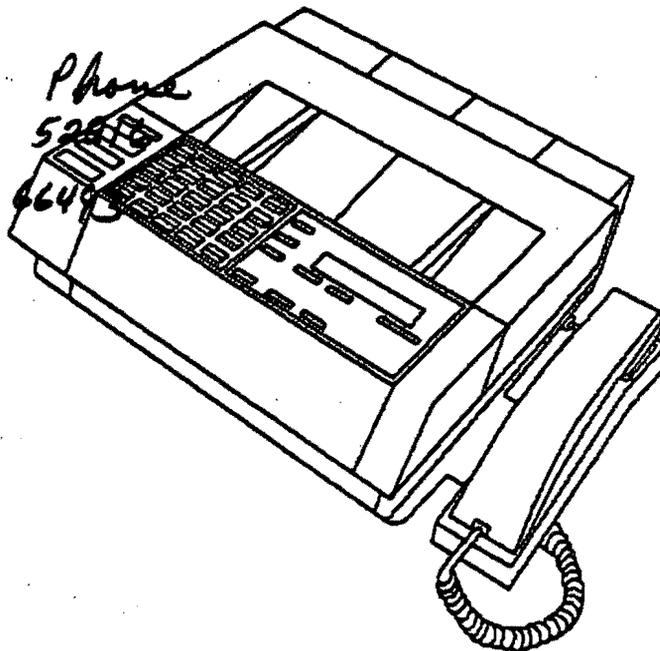
AUG 15 REC'D

**EXECUTIVE OFFICE OF THE PRESIDENT
Office of Management and Budget**

FAX COVER SHEET

TO:

FAX
Carol Rasco X 62878
Barbara Chow X 6 2604
John Angell *land console*



FROM:

Nancy-Ann Min

PHONE NUMBER: 202/395-5178

FAX NUMBER: 202/395-57289

COMMENTS: Attached is a statement re vaccines to be added to a letter going to the House/Senate Appropriations Committees re the FY '95 Labor/HHS/Education appropriations bill. Ken Apfel and I worked this out. If you have problems/concerns, please let me know this afternoon.

Date: 8/15/94

Time:

Number of Pages (including this page) _

If you do not receive all the pages, please call as soon as possible.

Vaccines for Children (VFC) Program

The Administration commends the House and the Senate for fully funding the President's Immunization Initiative, a priority investment program to ensure that all children who do not have health insurance coverage for immunizations have access to immunizations at the appropriate age. However, the Administration has strong concerns about Senate bill language that could delay the start of the program, which is scheduled to begin on October 1, 1994. The Administration notes the Senate's concerns regarding the distribution system for VFC, however, and has advised Congress, by letter, that the Administration will work through the private sector and with the States to distribute VFC vaccine. In addition, the Administration is working with the appropriate authorizing committees to make necessary statutory changes to assure that a private sector delivery system can be implemented on time.

The Administration also objects to the Senate provision on the basis that it infringes on executive authority. The provision requires Congressional approval before the Executive Branch obligates or spends appropriated funds for certain purposes. While the Administration is willing to comply with the other stated conditions, we will interpret this provision to require notification only, since any other interpretation would contradict the Supreme Court ruling in INS v. Chadha.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington D.C. 20201

FACSIMILE

DATE AUG 25 1994

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Carol Rasco
Assistant to the President
for Domestic Policy

456-2216

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):

Kevin Thurm
Chief of Staff

690-6133

RECIPIENT'S FAX NUMBER: () 456-2878

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 11

COMMENTS:



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

AUG 25 1994

MEMORANDUM

TO: CAROL RASCO
FROM: KEVIN THURM *KT*
SUBJECT: Immunization

Attached please find the latest draft supplied by Mary Ann Chafee. This draft, with sections 3 and 4B, exceeds the agreement between Senator Bumpers and Congressman Waxman as we understand it. We would like to oppose the addition of these two sections because they will pose significant problems for states and providers.

Please let me know if you have any questions or comments.

AUG 25 '94 12:28

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28-15-94 10:56AM FROM SENATOR BUMPERS D.C. TO 57090

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DISCUSSION DRAFT

S.L.C.

103RD CONGRESS
2^D SESSION

S. _____

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill, which was read twice and referred to the Committee on _____

A BILL

To amend title XIX of the Social Security Act to revise the program for distribution of pediatric vaccines established under the Omnibus Budget Reconciliation Act of 1993.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Vaccines for Children
5 Technical Corrections Act of 1994".

6 **SEC. 2. TREATMENT OF MEDICAID PROVIDERS AS PRO-**
7 **GRAM-REGISTERED PROVIDERS.**

8 (a) IN GENERAL.—Section 1928(c)(1) of the Social
9 Security Act (42 U.S.C. 1396a(c)(1)) is amended—

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PAGE.002

08-25-94 10:36AM FROM SENATOR BURGESS D.C. TO 57:30

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DISCUSSION DRAFT

S.L.C.

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1 (1) by redesignating subparagraphs (A) through
2 (C) as clauses (i) through (iii); and

3 (2) by striking "State, any health care provider
4 that—" and inserting "State—

5 "(A) any individual or entity participating
6 as a provider under the State plan under this
7 title; or

8 "(B) any other health care provider that—
9 ".

10 (b) CONFORMING AMENDMENT.—Section 1928(c)(2)
11 of such Act (42 U.S.C. 1396s(c)(2)) is amended by strik-
12 ing "A provider" and inserting "For purposes of para-
13 graph (1)(B)(ii), a provider".

14 SEC. 3. REQUIREMENT ON PROVIDERS TO ACCOUNT FOR
15 CHILDREN IMMUNIZED BY NAME AND TYPE
16 OF VACCINE ADMINISTERED.

17 Section 1928(c)(2)(A) of the Social Security Act (42
18 U.S.C. 1396(c)(2)(A)) is amended by adding at the end
19 the following new clause:

20 "(iv) The provider will account for the
21 administration of qualified pediatric vac-
22 cines by name of the child immunized and
23 type of qualified pediatric vaccine adminis-
24 tered in accordance with guidelines issued
25 by the Secretary for purposes of preventing

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DISCUSSION DRAFT

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1 fraud and abuse in the administration of
2 the program under this section".

3 SEC. 4. CLARIFICATION OF TREATMENT OF DELIVERY
4 COSTS UNDER NEGOTIATED DISCOUNT
5 PRICES.

6 (a) TREATMENT OF DEPOT DELIVERY.—Section
7 1928(d)(3) of the Social Security Act (42 U.S.C.
8 1396a(d)(3)) is amended—

9 (1) in subparagraph (B), by striking "and any
10 applicable" and all that follows through "of 1986"
11 and inserting "to State depots"; and

12 (2) in subparagraph (C), by striking "such vac-
13 cine" and inserting "such vaccine (including delivery
14 costs to State depots)".



15 (b) ADDITIONAL CONTRACT AUTHORITY FOR OTHER
16 DELIVERY METHODS.—Section 1928(d)(3) of such Act
17 (42 U.S.C. 1396a(d)(3)) is amended by adding at the end
18 the following new subparagraph:

19 "(D) ADDITIONAL CONTRACTING AUTHORITY
20 FOR OTHER DELIVERY METHODS.—

21 "(i) IN GENERAL.—With respect to
22 contracts entered into under this sub-
23 section for pediatric vaccines, the Secretary
24 shall, at the request of a State, negotiate
25 with manufacturers of the vaccines or with

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DISCUSSION DRAFT

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licensed distributors of the vaccines to provide for the delivery of the vaccines through a program described in clause (ii) rather than through delivery of vaccines to a State depot.

"(ii) PROGRAM DESCRIBED.—A program described in this clause is

"(I) a replacement program under which a manufacturer or licensed distributor supplies doses of a pediatric vaccine to program-registered providers administering such vaccine to federally vaccine-eligible children and periodically replaces the supply of such vaccine; or

"(II) an alternative delivery system that is operated by the State under which a manufacturer or licensed distributor supplies doses of a pediatric vaccine to program-registered providers administering such vaccine to federally vaccine-eligible children and that has been demonstrated by the State to result in delivery costs and quantities of vaccines

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DISCUSSION DRAFT

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1 purchased that do not exceed what
2 such costs and quantities would be
3 under a replacement program de-
4 scribed in subclause (I)."

5 (c) CLARIFICATION OF PROVISION RELATING TO
6 QUANTITIES OF VACCINES.—Section 1928(d)(4) of such
7 Act (42 U.S.C. 1396s(d)(4)) is amended—

8 (1) in the heading, by striking "AND TERMS OF
9 DELIVERY"; and

10 (2) in subparagraph (A), by striking "and deliv-
11 ery".

12 (d) CLARIFICATION OF PROVISION RELATING TO RE-
13 PORTS.—Section 1928(d)(5) of such Act (42 U.S.C.
14 1396s(d)(5)) is amended—

15 (1) in the heading, by striking "CHARGES FOR
16 SHIPPING AND HANDLING" and inserting "RE-
17 PORTS"; and

18 (2) by striking "and if," and all that follows
19 and inserting a period.

20 (e) CONFORMING AMENDMENT.—The heading of sec-
21 tion 1928(d) of such Act (42 U.S.C. 1396s(d)) is amended
22 by striking "WITH MANUFACTURERS".

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DISCUSSION DRAFT

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1 **SEC. 4. LIMITATION ON STATE ABILITY TO PURCHASE VAC-**
2 **CINES AT FEDERAL PRICE.**

3 (a) **IN GENERAL.**—Section 1928(d)(4)(B) of the So-
4 cial Security Act (42 U.S.C. 1396s(d)(4)(B)) is amended
5 by striking "each State" and inserting "each eligible State
6 (as described in paragraph (5))".

7 (b) **STATES ELIGIBLE TO PURCHASE AT FEDERAL**
8 **PRICE DESCRIBED.**—Section 1928(d) of such Act (42
9 U.S.C. 1396s(d)) is amended—

10 (1) by redesignating paragraphs (5) through
11 (7) as paragraphs (6) through (8); and

12 (2) by inserting after paragraph (4) the follow-
13 ing new paragraph:

14 "(5) **STATES ELIGIBLE TO PURCHASE AT FED-**
15 **ERAL PRICE DESCRIBED.**—

16 "(A) **IN GENERAL.**—A State is eligible for
17 purposes of paragraph (4)(B) if the State—

18 "(i) is a universal purchase State (as
19 defined in subparagraph (B)); and

20 "(ii) does not have in operation a
21 trust fund or similar mechanism consisting
22 of contributions from private entities that
23 provide health care or offer or sell health
24 plans from which amounts are used to pur-
25 chase vaccines pursuant to contracts of the
26 Centers for Disease Control and Preven-

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DISCUSSION DRAFT

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1 tion with vaccine manufacturers (unless
2 such trust fund was in operation as of July
3 1, 1994).

4 "(B) UNIVERSAL PURCHASE STATE DE-
5 FINED.—

6 "(I) IN GENERAL.—In paragraph
7 (4)(B), the term 'universal purchase state'
8 means any of the following:

9 "(I) A State which has in effect
10 as of July 1, 1994, a vaccine purchase
11 program designed to assure immuni-
12 zation of all children in the State with
13 the vaccines specified in subparagraph
14 (C) without charge.

15 "(II) A State which advises the
16 Centers for Disease Control and Pre-
17 vention as of July 20, 1994, of its in-
18 tent to provide the vaccines specified
19 in subparagraph (C), and, by October
20 1, 1994, provides all such vaccines in
21 volumes necessary to assure immuni-
22 zation of all children in the State,
23 pursuant to contracts of the Centers
24 for Disease Control and Prevention
25 with vaccine manufacturers with effec-

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DISCUSSION DRAFT

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1 tive dates on or before October 1,
2 1994.

3 "(III) A State which manufactur-
4 ers any of the vaccines specified in
5 subparagraph (C).

6 "(C) VACCINES SPECIFIED.—The vaccines
7 specified in this subparagraph are as follows:
8 diphtheria, pertussis, tetanus, oral polio, mea-
9 sles, mumps, and rubella."

10 (c) CONFORMING AMENDMENT.—Section
11 1928(d)(4)(A) of such Act (42 U.S.C. 1396s(d)(4)(A)) is
12 amended by striking "paragraph (6)" and inserting "para-
13 graph (7)".

14 **SEC. 6. EXTENSION OF VACCINE REPLACEMENT PROGRAM**

15 Section 1902(a)(32)(D) of the Social Security Act
16 (42 U.S.C. 1396a(a)(32)(D)) is amended by striking "Oc-
17 tober 1, 1994" and inserting "January 1, 1995".

18 **SEC. 7. DISCOUNTED PRICES FOR CERTAIN VACCINES**

19 **UNDER THE PUBLIC HEALTH SERVICE ACT.**

20 Section 317(j)(1) of the Public Health Service Act
21 (42 U.S.C. 247b(j)(1)) is amended by adding at the end
22 the following new subparagraph:

23 "(C) With respect to contracts entered into under
24 this paragraph for a pediatric vaccine for which the Cen-
25 ters for Disease Control and Prevention (referred to in

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DISCUSSION DRAFT

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1 this subparagraph as the "CDCP") had a contract in ef.
2 fect under this paragraph as of May 1, 1993, no price
3 for the purchase of such vaccine shall be agreed to by the
4 CDCP under this paragraph if the price per dose of such
5 vaccine (including delivery costs) exceeds the price per
6 dose for the vaccine in effect under such contract as of
7 such date increased by the percentage increase in the
8 consumer price index for all urban consumers (all items;
9 United States city average) from May 1993 to the month
10 before the month in which such contract is entered into."

11 **SEC. 8. EFFECTIVE DATE.**

12 The amendments made by this Act shall take effect
13 as if included in the enactment of section 13881 of the
14 Omnibus Budget Reconciliation Act of 1993.