TO: Sara Rosenbaum

FROM: Carol H. Rasco

SUBJ: Vaccine

DATE: December 9, 1993

I need to talk to you about the attached materials....could you give me a call before you do any talking to anyone about this and let's see what we know collectively and what advice you might give me. Many, many thanks!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

DEC 14 1993

TO: Carol Rasco

FROM: Kevin Thurm

SUBJECT: Meeting to Discuss the Status of the President's Immunization Initiative, December 15, 1993, 11:00 a.m.--BRIEFING

PARTICIPANTS

Office of the Secretary

Kevin Thurm
Chief of Staff

Office of the Assistant Secretary for Health

William Corr
Deputy Assistant Secretary for Health

D.A. Henderson, M.D.
Deputy Assistant Secretary for Health and Science

Anthony Robbins, M.D.
Director Designate
National Vaccine Program Office

Richard Leach
Associate Director for Outreach
National Vaccine Program Office

BACKGROUND

In April 1993, President Clinton introduced the "Comprehensive Childhood Immunization Initiative Act of 1993" to ensure that all children in the United States are protected against vaccine-preventable infectious diseases by their second birthday. Specifically the Immunization Initiative called for: (1) Federal purchase and distribution of childhood vaccines in quantities sufficient to meet the immunization needs of all children; (2) continued development of public health capacity to build a sustainable delivery system; (3) establishment of a national immunization tracking system through grants to the States; and (4) expanded education and mobilization efforts aimed at providers, payers, and parents.

The President's immunization bill was not fully enacted, but the key provisions have been implemented through other Congressional actions and, within the Executive Branch, under the authority of the National Vaccine Program (NVP). The National Vaccine Program Office (NVPO), located within the Office of the Assistant Secretary for Health, Department of Health and Human Services is responsible for coordinating the myriad inter-Departmental activities of the NVP. A summary of these activities is appended as Attachment B.

STATUS

Vaccines for Children Program

The Omnibus Budget Reconciliation Act (OBRA) of 1993 authorized the Federal purchase and distribution of free vaccines to health care providers for use in four defined groups of children: (1) those eligible for Medicaid; (2) those with no insurance; (3) all Native Americans; and (4) those with insurance that does not cover vaccines as a benefit (if provided by Federally qualified health centers or Rural Health Centers).

- This program takes effect on October 1, 1994.
- This program removes restrictions imposed by manufacturers and permits all States to purchase any amount of additional vaccines at Federal price.
- Funds appropriated to purchase vaccine under Section 317 may also be used to serve children in State public health programs.
- NVPO, the Centers for Disease Control and Prevention (CDC), and the Health Care Financing Administration are collaborating to implement the program.
- The program is modeled after an existing PHS program for bulk, discount purchase and will be administered primarily through CDC and State health departments.
- The implementation team has met with State health officers, State Medicaid Directors, the four key manufacturers, and others to discuss the program.
- We are currently gathering information from the States on the volume of vaccines needed and the best methods for distribution to providers.

Immunization Coverage and Disease Targets

The Nation is at risk of additional measles outbreaks, an increasing number of pertussis cases, and a return of polio, because of low immunization coverage. The 1991 National Health Interview Survey data for children 19-35 months of age indicated immunization coverage ranging from a low 53.2 percent for polio vaccine to a high of 82 percent for the measles vaccine.

- The NVP has established immunization coverage targets which accelerate the immunization goals of Healthy People 2000 (Attachment A).

- Coverage targets for each antigen is 90 percent in two-year-olds in 1996, with the exception of hepatitis B (70 percent).

- The NVP has proposed targets for reduced occurrence of specific vaccine-preventable diseases (Attachment A).

- The target for 1996 is no reported cases for measles, rubella, polio, diphtheria, tetanus (under 15 years), and *Haemophilus influenzae* type b (under 5 years).

Immunization Action Plans (IAPs)

IAPs are community-based planning efforts designed to overcome the barriers associated with low pre-school immunization levels. IAPs are developed by State and local governments and submitted to CDC for grant funding. The IAP awards to 87 grantees are used to supplement ongoing activities and to establish new initiatives that focus on improved immunization coverage.

- A total of $86.1 million will be awarded by January 1, 1994, representing 68 percent of the IAP monies available for award in Fiscal Year 1994.

- The remaining funds will be awarded as incentive payments for demonstrated progress toward achieving performance standards incorporated into the IAPs.

- Each grantee will be visited by a CDC team to assess implementation of the plans and progress toward outcome objectives.

Education and Mobilization

The National Outreach Campaign sets forth our plan for immunization education and mobilization activities. The Campaign is an integrated strategy designed to create a rapid increase in immunization rates and to promote a social norm concerning the need for proper immunization. The Campaign consists of a National Immunization Promotion effort and State/Community Mobilization activities.

- The initial phase of the Campaign will begin with a National Immunization Summit and continue through National Pre-School Immunization Week (April 24-30).

- A National Immunization Promotion Team has been assembled and is developing a theme and appropriate messages to reach the target audiences.

- Regional outreach consultants are being hired to coordinate community, State and region coalition building.

- Mass media announcements focusing on parents, urban minority populations, and health care providers, will be aired before National Pre-School Immunization Week.

- NVPO has proposed to the Group Health Association of America (GHAA) that Health Maintenance Organizations be challenged to meet the immunization targets by 1995.

Monitoring and Surveillance

Infectious disease surveillance is a critical component of the immunization program. Surveillance identifies targets of opportunity and allows monitoring of vaccine effectiveness following the introduction of new vaccines into susceptible populations. The capability to respond to disease outbreaks as early as possible following their occurrence is critical.

- Each case of the targeted diseases will be viewed as a program failure and will be carefully investigated.

- We have established multiple means of getting better coverage data.

- National immunization coverage data will be obtained through the National Health Interview Survey on a quarterly basis.

- Coverage for 78 major areas will be measured by random digit dialing surveys. Data will be available on a quarterly basis in November 1994.

- A manual for conducting special household probability sampling techniques to determine immunization coverage will be available beginning in April 1994.

- Approximately $5 million in grants to enhance surveillance will be awarded to States in January 1994.

Interdepartmental Cooperation

- U.S. Office of Personnel Management (vaccines now covered under all Federal Employee Health Benefit plans)
- Department of Agriculture--WIC, Cooperative Extension Agents
- Department of Education
- Housing and Urban Development

Need for White House Assistance

- President's participation in Immunization Summit in mid-February and National Pre-School Immunization Week in April.

- Collaboration on interagency activities.

Attachments:
Coverage and Disease Targets
Summary of Activities

ATTACHMENT A

TARGETS FOR IMMUNIZATION COVERAGE OF CHILDREN TWO YEARS OF AGE 1994-1996*

	1991 Baseline	92	1994	1995	1996
DTP-3	69%	83	80%	85%	90%
Polio-3	53%	72	75%	85%	90%
MMR-1	82%	83	85%	90%	90%
Hib-3	**		75%	85%	90%
Hep B-3	**		30%	50%	70%***

* Surveys will assess children 19-35 months of age.
** Not available.
*** Target is 90% in 1998.

D - diphtheria, P - pertussis, T - tetanus
M - measles, M - mumps, R - rubella
Hib - *Haemophilus influenzae* type b
Hep B - Hepatitis B

VACCINE-PREVENTABLE DISEASE CASES AND TARGETS

Disease	Cases 1992	Cases Through 11/27/93	1996 Target
Measles	2,237	277	0
Rubella	160	182	0
Polio (wild virus)	0	0	0
Diphtheria	4	2	0
Tetanus [target for children < 15 years of age]	3	*	0
Haemophilus influenzae type b [target for children < 5 years of age]	592	*	0
Pertussis	4,083	5,273	**
Mumps	2,572	1,456	**
Hepatitis B	16,126	10,870	**

* Not available.
** To be determined.

ATTACHMENT B

Attachment B

PRESIDENT'S IMMUNIZATION INITIATIVE

Summary of Activities

Immunization Coverage and Disease Targets

- Coverage for each antigen will reach 90 percent in two-year-olds in 1996, except for hepatitis b (70 percent).

- The target for 1996 is no reported cases for measles, rubella, polio, diphtheria, tetanus (under 15 years), and *Haemophilus influenzae* type b (under 5 years).

Rebuilding Public Health Capacity

- Infrastructure monies ($86.1 million) for Fiscal Year 1994 from the Immunization Action Plan grants will be available to the States on January 1, 1994. Grantees received $45.4 million in Fiscal Year 1993 and will receive an additional $42.4 million this fiscal year. This last distribution will be determined by measured performance against agreed upon coverage goals.

- The Department's infrastructure budget request for Fiscal Year 1995 is $306 million to fully fund the Immunization Action Plans.

Vaccines for Children Program

- Title XIX authorizes spending authority in advance of appropriations to provide free vaccines to States for children (0 to 18 years.) who are:

    - Medicaid eligible
    - Uninsured
    - Native Americans
    - The underinsured served at Federally Qualified Health Centers

- This program removes restrictions imposed by manufacturers and permits all States to purchase any amount of additional vaccines at Federal price.

- Funds appropriated to purchase vaccine under Section 317 may also be used to serve children in State public health programs.

- The program takes effect on October 1, 1994 and will be based on existing State programs.

Enhanced Monitoring/Surveillance

- Status of immunization to be determined by ongoing State surveys and special municipality-wide surveys.
- Clinic audits to be conducted/encouraged in clinics/group practices.
- Group Health Association of America (HMOs) to provide quarterly reports of coverage.
- Registries to be developed/expanded throughout the country.

Outreach Campaign

- Two-part strategy:
  - National Immunization Promotion: develop and disseminate targeted messages and theme.
  - State/Community Education and Mobilization.
- Schedule for first phase:
  - National Immunization Summit in early to mid-February.
  - Regional meetings February-March.
  - National Pre-School Immunization Week (April 24-30).

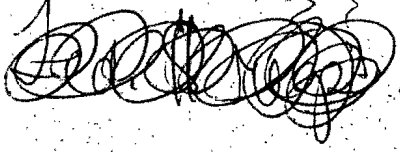
Interdepartmental Cooperation

- U.S. Office of Personnel Management (vaccines now covered under all Federal Employee Health Benefit plans)
- Department of Agriculture--WIC, Cooperative Extension Agents
- Department of Education
- Housing and Urban Development

First state by state
data next Nov., then
@ 3 mos.

Lking at city surveys
(April-May 1st surveys)

3rd wk in Jan all IAP
directors / Atlanta



11 states are full coverage

Instead of liking at
"fully immunized"
we're liking at it
by antigen which is
worldwide method

DTP goes down to 3+ from
4 → now 4th is
anytime between
2 & start of school

RWJ > 12 pilot projects
on registry

Carol – I've got to go to a mtg w/ CBO – on health care saving. I'd rather stay here – this was helpful.

Thanks,

Nancy-Ann

Nothing is Simple

- Timelines for design & legal issues

- Technical corrections needed? (delivery costs to providers?) (decision in Jan.)
- Provider outreach design (end of Jan.?)
- Distribution design (Feb.?)
- Purchase & distribution contracts (mid spring?)
- Compre. notif. to states by early Feb.?
- Lederle

317 $'s

for add. vacs beyond
Fed $ in OBRA '93

December 15, 1993

Problems:

1. Major family outreach campaign starts well before the free vaccine program begins.

2. No clear plan for signing up providers

3. No HHS interpretation as yet of provisions critical for signing up providers:

- o medicaid eligibility determination for children
- o provider record-keeping
- o provider qualification

4. No provider distribution system(s) as yet

5. No final decision on the question of whether contract price binds for all delivery activities which Secretary must carry out or only those activities for which a contract was in effect as of May, 1993.

CARIBE

HILTON

AND CASINO

Meeting file
Calco should call
Tues - pls remind me

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TO: Carol Rasco

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CITY:

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FROM: Sara R.

COMPANY:

ROOM NUMBER:

DATE:

NUMBER OF PAGES (INCLUDING THIS ONE)

IF YOU DO NOT RECEIVE ALL PAGES, PLS. CALL
(809) 721-0303 EXT. 2460

MESSAGE

Carol - Here is the memo for Wednesday.
Will be in office tomorrow a.m. if questions.
SR

December 11, 1993

MEMORANDUM

TO: Carol Rasco

FR: Sara Rosenbaum

RE: Vaccines

This memorandum is written in preparation for our meeting on December 15th. It covers the following items:

- The OBRA 1993 Medicaid vaccine amendments and their implementation status
- The letter from Lederle Praxis and the accompanying materials

Other vaccine related legislative measures can be found in the 1994 appropriations statute and the so-called "Byrd-droppings" legislation now pending in Congress. These provisions relate primarily to the establishment of vaccine registries and funding for expanded public health agency activities. In a meeting on the morning of December 14th with the Interagency Task Force on Childhood Immunization will be learning more about the implementation status of these initiatives. I met with D.A. Henderson and Tony Robbins last week to determine the status of the Medicaid provisions enacted this past summer.

1. OBRA 1993

I am concerned that the Department has not paid the level of attention required of the OBRA 93 Medicaid amendments or their implementation and that we will not know, until perilously close the 10/1/94 effective date of the new program whether all the requisite pieces make sense and are in place.

The OBRA 1993 amendments do the following:

- Require the Secretary to establish a new program that delivers free vaccines to participating providers for administration to "vaccine eligible" children. Vaccine eligible children include Medicaid children, uninsured children, Indian children and children receiving services at federally qualified health centers. At state option, vaccine-eligible children also can include other children (e.g., all children; under-insured children, etc)
- Require the Secretary to set up a new delivery system directly to participating providers
- Require the Secretary to negotiate contracts with manufacturers that cover delivery and purchase costs and to buy sufficient vaccines to meet the requirements of the new purchasing and distribution system
- Place new requirements on states to set up a provider participation system and assure that providers follow the

provider participation guidelines.
- Require states to assure that their Medicaid EPSDT programs are updated to cover all of the vaccines covered under the new federal purchase and distribution system.

The program is being jointly administered by HCFA and the Public Health Service. Potentially all children are covered under the new federal purchase and distribution program depending on state election. Medicaid-eligible and uninsured children together comprise roughly 40-45 percent of all children under age 6. Therefore, getting free vaccines to all participating providers -- and getting providers to sign up for the program -- will have a major impact on ready access to vaccination services.

Between now and October 1, 1994, the Secretary must

- set up the distribution system,
- provide states with technical assistance on enrolling providers,
- negotiate new contracts with manufacturers, and
- launch a major effort to enroll providers in the program.

At this point -- nearly 5 months after passage of the legislation -- , no final decisions have been made about the scope of the Department's legal negotiating authority over delivery costs. Nor has a provider distribution scheme been designed. States have received minimal to no information about the program. No major outreach effort to enroll providers has been undertaken. Even public providers have received scant information.

The legal issue is quite important, since it concerns the effectiveness of the provider delivery system and thus, the effectiveness of the entire program for children. Under the law the the Secretary is required to deliver the vaccines to providers, not just to states. Indeed, state administrative costs for provider delivery are a non-allowable expense. Therefore, our delivery system must get the vaccines to the providers; otherwise the program will be ineffective. Department staff are concerned that because of a technical error in the statute, they are potentially limited to paying for delivery charge costs in such a manner that door-to-door delivery by manufacturers may be impossible unless the manufacturers even more deeply discount their costs under their existing contracts. While I want to see us get the best bargain possible, I also want the Administration to have the legal power it needs to do the job right for children. I also want to avoid a needless clash with manufacturers, to whom we have tried to give good faith assurances.

While I believe that we may be able to avoid the problem through a slightly different interpretation of the statute, Congressional staff have offered a technical correction if needed. So far no decision has been reached -- after nearly 5 months --

and the chance for technical amendments may be lost. The manufacturers are upset, as is Congressional staff. Even if we need to Congress is ready to include any necessary technical corrections the Department needs in the technical corrections bill, but to date, HHS staff and general counsel have reached no closure on this matter.

States have not received detailed information about the vaccines that will be covered under the new purchasing and distribution system. Many questions have been raised about how providers actually will receive their vaccines. CDC is apparently showing little leadership over the new law, and it is unclear whether and how HCFA has staffed up to carry out its new duties. The entire situation is quite frustrating.

My recommendations are that the White House:

- establish clear timelines for resolving design and legal matters
- require the Department to reach closure on whether it needs technical corrections by the first of the year so that technical corrections can be included in the technicals bill
- require a comprehensive provider outreach design by the end of January
- require a distribution design by the end of February
- require purchase and distribution contracts to be completed by mid-spring
- require comprehensive notification to states by early February.

2. The Lederle letter

As you instructed, I have not spoken with anyone about the Lederle letter. Here is my best guess:

- I believe that Lederle already sells CDC simple DTP vaccine under contract
- Lederle now wants a contract to sell combination vaccine (DTP plus Hib).
- CDC may be unhappy with the Lederle DTP-Hib contract offer, and rather than buying combination vaccine from Lederle, has instead chosen to buy Hib vaccine from Connaught to be mixed with DTP already under contract from Lederle.
- Lederle is correct that the OBRA legislation bars payment for "inappropriate" single dose antigens. But for all we know, Lederle may have refused to fairly price its combined contract. In this instance a single dosage may not be at all inappropriate. I just do not know.
- The OBRA legislation encourages multiple contracts, rather than a sole source contracts. I don't know why CDC went with a sole source contract.

CDC may well have acted reasonably in passing up the Lederle

contract in favor of Connaught. I assume that the Connaught vaccine has been approved for U.S. use, or else CDC could not have purchased it. CDC obviously looks for the best price, so that may have been the determining factor. I suspect that Lederle is overstating the problems of on-site mixing, although it certainly sounds more sensible to buy the vaccines already mixed.

I do know that Lederle is a very difficult company. I also know that this problem is coming on top of the problems around implementation of the OBRA 93 vaccine provisions, noted above.

THE WHITE HOUSE

WASHINGTON

November 24, 1993

MEMORANDUM FOR KEVIN THURM

FROM: Carol H. Rasco CHR

SUBJECT: Immunization program

At some point in December and prior to the 20th if possible, I would like to have a briefing in my office on the immunization initiative to date as well as future plans. OMB has asked to send representation as well. Would you please have the appropriate person call Rosalyn Miller in my office (456-2216) to set up this briefing?

Thank you and Happy Thanksgiving!

Nancy Ann
Belle involved(?)

THE WHITE HOUSE

WASHINGTON

FAX COVER SHEET

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FROM: CAROL H. RASCO

DATE: 11/24/93

NUMBER OF PAGES (including cover sheet): 2

COMMENTS:

If you have any problems with the fax transmission, please call _____ at (202)456-2216.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

09-Dec-1993 09:15am

TO: Rosalyn A. Miller

FROM: Carol H. Rasco
Economic and Domestic Policy

SUBJECT: Be sure Nancy Ann Min is

is invited to the immunization briefing HHS will give me as well as Sara Rosenbaum. It would be helpful if Sara could come a little early to talk to me about the issue.