



**CENTER FOR HEALTH POLICY RESEARCH**

**FAX FROM:**

*Sara Rosenbaum, J.D.*  
*Voice: (202) 296-6922*  
*Fax: (202) 296-0025*

**TO:** Carol Rasco

**FAX NUMBER:**( ) 202 - 456 - 2878      **PAGES SENT:** 2

**MESSAGE:**

August 25, 1994

## MEMORANDUM

TO: Carol Rasco

FR: Sara Rosenbaum

RE: Vaccines

It's 5:30 p.m. and I have just reviewed the Bumpers/Danforth version of the vaccine bill (I note the time only because there have been several versions). This bill is very bad in certain respects, particularly because it would tie states' hands and force them to maintain vaccine replacement programs even if that is not what they do now. It is my understanding that the House has informed Senator Bumpers' staff that they cannot support the measure for several reasons.

The Department is now willing to reconsider its restrictive interpretation of the VFC statute regarding contracts with manufacturers. It was that restrictive interpretation that led to all of these problems to begin with. A letter from the House and Senate hopefully is on its way to the Secretary indicating that they would encourage her to liberalize her reading of the bill to permit delivery contracts with manufacturers. Since we already have cancelled the warehouse, this would permit the Department to work out an alternative delivery system without legislation.

I have urged this action since last November, when the original strict interpretation of the statute was first discussed. I said then, and I will say today, that there is no point in reading this bill in a way that does in an option to contract with the manufacturers. If the liberal reading had been adopted, we never would have gone the warehouse route and never would have given the manufacturers such a wide opening.

I think that it is imperative for the states (who all want this program) for the doctors (who want this program) and for the children (who need the program) that you tell the Department that it should take the most liberal interpretation of the law possible so that we are not faced with incredibly damaging further legislation that takes away the vaccine benefits altogether or makes the whole system inoperable.

I will be picking up Rachel from camp this weekend and can be reached at the Days Inn in Liberty, NY beginning tomorrow evening (914/292-7600). I'm sure that you are overwhelmed over there. But if you have questions, please feel free to call.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

AUG 25 1994

AUG 26 REC'D

**MEMORANDUM**

**TO:** CAROL RASCO  
**FROM:** KEVIN THURN   
**SUBJECT:** Vaccine Initiative

Attached please find a letter just faxed to me concerning the vaccine initiative. It conveys Congressional intent that delivery to private doctors by manufacturers could be paid for outside the capped price.

Let's try and catch up on this and other related issues tonight or tomorrow morning.

**Congress of the United States**  
**Washington, DC 20515**

August 25, 1994

The Honorable Donna Shalala  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Madame Secretary:

As the effective date of the Vaccines for Children (VFC) program approaches, we are concerned that the delivery system for vaccines to be used in private physicians' offices has not been put in place. Based on discussions among our staffs after the Administration abandoned its plan to deliver vaccine through a consolidated warehouse, it has become clear that the Administration has refrained from initiating negotiations directly with the manufacturers because of a concern that the authorizing statute did not allow such delivery payments to the manufacturers.

We did not intend for the VFC law be so restrictive. The intent of the Congress was to anchor vaccine prices to the CDC contract in place on May 1, 1993, and to include within that capped price the costs that were included within the CDC contract. As you have already correctly concluded, that contract price did not include excise taxes and, therefore, the excise taxes should be paid as part of the VFC program, over and above the capped price. Similarly, that contract price included only charges for bulk delivery and did not include charges for direct delivery to physicians' offices. We believe that you should likewise conclude that the Congress did not intend to restrict VFC payments for direct delivery and that, therefore, the direct delivery costs should be paid as part of the VFC program, over and above the capped price.

We would encourage you, based upon this understanding of Congressional intent, to re-examine your position on this matter as soon as possible and to initiate negotiations for the delivery of VFC vaccine immediately. We will continue to work to make this position explicit in the

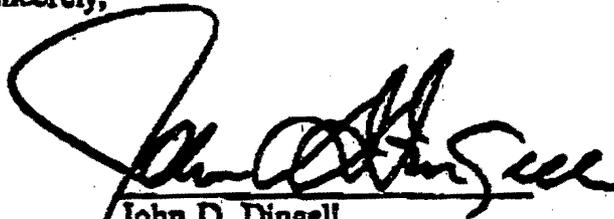
The Honorable Donna Shalala  
Page (2) of (2)

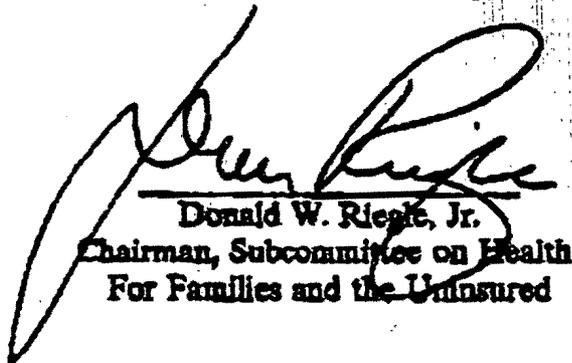
statute, but, since we believe that the statute as it stands is not as restrictive as you have interpreted it to be, we do not believe that you should delay action until the completion of that legislation.

Thank you for your attention to this matter.

Sincerely,

  
Henry A. Waxman  
Chairman, Subcommittee on  
Health and the Environment

  
John D. Dingell  
Chairman, Committee on  
Energy and Commerce

  
Donald W. Riegle, Jr.  
Chairman, Subcommittee on Health  
For Families and the Uninsured



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): 4

COMMENTS:

7/25 9 a.m. → Tues. Conf. Call

Sen.

① Statements for record

Sens approach Bumpers directly  
Report lang. spills into Fin Comm. (handle in conf.)  
Week or more to work

- ② Continue to work w/ Bumpers
- ③ Redline

House

Pass. of Motion + Instr.

Is prov. unconstit.?

Jurisdictional issue

Pay go problem? If so, pt of order

Jury: de w/ Ober's COS a preemp<sup>MTI</sup>

Conf.

Liderle - no to any other delivery

Merck - prob. no " vaccine co, maybe a 3rd party

GSA/HHS continue briefings on HHS/Sec

7/26

Wed. → Bumpers

Klept - Briefing from for House approp.  
2- Re-emptive motion to instruct  
HHS drafting 2-3 options

# Redline proposed

Cut back on requirements - Elim 2nd yr

Nancy Au -  
Cost figures  
P. Day Buford

Ken A. CDC → how fast competitive  
avid process? 4 mos.

Emer. desig 2-3 wks cut off

Qam

THE WHITE HOUSE  
WASHINGTON

Qam Wed

456-6777

J. Klein

may be  
(a few min  
late)

Leg. Affairs: Thornton  
Chow

HHS

Flurron

GSA

Silley <sup>501-</sup>0800

OMB

Min 55178  
(Clendenue)

Jerry R → Thurs.

Nancy Ann Min →

HHS

Satcher

Bell Cowe

Walt Orenstein

GSA:

Roger-Frank

~~Ratchford~~  
~~etc~~

Waxman called Shalala

Karen

Jim

Ruth

K Halcombs - Benzell's staff

---

THE WHITE HOUSE

K. 690-6133

Silby

501-0800

~~20 min 9:00~~

HAS

OK

Thurston

Leg Affairs

OMB

gan

486-1777

gam

---

Barbara Silby

---

GSA OK

Proposed Children's Vaccine Provision  
in Health Care Reform  
July 25, 1994

General Requirements

o Every family health insurance policy (including self-insured health plans) which is issued or renewed during 1995 will be required to include coverage for children's preventive health care.

o During first policy year, family health plans would cover, at a minimum, without deductibles and coinsurance:

- childhood immunizations, including administration
- well child care (as defined by American Academy of Pediatrics)

o During second policy year, family health plans would add coverage, at a minimum, for:

- prenatal care
- delivery
- new born care

*Includes self-insured*

Changes in VFC Program

o The current VFC program would be modified in two major ways:

- Eligibility would be changed to remove any reference to the "underinsured" *vs. uninsured, Nat. Amer., Alaskan not, XIX*
- States ability to purchase additional vaccines at the CDC price for non-VFC children would be restricted.

States' Ability to Purchase Additional Vaccine

o Current 12 "universal purchase" States would be grandfathered.

o Current 11 States that have indicated their intention to become universal purchase States (at CDC price) may do so only if:

- they purchase the three major vaccines for all additional children -- MMR,  PV, DTP
- they purchase vaccine during the current CDC contract negotiations for use beginning October 1, 1994

*Lederle floated on earlier draft: Waxman Matsui Wadd Riegle? Lederle claims they've talked to EKSA 8/9.*

o No State (except New Hampshire) may establish a trust fund, or other similar dedicated funding source, for the purpose of seeking contributions from private insurance companies to allow the State to purchase additional vaccine

o All States would be allowed to purchase vaccine under current "optional use" provision in CDC contracts

Enforcement

o Civil action to enforce insurance mandate may be brought by covered individuals, State Attorney General, the U.S. Attorney General, and the Secretary of Labor in the case of a self-insured plan. Civil money penalties are applicable.

*As who }  
currently }  
seek to }  
do this }  
have }  
been }  
allowed }*

# Immunization

7/25

## Bumpers Amendment

- Have states been notified?

- Bid solicitation begun? (See Report Lang)

- Fee issue

- Bottom line - if this amend. starts -  
Oct. 1 - what happens to kids?

M 5-6

W 1 hr. Sr. staff

Th Review  
Forward look

THE WHITE HOUSE  
WASHINGTON

7/20/94

Gerry Klepner dropped off  
the attached bumper's  
Amendment.

Roz

## GSA AMENDMENT

JUL 20 REC'D

BILL LANGUAGE

None of the funds made available by this Act shall be obligated or expended for storage or distribution of publicly-purchased pediatric vaccine through a warehouse and distribution facility operated by the General Services Administration until such time as the Secretary of Health and Human Services receives written approval by the Appropriations Committees of both the House and Senate: Provided, That such approval shall be contingent upon the following requirements:

- a) All aspects of the ordering, storage, packaging and distribution system are fully developed, tested and validated in accordance with requirements imposed on commercial manufacturers and distributors;
- b) The Commissioner of FDA has conducted a complete review of all aspects of the system, has reviewed and verified documentation of testing and validation procedures, and has provided documentation to the Committees of both the House and the Senate that all licensing and performance standards required of commercial distributors have been met by the General Services Administration system; and
- c) The Secretary has provided documentation to the Committees of both Houses that the cost of the General Services Administration system is lower than the cost of private sector bids.

REPORT LANGUAGE

The General Accounting Office has found that the joint HHS/GSA plan to store and distribute pediatric vaccine cannot be implemented by October 1, 1994 without risk to the supply and availability of the vaccine. The General Accounting Office has also found that storage and distribution of the vaccine supply may be accomplished more quickly and cost-effectively by private sector distributors and manufacturers than by the GSA.

The Committee directs DHHS to immediately begin the contract process to solicit bids for private sector storage and distribution of pediatric vaccine. The Secretary is directed to report to the Committee on a monthly basis regarding the status of the bid solicitation process.

The Secretary may choose to continue development of a CDC/GSA warehouse and distribution system at the same time the contract solicitation process is underway. Should the Secretary do so, and should that process be completed in full compliance with FDA Current Good Manufacturing Practices, the Secretary must demonstrate that the cost of the CDC/GSA system is lower than the cost of private sector bids. The Secretary must then submit documentation to the Committees of both Houses for review and

approval for use of funds.

Any CDC/GSA storage and distribution system must meet all applicable FDA guidelines required of commercial vaccine distribution facilities and systems. The Committee directs the Secretary to ensure that the Commissioner of the FDA: (1) conduct a complete review of the proposed ordering, storage and distribution system (including the information systems used for ordering, storage and distribution), and an inspection of the GSA facility and equipment, consistent with review and inspection of commercial vaccine distribution facilities; and, (2) document for the Congress that GSA has met all requirements and has been held to the same licensing and performance standards required of the private sector.

Until a new storage and distribution system can be developed and approved by the FDA or contracted for with commercial providers, the Secretary is directed to maintain the current system of bulk delivery for vaccine to be purchased through the 317 and VFC programs. For those states that choose not to take bulk delivery for vaccine administered to Medicaid-eligible children, the Secretary is directed to maintain the current system of reimbursement to providers for vaccine administered to Medicaid-eligible children. The Federal Medical Assistance percentage for vaccine will be fixed at 100 percent, consistent with OBRA '93.

The Secretary has also established a fee schedule, based on customary charges, for private physicians who administer VFC-purchased vaccine. The General Accounting Office has found that this schedule is not in accordance with OBRA 93, which requires that fees be based on actual costs, rather than prevailing charges. The Committee shares GAO's concern that the Secretary's fee schedule represents an incentive to physicians at the expense of children who are uninsured. Accordingly, the Committee directs the Secretary to compute the actual cost of administering vaccines and to revise the fee schedule prior to October 1, 1994 and in accordance with the requirements of OBRA '93.

The Committee will request the General Accounting Office to continue monitoring the immunization program and to provide periodic reports on the Department's activities and performance.

THE WHITE HOUSE  
OFFICE OF DOMESTIC POLICY

**CAROL H. RASCO**  
*Assistant to the President for Domestic Policy*

To: \_\_\_\_\_  
\_\_\_\_\_

Draft response for POTUS  
and forward to CHR by: \_\_\_\_\_

Draft response for CHR by: \_\_\_\_\_

Please reply directly to the writer  
(copy to CHR) by: \_\_\_\_\_

Please advise by: \_\_\_\_\_

Let's discuss: \_\_\_\_\_

For your information: \_\_\_\_\_

Reply using form code: \_\_\_\_\_

File: \_\_\_\_\_

Send copy to (original to CHR): \_\_\_\_\_

Schedule ? :       Accept       Pending       Regret

Designee to attend: \_\_\_\_\_

Remarks: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington D.C. 20201

**FACSIMILE**

~~JUL 19 REC'D~~

DATE JUL 19 1994

JUL 20 REC'D

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): 3

COMMENTS:



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Chief of Staff

Washington, D.C. 20201

JUL 19 1994

MEMORANDUM

TO: Carol Rasco

FROM: Kevin Thurn 

SUBJECT: Immunization: Medicaid Transition Plan

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Attached please find a copy of a memorandum from Ken Apfel describing the six-month transition period for Medicaid providers about which we spoke earlier today.

If you have any questions, please do not hesitate to call me.

Attachment

CC: *Kevin Thurn*

## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

JUL 19 1994

NOTE TO NANCY-ANN MIN

From : Ken Apfel *KA*  
Subject : IMMUNIZATION: Medicaid Transition Plan

I wanted to let you know that we're planning a minor implementation adjustment--at no additional cost--in order to facilitate a smoother transition for the Vaccines For Children program. We intend to provide a limited 6 month transition period for Medicaid providers in which they will continue to receive reimbursement through the Medicaid program for childhood immunizations while we begin implementing VFC. (The Chair of the State Medicaid Directors' Association has requested a 1-year transition period.) During this time period, full Federal matching funds for vaccine costs would continue. States are concerned that where Medicaid providers have not elected to become VFC participants, they will have to bear 100 percent of the costs to vaccinate Medicaid eligible children. We are concerned that if we withdraw Federal matching funds, current Medicaid providers who do not join VFC may stop immunizing Medicaid-eligible children, or possibly end their Medicaid participation altogether. (This could be a serious problem in areas with limited access to public health clinics.)

We expect the budget impact to be negligible--that is, simply a slight shift from the VFC program to Medicaid without any cost increase. (You will recall that we shifted \$170 million from the Medicaid program to VFC last January.) Where States reimburse for Medicaid vaccine, we expect that our outlay will be less because of the State match--even for vaccine purchased at the catalog price. However, since there is a strong incentive for States to immunize children with vaccine purchased with 100 percent Federal funds under VFC, we expect that most States will phase out Medicaid payments quickly. From our perspective, if indicated, we can make a scoring adjustment to reflect a revised FY 1995 estimate for the VFC entitlement program next January.

Some may argue that this transition period indicates that the Administration's resolve for VFC implementation is wavering, but I'm confident that we can handle this and any unwarranted criticism. Limiting the transition period provides a clear expectation that VFC will be fully operational in all States by April 1, 1995, and at the same time, provides necessary time for States to recruit additional providers.

cc: Barry Clendenin



DREW E. ALTMAN, PH.D.  
PRESIDENT

JUL 22 REC'D

To: Carol, Jennifer

Fr: Sara

F 202/456-2878

T 202/456-2216

July 21, 1994

MEMORANDUM

TO: Carol

FR: Sara

RE: Immunization

This memo lays out what I think are key points as we fashion our immediate response to the Bumpers amendment and work to craft a longer-term solution.

- ▶ It's really important to immediately let states know in a carefully worded transmittal that the amendment has occurred, explains what it does, and indicates that the Administration is working on ways to ensure that both we and the states can carry out the program in a timely fashion. The Bumpers Amendment changes neither the Secretary's legal obligation to assure that VFC-eligible children receive vaccine nor states' obligation to maintain the VFC program as part of their Medicaid plans. States need reassurance that there are several options we are pursuing.
- ▶ I think that a strong positive message to states is essential both for the program and to dispel the sense that we are negotiating from a position of weakness and fear rather than from a resolve to do what is important for children. We will need to do a great deal of negotiation in the next few weeks. These talks should happen in the context of our resolve to carry out the program for children not because we are being buffeted by external events.
- ▶ The amendment leaves us with two immediate delivery options, either of which *may* require a delay in the effective date of the law, although it is too soon to tell. First, the Department could invoke its emergency powers and suspend normal contract rules to quickly secure a private wholesale bid for a national warehouse and distribution system. The emergency in this case is an October 1 program affecting 80% of the nation's children and the bulk of the national pediatric vaccine supply. A second alternative route is to contract with states to receive all VFC vaccines through their depots and to ship to VFC providers, just as the 12 universal states in effect do right now.

*For Constitutional reasons discussed below, I believe that both approaches must be pursued.*

- ▶ We need to decide what to do about the legal problems posed by the Bumpers amendment. First, the amendment may have Budget Act implications. Second, the amendment may be unconstitutional for several reasons.

*Budget Act:* By leaving the current Medicaid system in place, the amendment

effectively compels higher Medicaid spending than the levels contemplated under OBRA 1993. In addition, by effectively forcing us to use a more expensive distribution system<sup>1</sup> the Bumpers amendment may force distribution spending well over the level contemplated by the 1993 law. Given the issues raised by the amendment, we need a fast decision about whether to try to strip the provision and an assessment of what might occur next if we were to take the provision on in this way.

*Constitutional issues:* To the extent that the amendment requires states to distribute VFC while the Secretary negotiates a private contract or proceeds with the GSA system, the provision arguably an unconstitutional exercise of the Congress' Spending Powers and may violate the 10th Amendment. *We cannot compel states to act as our agents. We must have a federal system for states that elect not to deliver (as the 12 universal states do).* This is the same issue we ran into in health reform.

- ▶ As we have discussed, even if we can get through this round, (either by coming up with a fast distribution alternative or by killing the amendment somehow) we face a further effort to kill the program as part of the national health reform debate on the Senate floor. We need to be ready with what we want in exchange. This could be a fast phase-in of insurance for children and mothers, mandatory immunization coverage for all under-insured children, a return to the residual §317 program for state health agencies and a Medicaid replacement program for the period between reform and the consolidation of all children into a unified health insurance system. All states that currently have universal programs would be allowed to continue. We need to decide what to do with the states do not yet have such a program but that want one (which is by no means inconsistent with universal insurance coverage). The manufacturers above all want to terminate the state optional use clause.

It seems to me that if we trade VFC for comprehensive insurance coverage for all children with the blessing of everyone who wants to see VFC disappear, we will have lost the battle but won the war. We need to make these *our* moves, however, and not let someone else gain the upper hand.

I do not believe that people should rush up to Those who are opposed to the program should not be able to get the to they are entitled the law. Until the actual law changes the Administration can and must carry it out. While the Bumpers amendment limits our means for delivering vaccines, the obligation remains.

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<sup>1</sup> Any contract with a private wholesaler will be higher than the GSA contract. Furthermore, we might need several contracts because of Merck's refusal to let anyone ship its vaccine.



CENTER FOR HEALTH POLICY RESEARCH

JUL 20 REC'D

Number of sheets including cover sheet: 17

TO: Carol Rasco, c/o Roz

OF: \_\_\_\_\_

PHONE: \_\_\_\_\_

FAX: 456-2878

FROM: ELIZABETH WEHR - for Sara Rozubanu

PHONE: (202) 296-6922 after 6 p.m. 296-6822

FAX: (202) 296-0025

MESSAGE: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## MEMORANDUM

**TO:** File

**FROM:** Elizabeth Wehr

**DATE:** July 19, 1994

**RE:** Press Conferences of July 19, on GAO report, *Vaccines for Children; Critical Issues in Design and Implementation*

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### 1) Members of Congress (Senate Press Gallery):

#### Senator Bumpers:

- plans "prohibition" of expenditure of funds on appropriations (won't try to amend health reform, b/c doubtful HR will pass)
- will hold hearing Thursday, July 21
- nothing in distribution program will raise vaccine rates
- cost has not been eliminated as a barrier b/c doctors can charge administration fees. The fees averaged \$5-\$7 at time of enactment, now have been raised to \$12-\$15.
- cost not the reason kids not being immunized; issues are missed opportunities, outreach
- information at time of passage "badly flawed"

#### Senator Danforth:

- favors scrapping VFC

#### Representative Klug:

- VFC sold to congress on basis of false information
- GSA has failed in the past; is inexperienced; all vaccines will be lost

#### Representative Wyden:

- GAO showed problems, but not that program should be scrapped
- Oregon health dept told him the October 1 deadline was unrealistic

2) HHS: Secretary Shalala (speakerphone), Dr. David Satcher (CDC), Roger Johnson (GSA), Kessler (FDA), Orenstein (CDC) Dr. Louis Cooper (AAP), Dr. George Rutherford, Deputy Director, California Department of Health Services (for ASTHO); & Texas Medicaid Director r made the following points: California preventive health & Texas medicaid

director, made the following points (many made by more than one speaker):

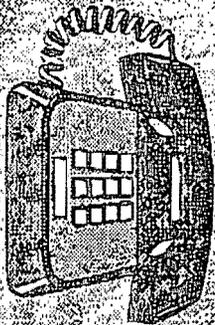
- purpose of immunization program is to put permanent infrastructure in place, to improve immunization, return kids to "medical homes"
- a "partnership w/ private sector"
- GAO report usefully points out issues to be resolved
- they're all resolveable
- by October first
- not all providers have to be signed up by October first; signups will continue after
- GSA managed to return lots of surplus, frozen food from desert storm operations to U.S., & to get it to 50 states, Puerto Rick, where it was redistributed to homeless. No spoilage. No advance notice to prepare
- FDA will apply industry standards to GSA packaging and shipping
- Only 8% nations' vaccine supply at GSA at any one time
- well over 1 million kids 19 months to 35 months not immunized; rates of 50% in some cities
- for lots of families, the vaccine cost is what makes them put off immunizations (Cooper, AAP)
- won't be w/out glitches, but "absolutely committed" to working them out (AAP)
- Cal, other state health departments so far along now, have already signed up lots of doctors & clinics. stop-start wrong message to send, would lose doctors that would otherwise paarticipate. "like trying to turn a battleship in the middle of the Potomac"
- "very, very important" to have GSA option to supplement state distribution; 1 million Texas kids un-, underimmunized; to tell the 260 local volunteer groups geared up to improve immunization to delay is the "wrong message" (Texas Medicaid)
- we're not relying on vaccine distribution alone to fix problem; Orenstein cited \$128.5 million for infrastructure & \$33 million for incentives for current year
- if capped price cuts into R& D, sec can go back to Congress to fix
- CDC shipping cost: 40 center a dose; Medicaid replacement program cost: \$2.00 a

dose

congressional press conf 7/19  
and report

# Current Distribution (Pediatric Vaccine, Public Sector)

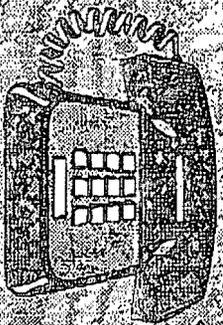
Physician



Manufacturer

Public Health

State

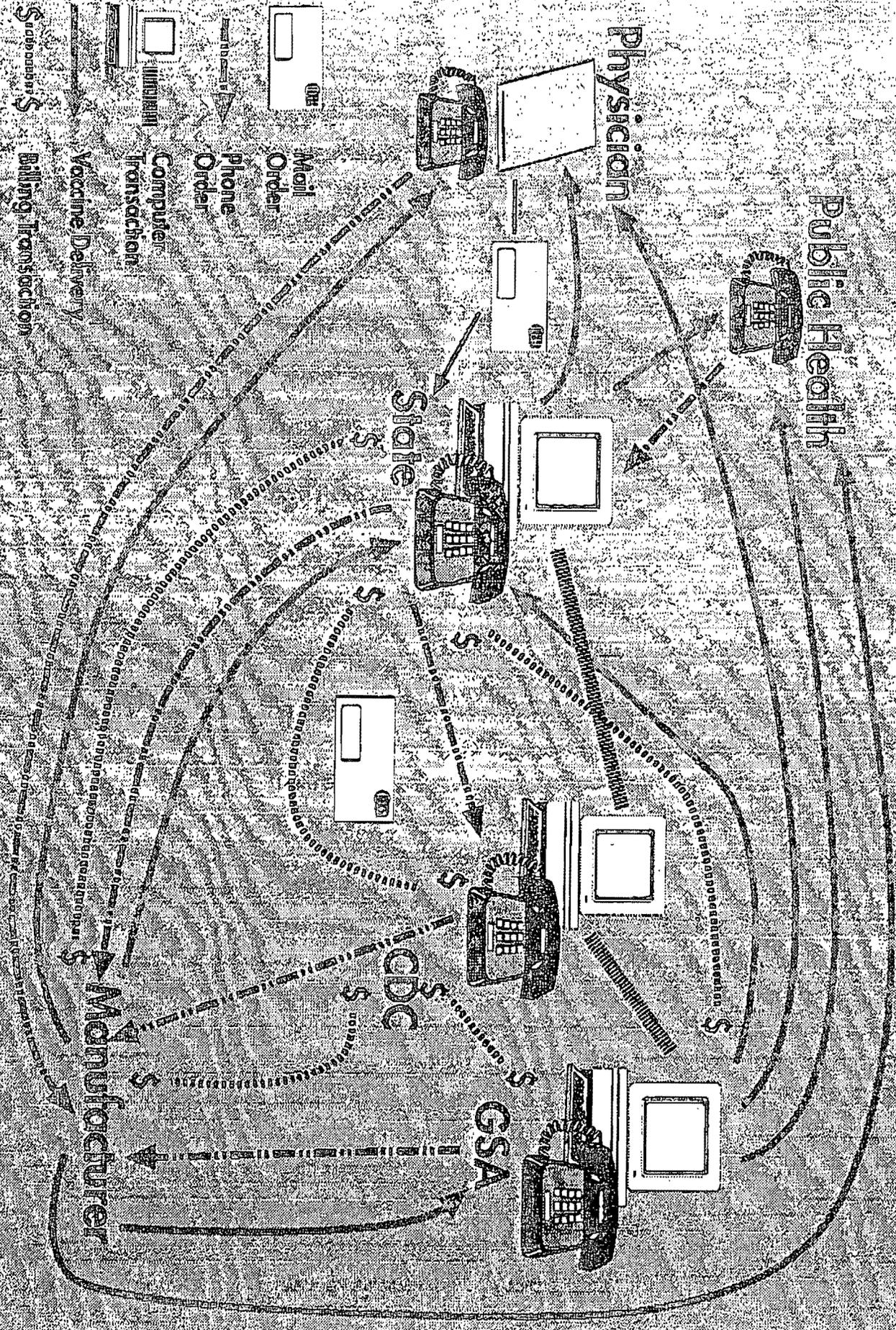


CDC



From Congressional press conf 7/19  
GAO report

# HHS Proposed "Seamless" Distribution System



FOR IMMEDIATE RELEASE  
Tuesday, July 19, 1994



**CDF CALLS VACCINE COST A SIGNIFICANT BARRIER TO TIMELY IMMUNIZATION OF NATION'S PRESCHOOLERS**

WASHINGTON, D.C. -- The Children's Defense Fund (CDF) today released the following statement in response to reported findings of the forthcoming General Accounting Office study of the Vaccines for Children program:

"CDF is concerned that a delay in the implementation of the Vaccines for Children program will increase the likelihood that thousands of children will not receive the immunizations they need to protect them from diseases that can cripple or kill such as measles and polio. Safe, effective, and timely implementation of the program is a key step in providing all children with basic preventive health care."

"Children cannot wait for more studies and reports -- nearly one-third currently fail to receive the full series of shots they need by age two."

"Certainly, well informed parents are critical to securing preventive health care for their children. But without access to affordable vaccines in their regular doctors' offices, parents who want to protect their children will be discouraged by long waits at public clinics and skyrocketing costs of vaccines, which rose this year to \$267.45 from \$16.97 in 1977.

"Contrary to recent claims, numerous studies have shown that the cost of vaccines is a significant barrier to timely immunization of America's preschool-age children. This is particularly true for many low and moderate income children whose usual source of health care is not a public clinic. The impact of vaccine cost as a barrier to timely immunization is demonstrated by those states that operate universal vaccine purchase systems that provide free vaccines for all children and evidence significantly higher immunization rates."



## VACCINE COSTS INHIBIT HIGHER IMMUNIZATION RATES

Contrary to some reported findings of the forthcoming General Accounting Office (GAO) report on the implementation of the Vaccines for Children program, vaccine costs are a major factor inhibiting the timely and appropriate immunization of America's preschool-age children. The Vaccines for Children program is designed to remove this barrier to immunization. The safe, effective, and timely implementation of the Vaccines for Children program must proceed as part of the nation's effort to raise our embarrassingly low immunization rates.

From 1977 to 1994 the cost of a full set of immunizations rose from \$16.97 to \$267.45. During the same period, the median income of young families with young children has plummeted. The combination of rising vaccine prices and falling incomes for young families has pushed full and timely immunizations beyond the financial reach of many poor and moderate-income children who are uninsured or have insurance that does not cover immunizations. **The cost of vaccines now is a very significant barrier to the goal of fully immunizing America's preschool-age children.**

The nation's low immunization rates are in part the product of overburdened public health clinics and missed opportunities to immunize children in private physicians' offices. In the face of rising vaccine costs, private doctors increasingly have suggested that families of modest means with no insurance for immunizations go to public clinics for immunization services. Rising vaccine costs also have outstripped Medicaid reimbursement rates in many states, prompting physicians to refer Medicaid children to public clinics for immunization services as well. This pattern of referrals have overwhelmed public clinics in many areas, increased dramatically the number of missed opportunities to immunize children, and allowed far too many children to fall through the cracks and go unprotected against potentially deadly but preventable diseases.

Several studies document the role of vaccine cost in the increasing practice of referring children away from their usual source of care to public immunization clinics.

- A 1993 survey of licensed pediatricians and family physicians in North Carolina showed that 93 percent of doctors referred children to public clinics for immunizations. Nearly all of the physicians (95 percent) cited parents' concerns over the cost of vaccines as a very important determinant in their decision to refer children to the health department. The authors concluded, "If out of pocket

costs to patients for immunizations were significantly reduced or eliminated, referrals to health departments for immunizations would decrease substantially and physicians would immunize a much greater proportion of patients in their offices. This change could potentially enhance both immunization rates and continuity of care."<sup>1</sup>

- The number of children in Dallas referred to public clinics for immunization increased nearly 700 percent between 1979 and 1988. The report stated, "A new influx of patients are using public sector immunizations, potentially creating additional financial stress for public health programs. In addition, this shift to the public sector may undermine the health departments' ability to provide new vaccines or protect greater numbers of children with immunization." In an earlier study, the authors found that 65 percent of children using public clinics for immunization did so because of high costs in private facilities.<sup>2</sup>
- Milwaukee physicians reported immunizing uninsured patients in their offices less often than patients with insurance. When insurance does not pay for immunizations, most physicians (81.6 percent) said they left the decision of whether to pay for private immunizations or seek free immunizations from the city health department to the family. Physicians estimated that approximately half of their uninsured patients decline private immunizations. The authors concluded that "when children leave their physicians' offices without receiving immunization, an opportunity -- is lost. There is no assurance that families who decline immunizations in their physicians' offices for financial reasons will subsequently have their children immunized in a timely manner."<sup>3</sup>
- After experiencing dramatic increases in the number of children seeking immunizations at public clinics, Orange County, California, health officials wrote, "Most private health insurance plans in the nation fail to provide coverage for preventive immunizations. As a result, many parents forego having their children immunized or use public clinics for immunization services. The public health system has been overloaded by the need to provide immunizations. As those in moderately difficult financial circumstances use the immunization services provided by the public sector, the traditionally underserved population in greatest need of immunization and at higher risk for vaccine-preventable diseases may be increasingly displaced. This factor may be exacerbating and feeding the U.S. measles epidemic. American families must be given the financial means to gain access to private physicians in their communities for childhood immunizations."<sup>4</sup>
- In a northern California study, 61 percent of public immunization clinic patients had a family doctor or other medical home and would have preferred to have their children immunized by those providers. Most named cost as the main barrier to immunization at their usual well-child care sources.<sup>5</sup>

The impact of vaccine cost as a barrier to timely immunization is demonstrated by those states that eliminate this barrier by operating universal vaccine purchase systems. It has been shown that when other factors are held constant, states with universal programs have significantly higher immunization rates -- approximately ten percentage points higher than other states.<sup>6</sup> States are well aware of the advantages of a universal vaccine system. Twelve states currently operate a universal system and nine additional states intend to develop such a system under the Vaccines for Children program. When asked, twenty other states said that they would prefer to have state universal purchase and that financing was the only thing preventing them from having a universal system.

In short, study after study has shown that the cost of vaccines is a barrier to timely immunization for many children whose usual source of health care is not a public clinic. It is not a sufficient answer to say that vaccines are "affordable" because they are available at public clinics. The burden placed on public clinics by the influx of children seeking immunization services means reduced access for those children who use public clinics as their usual source of care, long waiting times for vaccinations at the clinics, and uncounted missed opportunities as the referrals and red tape deter families from following the vaccine. Vaccines must be affordable at families' regular source of care.

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ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS  
415 Second Street, N.E., Suite 200, Washington, D.C. 20002  
(202) 546-5400

## ASTHO STATEMENT ON THE VACCINES FOR CHILDREN PROGRAM

July 19, 1994

The Association of State and Territorial Health Officials (ASTHO), which represents the chief health official from each state and U.S. territory, strongly supports any initiative that effectively strengthens state health agency capacity to improve immunization rates for the nation's children. The Vaccines for Children program, a key component of the President's Childhood Immunization Initiative, offers the promise of achieving this. By providing state health agencies with the resources necessary to equip both public and private providers with federally funded vaccines, the program effectively eliminates cost as a barrier to immunizing uninsured children and offers them protection from a host of deadly vaccine preventable diseases.

Throughout the past year, states have collaborated closely with the Centers for Disease Control and Prevention and our health care provider colleagues in the private sector, to anticipate and resolve potential barriers to successful implementation of the Vaccines for Children program. Today, despite the less than optimistic report from the Government Accounting Office, ASTHO remains committed to assuring successful implementation of the Vaccines for Children program on October 1, 1994.

States are fully acquainted with the procedures necessary to assure the safety and efficacy of vaccine storage and delivery systems. Many states have long histories of success in developing and utilizing their own statewide vaccine storage and distribution facilities. For approximately half of the states, the national distribution system offers a cost-effective alternative to establishing a separate statewide distribution system.

Implementation of any historic national initiative with the potential to improve the health status of so many of our youngest, most vulnerable Americans, requires time, energy and commitment. On October 1, this investment will only begin to return the dividends of healthier children--a benefit we will enjoy for years to come. The program will not be flawless on this date; issues will remain that will require the partnership of all of us here today to resolve. We must accept this challenge. We urge Congress to recognize the investments already made in the Vaccines for Children program, and to join states in our commitment to implement this important immunization initiative as planned.

V1711 1000 4 001  
HHS

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# United States Senate

COMMITTEE ON FINANCE  
WASHINGTON, DC 20510-6200

LAWRENCE O'DONNELL, JR., STAFF DIRECTOR  
LINDY L. PAULL, MINORITY STAFF DIRECTOR AND CHIEF COUNSEL

July 15, 1994

Senator Daniel P. Moynihan  
Chairman  
Senate Finance Committee  
Dirksen Senate Office Building  
Washington, D.C. 20510

Dear Mr. Chairman:

One of the major achievements of the first session of the 103rd Congress was the President's Childhood Immunization Initiative, a vitally needed program to improve vaccine and immunization services to children.

The Childhood Immunization Initiative was enacted after close Congressional scrutiny showed that several barriers currently prevent our most vulnerable population, infants up to two-years-of-age, from receiving age appropriate immunizations. These barriers include a decaying immunization infrastructure, overburdened public health clinics, inconsistent messages to parents and health-care providers on the importance of immunization and the costs of vaccines and immunization services. This initiative is a multi-faceted effort to reduce and eliminate barriers to immunization and to achieve and maintain immunization coverage levels of over 90 percent for all recommended childhood vaccines.

But despite these laudable goals, there has been a great deal of misunderstanding about the Vaccines for Children Program (VFC), the part of the initiative that creates a national system for eligible children to receive free vaccines in their doctor's offices and other appropriate sites.

During Finance Committee consideration of the Health Security Act, two of our distinguished colleagues argued that the VFC is no longer necessary because the most recent data indicates immunization rates for children 0-2 have already risen close to 90 percent. Unfortunately, this is not the case.

As the accompanying chart indicates, national rates show that we still lag far behind in our national goal of 90 percent immunization coverage for the basic series of vaccines as recommended by the Advisory Committee on Immunization Practices (ACIP). The basic series of vaccines recommended by ACIP is: four doses of diphtheria, tetanus and pertussis; three polio doses;

July 15, 1994  
Page Two

and one dose of measles, mumps and rubella vaccine (4DPT/3polio/1MMR). National rates show coverage of only 72 percent by age three for this basic series. Experts, however, attribute this jump in immunization rates (from 55 percent in 1992) to national, State, and local efforts to make immunization of preschool children a priority and increased awareness of the importance of vaccinations following the measles resurgence between 1989 and 1991.

While relatively high immunization rates for specific antigens do show improvement, this does not mean that children have received the appropriate combination of recommended vaccines. For example, the chart shows that rates for the recommended number of DTP shots (4) increased from 59 percent in 1992 to 75 percent in 1993, but the overall rate for recommended vaccines, as stated above, is still 72 percent.

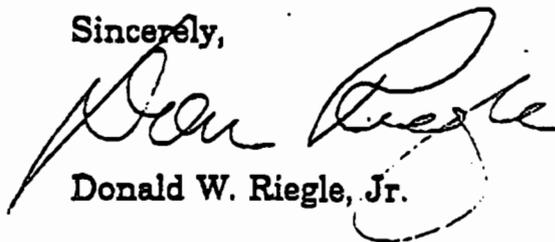
During last year's consideration of the Childhood Immunization Initiative, the Administration cited, and clearly noted, two sources of immunization data. The first, reproduced from a March 1993 General Accounting Office report, indicated the U.S. was far below in immunization rates for preschool children compared with European countries. The second source of data was drawn from the 1991 National Health Interview Survey -- the most current data available at that time. That data indicated extremely low immunization rates for the basic immunizations and estimated basic coverage at between 37-56 percent.

Immunization coverage in the U.S. is not spread evenly, resulting in large pockets of under-vaccinated children and leaving over a quarter of our children with inadequate protection. Progress needs to be made now, and continued in the future, if we are to ensure that all our children are protected against killer diseases. By creating an immunization infrastructure, we can reach and sustain the goal of 90 percent coverage for all recommended vaccines. The Childhood Immunization Initiative, and particularly the Vaccines for children program, is the cornerstone of this endeavor.

July 15, 1994  
Page Three

I would like to work with you on implementing this vital program. If you or your staff have any questions about this program, please feel free to contact me or my staff at 224-4822.

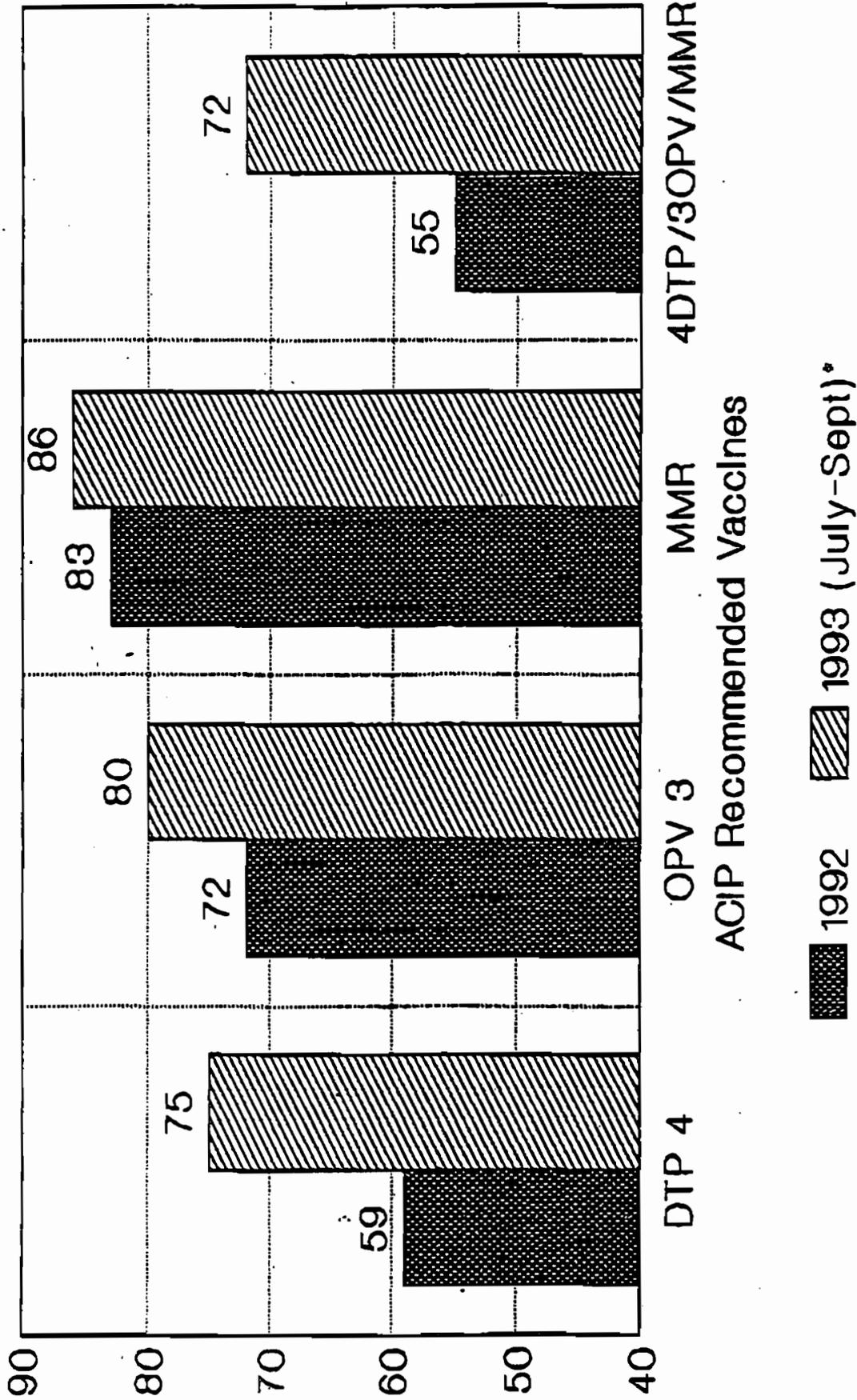
Sincerely,

A handwritten signature in cursive script, appearing to read "Don Riegle". The signature is written in black ink and is positioned above the printed name.

Donald W. Riegle, Jr.

encl.

# Immunization Rates by Vaccine Children -- 19-35 Months (Percentages)



\*Provisional Data

EXECUTIVE OFFICE OF THE PRESIDENT

14-Jul-1994 04:11pm

TO: Carol H. Rasco  
FROM: Stephen C. Warnath  
Domestic Policy Council  
SUBJECT: Meisner briefing for Agency Chiefs of Staff

*made*

Carol --

Welcome back!

Several things:

1) Doris' schedule permits her to brief agency chiefs of staff on Friday July 22 between 2-3pm. The format would be a presentation by Doris for 1/2 hour and to have a discussion/Q&A of their thoughts and concerns for the remainder of the time. What do you think of that in terms of timing and approach?

2) Susan Martin has invited me, Bob Bach of INS and Lin Lui to meet with her this afternoon. This will give us a better idea of their preliminary recommendations. Do you see any problem with meeting with her? I promise not to endorse the idea of a national I.D. -- or anything else for that matter. I invited her to come and brief agency representatives in the next week or so and she would be delighted to do that. Barbara Jordan's testimony has been moved back and is scheduled for August 3rd. I raised the possibility of Barbara Jordan meeting w/ you and/or the President on that day depending on schedules, etc. and she thought that sounded great. It would probably have to be immediately after she finished her testimony because she has to go to Massachusetts that evening.

*E.M.  
ailed  
Picki  
7/18*

3) I will bring you my memo regarding the President's immigration report later this afternoon.

4) I will have a memo for you on reinvigorating the immigration interagency working group tomorrow.

5) I provided some material to Public Affairs regarding immigration in preparation for the President's trip to Florida. I will bring you a copy of that material as well.

Thanks.

Blue back

Read report

Can't pass, get up & running  
by Oct. 1 - disastrous  
to try

- Only 5 states have asked prior docs

Plenty of errors can be antic

HH S doesn't have a clue as to  
all the probs in temp.  
distrib.

6-11 mos. to validate ~~leg.~~ shipping  
lists

Almer  
Assor  
off-leds  
Press  
conf

Bumper  
Wagner  
Danforth  
Reuz  
Call for elim. of pref.  
seek  
substantive  
delay  
Press  
Conf.

224-4843

EXECUTIVE OFFICE OF THE PRESIDENT

18-Jul-1994 08:58am

TO: Rosalyn A. Miller  
TO: Patricia E. Romani  
  
FROM: Carol H. Rasco  
Economic and Domestic Policy

SUBJECT: Sen. Bumpers

*on hold*

The chances are good Sen. Bumpers may call me today and I know I had given signals I am to be found at all costs. I cannot, however, talk to him until I have a faxed document from HHS that we need to be on the serious outlook for...about immunization program. If his office calls and I haven't gotten that piece of paper you need to tell them I am out of the building, that you can certainly reach me and/or shall I call at another time convenient to him. Then notify me so I can hit hard on HHS if that piece of paper isn't here. I assume the paper hasn't arrived this a.m.?

Thanks.

THE WHITE HOUSE  
WASHINGTON

Jax Kevin

+ 4 of 15 contracts signed  
2 more mos. to negotiate

+ Provider enrollment

# is very low

S.R. suggests we enroll  
all public providers

+ Provider reimbursement

No one understands GAO

There is a <sup>the</sup> schedule, it is  
reasonable

+ Software

On schedule but training  
of state folks has only  
just begun

+ Distribution

We won't move on any step  
w/out FDA cert.

+ Accountability

# CDC

**CENTERS FOR DISEASE CONTROL AND PREVENTION**  
*"The Nation's Prevention Agency"*

**CENTERS FOR DISEASE CONTROL  
AND PREVENTION  
Washington Office  
202-690-8598  
FAX: 202-690-7519**

DATE 7/14/94 PAGES ~~8~~ 7 + Cover

TO Sara Rosenbaum  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Phone: \_\_\_\_\_

Fax: ~~202-690-8598~~ 202-456-2878

FROM Dr. Walt Orenstein  
\_\_\_\_\_  
\_\_\_\_\_

Phone: \_\_\_\_\_

COMMENTS/NOTES \_\_\_\_\_

*Final 7/13/94***GAO ISSUES REGARDING VFC PROGRAM**

CDC recognizes GAO's three basic issues related to implementing the VFC program and has the following strategies for addressing them. According to GAO, no time was available for them to conduct independent testing of the VFC plans, and therefore, GAO based their thoughts on opinions of vaccine manufacturers, GSA, and limited questioning of states. Although GAO indicated that GSA and some States noted it would be helpful to have additional time to implement the program, based on our discussions with GSA and states, our indications are that the VFC program will be implemented by October 1.

**1. Validity testing of the Vaccine Delivery System.**

CDC recognizes that the GSA vaccine distribution system will require field testing. Based on CDC's technical expertise and States' experience, the following will take place in coordination with the GSA distribution center:

- The GSA distribution center will meet FDA and State of New Jersey requirements. (FDA will inspect the facility and evaluate the packaging procedures.)
- All packaging and shipping materials will be in accordance with safety standards for the shipping of both vaccines kept frozen and other vaccines that require refrigeration.
- The packaging will be tested and the vaccines will be shipped with analysis of the cold chain at every point of transfer between the GSA distribution center and the various destinations.
- CDC has worldwide experience in vaccine transport and cold chains as evidenced by smallpox eradication and the elimination of polio from the Americas. CDC will utilize this expertise in assisting GSA in the vaccine delivery system.

**2. Provider Accountability**

The OBRA legislation requires that all providers participating in the VFC program screen patients for VFC eligibility, maintain records, and make the records available. To establish accountability, the CDC is requiring the following of all States:

- As part of enrollment, providers agree to comply with VFC program requirements.

- Providers complete a Program Profile estimating their practice size and number of VFC eligible children.
- Providers screen every patient for VFC eligibility and keep records on all who are immunized through the VFC program.
- Providers/make records available to the State upon request.
- States will cross-check "Provider Profiles" against vaccine orders for accuracy and appropriateness. The ordering software will identify unusual orders from providers.
- States will establish quality control measures, including clinic audits. For example, New York State will conduct random audits in providers' offices.
- CDC will further "fine tune" this oversight function once the program starts up.

### 3. Program evaluation

We agree with the need to properly evaluate the VFC program in a timely manner. CDC has begun developing an evaluation plan to demonstrate the effectiveness of the VFC program. Although the VFC program has not yet been implemented, CDC will eventually have data to demonstrate the impact of this initiative on immunization levels.

### Conclusion

In expressing concern of VFC plans, GAO should take into consideration the impact of its presentation of these issues. Under current authorization and appropriation acts, no back-up program to VFC exists to provide vaccines to needy children after September 30. If the VFC program were to be terminated or delayed, it is possible that a significant public health problem could occur due to disruption of vaccine supplies. Because current vaccine contracts expire on September 30, several additional months would be required to award new contracts to provide vaccines. The price for vaccines purchased outside the VFC program would not be limited by the OBRA statutory cap. In addition, FY 95 appropriations may not be available to CDC in time to preclude disruptions in vaccine supplies.

**DRAFT**1. Contract Negotiations.

CDC has completed the first round of negotiations for all contracts. Four contracts have already been awarded. Remaining contracts can be awarded in time for program implementation if vaccine manufacturers are willing to cooperate. It must be noted that the completion of this issue is out of HHS' control.

2. Enrollment of Providers.

States are operating in accordance with the established timelines for provider recruitment, placing emphasis in July and August on provider enrollment to be followed in August and September by vaccine order placement and vaccine distribution.

-The GAO analysis makes reference to only 8 states having mailed "Private Provider Kits" and only 5 states having mailed "Provider Recruitment Kits." This is not the best criteria for making an analysis about efforts to recruit providers. Some states did not view these materials, developed by CDC, as necessary to their recruiting efforts. However, most states will be using these materials. States have already ordered and received from CDC 130,000 of the 150,000 "Private Provider Kits" and 4,200 of the 5,000 "Provider Recruitment Kits" that were printed.

-It is the strategy of many States to prioritize recruiting with enrollment of public health departments, Medicaid providers and community and migrant health centers, and rural health clinics followed by the recruitment of private providers as they make informed decisions about enrollment.

-In states with universal vaccine supply policies, private provider enrollment is commonly viewed as a relatively simple task which they already perform on an annual basis.

3. Provider Reimbursement

If the VFC program is to be successful it must have support and participation from the private health care sector. Fees for vaccine administration must be sufficient if we expect significant enrollment from private providers in the VFC program.

-The vaccine administration fee caps are based upon charge data purchased by HCFA from the American Academy of Pediatrics, reflecting the input that was solicited from the private medical community before VFC policies were established.

-These are only fee caps and not necessarily the actual charges that providers will make of patients nor the reimbursement rates that providers will receive from Medicaid.

**DRAFT**

-A provider cannot refuse to immunize a VFC-eligible child merely because the parent cannot afford to pay the vaccine administration fee.

#### 4. Vaccine Ordering Process

In June, CDC had already developed, and is presently testing, with good results, the VFC program software to be used by the States, CDC and the distribution center. It promises to be the most effective communication system that CDC has ever utilized for the management of the vaccine ordering system. CDC believes the establishment of the vaccine distribution center is the most cost effective means available to store and ship vaccines directly to providers as required by law. According to the Association of State and Territorial Health Officials this view is also shared by at least 41 of the States.

- Training of about 150 State officials on the vaccine ordering system software will have been completed and computers provided to the States before the end of July.
- Staff sent by the States to the CDC computer training workshops will either manage the system in their respective States or provide the necessary training for system operation with CDC technical assistance available as a back-up.
- Grant awards to the States in support of their vaccine ordering and distribution systems will be made in July, 1994. Because it is necessary to have the computerized vaccine ordering system in place in August, some States are adjusting staff duties to be ready for program implementation. Personnel reassignments will continue until such time that additional staff can be hired.
- The national vaccine distribution center was decided upon only after careful interpretation of the law, the opinions of the vaccine manufacturers, cost estimates based on current manufacturer shipping charges, and after meetings with business interests representing wholesale distributors and shipping companies.

#### 5. Vaccine Distribution, Packaging and Container Testing

Both CDC and GSA believe the vaccine distribution center will be operational and capable of meeting the vaccine supply needs of that portion of the country that will be using it beginning in September 1994. Under optimal circumstances, the GSA would have preferred more time, but the system is "within their capacity" and that of CDC.

**DRAFT**

SENT BY: CDC/Washington Ofc.

: 7-14-94 :11:11AM :

- The GSA vaccine distribution center will meet FDA and State of New Jersey requirements for this process.
- GSA will be able to receive vaccine orders, properly store the vaccines, ship the vaccines using Federal Express and track and document shipments.
- Freezer installation began and will be completed the week of July 11th. Refrigeration space is already sufficient and is complete with back-up systems and safety devices including a generator and monitoring equipment.
- Expertise in managing products in refrigerated systems will come from 3 private engineering firms.
- All packaging and shipping materials will be in accordance with safety standards for the shipping of both vaccines kept frozen and other vaccines that require refrigeration.
- The packaging will be tested and vaccines will be shipped with analysis of the cold chain and temperature range at every point of transfer between the GSA distribution center and the various destinations.
- CDC has worldwide experience in vaccine transport and cold chains as evidenced by smallpox eradication and the elimination of polio from the Americas. CDC will utilize this expertise in assisting GSA in the vaccine delivery system.

GAO was concerned that HHS had no formal assessment of distribution system options. Although HHS did not formally document each step of the process, HHS completed an extensive evaluation of potential distribution system options. A summary of activities is shown below.

- o Discussions with Congressional staff, White House staff, and Department officials led to the conclusion that legislative amendments were not feasible because any legislative changes needed to be budget neutral.
- o Early discussions with States indicated that many were unable to take on the responsibility of distributing vaccines to individual providers.
- o During discussions with CDC and NVPO staff, vaccine manufacturers indicated that they would not bid on Federal vaccine contracts if required to distribute vaccines to individual providers under the price cap.
- o At least one vaccine manufacturer indicated that they would not ship vaccine to a private distributor.

**UKAFI**

- o CDC and NVPO staff evaluated alternative approaches to vaccine distribution, including contracting with third party distributors.
- o CDC had discussions with HCFA, OMB, and PHS to confirm their interpretation that distribution costs were covered by OBRA.
- o Given the complexities of establishing a "prime vendor" type contract distribution system, as well as evidence that at least one manufacturer would be unwilling to ship to a distribution contractor, the October 1 implementation date would have been seriously jeopardized by a decision to go forward with a commercial distribution contract.

#### 6. Accountability

GAO feels that the VFC accountability system should report information on each VFC child to ensure that only eligible children receive VFC vaccine. However, GAO has suggested an approach which is inconsistent with at least one provision of the legislation. Section 1928(c)(2)(A)(i) of the legislation specifically states that "the provider need not independently verify the answers to such (eligibility) questions." Thus, while HHS has developed an appropriate screening form to document that only eligible children receive VFC vaccine, HHS is not able to require providers to further document that only eligible children receive VFC vaccine.

GAO has also ignored the fact that financial accountability and program evaluation are essential components of the VFC program.

- o States are primarily responsible for monitoring vaccine usage, as noted in the VFC "Operations Manual" and grant guidance.
- o States must develop effective monitoring measures to detect any fraud or abuse of VFC vaccine. These could include requiring vaccine usage reporting, conducting "spot checks" of providers, or conducting random audits or surveys of providers.
- o To further support accountability at the State level, HHS has provided appropriate control forms, computer software/hardware, technical assistance, and funding.
- o In addition, as the program develops, other monitoring procedures can be implemented to address concerns.

States can best decide how to target audit resources. States have extensive experience with vaccine usage and are more aware of their unique circumstances and provider practices than a Federal entity.

- o A Federal mandate requiring one national system would not be as effective as assuring that States develop their own customized and targeted review systems. For example, for States indicating they will provide universal coverage, audits or extensive paper tracking systems, would only be

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wasteful, since all children in these States receive public purchased vaccines.

- o Many States contribute their own State funds to purchase vaccine. These States certainly have an added motivation to implement effective monitoring systems to assure that State funds are also appropriately used.
- o Many States will also continue to use dosage administered forms to account for such vaccines.
- o States may request funding to provide resources to establish such oversight functions.

Federal and State audit organizations also can provide extensive verification of vaccine usage.

- o Forty-three States have Medicaid Fraud Control Units dedicated to fraud and abuse reviews of such Medicaid programs.
- o The HHS Inspector General also has staff devoted to reviewing HHS programs. In fact, the Inspector General has begun a survey which includes State VFC accountability procedures.
- o The GAO may conduct similar reviews of State operations.

delek

~~Another example of the hurried pace of GAO's review is that the agency did not have the time to discuss the accountability issue with representatives of the American Academy of Pediatrics (AAP), the American Medical Association (AMA), or the American Academy of Family Practitioners (AAFP). GAO's suggestion that the VFC accountability system should report information on each VFC child would create a significant administrative burden. Discussions with such groups would certainly have provided a more balanced range of perspectives on the accountability issue and the associated administrative burden GAO is suggesting.~~

GAO has agreed that attention must be given to the balance between program accountability and provider participation.

- o VFC requires private physician participation.
- o However, many private provider associations, such as the AAP, AMA, and AAFP, and individual physicians have consistently and pointedly warned CDC that private physicians would not participate in the program if paperwork or other intrusive auditing procedures were a mandated requirement.
- o Thus, in developing an appropriate approach to program accountability, CDC fashioned a targeted and effective approach, rather than an inflexible Federal mandate, which may only drive away physicians.

7. Program evaluation

We agree with the need to properly evaluate the VFC program in a timely manner. CDC has begun developing an evaluation plan to demonstrate the effectiveness of the VFC program. Although the VFC program has not yet been implemented, CDC will eventually have data to demonstrate the impact of this initiative on immunization levels.