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DOCUMENT NO. & TYPE	SUBJECT/TITLE	DATE	RESTRICTION
1. Memo	To Carol Rasco from Sara Rosenbaum Re: Immunization strategy options and meeting , 1 p (partial)	7/19/94	P6/B6

RESTRICTIONS

- P1** National security classified information [(a)(1) of the PRA].
- P2** Relating to appointment to Federal office [(a)(2) of the PRA].
- P3** Release would violate a Federal statute [(a)(3) of the PRA].
- P4** Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA].
- P5** Release would disclose confidential advice between the President and his advisors, or between such advisors [(a)(5) of the PRA].
- P6** Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA].
- PRM** Personal records misfile defined in accordance with 44 USC 2201 (3).

- B1** National security classified information [(b) (1) of the FOIA].
- B2** Release could disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA].
- B3** Release would violate a Federal statute [(b)(3) of the FOIA].
- B4** Release would disclose trade secrets or confidential commercial financial information [(b)(4) of the FOIA].
- B6** Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA].
- B7** Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA].
- B8** Release would disclose information concerning the regulation of financial institutions [(b)(9) of the FOIA].
- B9** Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA].



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington D.C. 20201

FACSIMILE

DATE JUL 18 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): 10

COMMENTS:



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

July 18, 1994

NOTE TO CAROL RASCO

This is in draft. We now believe Robert Pear had an earlier draft of the GAO report from GAO. The final report to be delivered today does not draw any conclusions and states that CDC says it will be ready by October 1.

Kevin Thurm
Kevin Thurm

7/18 1130AM Draft

HHS RESPONSE TO GAO'S VACCINES FOR CHILDREN ISSUES

The General Accounting Office (GAO) was in the unusual position of evaluating the Vaccines For Children (VFC) Program three months before the October 1 implementation date, rather than after program implementation when results are available.

Although GAO has identified some areas which need additional attention, they have not concluded the VFC program will not be operational by October 1. In its exit conference, GAO merely noted that it cannot say if HHS will accomplish its goal. GAO has specifically refrained from reaching conclusions at this stage.

HHS will be able to effectively implement the Vaccines for Children (VFC) program by October 1. Such implementation will include available vaccine for participating providers, a functioning vaccine ordering and distributing system, and enrollment of public providers and participation of some private providers. Enrollment, particularly of private providers, will continue beyond the October 1 start-up date.

HHS recognizes GAO's seven important categories related to implementing the Vaccines for Children (VFC) program and has established strategies to assure these, and other, program components are being addressed. While HHS agrees that additional, planned activities need to occur, the following will help clarify GAO's concerns.

1. Contract Negotiations

GAO was concerned that contract negotiations may not be concluded in a timely manner.

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. Completion of this task is, in large part, in the hands of the vaccine manufacturers.

2. Enrollment of Providers

GAO was concerned that States were behind in their efforts to recruit private providers into the VFC program.

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

- The GAO analysis, which occurred in late June, makes reference to 8 states having mailed "Private Provider Kits" and 5 states having mailed "Provider Recruitment Kits." This does not mean that the other states are behind on their recruitment efforts. States did not view these materials as their only recruiting efforts. States have already ordered and received from CDC 130,000 "Private Provider Kits" and 4,200 "Provider Recruitment Kits". These kits should be sent out shortly by most States.
- Many States have chosen to prioritize recruiting and 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 (12 states currently), private provider enrollment is viewed as a simple task which they already perform on an annual basis.
- To maximize private provider enrollment, HHS is also working closely at the national level with the American Academy of Pediatrics, the American Medical Association, the American Academy of Family Physicians, the National Medical Association, the Interamerican College of Physicians and Surgeons, the American Osteopathic Association, and other groups to obtain optimum private provider enrollment.
- Providers benefit from VFC participation because they can receive all vaccines recommended by the ACIP for eligible children at no cost. Accordingly, this will return some children to their routine provider for comprehensive health care.

3. Provider Reimbursement

GAO was concerned that the administration fee caps to be established by HCFA are too high and are based on "charge" versus "cost" data.

The VFC program includes 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. GAO has stated that it understands the rationale to establish the vaccine administration fee caps based upon data provided by the American Academy of Pediatrics.

- The administration fee caps are based upon "charge" data purchased by HCFA from the American Academy of Pediatrics, reflecting input from the private medical community.
- These are only fee caps and will not normally represent the actual charges providers will request of patients, nor the

reimbursement rates that providers will get from Medicaid.

- 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

GAO was concerned that the States' vaccine ordering systems would not be sufficient to effectively process orders from all VFC providers before October 1.

Providers will submit orders to State Health Departments which in turn will submit these orders electronically to CDC. From there orders will be forwarded to the GSA distribution center or directly to the manufacturers.

GAO has stated that the VFC ordering software is on target. CDC has essentially developed and is presently testing, with good results, the VFC program software to be used by the States, CDC and the distribution center.

- Training of about 150 State officials on the vaccine ordering system software will be completed between July 6 and July 28. Software and computers are also being provided to the States during July.
- Staff sent by the States to the CDC computer training workshops will either manage the system in their States or provide the necessary training for system operation, with CDC technical assistance available as needed.
- Grant awards to the States in support of their vaccine ordering and distribution systems will be made the week of July 18, 1994. Some States are adjusting staff duties to be ready for program implementation. Personnel reassignments will continue until such time that new staff can be hired.

5. Vaccine Distribution, Packaging and Container Testing

GAO was concerned that there were no written protocols to test vaccine packaging and distribution.

A safe and effective vaccine supply is the only acceptable objective of CDC, GSA, and FDA in developing this distribution system. These agencies will work closely together to assure that this objective is achieved.

The Omnibus Budget Reconciliation Act of 1993 (OBRA) allowed States the opportunity to select their own vaccine distribution systems. In so doing, 49 percent of the States chose to entirely

manage and operate their own system. An additional 31 percent of States chose to manage and operate their system to distribute vaccines to public clinics, with private provider distribution shipped directly from the national vaccine distribution center. Only 10 percent of the States chose to use the national vaccine distribution center exclusively.

CDC believes the establishment of the vaccine distribution center is the most cost effective means available to deliver vaccines directly to providers as required by law for those States that do not wish to undertake distribution themselves. According to the Association of State and Territorial Health Officials, this view is also shared by at least 41 States. The national vaccine distribution center was selected 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.

Both CDC and GSA believe the vaccine distribution center will be operational by September 1994. Under optimal circumstances, the GSA would have preferred more time, but the system is "within their capacity" and that of CDC.

- 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 to assist GSA in vaccine delivery.
- 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 effectively using Federal Express, and track and document shipments.
- Freezer installation has begun 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 who are already on-board.
- 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. FDA will work with GSA and CDC to assure proper packaging.
- The packaging will be tested and vaccines will be shipped with analysis of the cold chain at every point of transfer.

between the CSA distribution center and the various destinations.

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.

- 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.
- Early discussions with States indicated that many were unwilling or unable to take on the responsibility of distributing vaccines to individual providers.
- 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.
- At least one vaccine manufacturer indicated that they would not ship vaccine to a private distributor.
- CDC had discussions with HCFA, OMB, and PHS to confirm their interpretation that distribution costs were covered by OBRA.
- CDC and NVPO staff evaluated alternative approaches to vaccine distribution, including contracting with third party distributors.
- 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.

CDC, GSA, and Federal Express are planning to test the effectiveness of the vaccine distribution system with specific analysis of the cold-chain from packing through delivery. In late July, this will be done through packaging analysis and temperature measurement of a number of test shipments sent to various destinations within the United States.

6. Accountability

GAO was concerned that the VFC accountability system does not document an audit trail and report information on each VFC child such that only eligible children receive VFC vaccine.

The most important accountability goal is to assure that children receive vaccines. Several opportunities exist to address this need, such as,

- developing registry systems to specifically monitor each child's immunization status.
- targeting Immunization Action Plan funding to work with providers to assure proper immunization, and
- employing State surveys to help assure appropriate vaccination.

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

- VFC requires private physician participation.
- 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.
- Thus, in developing an appropriate approach to program accountability, CDC fashioned a targeted and effective approach, rather than an inflexible Federal mandate, which would limit physician participation.

GAO noted that the VFC accountability system does not document an audit trail and report information on each VFC child to ensure that only eligible children receive VFC vaccine. However, such an accountability system is inconsistent with at least one provision of the legislation. Section 1928(c)(2)(A)(i) of the legislation 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.

Financial accountability and program evaluation are essential components of the VFC program.

- States are primarily responsible for monitoring vaccine usage, as noted in the VFC "Operations Manual" and grant guidance.

- States are required to 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.
- To further support accountability at the State level, HHS has provided appropriate control forms, computer software/hardware, technical assistance, and funding.
- In addition, as the program develops, other monitoring procedures can be implemented to address concerns.

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

- A Federal mandate requiring one national accounting system would not be as effective as States developing their own customized and targeted review systems. For example, for the 22 States indicating they will provide universal coverage, extensive paper tracking systems would be wasteful, since all children in these States receive public purchased vaccines.
- Almost all States contribute their own State funds to purchase vaccine. These States have an added motivation to implement effective monitoring systems to assure that State funds are also appropriately used.
- Many States will also continue to use "vaccine usage reporting" to account for vaccines.
- States may request VFC funding to establish such oversight functions.

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

- Forty-three States have Medicaid Fraud Control Units dedicated to fraud and abuse reviews of such Medicaid programs.
- 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.

7. Program evaluation

GAO was concerned that a formal evaluation plan for the VFC program was not available.

We agree with the need to properly evaluate the VFC program in a timely manner. CDC has begun developing a plan to evaluate the effectiveness of the Childhood Immunization Initiative which includes the VFC program.

CONSEQUENCES OF NOT STARTING THE VFC PROGRAM ON OCTOBER 1

The potential impact of this issue must be recognized. Under current authorization and appropriation acts, no back-up program to VFC exists to provide vaccines through the public sector 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 vaccine manufacturers. Should contracts be awarded, the price for vaccines purchased outside the VFC program would not be limited by the OBRA vaccine price cap. In addition, FY 95 appropriations may not be available to CDC in time to preclude disruptions in vaccine supplies.

Doc # 43101 - 7/18 11:00pm



**CENTER FOR HEALTH
POLICY RESEARCH**

FAX FROM:

Sara Rosenbaum
Voice: (202) 296-6922
Fax: (202) 785-0114

TO: Carol Rasco

FAX NUMBER: (202) 456-2878

PAGES SENT: 5

MESSAGE:

cc: Jennifer Klein

THIS FORM MARKS THE FILE LOCATIN OF ITEM NUMBER 1
LISTED IN THE WITHDRAWAL SHEET AT THE FRONT OF THIS FOLDER.

THE FOLLOWING PAGE HAS HAD MATERIAL REDACTED. CONSULT THE
WITHDRAWAL SHEET AT THE FRONT OF THIS FOLDER FOR FURTHER
INFORMATION.

July 19, 1994

MEMORANDUM

TO: Carol H. Rasco

FR: Sara Rosenbaum

RE: Immunization strategy options and meeting

For the reasons discussed below, I recommend that you schedule for either the end of the day on Tuesday¹ or any time beginning on Wednesday of next week a meeting to discuss options for dealing with the major issues that will arise over the next several weeks as the Department process with implementation of the VFC program.

Millie and Tracy, my summer intern, have all of my telephone numbers and addresses from Tuesday afternoon through the end of the week if you need me.

The attached memo lays out background and my recommended steps.

¹I am on work travel through the end of the week. [REDACTED] which means that I will not be able to return to full functional level until Tuesday afternoon at the earliest. Obviously if this meeting needs to happen before that it should, but if there is any way to wait I would be grateful. My sense is that for the next several days the Department will be dealing with the Bumpers amendment. They will also need a few days to prepare for the meeting I am suggesting.

Background

There are several matters looming on the horizon:

- the Bumpers amendment (joined by Wyden, Danforth and Klug) to enjoin the GSA warehouse system as an appropriations matter;
- a possible Danforth amendment (co-sponsors not yet known) to repeal the program;
- refusal by manufacturers to bid on the HHS vaccine contracts.

The first issue is highly damaging but not lethal. The second two would have a profound impact.

The Department will need the next several days to address the first problem. We then have a couple of weeks' breathing space which should be put to use on developing a strategy for reshaping the VFC program so that it can proceed unfettered.

Bumpers : It is my understanding (Tuesday, noon) that the Bumpers amendment would enjoin the use of a federal government distribution program and would instead provide for direct shipment by manufacturers to state depots, followed by state delivery to local clinics and providers. The amendment is not lethal. However, it will require a huge change in the shape of the program as it now stands.

Danforth: Senator Danforth is expected to offer an amendment to kill the entire program and return to the status quo. The amendment would be offered during the health reform debate.

Manufacturer bids: We may well face a situation in several weeks in which no manufacturer will bid on the VFC contracts, leaving the Secretary in the position of either (a) having no vaccine with which to supply VFC providers or (b) having to purchase vaccine from other countries (e.g. , WHO-approved vaccine). I am convinced that if she attempts to pursue the latter course the program will be completely enjoined by Congress because of concerns over using non-FDA-approved vaccine (it would be ironic for us to extoll the importance of the FDA approval process and then recommend the importation of non-approved drugs).

Issues

Bumpers: Once we know the upshot of the Bumpers amendment, we need to know whether the Department wants to (a) proceed and fight Bumpers in conference; or (b) accede and switch systems. To follow (a) creates a higher stakes position for the President, so we need to know people's thoughts on how the fight will be waged. To follow (b) would mean delaying the implementation date, with extensions of the current 317 and Medicaid systems for an interim period. There are some who would say that (b) basically kills the program and returns us to the prior status. Bumpers stresses, however, that he does not intend to kill off VFC vaccine as an entitlement for children, nor does he mean to knock out the private provider distribution system.

Danforth: It is highly likely that people would agree to insert in place of VFC another approach to dealing with children's health needs. Regardless of whether we are dealing with a mandatory health insurance bill in the Senate (assuming the Majority Leader succeeds in holding such a bill) or a voluntary plan (assuming that such a bill ends up being the floor vehicle) phasing will be a highly likely component.

There are enough people concerned about child health so that a strategy for phasing out VFC that is tied to insuring children could be developed. Such a strategy might involve extending subsidized coverage to children who have none, rolling, mandating vaccine coverage for children who currently hold private coverage, and returning to the basic 317 program in any state in which all children are insured.

We need to decide whether to fight a VFC repeal amendment on an all-out basis or, in the alternative, whether we want to move to substitute universal children's coverage for the VFC immunization system. Senators Riegle and Kennedy might offer such a plan.

In thinking over such a strategy, we need to think about the children's substitute in the context of health reform. How much coverage would we insist on (ambulatory only? ambulatory plus inpatient? the full benefit package?) Would this be a provision only to insure uninsured children or also to amend employer plans to require vaccine coverage of minor dependents (the pharmaceutical industry and the AAP favor this).

Another major issue for resolution is whether to prohibit states that achieve full insurance coverage for children from adopting universal vaccine purchase programs for their insured children (the 12 states with universal buy for both public and private insurers today, as well as for uninsured children). We also need to decide whether to prohibit states which have achieved universal coverage from using universal bulk purchase arrangements for their insured populations. **Among all matters, the manufacturers place repeal of the universal state option at the top of their list. They will gladly help get all children insured in exchange for eliminating the universal program.**

Manufacturer refusal to bid: There is not too much we can ask the Department about the bid process. But they know that they are in trouble if there are no contracts by mid-august. As noted, I do not think that the Secretary could buy abroad. Therefore, even if we stave off all amendments, we will face the "checkmate" of no vaccines, which will back-door us right into having to change the program, since all of the vaccines for public and private providers are now tied up in the VFC contract. Therefore, we need to know how the Department plans to deal with this problem.

Conclusion

After thinking about this a lot, I have concluded that the bid problem is so utterly destructive of the program that even if the amendments do not materialize we face the need to work fast to have modifications ready that will (a) protect children; (b) protect the vaccine supply for children; (c) use the VFC modifications as a chance to get children the vaccines they need

through insurance reform (which everyone supports). The Department should be asked to prepare options for each of these possible problems (as well as other things I might have missed), to offer policy proposals and a political assessment of which approach seems best.

I would specifically ask Kevin Thurm to ready the Department for a presentation in a week on:

- Bumpers and next steps;
- options for dealing with a floor amendment to repeal the program;
- the lack of a vaccine bid from the manufacturers.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington D.C. 20201

FACSIMILE

DATE JUL 19 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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

JUL 19 1994

MEMORANDUM

TO: Carol Rasco
Christine Varney

From: Kevin Thurn *[Signature]*

Subject: Press Conference on Immunization Initiative

Attached please find copies of materials distributed at today's press conference on the immunization initiative.

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

Attachments

FOR RELEASE UPON DELIVERY
TUESDAY, JULY 19, 1994

•REMARKS BY

DONNA E. SHALALA

SECRETARY OF HEALTH AND HUMAN SERVICES

PRESS CONFERENCE ON VACCINE FOR CHILDREN PROGRAM

HUBERT H. HUMPHREY BUILDING

WASHINGTON, D.C.

*THIS TEXT IS THE BASIS OF SECRETARY SHALALA'S ORAL REMARKS.
IT SHOULD BE USED WITH THE UNDERSTANDING THAT SOME MATERIAL MAY
BE ADDED OR OMITTED DURING PRESENTATION.

There are few issues closer to my heart than getting our nation's kids properly immunized and preventing needless disease and death. I'm sorry I can't be there with you to address these crucial issues in person.

Last year, the Administration and Congress worked together to pass a major initiative designed to raise immunization rates for pre-schoolers to at least 90%, and, just as importantly, to keep them there.

Months and months of hard work have gone into fulfilling that vision. Working with the General Services Administration, the states, and the private sector, we've made great strides. Our work is not done, but I am confident that, as you will hear from Dr. Satcher in a moment, our new system will be up and running on October 1.

I think it's important to note that the GAO, in releasing its interim findings, specifically stated that it was not making any recommendations in its report.

One of the dictionary definitions for "interim" is "temporary." By its very nature, this report is a snapshot in time.

If there is one message I wish to leave with you today, it is that we will meet, and we will master, the challenges cited in this report. If our new system is given a chance, you in the press will be writing a very different story come October 1-- and an even more glowing story on October 1, 1995.

- 2 -

Nobody ever said that immunizing 90% of our children would be easy. But then, nobody said that eradicating smallpox would be easy -- yet that's precisely what our great Centers for Disease Control and Prevention took the lead in doing.

CDC has provided systems and technical training for the delivery of vaccine supplies to the most remote corners of the world -- and they did it without the Federal Express couriers and the state-of-the-art computer hardware and software our system incorporates.

An organization with that track record can certainly safely store and deliver vaccines to Little Rock, and Portland, and St. Louis, and Madison, Wisconsin.

The greatest risks are not those cited by the GAO. The greatest risk is that we overreact to this interim report and take some precipitous action that would interrupt our momentum.

The GAO report itself notes that, despite progress in raising immunization levels among preschoolers, there remain pockets in this country with shockingly low immunization rates.

The President's Childhood Immunization Initiative will bring those immunization levels up -- and keep them up. It recognizes that high costs are among the barriers to getting children immunized.

The initiative addresses the cost issue, but it also provides grants that will support states' action plans.

It will also enhance community participation and education for providers.

- More -

- 3 -

And it aims to develop improved and combined vaccines to simplify the immunization schedule.

We've already created partnerships with Major League Baseball, the National Football League, McDonald's and others to spread the word on immunizing our children.

This is no time to reverse course. Congress and the President have set a course and our goal is within reach.

This is no time to quit. We must press on. We owe it to our kids.

###

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**STATEMENT OF DAVID SATCHER, M.D., Ph.D.
DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION**

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

Thank you. I appreciate the opportunity to speak with you this afternoon about a topic that takes us to the heart of the mission of this Department and to the heart of my mission as Director of CDC. There can be nothing more important to all of us than the health of our children.

The Agency I have the privilege of representing today is one of the world's great public health institutions. Time and time again, the women and men of CDC have faced health challenges head on and met them. We've designed systems to ensure safe and effective delivery systems of perishable vaccines in environments harsher and with more meager health care structures and resources than the United States---in Asia, in Africa, in South and Central America. We have been there and know we can get the job done.

The immunization of children against diseases that can disable--even kill--has been part of the cornerstone of public health. While we have made major progress in immunizing our children, we still have pockets in some inner city and other populations where only 25% of children are properly immunized. We welcome wholeheartedly the opportunity the Vaccines for

Children (VFC) and the Childhood Immunization Initiative provides to enhance childhood immunization in this country--to reach more children, including the most needy--through a new partnership with states and private health care providers. This program will improve the health of children by providing greater access to vaccines.

As you know, the VFC is just one component-- but an absolutely essential component-- of the Administration's children's immunization initiative. The big picture includes five activities:

--Improving the quantity and quality of vaccination delivery services.

--Reducing vaccine costs as a barrier to immunization for parents.

--Enhancing community participation, parent and provider education and building partnerships.

--Improving the measurement of immunization coverage and the detection of vaccine preventable diseases.

--Improving vaccines and simplifying the immunization schedule.

The VFC helps us achieve the second of these. It helps assure that the high cost of vaccine does not keep parents from bringing the miracle of vaccination to their children. It helps us, therefore, bring good health to all children, especially those of the working poor and underinsured.

We are confident that we will have the Vaccine for Children program up and running on October 1, 1994, the date this Congressionally mandated entitlement program takes effect. By that time, we will have in place all necessary systems to order, purchase and deliver vaccine in a safe and efficacious way. We will have enrolled all public clinics in the program. We will have set in place the mechanisms for recruiting and enrolling private providers, and we will have begun the task of bringing as many as possible into the program. Program implementation does not depend on full enrollment of 79,000 private physicians by October 1. In developing this program, we have worked very closely with the American Academy of Pediatrics and other major provider organizations.

I am sure that many of you are aware that the GAO has recently completed an inquiry into the status of preparations for the VFC and that they have concluded that some facets of our effort are behind schedule. We agree with that analysis. But I must stress that the GAO report represents a snapshot--a snapshot taken three months before the VFC program is scheduled to begin.

We acknowledge that much is yet to be done to make the VFC operational by October 1. But all of us--CDC and our partners with us today, the FDA and GSA--are committed to make it happen.

I welcome the careful scrutiny the GAO has brought to our efforts. We have learned much from our interaction with the GAO, and we are addressing the concerns they have raised.

It should not be forgotten that CDC has developed unparalleled expertise in delivering vaccine safely and efficiently. CDC has real world experience in designing and implementing systems to deliver vaccine throughout the world. This experience helped eradicate smallpox from the world. And it has helped bring child immunization programs to children in the developing world. We know how to do this job and we will get it done. At the same time, we are taking nothing for granted and are mindful of the complexity of our task. We look forward to continuing to work in partnership to make the vaccines for children a success story for our nation.

Plan for testing Packing / Packaging material

GSA's distribution of vaccines will use the specialized containers and packaging materials that have been developed and used successfully by industry. Packing / packaging will be tested based upon industry standards promulgated by the American Society for Testing Materials (ASTM) and the National Safe Transit Association (NSTA).

Fedex, GSA's contract carrier, and ActionPak will test GSA's packing cartons in consultation with CDC experts. ActionPak is a full service professional packaging company that designs and tests packaging. They are members of The National Institute of Packaging, Handling & Logistic Engineers (NIPHLE).

Plan for testing Shipping process

There are two aspects to the shipping process. They are timeliness and analysis of the cold chain.

Timeliness

We will ship test cartons without product to selected participating States / project sites. Random and varied shipments will be made as part of GSA/CDC testing.

Analysis of Cold chain

CDC will provide GSA with vaccines for testing in the shipping process. These test shipments will occur in August. Test orders received from the CDC will be shipped by GSA during the testing period. The providers will report the results of these shipments. CDC will work closely with GSA monitoring and advising throughout all testing.

~~-----~~
maintain freezers in a cold condition at desired temperature setting for 2 weeks. GSA will regularly check temperature gauges/charts to ensure that a proper temperature is maintained. Freezer doors will be opened for 3 minute periods for observation of temperature. This will be done on a daily basis during the 2 week testing period. GSA will consult with CDC on all results.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

RESPONSE TO THE GAO REPORT ON VACCINES FOR CHILDREN

The Centers for Disease Control and Prevention is confident that it can and will meet all of its implementation goals for a U.S. vaccine ordering and delivery system by October 1, 1994.

The CDC houses many of the world's great experts on vaccines, their development and their delivery. Its technical experts have helped create safe and effective delivery systems for perishable vaccines from Namibia to Indonesia.

Working with the states, the General Services Administration, the Federal Express Corp., and the pharmaceutical industry, CDC is confident that it is on track to have the following elements in place by October 1:

-- All hardware, software, and transportation systems necessary to order, purchase and deliver vaccines will be tested, up and running. The General Services Administration's refrigerated distribution center will be fully operational.

-- All public health clinics and federally qualified health centers (FQHC) will be enrolled in the program.

-- Procedures will be in place in all 50 states to recruit and enroll private doctors.

The GAO, in its interim findings, specifically stated that it was not making any recommendations in its report. One of the dictionary definitions for interim is "temporary." An interim report, by its very nature, is a snapshot in time. It is not an adequate basis for predicting success or failure. It is premature to make judgments about this program.

The following is a point-by-point analysis of the GAO's report:

1. CONTRACT NEGOTIATIONS

GAO observed that contract negotiations may not be concluded in a timely manner.

CDC is in the midst of intense negotiations for all necessary contracts. Five contracts have already been awarded. The remaining contracts will be awarded in time for program

implementation, assuming the vaccine companies negotiate in good faith.

2. PROVIDER RECRUITMENT

GAO raised questions about the number of private providers recruited into the VFC program.

- States, right now, are placing emphasis on provider enrollment, to be followed in late August and September by vaccine ordering and distribution. Vigorous recruitment of physicians prior to this would have been premature and unnecessary.
- States have already ordered and received from CDC 130,000 "Private Provider Kits" and 4,200 "Provider Recruitment Kits" that will be sent out shortly by the States.
- States will first enroll public health departments, community and migrant health centers, and rural health clinics, followed by private Medicaid providers. The next priority is recruitment of other private providers.
- In those states with universal vaccine supply policies (12 states currently), private provider enrollment into health department immunization programs already occurs on an annual basis. Recruitment into VFC will be accomplished without major difficulties.
- HHS is working closely with professional physician and other provider associations to obtain optimum private provider enrollment.

3. ADMINISTRATIVE FEES

GAO claims that the vaccine administration fee caps are too high and are improperly based on "charge" instead of "cost" data.

- These caps only establish the maximum amounts which providers can charge. Providers will not always charge this maximum and some may not charge at all. Moreover, the providers cannot refuse to give a vaccine because of the family's inability to pay. In addition, Medicaid children, who comprise over half of VFC eligibles, will have their vaccine administration cost paid by Medicaid, not the family.
- Reliable data on the "actual cost" of a vaccine administration is simply not available and could not be obtained in a reasonable manner. Our proposed administration fee caps are based upon "charge" data purchased from the American Academy of Pediatrics,

reflecting input from the private medical community. We do not have any valid basis for discounting this charge data in an effort to represent actual cost.

- Medicaid fees are typically much lower than the amounts paid by other insurers or programs and do not represent a valid comparison.

4. VACCINE ORDERING

GAO expressed reservations about the states' ability to implement the vaccine ordering system by October 1.

- CDC has developed, and is presently testing with good results, the VFC program software to be used by the states, CDC and the distribution center.
- Providers will submit orders to state health departments, which in turn will submit these orders electronically to CDC. From there, orders will be forwarded to the GSA distribution center or directly to the manufacturers.
- Training of about 150 state officials on the vaccine ordering system software will be completed by July 28. Software and computers are also being provided to the states during July.
- Staff sent by the states to the CDC computer training workshops will either manage the system in their states or provide the necessary training for system operation, with CDC technical assistance available as needed.
- Grant awards to the states in support of their vaccine ordering and distribution systems will be made this week. Some states are adjusting staff duties to be ready for program implementation.

5. VACCINE DISTRIBUTION

GAO observed that packaging and shipping were not going to be tested prior to implementation.

- The vaccine distribution center will be operational by September 1994, operating in full compliance with all Federal and state requirements.
- CDC and the states have extensive experience in handling the distribution of vaccines. We have not identified any serious problems with packaging and shipping.
- CDC has worldwide experience in vaccine transport and cold chains as evidenced by smallpox eradication and provision of

vaccines to refugees in camps throughout southeast Asia. CDC will utilize this expertise to assist GSA in vaccine delivery.

- o The GSA vaccine distribution center will meet FDA and State of New Jersey requirements for this process.
- o Freezer and refrigeration space is already sufficient, complete with back-up systems and safety devices including a generator and monitoring equipment. Expertise in managing products in refrigerated systems will come from three private firms who are already onboard.
- o The packaging will be tested and vaccines will be shipped with analysis of the cold chain at every point of transfer between the GSA center and various destinations.
- o CDC, GSA, and Federal Express are planning to test the effectiveness of the vaccine distribution system, with specific analysis of the cold-chain from packing through delivery. This will be done, prior to the system going on-line, by test shipments sent to various destinations within the United States.

6. ACCOUNTABILITY

GAO was concerned that, by relying on the states to assume accountability for VFC vaccines, HHS will not adequately protect against misuse of these vaccines.

- o Financial accountability and program evaluation are essential components of the VFC program.
- o States will be responsible for monitoring vaccine usage. States are required to 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 These are tasks the states consistently perform for the existing immunization program and for which they have demonstrated competence.
- o To further support accountability at the state level, HHS has provided appropriate control forms, computer software/hardware, technical assistance, and funding.
- o GAO agreed that attention must be given to the balance between program accountability and provider participation. Many private provider associations, and individual physicians have consistently indicated that private

physicians would not participate if excessive auditing procedures were mandated.

7. EVALUATION

GAO observed that a formal evaluation plan for the VFC program was not available.

- o We agree with the need to properly evaluate the VFC program in a timely manner. CDC, working with other components of HHS, is developing a plan to evaluate the effectiveness of the entire Childhood Immunization Initiative, including specifically the VFC program.

8. VACCINE COST

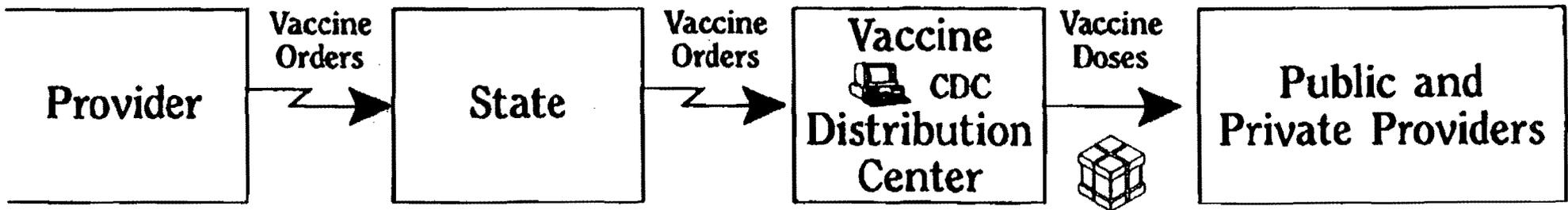
GAO suggested that the cost of vaccine is not an important barrier to children receiving immunizations.

- o Cost is clearly an important consideration for poor families. The cost for a full series of vaccines for an infant now exceeds \$280. Public purchase of vaccines, using several sources of funding, will make vaccines readily available to all children. The advantage of the VFD program is that it will enable many children to receive vaccinations from a physician or private provider, in conjunction with other prevention and health care services, rather than having to find a public clinic.

CONSEQUENCES OF NOT STARTING THE VFC PROGRAM ON OCTOBER 1

Many states are counting on the VFC program to handle vaccine purchase and vaccine distribution for both public and private providers. If the VFC program is delayed, these states will have to find alternative means of distributing vaccine to public and private providers. In addition, the price of vaccine purchased outside the VFC program would not be subject to the price cap established under the OBRA 1993 legislation. Consequently, there could be a major disruption in the immunization of our children and the end result would likely be a costlier program, as well.

Vaccine Distribution System Shipment Directly to Public and Private Providers



JUL-19-1994 02:41 FROM DEP SEC HHS

TO

94562878

P.18



DEPARTMENT OF HEALTH & HUMAN SERVICES



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.

DANIEL PATRICK MOYNIHAN NEW YORK CHAIRMAN

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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

LAWRENCE O DONNELL, JR. STAFF DIRECTOR
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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.

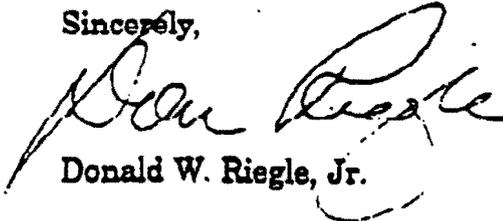
Immunization coverage in the U.S. is not spread evenly, resulting in large pockets of under-vaccinated children and leaving over a quarter of our children with inadequate protection. Progress needs to be made now, and continued in the future, if we are to ensure that all our children are protected against 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.

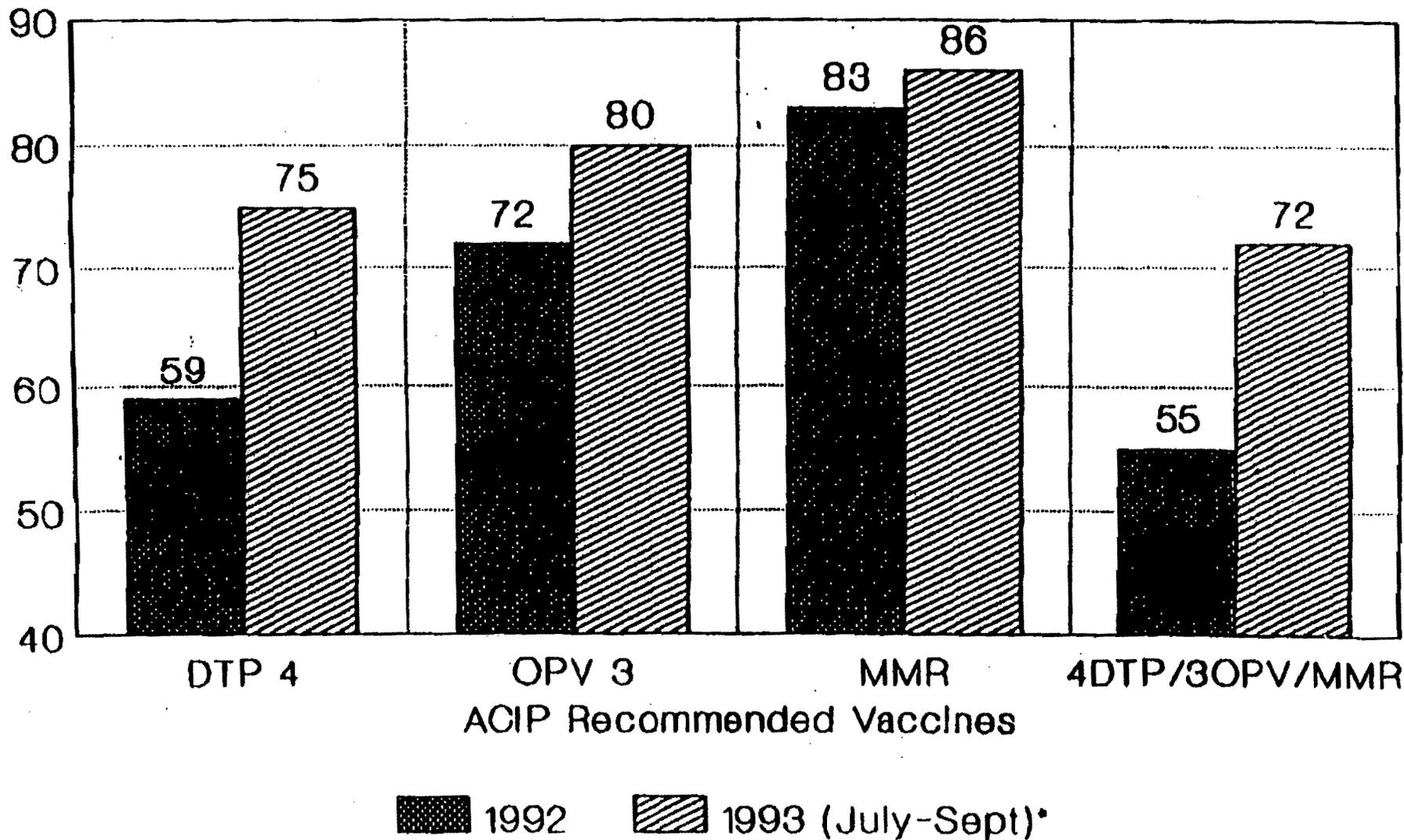
Sincerely,



Donald W. Riegle, Jr.

encl.

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



*Provisional Data



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Washington Office
Room 714 B, HHH Building
200 Independence Avenue S.W.
Washington DC 20201
Telephone (202) 690-6596

THE CHILDHOOD IMMUNIZATION INITIATIVE (CII)**GOALS**

- o 1996: Our goal is to eliminate most of the vaccine preventable diseases and immunize children under the age of two with 90 percent of the most critical vaccines by 1996.
- o 2000: By the year 2000 we want to fully immunize 90 percent of America's two year olds.

PROGRAM ELEMENTS

1. Improve the quality and quantity of vaccination delivery services.

Federal funding to the states and some cities tripled in 1994 to \$128 million to build up the public health infrastructure (the President's FY 1995 budget request will increase this to \$175 million). These funds will be used to provide more clinics in underserved areas, to extend clinic hours, and hire needed staff. Additional funding is being provided to establish computer immunization information systems to help remind parents when immunizations are due.

2. Reduce vaccine costs for parents.

The Vaccines for Children Program will provide free vaccine to needy children at their provider of choice. About 60 percent of children are eligible, including those without health insurance coverage, all those who are eligible for Medicaid, and Native Americans. The program becomes operational October 1, 1994.

3. Increase awareness of infant immunization, enhance community participation, and expand private-public partnerships.

The national outreach program is designed to increase awareness of age-appropriate immunization and expand community participation in the effort to promote proper immunization. Outreach workers and regional meetings will help enhance coordination and communication at the grass-roots level. Public service announcements have been produced for TV, radio, and print media and toll-free phone numbers have been established to provide information and, if necessary, to refer callers to local clinics.

4. Improve systems to detect disease and measure vaccination coverage levels.

Funding has been provided to states to help detect disease so it can be controlled before it leads to epidemics. Immunization coverage will be measured at the national, state, and local levels to monitor progress and detect underimmunized populations.

5. Improve vaccines and vaccine use.

Efforts are underway to develop a single childhood immunization schedule. The Initiative will also support research into new vaccines or vaccine combinations.

THE WHITE HOUSE
WASHINGTON

MEMORANDUM FOR LEON PANETTA

FROM: Carol H. Rasco *CHR*

SUBJ: Immunization

DATE: July 19, 1994

HP LEON
Carol CAROL
Statement to be
made TO BE
READ THURSDAY

I am somewhat puzzled as to the turnaround in opinion about releasing a statement on the President's support for his immunization program. I very clearly understood this morning that we had to be careful about not fighting the sentiment by the Congressional members holding the press conference regarding the distribution, but I felt you just as clearly stated we should support the program itself which is what I reported to Secretary Shalala. Now forty-five minutes before the HHS press conference and after work has proceeded all morning on a statement I learn from HHS the White House is not releasing a statement. Only later did I hear from Barry Toiv on the matter.

I would appreciate a better understanding.

Thank you.