

# Withdrawal/Redaction Sheet

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001. list	Immunization Briefing (partial) (1 page)	03/30/94	P6/b(6)
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**COLLECTION:**

Clinton Presidential Records  
 Domestic Policy Council  
 Carol Rasco (Meetings, Trips, Events)  
 OA/Box Number: 7262

**FOLDER TITLE:**

Immunization Briefing 4-1-94 (Roosevelt Room) 10:00-11:00 am

rw167

### RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the 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 advise 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]

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RR. Document will be reviewed upon request.

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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

file: Immun. briefing meeting



JIM GUY TUCKER  
GOVERNOR

# Arkansas DEPARTMENT OF HEALTH

4815 WEST MARKHAM STREET • LITTLE ROCK, ARKANSAS 72205-3867  
TELEPHONE AC 501 661-2000

SANDRA B. NICHOLS, M.D.  
DIRECTOR

March 23, 1994

Carol Rasco  
Assistant to the President  
for Domestic Policy  
White House  
2nd Floor, West Wing  
1600 Pennsylvania Avenue  
Washington, DC 20500

Dear Carol:

Thanks for taking time to meet with us on March 4 to share information and listen to our concerns! As discussed in the meeting, we are sending some specific questions/issues related to the Vaccines for Children Program. As you know, Arkansas has an outstanding immunization program; but, we realize we must do more to assure that our 0-2 year olds are adequately immunized and that we cannot do it alone. We will work hard to implement the new legislation, although it will produce many challenges and changes. Your support and assistance in helping address our concerns will enable us to work through these changes and successfully integrate them with the current program in Arkansas.

I am also sending some information on lead screening issues. Please call Martha Hlett at (501) 661-2243 if you have questions or need more information.

Again, we enjoyed the opportunity to visit with you. Dr. Nichols and I are planning to be in Washington, April 19 and 20 for an ASTHO meeting and hope to have a chance to follow up with you personally then.

Sincerely,

Nancy Kirsch, Director  
Bureau of Public Health Programs

NK:MH:lmh

## HCFA Rules vs. CDC Guidelines for Lead Poisoning

### ISSUE: RISK SCREENING QUESTIONNAIRE

A recent collection of articles in the pediatric literature concerning the set of questions recommended by CDC to assess risk for lead toxicity suggests that the first question alone, or perhaps question 1 combined with the second question, has a negative predictive value equivalent to that of all five questions. Some of the studies suggest that the other questions, such as those concerning residence near a "major highway" or parental occupation in a lead-related activity, have absolutely no usefulness in predicting childhood lead poisoning in suburban or rural areas. Furthermore, there is absolutely no literature regarding the additional four questions imposed by HCFA. The question pertaining to lead in water supply lines is particularly objectionable in view of the low contribution of water lead to blood lead levels and the extreme unlikelihood of finding an elevated blood lead in a child for whom this is the only "risk factor." Many parents in the Medicaid population will not know the answer to the question and thus will have to be presumed "high-risk;" for those who do know, the answer will usually be yes, meaning that there is almost no point in administering the assessment at all. If an assessment tool must be used, it therefore should incorporate only the first CDC question in order to maximize cost-effectiveness.

### ISSUE: FOLLOW-UP TESTING FREQUENCY

For children who are deemed "high-risk" on the basis of the verbal assessment, there needs to be some mechanism in place for curtailing routine blood lead screening after they have had repeatedly negative blood lead test results. The CDC recommends testing children deemed "high-risk," and with negative initial results, every six months until two consecutive measurements are  $<10 \mu\text{g}/\text{dL}$ , then yearly thereafter. However, the HCFA rules mandate blood lead testing at every periodic visit as long as the "high-risk" status remains in effect, regardless of previous results. This means that in many states an infant so designated could have a blood lead test at six months, nine months, 12 months, 15 months, 18 months, and 24 months of age, despite all results being negative. The physical trauma for such children is unnecessary (abusive); furthermore, precious resources are being wasted.

### ISSUE: LEAD LEVEL REQUIRING FOLLOW-UP TESTING

The requirement that all capillary results of  $\geq 10 \mu\text{g}/\text{dL}$  be followed up with a venous determination is also contradictory to the CDC guidelines and lacking in scientific basis. First of all, any test determination in the  $10\text{-}14 \mu\text{g}/\text{dL}$  range (venous or capillary) is accurate only within plus or minus  $3\text{-}4 \mu\text{g}/\text{dL}$ . Secondly, there is no recommended follow-up for these results other than a repeat test in several months. Therefore, since venous blood sticks are more invasive and technically more difficult to do (hence more traumatic), why not at least allow providers to appropriately follow up on these levels based on a capillary result rather than require a venous sample? This would again result in overall savings to the program.

### ISSUE: RECOGNITION OF "LEAD-FREE" ZONES

The absence of a provision for designation of "lead-free" zones in the HCFA rules is a major omission. Despite the lack of clear guidance from CDC in this regard, there should be no doubt that state public health agencies are in the best position both to establish a reasonable definition for such zones as well as to designate these, where appropriate. Our own experience the past two years has established several counties where screening of hundreds or even thousands of Medicaid recipients has yielded a less than 0.5% prevalence of confirmed blood lead levels  $>15 \text{ mg}/\text{dL}$ . Clearly, resources have been, and continue to be, misappropriated in these regions. Support has also been growing within the pediatric community for a more targeted approach to screening. Both Dr. Birt Harvey, past president of the American Academy of

Pediatrics, and Dr. Sergio Piomelli, Professor of Pediatrics at Columbia University and a member of the CDC committee which issued the latest guidelines, have recently published commentaries in the journal *Pediatrics* that call for a re-evaluation of the AAP and CDC recommendations for mass screening. Substantive issues of cost-effectiveness for the recommended approach have never been addressed, according to the authors. It is clear that an unbiased re-examination of the data is in order, but in the meantime, HCFA should allow more flexibility for states to target screening efforts based upon their own analysis of pertinent screening data.

## VACCINES FOR CHILDREN PROGRAM (VCF)

### **ISSUE: Communications between CDC, and the National Vaccine Program Office and State Health Departments.**

We have concerns that CDC and particularly the National Vaccine Program Office, HHS, are not working closely with states on program/policy development.

It is critical to the success of the Vaccines for Children Program for CDC and the National Vaccine Program Office, HHS to work closely with states to get input before making decisions and implementing new programs/initiatives, etc. Some examples include:

- 1) National Media Campaign - Many states already have media campaigns which were developed as part of their Immunization Action Plans, but the new national campaign was developed without getting input from states on what was already in place.
- 2) CDC recently held a meeting for private providers but didn't invite any health department representatives nor notify states who would be attending. Since health departments will be responsible for enrolling private providers, having representatives from health departments at the meeting could have helped to promote cooperation and coordination and assure that health departments and other providers heard/received the same information.
- 3) We were told at the Atlanta meeting in January that CDC would convene workgroups to discuss the vaccine ordering/distribution system(s). To our knowledge, no meetings have occurred. Rather than CDC mandating one distribution system, states need as much flexibility as possible to establish the system that works best within each respective state. For example, in Arkansas, the Health Department would like to distribute vaccine to all public providers but have CDC (Federal government) or the manufacturer ship directly to privately providers. In another state, the health department may choose to distribute the vaccine to all providers.

### **ISSUE: Status of 317 grant funding.**

We have been given various answers concerning the future of 317 grant funds to states (regular Immunization Grants, especially direct assistance). We've been told that they would: continue at the present level, continue at a reduced level, and/or be phased out. Continuation of these funds is critical to immunization programs in state health departments! In addition, it is impossible to plan without knowing the status of these grant funds.

We have also been told that money would be available to assist states with vaccine ordering and distribution systems. We don't know how much will be available, when it will be available, or how it will be distributed, e.g., formula-based, per grant request, etc. States need these answers soon, as we must start to look at developing/operating the distribution system.

**ISSUE: Vaccine for the underinsured.**

Under the new legislation, only FQHC's can receive vaccine to immunize the underinsured. In Arkansas, this will place a tremendous burden on clients due to the limited number of community health centers (CHC's) and where they are located. Also, many CHC's that have been providing immunizations on a limited basis will find it difficult to handle an increased demand for this service. At the January meeting, other states also voiced concerns related to this issue. We understand that efforts are underway at the Federal level for CHC's to "deputize" public health units as FQHC's to allow them to give immunizations to underinsured children. This type of arrangement or something similar must be developed for states like Arkansas to achieve 90% levels by 1996.

**ISSUE: Physician participation in Immunization Registries**

A key role for health departments is assurance that immunizations are given; this can be achieved through monitoring of immunization levels, tracking, and followup. In states like Arkansas, this can be done through immunization registries; but states must be given some authority and flexibility to help assure success of the VCF Program.

**ISSUE: Lead responsibility for the VCF Program**

At the Atlanta meeting, there seemed to be some confusion about the lead agency, as the National Vaccine Program Office staff appeared to be in charge of the meeting. This seemed to contribute to the lack of answers regarding the program and a delay in getting guidelines out to states. Because states have worked successfully with CDC in the past, we feel positive about their experience, expertise, and coordination with state programs and that CDC is the obvious, logical choice to run the Program. As discussed earlier, CDC must work closely with states on an ongoing basis; and, short term, must get VCF Program guidelines to the states as soon as possible. (We have been told we will get them by mid-April; October 1 is only about 6 months away.)

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## Association of State and Territorial Health Officials

415 Second Street, NE, Suite 200 • Washington, DC 20002

(202) 546-5400 Fax (202) 544-9349

# Memorandum

**To:** Carol Roscoe  
**From:** George Degnon  
**Date:** March 24, 1994  
**Subject:** Immunization Program

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Carol, thank you for your interest in the implementation of the President's Immunization Initiative at the State level. As we discussed, we share similar concerns about this program. ASTHO remains committed to increasing the immunization rates of our nation's children. We remain dedicated to working with the federal government in achieving this goal. In light of that commitment, I would like to raise the following issues related to the implementation of the President's Immunization Initiative:

1) Six months after passage of the law, we are now working closely with the CDC on the implementation of the Vaccines for Children portion of the President's initiative. We recognize that CDC, as well as states, is working under almost impossible deadlines to fully implement this program on October 1 of this year. CDC appears to be facing some problems in making policy decisions, these problems appear to be coming from "upstairs" within HHS as well as OMB as well. These issues, such as resources to states for capacity building, distribution of vaccines, accountability, etc. are delaying their ability to quickly relay information to the states. Training meetings on the implementation of the Vaccines for Children Program are scheduled in May, but we are concerned that the information flow in preparation for this meeting, as well as the ability for CDC to respond in a timely manner to state concerns raised at the meeting, will make it difficult for states to take the steps necessary to implement the program in the four months remaining after the May meetings. Little has been done to begin educating private providers on this program and to encourage their participation. States are not yet equipped to carry forward a message to their own private providers, because they really don't know what the message is yet. This is especially alarming considering that states will have to set up ordering processes and begin to take orders long before the October 1 kickoff date. With appropriate and timely information, states can do an effective PR job in promoting this law.

2) The second issue is the Outreach Campaign of the President's Initiative. The best way to ensure that a nationwide initiative is successful at the state level is to secure the involvement of state officials in the development of the concept, implementation plans and strategies at an early level. Because these are such visible programs we are concerned that if not done in strong collaboration with states and other appropriate parties they have the

potential of impeding state progress beyond this one-time campaign. Again, ASTHO and the states stand ready to work in any way possible to make this a success. We encourage that national efforts be coordinated with state programs to ensure that there is not duplicate efforts and messages.

3) We are also concerned that we are having a National Infant Immunization Week, five months before the Vaccines for Children Program takes effect. Therefore, private providers may still be referring their clients to public health agencies that may not be fully prepared for the hopeful onslaught of children seeking vaccinations. This is even further complicated by the fact that last year's vaccine law required a retroactive tax on state vaccine floor stock that equaled about \$37 million. CDC paid this tax (with state approval and appreciation) from the 1994 Immunization Program Resources. However, this means that state purchasing power with federal vaccine dollars has decreased by this amount for the remainder of this year. If a larger number of children than expected present for immunizations during the Immunization Week, we are likely to face shortfalls before the end of September. We believe that the retroactive excise tax was particularly burdensome since we have a letter from the Administration that the National Vaccine Injury Program is viable and that the retroactive portion of the tax was not needed for the solvency of the fund.

4) Another issue related to the Outreach Campaign is the Regional Coordinators/Regional Workshops. The second phase of the campaign is to hire regional coordinators in each of the 10 HHS regions. These coordinators are to work with local communities to get them involved in the immunization effort. ASTHO strongly questions this effort. We do not believe that it is the role of the federal government to by-pass states and work directly with communities in establishing coalitions and networks on any issue. This is a fundamental, mandated responsibility of state and local public health agencies. We believe that the resources being spent on this effort could and would be more adequately spent on providing states with needed money to develop or enhance their own efforts. Most states have started community building and are best equipped to respond to the needs of different communities in their state. Also the National Vaccine Program Office is proposing to do regional meetings in each region to promote coordination among community groups and public health agencies. To date, the dates of the meetings have not been announced but they are suppose to occur in June/July. As time comes closer it will become more and more difficult to secure the participation of appropriate parties. Also while this takes a regional approach to coalition building (which is better than a national approach) it still misses the fact that even states in the same region have different needs and even within individual states, communities have different needs. Pulling a group together to get them exercised about immunizations, when at the local level there may not be the resources to fully follow-through in providing the vaccines, we believe has the potential of being counterproductive.

5) States and ASTHO have serious concerns about the role of the National Vaccine Program Office. We believe that this office is just adding another layer of bureaucracy to an already understaffed program. We understand the importance that the President places on this issue and applaud his efforts. However, we are concerned that the National Vaccine Program Office is disrupting CDC management operations and procedures. If CDC is the responsible agency for implementing the Vaccines for Children Program, then CDC should be provided with all resources necessary to properly coordinate the campaign.



6) Finally, we have concerns about the actual Vaccines for Children Law. This law provides that federally purchased vaccines will be provided to any child without health insurance or on Medicaid. The law only provides federal vaccines to underinsured children that present at community health centers, rural health clinics or FQHCs. This is raising serious problems in many states. For example, in Alaska, there is only one community health center. This lack of recognition of the important role public health agencies play in immunizing children, is extremely damaging to the President's immunization goals since it is public health initiatives which have had the most success in getting children immunized. This whole issue was further compounded by the cuts in the CDC immunization program in the President's budget. By reducing the resources that states will have available to purchase vaccines for this underinsured population, more and more children are likely to be referred to FQHCs thus creating another barrier to immunizations. This problem of non coverage for underinsured children is also an issue for private physicians. Without coverage of this population by private doctors it is unlikely that many of them will choose to participate in the program – few doctors see children without health insurance, many see children whose insurance does not cover vaccines.

ASTHO remains committed to higher immunization rates. Public health practices have had the most significant impact in increasing immunization rates in this nation. We encourage the Administration to access our talents. States and ASTHO can provide the following:

- Incredibly dedicated program staff to get the job done - given the opportunity, the information and the necessary resources. This has not yet happened!
- Effective public information teams that can work with the state health officers and governors to put childhood immunizations before the public. Although we had assurances that these efforts would be coordinated with the states, state public relations directors have not yet been properly consulted!
- Teams of local liaison staff in each state that can build strong community relationships. They are not being utilized, but instead are being preempted by regional coordinators.

It is crucial that this or any other "one-time" initiative be coordinated with and support the ongoing public health programs of state agencies.

We are committed to ensuring the success of this program. While CDC has been most responsive in advising us on their progress, we again reiterate our interest in being part of the team at every step of the process, from determination of private provider reimbursement to the agenda for the Regional Meetings – we are in the trenches on these issues every day and believe we can contribute to this cooperative effort. Again, we are ready to assist in these efforts in any way and continue to work with the CDC. I would be happy to discuss this further with you. Thanks again for your interest. Enclosed for your information is our communication to states on this subject which puts a "positive-spin" on a trying process.



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

TO: STATE HEALTH OFFICIALS  
FROM: GEORGE K. DEGNON AND VALERIE MORELLI  
DATE: MARCH 23, 1994  
  
RE: PRESIDENT'S IMMUNIZATION INITIATIVE

This memorandum is to share information with you related to the President's Immunization Initiative. At a CDC meeting in Atlanta in January to discuss the initiative, it became clear that states had been little-consulted on implementation of the initiative. Since that meeting, ASTHO has continued to meet with CDC and the National Vaccine Program Office to raise issues about various components of the program and to ensure that state concerns are being heard. During the past few weeks, we have achieved a much closer working relationship with these offices.

Some of the areas and issues we would like to bring to your attention include:

1) **ADMINISTRATION OF THE VACCINES FOR CHILDREN PROGRAM** -- OBRA 93 included language to provide federally purchased vaccines to children without health insurance or insured by Medicaid (and underinsured children presenting at FQHCs.) This program was being implemented both by the CDC and the National Vaccine Program Office. ASTHO raised its concerns about dual involvement, especially since CDC has a long track record in dealing with states on immunizations. Shortly after we met with CDC Director David Satcher, it was announced that the CDC would be administering the entire program out of Atlanta.

2) **VACCINES FOR CHILDREN PROGRAM** -- ASTHO is continuing to work closely with the CDC on the implementation of the Vaccines for Children law. This law, scheduled to take effect on October 1, 1994, will have a profound impact on many state agencies. Through its Immunization Task Force, ASTHO is working to ensure that the maximum amount of state flexibility is provided and that the minimum amount of reporting requirements and "red tape" are required. ASTHO will be reviewing the operational manual for the program prior to its release. Also, CDC will be hosting training sessions for the regions during May. ASTHO has requested that the operational manual be made available prior to the training sessions so that states can come better prepared to discuss the implementation process.

3) **PUBLIC SERVICE ANNOUNCEMENTS** -- At the January meeting, the CDC announced a major national media campaign to be aired in late April around National Infant Immunization Week. It was also announced that the ads were reaching final production stages. Since it was the first that most states had heard of this campaign, there was little we could do to influence or discuss the ads or their integration with state programs. However, ASTHO was successful in working with CDC to allow states to determine if they wanted to locally tag the ads with their state information. Many states chose to tag the ads which will soon be distributed to your media markets based on directions provided by you and your public information staff.

4) **REGIONAL COORDINATORS** -- CDC has hired or is in the process of hiring regional coordinators for each region to work with states to assist in developing community organization interest in immunization initiatives. These individuals, who will serve through October, will help facilitate coordination at the state and local level for those interested in promoting child health. Those hired are being solicited for their grassroots and coalition building skills. You are encouraged to work with these individuals and to use their skills so that they can help state programs to achieve their objectives.

5) **REGIONAL MEETINGS** -- Also in January it was announced that Regional Meetings will be held in the summer to bring together a variety of individuals, corporations, non-profit organizations and public agencies to discuss how to motivate community activities to get more children immunized. The CDC has indicated it sees these as locally run meetings and that the Feds are only there to help coordinate. To that end, ASTHO will be serving on the planning committee to ensure that state issues and concerns are addressed.

We encourage you to share any issues you have related to the implementation of this initiative with us at the ASTHO office. ASTHO remains committed to improving the immunization rates of all children and continues to work hard to ensure that the new law and the initiative are successful for the states.



## Association of State and Territorial Health Officials

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# Memorandum

**To:** Carol Roscoe  
**From:** George Degnon  
**Date:** March 24, 1994

**Subject:** ASTHO HILL DAY/PUBLIC HEALTH IN HEALTH CARE REFORM

ASTHO is supportive of health care reform efforts. We believe that public health must be an integral part of any reform effort and believe that the President's plan is the only initiative on the table which truly begins to address public health. ASTHO has been supportive of reform even prior to the President's efforts to bring attention to this subject. (See attached statement on Health Care Reform adopted in May, 1992.) We also have developed a paper on the President's plan which supports his endeavors and makes suggestions on ways to strengthen the bill (see attached 1994 document).

However, since the early days of the planned development of the President's plan, the ASTHO membership, save for 1 or 2 health officers, have not had the opportunity to dialog with the President or First Lady on this issue. We were hopeful that the President or the First Lady ~~would be able to meet with us during last year's Hill Day. However, Hill Day~~ occurred during the family's personal tragedy of losing Mr. Rodham so the meeting did not occur.

State Health Officials will be in town Tuesday, April 19 and Wednesday, April 20 to again meet with Congress. The purpose of this meeting will be specifically on public health in health care reform. I would appreciate any and all efforts you could provide in affecting a meeting with the President or the First Lady with the Health Officers. The Health Officers all remain dedicated to health care reform and believe that the President's Core Public Health Functions are a true recognition of the need for public health.

Again, any assistance you could provide would be greatly appreciated. I will follow up with you next week on this issue. Thanks.

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ASSOCIATION OF STATE  
AND TERRITORIAL  
HEALTH OFFICIALS

STATEMENT ON HEALTH  
CARE REFORM

May, 1992

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ASTHO PRIORITY RECOMMENDATIONS  
FOR STRENGTHENING  
PUBLIC HEALTH IN THE  
HEALTH SECURITY ACT

February, 1994



The Association of State and Territorial Health Officials



# **The Childhood Immunization Initiative**

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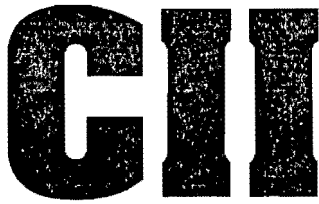
*Setcher:  
Choice of parents*

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*Briefing for  
Carol Rasco*

*April 1, 1994*

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# The Childhood Immunization Initiative

## Challenges

- Vaccines are the most powerful and cost-effective ways to prevent nine infectious diseases in children.
  - Cases of measles, polio and other diseases have decreased by over 99 percent since introduction of vaccines.
  - The estimated benefit-cost ratio of vaccines (dollars saved by society for every dollar spent) is over 21:1 for measles/mumps/rubella vaccine, is over 30:1 for diphtheria/tetanus/pertussis vaccine, and is over 6:1 for polio vaccine.
- Although over 96 percent of children are adequately vaccinated by kindergarten, about 15 to 35 percent of children under age two are inadequately protected against these childhood diseases.
- Between 11-15 vaccine doses are due by age 2, requiring about 5 visits to providers. This is about 80 percent of all vaccine doses recommended for children.
- Failure to immunize children on time led to the 1989-1991 measles epidemic which resulted in over 55,000 cases and 11,000 hospitalizations.

130 deaths

## Goals

- The Childhood Immunization Initiative (CII) has been launched by President Clinton to make sure that children do not become sick or die from vaccine preventable diseases .
- Specific and urgent goals to be accomplished by 1996 are (*See Attachment*)
  - reduce most diseases preventable by childhood vaccination to zero.
  - increase vaccination levels for 2-year-old children to at least 90 percent for the initial and most critical doses in the vaccine series, and 70 percent for a more recent vaccine (Hepatitis B).
  - build a vaccine delivery system to maintain these achievements in the United States within a reformed health care system.
- By the year 2000, a comprehensive infrastructure will be in place to provide the full series of vaccines for at least 90 percent of all children.

## Actions

- Since 1963, the Centers for Disease Control and Prevention (CDC) has been responsible for providing vaccine, management, technical assistance, information, epidemiology, assessment, and other national immunization services. These efforts have been targeted to State and local health departments and other partners. The CII enhances CDC's traditional efforts with significant resources and activities that now address immunization issues in a comprehensive manner. CII enhances the following five broad areas designed to attain the goals for 1996 and beyond.

- I. Improve the quality and quantity of vaccination delivery services**
- II. Reduce vaccine costs for parents (through the Vaccines for Children Program)**
- III. Increase community participation, education, and partnerships**
- IV. Improve monitoring of disease and vaccination coverage**
- V. Improve vaccines and vaccine use**

CDC has developed an extensive Action Plan which includes objectives, action steps, and comprehensive timelines designed to achieve the CII goals.

# Action I

## Improve the Quality and Quantity of Vaccination Delivery Services

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### Challenges

- Since 1963, the Federal Immunization Grant Program ("317" Grants) has assisted States in purchasing vaccines and managing programs. However, Federal grant funds could not be used to improve the immunization delivery infrastructure e.g., hire staff to give vaccines.
- The public health system, which serves about 1/2 of our Nation's children, was seriously eroded in the 1980's
- Parents faced serious barriers and obstacles to immunization
  - Inadequate clinic staff, inconvenient hours, insufficient locations, and other barriers.
  - Many missed opportunities to provide vaccines at health care visits.
  - Inadequate systems to remind parents when vaccinations were due for their children and for doctors and nurses to determine immunization needs quickly at each office visit.

### Solutions

- Immunization Action Plans (IAPs) - Beginning in 1992 as a new component of 317 grants, Federal grant funds were awarded by CDC to begin making seriously needed improvements to the vaccine delivery infrastructure. These IAP funds were supplied to 87 State, Territorial, and local health agencies. In 1994, as part of the CII, IAP funding was tripled to \$128 million. These funds were awarded based on comprehensive State and local IAP's detailing the State and local actions needed to meet immunization coverage targets for children.
- Performance-based funding - About 30 percent of IAP funding is based on meeting coverage targets. In addition, \$33 million in new 1994 incentive funds are available for States achieving high coverage rates as outlined in legislation.
- *Standards for Pediatric Immunization Practices* - These Standards consist of 18 immunization practices that all immunization providers should carry out. The Standards are recommended by the National Vaccine Advisory Committee and endorsed by the American Academy of Pediatrics. Implementation of the Standards is designed to remove barriers that (1) impede vaccine delivery and (2) eliminate missed immunization opportunities at office visits. For example, the Standards emphasize use of simultaneous vaccination with multiple vaccines to avoid extra visits and that parents be given immunization cards to help them and providers know their child's immunization needs.
- CDC will strengthen involvement of private health care providers through improved communication and collaboration to obtain their input and support for the CII goals.
- CDC will award additional grant funds to States to help establish Statewide Immunization Information Systems to remind parents when vaccinations are due for their children.

# Action II

## Reduce Vaccine Costs for Parents

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### Challenges

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- Vaccine costs have risen substantially in recent years, to about \$280 per child.
- Parents have increasingly been referred by private providers to public health clinics where Federal or State supplied vaccines are free. This referral breaks a child's continuity of care and resulting in missed immunizations.
- Many States invest substantial funds in vaccine purchase, especially through their Medicaid program, thus limiting spending on improved immunization infrastructure.

### Solutions

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- The Vaccines for Children (VFC) program will provide free vaccine to about 60 percent of our Nation's children, starting in October 1994, by purchasing over \$400 million in vaccines.
  - Parents of eligible children can obtain vaccinations from their provider of choice, thus allowing continuity of care
  - Eligible children include those who are Medicaid eligible, those without any health insurance, and American Indians. Children served by Federally Qualified Health Centers (FQHC) and Rural Health Clinics can receive VFC vaccines if their health insurance does not cover immunization.
  - States can buy vaccines at significantly reduced Federal prices to allow expanded access to vaccine for children in these States. About one-half of the States are considering supplying vaccine to all their children.
- The attached schematic diagram generally outlines the proposed VFC distribution process.
- Federal immunization grant funds and State funds will continue to help meet the needs of children not eligible for the VFC.

*What  
is there  
all spend?*

## **Action III**

# **Increase Community Participation, Education, and Partnerships**

---

### **Challenges**

---

- Parental Awareness - while parents are aware immunizations are needed by school age, they are often unaware that 80% of vaccinations are required by 2 years of age (need to change social norm).
- Providers, sometimes not aware of the urgency and importance of age appropriate immunization, often do not use all opportunities to immunize children in their care.
- Need to improve coordination among the many public and private sector groups working at State and community levels to educate and motivate parents/providers (i.e., groups in Harlem unaware of each other) and increase understanding of community organizing methods (i.e., how to recruit/direct volunteers, develop plan/strategy to use and coordinate diverse organizations, how to use media).
- Need to access the good will and provide opportunities for the many organizations that are not involved but desire to participate in immunization related activities.

### **Solutions**

---

- An aggressive community participation, education and partnership program is a fundamental component of the CII. This component seeks to increase awareness of the importance of age-appropriate immunization and increase community participation in the effort to educate and mobilize parents and providers.
- CDC is working with State health departments and community-based groups to build or enhance capacity to establish or expand coalitions, including:
  - recruiting/hiring Outreach Coordinators in each HHS region to work with States and community-based groups.
  - convening regional meetings for each HHS region to enhance coordination and communication among States, community-based groups, and others.
- CDC is reaching out to a cross-section of national organizations, groups, and corporations to seek their involvement within coalitions at the State and local levels.
- CDC is providing other tools and taking additional action to expand awareness and educate parents and providers:
  - Produced public service announcements, based on extensive collaboration and focus group research, for TV, radio, print and other media in English and Spanish languages;
  - Established toll-free phone numbers that will provide information in English and Spanish, and will also refer parents to local health clinics, and;
  - Reached out to the business and entertainment community, such as Gerber, McDonalds, Childrens Television Workshop, and Hollywood, to encourage their promotion and marketing of immunization messages.
- CDC is committed to establishing a long-term program that will ensure sustained support for these activities.

## **Action IV**

# **Improve Monitoring of Disease and Vaccination Coverage**

---

### **Challenges**

---

- Epidemics begin in populations with low immunization rates. Quickly finding pockets of low immunization rates or disease allows targeting of efforts to high risk populations.
- Information on immunization coverage at the National, State, and local levels is essential for (1) evaluating program effectiveness, (2) identifying populations at high risk for underimmunization, and (3) targeting remedial action.
- No national immunization coverage data were available between 1986 and 1990.
- No standardized system to collect immunization coverage information at the State and local levels has been available.
- Cases of disease need to be rapidly detected to identify underimmunized populations and to institute control efforts.
- Surveillance systems to detect disease often have been inadequate to prevent those cases from leading to epidemics.

### **Solutions**

---

- CDC is providing grant funding, for the first time, and scientific/intervention assistance to public health agencies to address surveillance weaknesses. This effort will include the investigation of each case of vaccine-preventable disease targeted for elimination.
- As a result of increased CII funding in 1994, comprehensive systems to monitor immunization coverage are functioning, or are being developed by CDC, to provide local, State, and National data to help target interventions.
  - The National Health Interview Survey (NHIS) monitors immunization levels nationwide on a quarterly basis
  - State and local area immunization levels will be assessed on a quarterly basis through random-digit-dialing surveys in all 50 States and in 28 large urban areas.
  - Clinic assessments assist public and private providers to measure immunization levels in populations they serve.
- This systematic evaluation of the outcome of Federal and State programs toward reaching disease and coverage targets addresses an essential component of the CII, which is to generate data to focus accountability for program results.

# Action V

## Improve Vaccines and Vaccine Use

---

### **Challenges**

- Currently, children require about 11-15 separate immunizations prior to their second birthday. This large number makes it more difficult to obtain complete immunization on time.
- Because of dissemination of inaccurate information, some parents have become more fearful of immunizations than the diseases themselves. Such unfounded fears can reduce coverage.
- Providers can be confused by multiple immunization schedules.

### **Solutions**

- The Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians are working together to develop a single childhood immunization schedule.
- The Public Health Service (NIH, FDA, and CDC) will work with manufacturers and researchers to stimulate development of new and combined vaccines to reduce the number of immunizations.
- Although available vaccines are very safe and effective, CDC will work with States and selected provider institutions to enhance systems to detect rare adverse events following vaccination. This will provide better information to parents on the risks and benefits of vaccination.

**Attachment**

**Childhood Immunization Initiative  
Vaccination Coverage for 1992\* 1993\*<sup>§</sup> and Vaccine  
Coverage Goals for 1996 and 2000<sup>¶</sup>**

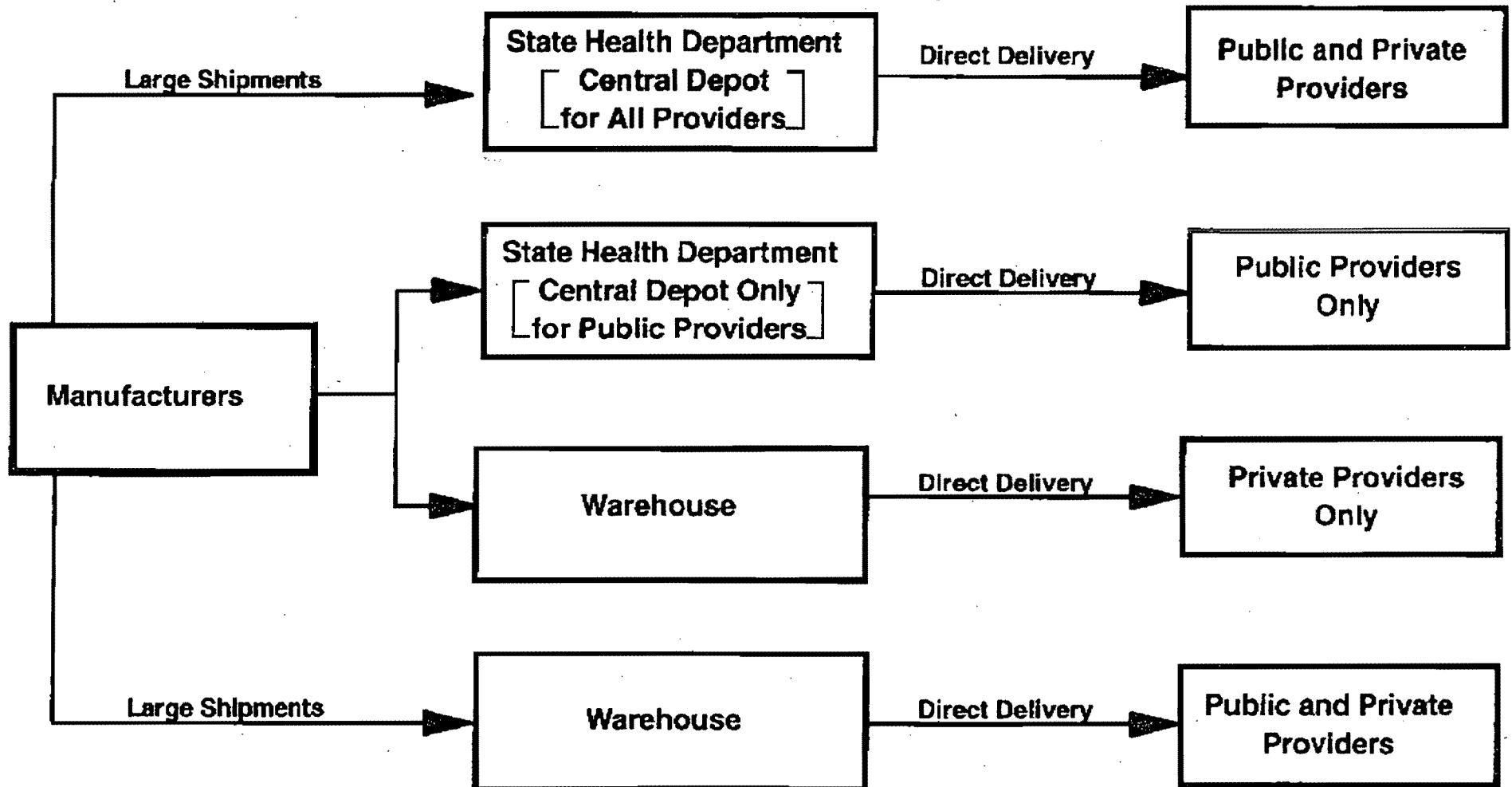
Vaccine	1992	1993	1996	2000
DTP 3+	83	87	90	90
OPV 3	72	78	90	90
MMR	83	81	90	90
Hib 3+	—	50	90	90
Hep B 3	—	13	70	90
DTP 4	59	71		90
DTP 4, OPV 3, MMR, Hib 3+, and Hep B 3**	55	65		90

*low because many kids surveyed - not age ready*

\* Coverage for children 19-35 months of age.  
<sup>§</sup> Provisional data based on 1st and 2nd quarters.  
<sup>¶</sup> Healthy People 2000 goals have not changed.  
 \*\* 1992 and 1993 data are only for DTP4, OPV 3, and MMR



# Proposed Vaccine Distribution



# **The Childhood Immunization Initiative**

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*Briefing for  
Carol Rasco*

*April 1, 1994*

---



# The Childhood Immunization Initiative

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## Challenges

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- Vaccines are the most powerful and cost-effective ways to prevent nine infectious diseases in children.
  - Cases of measles, polio and other diseases have decreased by over 99 percent since introduction of vaccines.
  - The estimated benefit-cost ratio of vaccines (dollars saved by society for every dollar spent) is over 21:1 for measles/mumps/rubella vaccine, is over 30:1 for diphtheria/tetanus/pertussis vaccine, and is over 6:1 for polio vaccine.
- Although over 96 percent of children are adequately vaccinated by kindergarten, about 15 to 35 percent of children under age two are inadequately protected against these childhood diseases.
- Between 11-15 vaccine doses are due by age 2, requiring about 5 visits to providers. This is about 80 percent of all vaccine doses recommended for children.
- Failure to immunize children on time led to the 1989-1991 measles epidemic which resulted in over 55,000 cases and 11,000 hospitalizations.

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## Goals

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- The Childhood Immunization Initiative (CII) has been launched by President Clinton to make sure that children do not become sick or die from vaccine preventable diseases .
- Specific and urgent goals to be accomplished by 1996 are (*See Attachment*)
  - reduce most diseases preventable by childhood vaccination to zero.
  - increase vaccination levels for 2-year-old children to at least 90 percent for the initial and most critical doses in the vaccine series, and 70 percent for a more recent vaccine (Hepatitis B).
  - build a vaccine delivery system to maintain these achievements in the United States within a reformed health care system.
- By the year 2000, a comprehensive infrastructure will be in place to provide the full series of vaccines for at least 90 percent of all children.

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## Actions

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- Since 1963, the Centers for Disease Control and Prevention (CDC) has been responsible for providing vaccine, management, technical assistance, information, epidemiology, assessment, and other national immunization services. These efforts have been targeted to State and local health departments and other partners. The CII enhances CDC's traditional efforts with significant resources and activities that now address immunization issues in a comprehensive manner. CII enhances the following five broad areas designed to attain the goals for 1996 and beyond.

- I. Improve the quality and quantity of vaccination delivery services
- II. Reduce vaccine costs for parents (through the Vaccines for Children Program)
- III. Increase community participation, education, and partnerships
- IV. Improve monitoring of disease and vaccination coverage
- V. Improve vaccines and vaccine use

CDC has developed an extensive Action Plan which includes objectives, action steps, and comprehensive timelines designed to achieve the CII goals.

# Action I

## Improve the Quality and Quantity of Vaccination Delivery Services

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### Challenges

- Since 1963, the Federal Immunization Grant Program ("317" Grants) has assisted States in purchasing vaccines and managing programs. However, Federal grant funds could not be used to improve the immunization delivery infrastructure e.g., hire staff to give vaccines.
- The public health system, which serves about 1/2 of our Nation's children, was seriously eroded in the 1980's
- Parents faced serious barriers and obstacles to immunization
  - Inadequate clinic staff, inconvenient hours, insufficient locations, and other barriers.
  - Many missed opportunities to provide vaccines at health care visits.
  - Inadequate systems to remind parents when vaccinations were due for their children and for doctors and nurses to determine immunization needs quickly at each office visit.

### Solutions

- Immunization Action Plans (IAPs) - Beginning in 1992 as a new component of 317 grants, Federal grant funds were awarded by CDC to begin making seriously needed improvements to the vaccine delivery infrastructure. These IAP funds were supplied to 87 State, Territorial, and local health agencies. In 1994, as part of the CII, IAP funding was tripled to \$128 million. These funds were awarded based on comprehensive State and local IAP's detailing the State and local actions needed to meet immunization coverage targets for children.
- Performance-based funding - About 30 percent of IAP funding is based on meeting coverage targets. In addition, \$33 million in new 1994 incentive funds are available for States achieving high coverage rates as outlined in legislation.
- *Standards for Pediatric Immunization Practices* - These Standards consist of 18 immunization practices that all immunization providers should carry out. The Standards are recommended by the National Vaccine Advisory Committee and endorsed by the American Academy of Pediatrics. Implementation of the Standards is designed to remove barriers that (1) impede vaccine delivery and (2) eliminate missed immunization opportunities at office visits. For example, the Standards emphasize use of simultaneous vaccination with multiple vaccines to avoid extra visits and that parents be given immunization cards to help them and providers know their child's immunization needs.
- CDC will strengthen involvement of private health care providers through improved communication and collaboration to obtain their input and support for the CII goals.
- CDC will award additional grant funds to States to help establish Statewide Immunization Information Systems to remind parents when vaccinations are due for their children.

## **Action II**

# **Reduce Vaccine Costs for Parents**

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### **Challenges**

- Vaccine costs have risen substantially in recent years, to about \$280 per child.
- Parents have increasingly been referred by private providers to public health clinics where Federal or State supplied vaccines are free. This referral breaks a child's continuity of care and resulting in missed immunizations.
- Many States invest substantial funds in vaccine purchase, especially through their Medicaid program, thus limiting spending on improved immunization infrastructure.

### **Solutions**

- The Vaccines for Children (VFC) program will provide free vaccine to about 60 percent of our Nation's children, starting in October 1994, by purchasing over \$400 million in vaccines.
  - Parents of eligible children can obtain vaccinations from their provider of choice, thus allowing continuity of care
  - Eligible children include those who are Medicaid eligible, those without any health insurance, and American Indians. Children served by Federally Qualified Health Centers (FQHC) and Rural Health Clinics can receive VFC vaccines if their health insurance does not cover immunization.
  - States can buy vaccines at significantly reduced Federal prices to allow expanded access to vaccine for children in these States. About one-half of the States are considering supplying vaccine to all their children.
- The attached schematic diagram generally outlines the proposed VFC distribution process.
- Federal immunization grant funds and State funds will continue to help meet the needs of children not eligible for the VFC.

## **Action III**

# **Increase Community Participation, Education, and Partnerships**

---

### **Challenges**

---

- Parental Awareness - while parents are aware immunizations are needed by school age, they are often unaware that 80% of vaccinations are required by 2 years of age (need to change social norm).
- Providers, sometimes not aware of the urgency and importance of age appropriate immunization, often do not use all opportunities to immunize children in their care.
- Need to improve coordination among the many public and private sector groups working at State and community levels to educate and motivate parents/providers (i.e., groups in Harlem unaware of each other) and increase understanding of community organizing methods (i.e., how to recruit/direct volunteers, develop plan/strategy to use and coordinate diverse organizations, how to use-media).
- Need to access the good will and provide opportunities for the many organizations that are not involved but desire to participate in immunization related activities.

### **Solutions**

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- CDC is working with State health departments and community-based groups to build or enhance capacity to establish or expand coalitions, including:
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- CDC is providing other tools and taking additional action to expand awareness and educate parents and providers:
  - Produced public service announcements, based on extensive collaboration and focus group research, for TV, radio, print and other media in English and Spanish languages;
  - Established toll-free phone numbers that will provide information in English and Spanish, and will also refer parents to local health clinics, and;
  - Reached out to the business and entertainment community, such as Gerber, McDonalds, Childrens Television Workshop, and Hollywood, to encourage their promotion and marketing of immunization messages.
- CDC is committed to establishing a long-term program that will ensure sustained support for these activities.

## **Action IV**

# **Improve Monitoring of Disease and Vaccination Coverage**

---

### **Challenges**

- Epidemics begin in populations with low immunization rates. Quickly finding pockets of low immunization rates or disease allows targeting of efforts to high risk populations.
- Information on immunization coverage at the National, State, and local levels is essential for (1) evaluating program effectiveness, (2) identifying populations at high risk for underimmunization, and (3) targeting remedial action.
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### **Solutions**

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# Action V

## Improve Vaccines and Vaccine Use

---

### Challenges

- Currently, children require about 11-15 separate immunizations prior to their second birthday. This large number makes it more difficult to obtain complete immunization on time.
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### Solutions

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## Attachment

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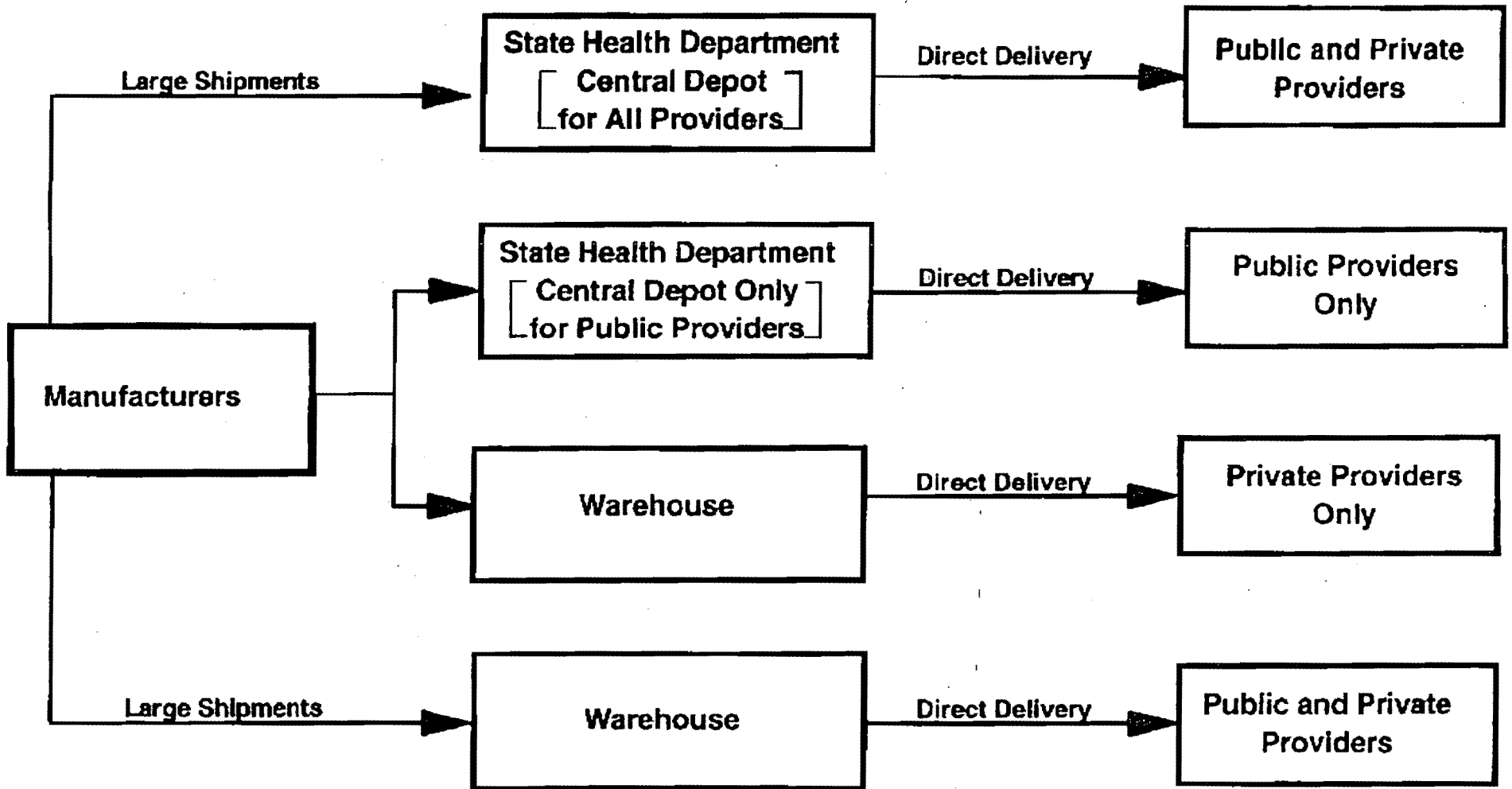
\* Coverage for children 19-35 months of age.

§ Provisional data based on 1st and 2nd quarters.

¶ Healthy People 2000 goals have not changed.

\*\* 1992 and 1993 data are only for DTP4, OPV 3, and MMR

# Proposed Vaccine Distribution





March 31, 1994

NOTE TO CAROL RASCO

*KATW  
3/31/94*

Attached is a briefing paper for tomorrow's meeting. Please distribute before hand as appropriate.

Kevin Thurm

Attachment

Immunization Briefing  
Roosevelt Room  
April 1, 1994  
10:00-11:00

White House

Bill Galston

Sara Rosenbaum

Jennifer Klein

Keith Mason

Wendy Nishikawa (Public Liaison)

Christine Varney

OMB

Nancy-Ann Min (+1)

# Withdrawal/Redaction Marker

## Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	Immunization Briefing (partial) (1 page)	03/30/94	P6/b(6)

**This marker identifies the original location of the withdrawn item listed above.  
For a complete list of items withdrawn from this folder, see the  
Withdrawal/Redaction Sheet at the front of the folder.**

### COLLECTION:

Clinton Presidential Records  
Domestic Policy Council  
Carol Rasco (Meetings, Trips, Events)  
OA/Box Number: 7262

### FOLDER TITLE:

Immunization Briefing 4-1-94 (Roosevelt Room) 10:00-11:00 am

rw167

### RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the 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 advise 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]

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
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- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
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- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

REVISED

IMMUNIZATION BRIEFING

April 1, 1994  
10:00 A.M.

NAME

DOB

SSN

Kevin Thurm  
Chief of Staff

Jo Ivey Boufford  
Principal Deputy Assistant  
Secretary for Health

William Corr  
Deputy Assistant Secretary  
for Health

David Satcher  
Director  
Centers for Disease Control  
and Prevention, PHS

Walter A. Ornstein  
Director  
National Immunization Program  
Centers for Disease Control  
and Prevention, PHS

Richard Leach  
Associate Director for  
Outreach  
National Vaccine Program Ofc.

Sally R. Richardson  
Director, Medicaid Bureau  
HCFA

~~Jerry Klepner~~  
~~Assistant Secretary for~~  
~~Legislation~~

[Redacted DOB column]

P6/b(6)

[Redacted SSN]

[Redacted SSN]

[Redacted SSN]

[Redacted SSN]

[Redacted SSN]

[Redacted SSN]

[Redacted SSN]

[Redacted SSN]

[Redacted DOB]

P6/b(6)

*Karen Pollitz*

*Handwritten note:*  
3/29/94  
[unclear]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington D.C. 20201

# FACSIMILE

DATE MAR 31 1994

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

*ATTN: Rosalyn*  
Carol Rasco  
Assistant to the President  
for Domestic Policy

456-2216

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

Kevin Thurn  
Chief of Staff

690-6133

RECIPIENT'S FAX NUMBER: ( ) 456-2878

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 1


COMMENTS:

THE WHITE HOUSE

WASHINGTON

March 14, 1994

MEMORANDUM FOR KEVIN THURM

FROM: Carol H. Rasco 

SUBJECT: Immunization Meeting

With the Vaccines for Children Program scheduled to go into effect in about 6 months, I would like to schedule a meeting at the White House to review the status of the following issues:

- the vaccine purchase contracts with the manufacturers
- the provider delivery system the Secretary will be using
- instructions to state Medicaid agencies regarding provider outreach and enrollment, state obligations with respect to ordering vaccines for participating providers, and conditions under which FFP is available for these activities as part of states' overall EPSDT program
- eligibility standards for children
- instructions to state health agencies and other agencies regarding supplemental vaccine purchasing
- special outreach efforts aimed at uninsured, underinsured and Indian children
- special outreach efforts aimed at enrolling providers
- any other matters related to the implementation of the program

As I understand it, CDC now has lead responsibility for this program; if at all possible, I would like to have personnel from Atlanta at the meeting along with other appropriate senior PHS staff. I also think that because HCFA in many ways will continue to play a pivotal role, senior staff from that agency also should be present.

I particularly want to know if any problems in implementation have come up, what they are, and how they are being resolved.

I have asked Rosalyn Miller in my office to expect a call from you so that mutually agreeable dates can be explored. If HHS wishes to prepare background briefing materials, I would welcome them.



THE WHITE HOUSE

WASHINGTON

March 30, 1994

MEMORANDUM FOR MACK MCLARTY  
PHIL LADER  
HAROLD ICKES  
DAVID GERGEN  
GEORGE STEPHANOPOULOS  
MARK GEARAN  
MARCIA HALE  
ALEXIS HERMAN  
PAT GRIFFIN  
CHRISTINE VARNEY

FROM: Carol H. Rasco  
SUBJECT: Immunization Program

I apologize for the late notice for this meeting. I have scheduled a briefing for this Friday, April 1 in the Roosevelt Room at 10 a.m. by HHS to include representatives from Public Health Services, HCFA, and CDC in Atlanta on the immunization program passed last year and due to take effect in October. I scheduled this meeting due to serious concerns brought to my attention by various states and other advocacy groups about the perceived inadequacy of the planning to date by the various divisions of HHS for this program. A failure of this program in October and publicity about not being prepared prior to that time could be devastating for health care reform, the future of this program---not to mention the need for immunization of children.

I have already included in the meeting DPC staff and OMB along with Sara Rosenbaum who is working with me on this program. Attached to this memo is the original memo that went to HHS regarding my request. I don't have other background materials to give you as HHS has not provided anything. While the meeting is scheduled for one hour I am prepared for it to last up to one and a half hours if necessary.

You or a designee are invited to attend if you wish. For planning purposes please indicate ASAP to Rosalyn Miller (by EMail or x62216) in my office if you plan to be present or have someone present. Also, you are certainly free to simply take this as an FYI; it is not a plea on my part for attendance but I did want you to know about it.

Thank you.

Invited:

CDC  
HHS } approx. 8  
HCFA

- S. Rosenbaum
- Nancy-Ana Min + 1
- A. Kate Keith
- K. Way ✓
- ~~C. Heenan~~
- ~~R. Griffin~~
- J. Klein ✓
- S. Dicker ✓
- C. H. ✓
- Galster ✓

✓  
clip  
for  
Romani

Roosevelt Rm  
Confirmed  
10-11:30



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington D.C. 20201

**FACSIMILE**

DATE MAR 29 1994

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

Carol Rasco  
Assistant to the President  
for Domestic Policy  
ATTN: Rosalyn  
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): 2

COMMENTS:

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Clinton Presidential Records  
Domestic Policy Council  
Carol Rasco (Meetings, Trips, Events)  
OA/Box Number: 7262

---

**FOLDER TITLE:**

Immunization Briefing 4-1-94 (Roosevelt Room) 10:00-11:00 am

rw167

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**RESTRICTION CODES**

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IMMUNIZATION BRIEFING

April 1, 1994

10:00 A.M.

<u>NAME</u>	<u>DOB</u>	<u>SSN</u>
Kevin Thurm Chief of Staff	[REDACTED]	[REDACTED]
Jo Ivey Boufford Principal Deputy Assistant Secretary for Health		[REDACTED]
William Corr Deputy Assistant Secretary for Health		[REDACTED]
David Satcher Director Centers for Disease Control and Prevention, PHS		[REDACTED]
Walter A. Ornstein Director National Immunization Program Centers for Disease Control and Prevention, PHS		[REDACTED]
Richard Leach Associate Director for Outreach National Vaccine Program Ofc.		[REDACTED]
Sally R. Richardson Director, Medicaid Bureau HCFA		[REDACTED]

P6/b(6)

*Karen Pollitz*

P6/b(6)



*Immunization Meeting file*

MAR 23 REC'D

CENTER FOR HEALTH POLICY RESEARCH

FAX COVER LETTER

Number of sheets including cover sheet: 8

TO: Carol Rasco

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

PHONE: 202 - 456 - 2216

FAX: 202 - 456 - 2878

FROM: SARA ROSENBAUM

PHONE: (202) 296-6922

FAX: (202) 785-0114

If there are problems or questions about fax, contact Millie Brobston at the number above.

MESSAGE:

March 23, 1994

## MEMORANDUM

TO: Tony Robbins

FR: Sara Rosenbaum

RE: The OBRA '93 vaccine floor stocks tax

About a month ago Tony called me about the vaccine floor stocks tax problem, which involves federal and state health agency liability for the retroactive floor stocks tax that was passed as part of OBRA '93. After several weeks of discussions with Treasury, it appears that while the law envisions liability on the part of all federal and state purchasers (as well as private buyers), in fact there may be less liability than meets the eye. It is impossible to determine who has any repayment obligations on the part of either the CDC or state health agencies ( and if so, how much), without sitting down with CDC program staff and legal counsel and learning more about how the CDC purchasing and distribution system works.

I would like to schedule a meeting with PHS/OGC and relevant program staff to determine whether (a) CDC owes anything given the fact that Congress did not appropriate the tax, and (b) whether states owe anything on §317-purchased vaccines in the absence of CDC payment given the fact that the tax comes out of the appropriation and given the fact that while the states may "hold" the vaccine, they may not have title to it, per the IRS ruling (attached).

Please let me know how you want to proceed.

cc: Jo Boufford

# IRS announcement of reinstatement

Office of Assistant Chief Counsel, Income Tax and Accounting, Internal Revenue Service. Other personnel from the Internal Revenue Service and the Treasury, however, assisted in developing these proposed regulations on matters of both substance and style.

## List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

## Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

### PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 \*\*\*

Par. 2. Section 1.263A-1 is amended by adding the text of paragraph (j)(4) to read as follows:

#### §1.263A-1 Uniform capitalization of costs.

\* \* \* \* \*

(j) \*\*\*

(4) \*\*\* The District Director may require appropriate adjustments to valuations of inventory and other property subject to section 263A if a transfer of property is made to another person for a principal purpose of tax avoidance. Thus, for example, the District Director may require a taxpayer using the simplified production method of §1.263A-2(b) to apply that method to transferred inventories immediately prior to a transfer under section 351 if a principal purpose of the transfer is tax avoidance.

Par. 3. Section 1.263A-1T(a)(4) is amended by revising the fourth sentence of paragraph (a)(4) to read as follows:

#### §1.263A-1T Capitalization and inclusion of inventory costs of certain expenses (temporary).

\* \* \* \* \*

(a) \*\*\*

(4) \*\*\* Paragraphs (a), (b), and (d) are not effective for costs incurred after December 31, 1993, in taxable years beginning after that date. \*\*\*

\* \* \* \* \*

Par. 4. Section 1.263A-3(c)(4)(vi) is amended by:

1. Adding paragraphs (A) (1) and (2) and the text of paragraph (B) to read as set forth below.

2. Removing paragraph (C).

#### §1.263A-3 Rules relating to property acquired for resale.

\* \* \* \* \*

(c) \*\*\*

(4) \*\*\*

(vi) \*\*\* (A) \*\*\* (1) In general

Distribution costs are any transportation costs incurred outside a storage facility in delivering goods to an unrelated customer. For this purpose, any costs incurred on a loading dock are treated as incurred outside a storage facility.

(2) Costs incurred transporting goods to a related person. Distribution costs do not include the costs of delivering goods by a taxpayer to a related person. Thus, for example, when the taxpayer sells goods to a related person, the costs of transporting such goods are included in determining the basis of the goods that are sold, and hence in determining the resulting gain or loss from such sale, for all purposes of the Internal Revenue Code and the regulations thereunder. See, e.g., sections 267, 707, and 1502. For purposes of this provision, persons are related if they are described in section 267(b) or section 707(b).

(B) \*\*\* Generally, costs incurred in transporting goods from the taxpayer's storage facility to its retail sales facility are transportation costs that must be capitalized. However, the costs incurred outside a storage facility in delivering custom-ordered items to a retail sales facility are not required to be capitalized. For this purpose, any costs incurred on a loading dock are treated as incurred outside a storage facility. Delivery of custom-ordered items occurs when the taxpayer can demonstrate that a delivery to the taxpayer's retail sales facility is made to fill an identifiable order of a particular customer (placed by the customer before the delivery of the goods occurs) for the particular goods in question. Factors that may demonstrate the existence of a specific, identifiable delivery include the following—

(1) The customer has paid for the item in advance of the delivery;

(2) The customer has submitted a written order for the item;

(3) The item is not normally available at the retail sales facility for on-site customer purchases; and

(4) The item will be returned to the storage facility (and not held for sale at the retail sales facility) if the customer cancels an order.

\* \* \* \* \*

Shirley D. Peterson,  
Commissioner of  
Internal Revenue.

(Filed by the Office of the Federal Register on August 6, 1993, 8:45 a.m., and published in the issue of the Federal Register for August 9, 1993, 58 FR 42263)

### Reinstatement of Vaccine Tax Announcement 93-107

The Omnibus Budget Reconciliation Act of 1993 has reinstated the vaccine excise tax, effective August 11, 1993. The taxable vaccines and the tax rates are as follows:

Vaccine	Tax Per Dose
DPT (diphtheria, pertussis, and tetanus)	\$4.56
DT (diphtheria-tetanus)	.06
MMR (measles, mumps, and rubella)	4.44
Polio	.29

The Act provides for a floor stocks tax on the taxable vaccines. The floor stocks tax applies to any person who holds a taxable vaccine for sale or use on August 10, 1993. There are no exceptions to this tax. Therefore, hospitals, doctors, Federal, state, and local governments, and other purchasers of vaccines will be subject to the floor stocks tax if they hold these vaccines in inventory on August 10, 1993. The vaccines must have been purchased on or before August 10, 1993, without tax imposed under section 4131 of the Internal Revenue Code.

Any person holding a taxable vaccine on August 10, 1993, must make an inventory of the number of doses in stock. The vaccine floor stocks tax must be paid by February 28, 1994, and will be reported on Form 720, Quarterly Federal Excise Tax Return.

The filing date will be determined by regulations. We will issue another announcement when the regulations are published.



# IRS announcement of Termination

involved in the direct skip with respect to the trustee of the trust arrangement, in the aggregate, is less than \$100,000.

(v) *Examples.* The following examples illustrate the application of this paragraph (c)(2) with respect to decedents dying on or after June 22, 1993.

*Example 5.* On August 1, 1993, A, the insured under a life insurance policy, dies. The insurance proceeds on A's life that are payable under policies issued by Company X are in the aggregate amount of \$200,000 and are includible in A's gross estate. Because the proceeds are includible in A's gross estate, the generation-skipping transfer that occurs upon A's death, if any, will be a direct skip rather than a taxable distribution or a taxable termination. Accordingly, because the aggregate amount of insurance proceeds with respect to Company X is less than \$250,000, Company X may pay the proceeds without regard to whether the beneficiary is a skip person in relation to the decedent-transferor.

Michael P. Dolan,  
Acting Commissioner of  
Internal Revenue.

(Filed by the Office of the Federal Register on December 23, 1992, 8:45 a.m., and published in the issue of the Federal Register for December 24, 1992, 57 F.R. 61353)

## Termination of Vaccine Tax

### Announcement 93-11

The Treasury Department has notified the Internal Revenue Service that the vaccine excise tax has been terminated as of January 1, 1993, pursuant to section 4131(c) of the Internal Revenue Code. That section requires the tax to be terminated if there is a positive projected balance in the Vaccine Injury Compensation Trust Fund as of December 31, 1992.

Consequently, the vaccine excise tax will not apply to sales of the following vaccines on or after January 1, 1993: DPT vaccine, DT vaccine, MMR vaccine, and Polio vaccine. Beginning with the 1st quarter of 1993, IRS Nos. 81, 82, 83, and 84 on Form 720 (Rev. January 1993) should not be completed. If Congress passes legislation that reinstates the vaccine tax in 1993, an announcement will be issued.

## Proposed Nondiscrimination Regulations Obsolete Revenue Rulings

### Announcement 93-12

In light of legislation, including the Tax Reform Act of 1986, and the promulgation of regulations under sections 401(a)(4), 401(a)(5), 401(a)(17), 401(D), 410(b), and 414(s) of the Internal Revenue Code (Code), the Internal Revenue Service has reviewed various revenue rulings that are published in the Internal Revenue Bulletin. This announcement issues, in proposed form, a revenue ruling that would declare obsolete a number of revenue rulings.

The goal of the Service and Treasury in publishing comprehensive regulatory guidance under various related statutory nondiscrimination provisions governing tax-qualified retirement plans is to provide taxpayers with an integrated framework for applying the nondiscrimination provisions of the Code. The Service and Treasury are attempting to further that goal by publishing this announcement and requesting comments on the accompanying proposed revenue ruling obsoleting certain previously published guidance. A previously published ruling that is declared obsolete is not considered determinative with respect to future transactions. A ruling may be declared obsolete because of changes in law or regulations, or because the substance has been included in regulations subsequently adopted.

### COMMENTS

The Service and Treasury invite comments on the accompanying lists of revenue rulings that are proposed to be declared obsolete. Comments should be submitted in writing, referencing Announcement 93-12, and should be addressed to—

Director, Employee Plans  
Technical and Actuarial Division  
Attention E:EP:P  
Room 6568  
Internal Revenue Service  
1111 Constitution Avenue, N.W.  
Washington, D.C. 20224

### Proposed Revenue Ruling

In light of the enactment of legislation, including the Tax Reform Act of 1986, and the promulgation of

regulations under sections 401(a)(4), 401(a)(5), 401(a)(17), 401(D), 410(b), and 414(s) (nondiscrimination regulations), the Internal Revenue Service has reviewed various revenue rulings that are published in the Internal Revenue Bulletin.

The purpose of this revenue ruling is to publish lists of revenue rulings having primary application in the employee plans area that, although not specifically revoked or superseded, are not considered determinative with respect to future transactions because (1) the applicable statutory provisions or regulations have been changed or repealed; (2) the ruling position is specifically covered by statute or regulations; or (3) the facts set forth no longer exist or are not sufficient to permit application of the current statute. Accordingly, the rulings in the two lists set forth below are declared obsolete as of the effective date of the nondiscrimination regulations (i.e., are not considered determinative with respect to transactions on or after that effective date).

The rulings listed in the first list below are obsolete with respect to all qualified plans. The rulings listed in the second list below are obsolete only with respect to qualified plans that are subject to section 410(b), as amended by section 1112(a) of the Tax Reform Act of 1986. The rulings listed in the second list below continue to be considered determinative with respect to future transactions in the case of, for example, a governmental plan (within the meaning of section 414(d)) or a church plan (within the meaning of section 414(e)) with respect to which the election provided by section 410(d) has not been made.

### (1) The following rulings are obsolete:

Rev. Rul. 56-692	1956-2 CB 287
Rev. Rul. 57-77	1957-1 CB 158
Rev. Rul. 57-587	1957-2 CB 260
Rev. Rul. 58-151	1958-1 CB 192
Rev. Rul. 58-604	1958-2 CB 147
Rev. Rul. 59-13	1959-1 CB 83
Rev. Rul. 60-337	1960-2 CB 151
Rev. Rul. 61-75	1961-1 CB 140
Rev. Rul. 61-147	1961-2 CB 102
Rev. Rul. 62-139	1962-2 CB 123
Rev. Rul. 62-152	1962-2 CB 126
Rev. Rul. 62-206	1962-2 CB 129
Rev. Rul. 65-107	1965-1 CB 173
Rev. Rul. 67-114	1967-1 CB 85
Rev. Rul. 67-261	1967-2 CB 148

# Regulations

holds the commercial aviation fuel at the first moment of October 1, 1995. Fuel is held by a person if the person has title to the fuel (whether or not delivery to that person has been made) at such time, as determined under applicable local law.

## *§47.3-10T Exceptions to the October 1, 1995, floor stocks tax (temporary).*

(a) *Exception for commercial aviation fuel held for use as supplies for vessels or aircraft.* The October 1, 1995, floor stocks tax does not apply to commercial aviation fuel held exclusively for use as supplies for vessels or aircraft within the meaning of section 4221(d)(3). In determining whether commercial aviation fuel is held exclusively for such use, the following rules apply:

(1) Commercial aviation fuel is held exclusively for use as supplies for vessels or aircraft only if the person that holds the commercial aviation fuel at the first moment of October 1, 1995, actually uses the aviation fuel in that exempt use.

(2) Commercial aviation fuel is not held exclusively for use as supplies for vessels or aircraft if, at the first moment of October 1, 1995, the commercial aviation fuel is held for resale (including resale to a person that will use the aviation fuel as supplies for vessels or aircraft). Thus, for example, commercial aviation fuel held by a fixed base operator for sale to an airline for use in foreign trade is not exempt from the October 1, 1995, floor stocks tax. However, the airline would be eligible to claim a credit or payment equal to the tax under section 6427.

(b) *Exception for certain amounts of fuel—(1) In general.* The October 1, 1995, floor stocks tax does not apply to commercial aviation fuel that a person holds at the first moment of October 1, 1995, if the aggregate amount of commercial aviation fuel held by that person at that moment does not exceed 2,000 gallons.

(2) *Additional rules relating to the 2,000 gallon exception—(i) Coordination with other exemptions.* In determining the aggregate amount of commercial aviation fuel held by a person at the first moment of October 1, 1995, there is to be excluded the amount of commercial aviation fuel exempt from the October 1, 1995, floor stocks tax by reason of paragraph (a) of this

section (relating to fuel held for an exempt use).

(ii) *All amounts held subject to tax if threshold exceeded.* The October 1, 1995, floor stocks tax applies to all amounts of commercial aviation fuel held by a person (and not exempt from tax under paragraph (a) of this section) if the aggregate amount of commercial aviation fuel held by the person at the first moment of October 1, 1995, exceeds 2,000 gallons.

(iii) *Controlled groups.* A member of a controlled group (as defined in §47.3-2T) holds more than 2,000 gallons of commercial aviation fuel if the aggregate amount of all commercial aviation fuel held by all members of the controlled group exceeds 2,000 gallons.

(3) *Example.* The following example illustrates the rules of this paragraph (b):

*Example.* D, E, and F are members of the same controlled group. On October 1, 1995, D holds 2,000 gallons of commercial aviation fuel, E holds 1,500 gallons of commercial aviation fuel, and F holds 500 gallons of commercial aviation fuel. None of the commercial aviation fuel is held for an exempt use. Because the aggregate amount held by all members of the group is 4,000 gallons, which exceeds 2,000 gallons, all commercial aviation fuel held by each member is subject to the floor stocks tax. Thus, D is liable for tax of \$85.00 (2,000 × \$.043), E is liable for tax of \$64.50 (1,500 × \$.043), and F is liable for tax of \$21.50 (500 × \$.043).

## *§47.3-11T Requirements with respect to payment and return for the October 1, 1995, floor stocks tax (temporary).*

(a) *Payment of tax.* The October 1, 1995, floor stocks tax is to be paid without assessment or notice on or before April 30, 1996.

(b) *Filing of returns—(1) Form 720.* Every person liable for the October 1, 1995, floor stocks tax must make a return of the tax on Form 720, Quarterly Federal Excise Tax Return. The return is to be prepared and filed in accordance with the instructions relating to the return.

(2) *Time for filing—(i) In general.* The Form 720 required by paragraph (b)(1) of this section must be filed on or before April 30, 1996, and is a return for the first calendar quarter of 1996. A first return reporting only October 1, 1995, floor stocks tax is also a final return and therefore, in accordance with the instructions to

Form 720, the box for "final return" must be marked.

(ii) *Return reporting other taxes.* A person must file only one Form 720 for a quarter. If a person is required under part 40 of this chapter to file Form 720 for the first calendar quarter of 1996 for other excise taxes on or before May 31, 1996, that person files a single Form 720 for the quarter on or before May 31, 1996. This paragraph (b)(2)(ii) does not extend the time for making deposits or paying any excise tax.

Margaret Milner Richardson,  
*Commissioner of Internal Revenue.*

Approved November 10, 1993.

Leslie Samuels,  
*Assistant Secretary of the Treasury.*

(Filed by the Office of the Federal Register on November 22, 1993, 8:34 p.m. and published in the issue of the Federal Register for November 29, 1993, 58 FR 62526)

## Section 4131.—Imposition of Tax

T.D. 8497

DEPARTMENT OF THE TREASURY  
Internal Revenue Service  
26 CFR Part 47

## Vaccine Floor Stocks Tax of 1993

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

**SUMMARY:** This document contains temporary regulations relating to the floor stocks tax on vaccines held on August 10, 1993. These rules reflect changes to the law made by the Omnibus Budget Reconciliation Act of 1993 (Act). The temporary regulations provide guidance relating to the person liable for the tax, an exception to the tax, and the time for reporting and paying the tax.

**EFFECTIVE DATE:** These regulations are effective August 10, 1993.

**FOR FURTHER INFORMATION CONTACT:** Edward Madden (202) 622-4537 (not a toll-free call).

**SUPPLEMENTARY INFORMATION:**

*Background*

The Act reinstates the manufacturers excise tax on vaccines under section 4131 of the Internal Revenue Code (Code) effective August 11, 1993. The vaccine tax is imposed on DPT (diphtheria, pertussis, tetanus) vaccine at the rate of \$4.56 per dose, DT (diphtheria, tetanus) vaccine at the rate of \$0.06 per dose, MMR (measles, mumps, rubella) vaccine at the rate of \$4.44 per dose, and polio vaccine at the rate of \$0.29 per dose.

The Act also imposes a floor stocks tax, which does not appear in the Code, on these vaccines. The floor stocks tax is a one-time tax on taxable vaccines that were sold by the manufacturer, producer, or importer on or before August 10, 1993, on which no tax was imposed by section 4131 of the Code, and that were held at the last moment of August 10, 1993, for sale or use. The rates of floor stocks tax are equal to the tax rates for sales by the manufacturer, producer, or importer.

*Explanation of provisions*

The regulations provide definitions relating to the floor stocks tax, identify the vaccines subject to the floor stocks tax, list the applicable rates of tax, and identify the persons liable for the tax (primarily doctors, public and private hospitals and clinics, and public health agencies).

The regulations also provide a *de minimis* exception to the floor stocks tax. Under this exception, any person that holds vaccines subject to a total tax of \$1,000 or less is not required to report or pay the tax. If the tax exceeds \$1,000, the full amount of tax must be reported and paid. Vaccines held by members of controlled groups must be aggregated for purposes of the *de minimis* exception. The *de minimis* exception is not prescribed by statute, but is being established for administrative convenience as were the *de minimis* exceptions contained in the Floor Stocks Tax provisions of the Environmental Tax Regulations (see 26 CFR 52.4682-4). The \$1,000 threshold for tax is consistent with the *de minimis* exemption requested by the Department of Health and Human Services, which administers the Vaccine Injury Compensation Trust Fund.

The regulations provide that a return on Form 720, Quarterly Federal Excise Tax Return, must be filed by February 28, 1994, and that the tax also must be paid by February 28, 1994. Persons that are also required to report other excise taxes for the fourth quarter of 1993 must report the floor stocks tax and the other excise taxes on the same Form 720. The due date for the return is February 28, 1994, even if returns for the other excise taxes are ordinarily due at an earlier date. This rule does not extend the time for making deposits or payments of any excise tax.

These regulations do not impose any specific recordkeeping requirements with respect to the floor stocks tax. However, the general recordkeeping requirements applicable to Form 720 apply. For example, inventories based on actual measurement, on a work-forward or work-back method, or any other method that accurately reflects vaccines held are acceptable.

*Special Analyses*

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these temporary regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

*Drafting Information*

The principal author of these regulations is Edward Madden, Office of Assistant Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury Department participated in their development.

\* \* \* \* \*

*Amendments to the Regulations*

Accordingly, 26 CFR chapter I is amended as follows:

Paragraph 1. Part 47 is added to read as follows:

**PART 47—Floor Stocks Taxes**

**SUBPART A—[Reserved]**

**Sec.**

47.1-1T through 47.1-5T [Reserved]

**SUBPART B—Vaccine Floor Stocks Tax of 1993**

47.2-1T Scope of subpart B (temporary).

47.2-2T Definitions relating to the vaccine floor stocks tax (temporary).

47.2-3T Imposition of vaccine floor stocks tax (temporary).

47.2-4T *De minimis* exception to vaccine floor stocks tax (temporary).

47.2-5T Requirements with respect to payment and return (temporary).

Authority: 26 U.S.C. 7805.

Section 47.2-5T also issued under section 13421(c) of the Omnibus Budget Reconciliation Act of 1993 (107 Stat. 312).

**SUBPART A—[Reserved]**

§§47.1-1T through 47.1-5T [Reserved]

**SUBPART B—Vaccine Floor Stocks Tax of 1993**

§47.2-1T Scope of subpart B (temporary).

The regulations in this subpart B relate to the vaccine floor stocks tax imposed by section 13421(c) of the Omnibus Budget Reconciliation Act of 1993 (107 Stat. 312). The tax is imposed on untaxed vaccines held at the last moment of August 10, 1993. This subpart describes the specific articles subject to tax, the rates of tax, and the persons liable for tax. This subpart also provides an exception to the tax and requirements for payment of tax and filing a return reporting the tax. This subpart is effective on August 10, 1993.

§47.2-2T Definitions relating to the vaccine floor stocks tax (temporary).

(a) *Terms used in section 4131.* For purposes of this subpart, terms that are also used in section 4131 have the same meaning as when so used.

(b) *Other terms.* For purposes of this section—

Act refers to the Omnibus Budget Reconciliation Act of 1993 (107 Stat. 312).

**Controlled group means—**

(i) Any controlled group of corporations within the meaning of section 1563(a), except that the phrase "more than 50 percent" is substituted for the phrase "at least 80 percent" each place it appears therein and a controlled group of corporations includes members that are described in section 1563(b)(2) (relating to excluded members); and

(ii) Any other group of organizations, at least one member of which is not a corporation, that is a brother-sister group under common control or a combined group under common control, with terms having the following meanings for this purpose:

(A) *Organization* means a sole proprietorship, a partnership, a trust, an estate, or a corporation.

(B) *Brother-sister group under common control* means two or more organizations if—

(1) The same five or fewer persons who are individuals, estates, or trusts own (directly and with the application of §1.414(c)-4 of this chapter) a controlling interest of each organization;

(2) Taking into account the ownership of each person only to the extent that person's ownership is identical with respect to each organization, such persons are in effective control of each organization; and

(3) The five or fewer persons whose ownership is considered for purposes of the controlling interest requirement for each organization are the same persons whose ownership is considered for purposes of the effective control requirement.

**(C) Controlling interest means—**

(1) In the case of a corporation, ownership of stock possessing at least 50 percent of the total combined voting power of all classes of stock entitled to vote or at least 50 percent of the total value of the shares of all classes of stock of the corporation;

(2) In the case of a trust or estate, ownership of an actuarial interest (determined under §1.52-1(f) of this chapter) of at least 50 percent of the trust or estate;

(3) In the case of a partnership, ownership of at least 50 percent of the profit interest or capital interest of the partnership; and

(4) In the case of a sole proprietorship, ownership of the sole proprietorship.

(D) *Effective control* has the meaning given that term in §1.52-1(d)(3) of this chapter.

(E) *Combined group under common control* has the meaning given that term in §1.52-1(e) of this chapter.

**§47.2-3T Imposition of vaccine floor stocks tax (temporary).**

(a) *Vaccines subject to tax.* Section 13421(c) of the Act imposes a floor stocks tax on any taxable vaccine (as defined in section 4132(a)(1) of the Internal Revenue Code)—

(1) Which was sold by the manufacturer, producer, or importer on or before August 10, 1993;

(2) On which no tax was imposed under section 4131 (or on which such tax was imposed and subsequently credited or refunded); and

(3) Which is held at the last moment of August 10, 1993, by any person for sale or use.

(b) *Rates of tax.* The rate of floor stocks tax on each taxable vaccine is the rate of tax specified in section 4131(b)(1) of the Code.

(c) *Person liable for tax.* The person liable for the floor stocks tax on any vaccine subject to tax is the person that holds the vaccine at the last moment of August 10, 1993. For purposes of the floor stocks tax, a vaccine is held at the last moment of August 10, 1993, by the person that has title to the vaccine (whether or not delivery to that person has been made) at such time, as determined under applicable local law. There is no exemption from the floor stocks tax for the United States or for State or local governments. Each business unit that has, or is required to have, its own employer identification number is treated as a separate person for purposes of the floor stocks tax.

**§47.2-4T De minimis exception to vaccine floor stocks tax (temporary).**

(a) *De minimis exception—(1) In general.* Except as otherwise provided in this section, if the aggregate amount of floor stocks tax payable by a person does not exceed \$1,000, that person is not required to report or pay the tax.

(2) *All amounts held subject to tax if threshold exceeded.* If the aggregate

amount of floor stocks tax payable by a person exceeds \$1,000, that person is required to report and pay the total amount of tax as determined without regard to this section.

(3) *Controlled groups.* A member of a controlled group (as defined in §47.2-2T) is not exempted from reporting and paying floor stocks tax under this section if the aggregate amount of floor stocks tax payable by all members of the controlled group exceeds \$1,000.

(b) *Examples.* The following examples illustrate the rules of this section:

*Example 1.* A holds 50 doses of DPT vaccine and 60 doses of polio vaccine on the last moment of August 10, 1993. A is not a member of a controlled group. A is not required to report and pay the floor stocks tax on any of the taxable vaccines because the aggregate amount of floor stocks tax payable by A (determined without regard to this section) does not exceed \$1,000 ( $50 \times \$4.56$  per dose of DPT vaccine) + ( $60 \times \$0.29$  per dose of polio vaccine) = \$249.40.

*Example 2.* D, E, and F are members of the same controlled group. On the last moment of August 10, 1993, D holds 100 doses of DPT vaccine and 160 doses of polio vaccine; E holds 80 doses of DPT vaccine, 10 doses of MMR vaccine and 60 doses of polio vaccine; and F holds 20 doses of MMR vaccine and 10 doses of DT vaccine. Without regard to this section, D is liable for a tax of \$502.40 ( $100 \times \$4.56$  per dose of DPT vaccine) + ( $160 \times \$0.29$  per dose of polio vaccine); E is liable for a tax of \$426.60 ( $80 \times \$4.56$  per dose of DPT vaccine) + ( $10 \times \$4.46$  per dose of MMR vaccine) + ( $60 \times \$0.29$  per dose of polio vaccine); and F is liable for a tax of \$89.40 ( $20 \times \$4.46$  per dose of MMR vaccine) + ( $10 \times \$0.06$  per dose of DT vaccine). Because the aggregate amount of floor stocks tax payable by all members of the group (\$1,018.40) exceeds \$1,000, each member of the controlled group must report and pay the floor stocks tax.

**§47.2-5T Requirements with respect to payment and return (temporary).**

(a) *Payment of tax.* The floor stocks tax is to be paid without assessment or notice on or before February 28, 1994.

(b) *Filing of return—(1) Form 720.* Except as provided in §47.2-4T(a) (relating to the *de minimis* exception), every person liable for the floor stocks tax must make a return of the tax on Form 720, Quarterly Federal Excise Tax Return. The return is to be prepared and filed in accordance with the instructions relating to the return.

(2) *Time for filing—(i) In general.* The Form 720 required by paragraph (b)(1) of this section must be filed on or before February 28, 1994, and is a return for the fourth calendar quarter of

1993. A first return reporting only floor stocks tax is also a final return and therefore, in accordance with the instructions to Form 720, the box for "final return" must be marked.

(ii) *Return reporting other taxes.* A person must file only one Form 720 for a quarter. If a person is required under part 40 of this chapter to file Form 720 for the fourth calendar quarter of 1993

for other excise taxes earlier than February 28, 1994, that person files a single Form 720 for the quarter by February 28, 1994. This paragraph (b)-(2)(ii) does not extend the time for making deposits or paying any excise tax.

Margaret Milner Richardson,  
*Commissioner of  
Internal Revenue.*

Approved November 13, 1993.

Leslie Samuels,  
*Assistant Secretary of  
the Treasury.*

(Filed by the Office of the Federal Register on November 22, 1993, 3:46 p.m. and published in the issue of the Federal Register for November 29, 1993, 58 F.R. 62524)

MAR 21 REC'D



**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:**

**MESSAGE:**

*Immigration  
meeting file*

March 21, 1994

MEMORANDUM

TO: Dr. Jo Boufford

FR: Sara Rosenbaum

RE: Vaccines for Children program issue: provider eligibility determinations

I think that we need a would like to schedule a meeting in the very near future to discuss the possibility of an alternative eligibility determination process to physician-based determinations in order to identify federally eligible children. Based on recent conversations with several physicians, as well as persons involved with universal state programs, I am deeply concerned that requiring doctors to collect child-specific eligibility data will depress physician participation, confuse operations for current, successful universal programs, and deter other states from establishing universal programs.

The purpose of the child-specific eligibility determination process is to ensure that the 100% federally-paid vaccines go only to "federally eligible" children (the mandatory children). States supplementing the federal supplies with their own bulk purchases will have to be able to identify which "pile" of vaccine children fall into. States not supplementing the federal vaccines with supplies of their own for additional children also will have to be able to verify the number of vials used. Currently as I understand it the plan is to have providers separate the children into piles, but it is increasingly evident that providers hate the whole idea. In some universal states in which providers now fully participate, office-based physicians are threatening to pull out

Since no verification of the provider's determination is required, having doctors make the determination is hardly foolproof. An allocation to the federal program that is based on reliable and audit-able state estimates of uninsured, Medicaid enrolled, Indian and FQHC/RHC children makes far more sense. Under this system, physicians would have to submit no child-specific claims unless they want to be paid a Medicaid administration fee.

To the best of my knowledge, we have assumed that we must use a physician-based eligibility determination system both because of the way the new law is written and because of the Medicaid "claims" rule (a claim has to be filed to get paid, and the free vaccine is tantamount to a "claim"). Yet, the first issue (what the new law actually requires in this regard) has not been formally reviewed by OGC. With respect to the second issue, unless the doctor claims an administration fee, there technically is no claim for payment (unless one treats the in-kind receipt of vaccine to be payment).

This is a potential killer issue with private physicians, just as the distribution financing problem was a killer issue. The point of the program was in large part to reduce missed opportunities to vaccinate by involving private physicians. It would be wrong to assume that we have to accept a bad outcome without a formal review of the problem. Perhaps this question has been put squarely to OGC already and has been resolved, but I am unaware of it. Therefore, if no formal consideration has been given, I would like to schedule a meeting next week with PHS, HCFA and OGC to discuss the problem and brainstorm about resolutions. I can have Millie (my administrative assistant) set up the meeting but thought that you might want to do it.

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: \_\_\_\_\_

*Handwritten:* Memorandum (Memorandum review)  
Meeting of 1/11/81

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_





MAR 16 REC'D

**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:** 9

**MESSAGE:**

March 16, 1994

## MEMORANDUM

TO: Carol Rasco

FR: Sara Rosenbaum

RE: Meeting with OMB re immunization initiative

Yesterday I sat in on a meeting between Nancy Ann Min and Ken Apfel and Jo Boufford to go through a number of final issues for resolution regarding implementation of the Vaccine for Children program. The issues for resolution revolve around the delivery system to be used for the initiative -- what it will look like and how it will be paid for. It is absolutely essential that any remaining issues be clarified literally within days, since the whole system needs to be up and running by October 1. It is also essential in my opinion that we resolve everything we can administratively, since getting amendments to clear up unresolved issues (if any) will be impossible.

This memo summarizes what was raised and where we stand.

**1. Payment for vaccine delivery costs:** As you will recall, a major issue has been who pays for deliveries and where the money is to come from. The program prohibits the secretary from charging either states or providers for delivery. The Secretary must use manufacturers in the delivery system but is not limited to manufacturer contracts. Thus, if manufacturer contract price ceilings are too low to provide for door-to-door delivery services (as negotiations up to now indicate) then the Secretary must supplement the manufacturer contracts with added delivery services (see discussion below). HHS Office of Legal Counsel has concluded that the delivery costs are indeed an integral part of the federal program cost of the new vaccine for children program. Since the new program is an amendment to Medicaid, this means that delivery costs effectively are part of the 100% FFP cost of the program. HCFA and PHS are in agreement on this issue.

However, because the legal ruling was reached after Ken prepared his Medicaid assumptions for 1994 and 1995, the delivery costs are not reflected in the baseline. Part of the purpose of yesterday's meeting was to clear this matter up with OMB. Since the delivery costs add only \$30 million to the estimated cost of the program (\$424 million), this does not appear to be a major adjustment in the baseline to me. Nancy Ann indicated that the Director will have to be briefed on the problem and asked for a ruling.

Without a favorable OMB ruling, we will need a legislative fix (either in the form of increased appropriations (highly unlikely) or a Medicaid amendment (also unlikely)). The HHS ruling, if adopted by OMB, should not result in enough new Medicaid spending to significantly change the baseline. So long as OMB permits the clarification of the assumption we have cured the delivery financing problem. We will not need clarifying Medicaid amendments and we will not need added discretionary appropriations to carry out the federal delivery services.

HHS is to provide OMB with a legal opinion regarding the delivery costs as well as backup documentation regarding its claim that manufacturers will not absorb door-to-door delivery costs within their existing contracts (which currently cover only depot costs).

## **2. Delivery system; apportionment system for states claiming 100% FFP for delivery costs**

As I understand it, HHS will have manufacturers deliver vaccines to depots. States that either now, or plan to, do their own deliveries, will do so any bill the feds at a 100% FFP rate. Rules on billings and an apportionment system are to be set up. In states that choose not to deliver, HHS will contract for delivery services to providers. The goal is to keep things simple and cost effective. Apparently, as part of REGO, HHS is talking with GSA about using its trucks and warehousing system to maintain and deliver vaccines. More details to come as part of the HHS briefing.

OMB is very concerned about HHS' development of a cost apportionment system, in order to get an accurate reading on the delivery costs and to segregate the federal costs from costs that states would bear if they order additional vaccines through the new discount system, as provided for under OBRA '93.

## **3. OMB request for briefing**

OMB wants a full briefing on the program for health staff as well as for Alice and the Director. It is my understanding that HHS is going to prepare such a briefing. I don't think that this should be consolidated with your briefing. It seems to me that the purposes are different and that the briefings should be kept separate. I would want to sit in on the OMB briefing in order to make sure that any follow-up issues get dealt with as part of your meeting.

## **4. 1996 Immunization Goals**

Nancy raised the issue of the wisdom of using 1996 goals for childhood immunization as well as Year 2000 goals. I told her that I had not had a follow-up with you from the December meeting. Bill Corr remembers that you signed off on using 1996 goals in early January prior to the issuance of the MMWR publication (attached). Since these goals are now public ( p.59) and since you already signed off, I see no reason to revisit them.

Furthermore, it seems to me that this is an issue on which the PHS, not OMB, should make the call. What is at stake here is a clinical judgement rather than a cost estimate or cost-related program management decision. The 1996 goal is a "bully pulpit" clinical marker which can be used to press for more aggressive efforts to immunize children. I would think that it is in the President's's interest to press as hard as he can to immunize children.

I have left my telephone number for the next 4 days with Ros and Millie. See you next week. Dinner was great fun last night. I think that we should get all the girls (yours, Diane's and mine) together.

**IMMEDIATE  
OFFICE OF THE ASSISTANT SECRETARY  
FOR HEALTH**



**716 G - HHH BUILDING  
200 INDEPENDENCE AVE., S.W.  
WASHINGTON, D.C. 20201**

**FAX: (202) 690-6960  
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**HEALTH "FAX"**



**TO:**

*Sarah Rosenbaum*

**FROM:**

*Dr. Boulton*

**FAX NUMBER:**

296-0025

**MESSAGE:**

**PLEASE CALL: FTS \_\_\_\_\_**

**ASK FOR \_\_\_\_\_**

**IF ANY PROBLEMS WITH TRANSMISSION**

**NUMBER OF PAGES \_\_\_\_\_**

**(NOT COUNTING COVER PAGE)**



February 4, 1994 / Vol. 43 / No. 4

# MNWR

**MORBIDITY AND MORTALITY WEEKLY REPORT**

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## Current Trends

### Reported Vaccine-Preventable Diseases — United States, 1993, and the Childhood Immunization Initiative

In the United States, children are routinely vaccinated against nine diseases—diphtheria, *Haemophilus influenzae* type b (Hib), hepatitis B, measles, mumps, pertussis, poliomyelitis (paralytic), rubella, and tetanus (7). Based on public health surveillance and epidemiologic assessment of most of these diseases, the impact of childhood vaccination on reported occurrence has been substantial (2,3): provisional surveillance data for 1993 indicate that for five of these diseases and for congenital rubella syndrome (CRS), the number of reported cases is at or near the lowest levels ever, suggesting near interruption of transmission of these diseases. This report presents provisional data for December 1993 for these 10 diseases, compares provisional data for 1993 with final data for 1992, and describes the Childhood Immunization Initiative (CII).

In December 1993, state health departments reported no cases of CRS, diphtheria, or poliomyelitis, and fewer than five cases each of measles and tetanus (Table 1). In addition, no cases of indigenously acquired measles were reported that could not be linked to chains of transmission from known imported cases during September–December, the longest such period since surveillance began in 1912.

Provisional data for 1993 indicate that the numbers of reported cases of CRS, diphtheria, measles, poliomyelitis, rubella, and tetanus were at or near the lowest levels ever (Table 1). Marked differences were observed in the age-specific incidence of invasive *H. influenzae* disease,\* acute hepatitis B, mumps, and pertussis; the number of persons with reported cases for whom age was known was 1211, 11,633, 1515, and 5793, respectively. For invasive *H. influenzae* disease, preschool-aged (aged <6 years) children constituted 399 (33%) cases; for acute hepatitis B, 142 (1%<sup>†</sup>); for mumps,

\* *H. influenzae* serotype is not routinely reported to the National Notifiable Diseases Surveillance System.

<sup>†</sup> Because most hepatitis B virus infections among infants and children aged <6 years are asymptomatic (although more likely to become chronic), acute disease surveillance does not reflect the incidence of this problem in this age group or the effectiveness of hepatitis B vaccination in infants.

244 p. 579 -  
Clip  
P.L.A. Tunney

*Childhood Immunization Initiative — Continued*

275 (16%); and for pertussis, 3753 (65%). Of preschool-aged children with pertussis, 2549 (68%) were aged <1 year (4).

Reported by: National Immunization Program, CDC.

**Editorial Note:** The findings in this report indicate that the incidences of most vaccine-preventable diseases during 1993 were at or near their lowest reported levels. However, decreases in disease burden and mortality can be sustained only by achieving and maintaining high vaccination levels among children aged 0-2 years. For example, although the incidence of measles was low during 1981-1988, during 1989-1991, a resurgence of measles—attributed primarily to a failure to vaccinate preschool-aged children on time (i.e., early during the second year of life) (5)—accounted for an estimated 55,000 measles cases, 11,000 hospitalizations, and 130 deaths (CDC, unpublished data, 1993).

The national response to the resurgence of measles has improved vaccination coverage among children aged 0-2 years. However, because no system has been fully established to ensure that all children complete the recommended series of 11-15 doses of vaccine by their second birthday, vaccination coverage remains unacceptably low in many areas of the United States (1,6). In 1993, the President initiated CII, a more comprehensive national response to undervaccination. The goals of CII are to 1) eliminate indigenous cases of six vaccine-preventable diseases (i.e., diphtheria, Hib disease [among children aged <5 years], measles, poliomyelitis, rubella, and tetanus

**TABLE 1. Number of reported cases of diseases preventable by routine childhood vaccination — United States, December 1993 and 1992-1993\***

Disease	No. cases, December 1993	Total cases		No. cases among children aged <5 years <sup>†</sup>	
		1992	1993	1992	1993
Congenital rubella syndrome (CRS)	0	9	7	9	5 <sup>‡</sup>
Diphtheria	0	3	0	1	0
<i>Haemophilus</i> <i>Influenzae</i> <sup>§</sup>	136	1,412	1,254	592	399
Hepatitis B <sup>¶</sup>	1,330	10,126	12,396	215	142
Measles	4	2,231	281	1,116	104
Mumps	157	2,485	1,840	364	275
Pertussis	700	3,925	6,336	2,261	3,053
Poliomyelitis, paralytic <sup>**</sup>	—	—	—	—	—
Rubella	11	187	185	24	36
Tetanus	4	44	43	0	1

\* Data for 1992 are final and for 1993, provisional.

<sup>†</sup> For 1992 and 1993, age data were available for 90% or more cases, except for 1992 age data for mumps and rubella, which were available for 84% and 64% of cases, respectively.

<sup>‡</sup> Age reported for five of seven persons with CRS through December 31, 1993.

<sup>§</sup> Invasive disease; *H. influenzae* serotype is not routinely reported to the National Notifiable Diseases Surveillance System.

<sup>¶</sup> Because most hepatitis B virus infections among infants and children aged <5 years are asymptomatic (although likely to become chronic), acute disease surveillance does not reflect the incidence of this problem in this age group or the effectiveness of hepatitis B vaccination in infants.

<sup>\*\*</sup> Four cases of suspected poliomyelitis were reported in 1993; four of the five suspected cases with onset in 1992 were confirmed, and the confirmed cases were vaccine-associated.

*Childhood Immunization Initiative — Continued***TABLE 2. Vaccination coverage levels targeted by the objectives for the Childhood Immunization Initiative, by vaccine and year\* — United States**

Vaccine	1992 Baseline <sup>†</sup>	1994	1995	1996
Diphtheria and tetanus toxoids and pertussis (3-4 doses)	83%	86%	87%	90%
Poliomyelitis (3 doses)	72%	75%	85%	90%
Measles-mumps-rubella (1 dose)	83%	86%	90%	90%
<i>Haemophilus influenzae</i> type b (3-4 doses)	—	75%	85%	90%
Hepatitis B (3 doses)	—	30%	50%	70% <sup>‡</sup>

\* Baseline data for 1993 are not yet available.

<sup>†</sup> Baseline data from 1992 National Health Interview Survey (6).

<sup>‡</sup> The goal is for 90% vaccination coverage by 1998.

[among children aged <15 years] by 1996<sup>§</sup>; 2) increase vaccination coverage levels to at least 90% among 2-year-old children by 1996 for each of the vaccinations recommended routinely for children (for hepatitis B, the objective is set for 1998) (Table 2); and 3) establish a vaccination-delivery system that maintains and further improves high coverage levels.

CII comprises six broad areas of activity that constitute the framework for meeting the nation's goals for 1996 and beyond:

- **Improve quality and quantity of vaccination-delivery services.** State and local health agencies will use new federal resources to hire personnel, extend clinic hours, and encourage health-care providers to use all health-care contacts to administer needed vaccines and reduce obstacles parents encounter in obtaining vaccinations for children (7). Computerized state vaccination information systems are being developed to remind parents when vaccinations are due and to assist health-care providers in determining the vaccination needs of patients.
- **Increase community participation and education.** A long-term, national outreach campaign will be initiated in April 1994 to improve parent awareness of the need for timely childhood vaccination and to prompt health-care providers to use all health-care contacts to administer needed vaccines to children. At the national level, elements of this campaign will include widespread distribution of radio, television, and print public service announcements; dissemination of a national theme and call to action; and other activities designed to unify efforts throughout the country. At the state and community levels, the campaign will include a grass roots organizing effort to unite all sectors of the community (e.g. public and private health-care providers, business groups, community leaders, minority groups, voluntary and service organizations, religious institutions, and media affiliates).
- **Reduce vaccine cost for parents.** To reduce vaccine cost as a barrier to vaccination, the U.S. Department of Health and Human Services will initiate the Vaccines for Children program on October 1, 1994. This program will purchase vaccines from manufacturers and provide them at no cost to participating public and private health-care providers for use in children aged 0-18 years who are eligible for Medicaid, are without health insurance, or are American Indian. Children with health insurance who are served by federally qualified health centers also will be able to

<sup>§</sup> Objectives to reduce cases of mumps, pertussis, and hepatitis B will be set during 1994.



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February 4, 1994

**Childhood Immunization Initiative — Continued**

receive free vaccine if their insurance does not cover vaccination. State vaccination programs will be permitted to purchase additional vaccines at reduced federal contract prices.

- **Improve surveillance for coverage and disease.** An improved system for measuring vaccination coverage at the national, state, and local levels among infants and young children is being established to identify undervaccinated populations and to monitor progress in achieving coverage goals. Clinic or office-based assessments are being completed to assist health-care providers in increasing coverage among the populations they serve. Surveillance for vaccine-preventable diseases will be intensified by investigating each case of disease targeted for elimination to determine how that case might have been prevented and enable initiation of aggressive control measures when cases are detected.
- **Form and strengthen partnerships.** Many federal agencies provide vaccinations to children, reimburse for vaccination services, or have access—through education, food, housing, or other assistance—to populations at high risk for undervaccination. Similarly, many private providers and organizations vaccinate children or otherwise serve or advocate for children. Coordination of these efforts will be strengthened and new partnerships formed to concentrate the efforts of these providers and organizations on improving the vaccination of children.
- **Improve vaccines.** Emphasis will be placed on the development and licensure of new and safer or more effective vaccines. Existing vaccination schedules will be simplified, and development of combination vaccines will be promoted.

To track progress toward achieving the goals of CII, CDC's National Immunization Program is initiating in this issue of *MMWR* monthly publication of a table that summarizes the number of cases of all diseases preventable by routine childhood vaccination reported during the previous month and year-to-date (provisional data) (Table 1). In addition, the table compares provisional data with final data for the previous year and highlights the number of reported cases among children aged <5 years—who are the primary focus of CII. Data in the table are derived from CDC's National Notifiable Diseases Surveillance System.

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THE WHITE HOUSE

WASHINGTON

March 14, 1994

MEMORANDUM FOR KEVIN THURM

FROM: Carol H. Rasco 

SUBJECT: Immunization Meeting

With the Vaccines for Children Program scheduled to go into effect in about 6 months, I would like to schedule a meeting at the White House to review the status of the following issues:

- the vaccine purchase contracts with the manufacturers
- the provider delivery system the Secretary will be using
- instructions to state Medicaid agencies regarding provider outreach and enrollment, state obligations with respect to ordering vaccines for participating providers, and conditions under which FFP is available for these activities as part of states' overall EPSDT program
- eligibility standards for children
- instructions to state health agencies and other agencies regarding supplemental vaccine purchasing
- special outreach efforts aimed at uninsured, underinsured and Indian children
- special outreach efforts aimed at enrolling providers
- any other matters related to the implementation of the program

As I understand it, CDC now has lead responsibility for this program; if at all possible, I would like to have personnel from Atlanta at the meeting along with other appropriate senior PHS staff. I also think that because HCFA in many ways will continue to play a pivotal role, senior staff from that agency also should be present.

I particularly want to know if any problems in implementation have come up, what they are, and how they are being resolved.

I have asked Rosalyn Miller in my office to expect a call from you so that mutually agreeable dates can be explored. If HHS wishes to prepare background briefing materials, I would welcome them.

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MEMORANDUM

Roy - Prepare for  
my ~~review~~ review.

TO: Kevin Thurm

FR: Carol Rasco

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I particularly want to know if any problems in implementation have come up, what they are, and how they are being resolved.

~~Finally, since this is a Presidential initiative, we should discuss ways that the President may want to be involved in launching the program.~~

Many thanks. I look forward to hearing from you. <sup>have asked Rosalyn Miller in my office</sup> to expect a call

bcc: Nancy Ann Min from you so that mutually agreeable dates can

be explored. ~~One~~ If HHS wishes to prepare background briefing materials I would welcome them.

- Notes to CHR
- Communications
- Health Reform
- Interg.
- Public Liaison
- COS
- Leg Affairs
- V/P
- OMB

THE WHITE HOUSE

WASHINGTON

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my memo to Kevin  
for unmun, inting~~

patients, which saw a fourfold increase in hospital admissions from 1983 (130,000) to 1991 (570,000).

The March 11 issue of Morbidity and Mortality Weekly (MMWR) will contain two articles on AIDS. One of the articles, "Impact of the Expanded AIDS Surveillance Definition for Adolescents and Adults on Case Reporting," will show a large increase in AIDS cases, largely because the definition for reporting has changed. The second article, "Heterosexually Acquired AIDS," has new numbers, but they are not remarkably different from previous studies.

The March 18 issue of MMWR may contain three articles that are potentially newsworthy. The first, "Health Risk Behaviors Among Persons Aged 12-21 Years," indicates that one-quarter or more of all children ages 12-13 engage in several health risk behaviors. These behaviors include drinking alcohol, using tobacco, failing to use a seat belt, and physical fighting. The second two articles analyze illness outbreaks in July 1993 attributed to food poisoning. One article links an outbreak at two Virginia day-care centers to rice that was stored at room temperature. The other covers the E-coli scare in California ground beef. The bacteria is rarely isolated from the implicated meat, and the authors urge caution with home-cooked hamburgers.

On March 14, the second meeting of the NIH Human Embryo Research Panel will take place in Bethesda. With the enactment of the NIH Revitalization Act of 1993, research involving human embryos may now be awarded Federal funding. Before any funding is awarded, this panel will provide recommendations on acceptable and unacceptable uses for human embryo research. For those recommended uses, the panel will draft guidelines for the Advisory Committee to the NIH Director. The recommendations and guidelines are not due until June or July, but the first meeting attracted reporters from NBC News, JAMA, and the Medical News Network.

The Surgeon General taped an interview with Jesse Jackson for his CNN show, "Both Sides with Jesse Jackson." It may air March 12. She will not be one of the live roundtable participants; her remarks will only be used as an introduction for a show he is doing on smoking.

The March 16 JAMA contains an article, written by Elizabeth R. Zell of CDC's National Immunization Program, on low vaccination levels for preschool and school-age children in the United States during 1991 and 1992. According to the study, which targeted urban areas, only 44 percent (median) of children were fully vaccinated by their second birthday. This level is far below the Public Health Service's goal of 90 percent immunization for two year-olds by the year 1996. The percentage of fully vaccinated children by age of school entry was 87 percent (median). In

other studies referenced in the article, it is clear that immunization rates in large urban areas are lower than those in more rural areas.

That edition of JAMA will also contain an article on infectious disease outbreaks among competitive athletes. The article, written by Dr. Richard Goodman of CDC's Epidemiology Program Office, underscores the need to better characterize the occurrence of these problems.

#### WEEK IN REVIEW

HCFA announced that it will not renew its contract with Blue Cross and Blue Shield of Michigan (BC/BS) for the administration of the Medicare program in Michigan. A Justice Department investigation is examining the performance of Michigan BC/BS in the auditing of cost reports submitted by hospitals and other providers. HCFA has taken the non-renewal action because the Medicare program in Michigan needs stronger management of payment safeguards and internal controls as well as better service for beneficiaries and health care providers.

The administration of both Parts A and B of the Medicare program in Michigan will be assumed by Health Care Service Corporation (HCSC) of Illinois. HCSC's outstanding performance record gives us confidence that it has the experience and resources to efficiently administer the program in Michigan. HCFA will require the new contractor to base its Michigan operations in the Detroit areas and offer positions to all non-managerial staff of Michigan BC/BS except in the Audit area. Since approximately 70 percent of Michigan BC/BS employees are represented by the United Auto Workers, continuation of the union relationship with the new contractor is a primary consideration. The movement of workload will be accomplished by the end of the year after a planned transition period to ensure that services to Medicare beneficiaries and providers will continue without disruption.

On Tuesday, March 8, HHS submitted its recommendations to OMB regarding requests from midwestern states for additional federal flood relief funding. Last October, HHS released \$65 million of a \$75 million emergency flood relief fund after reviewing state requests. HHS has now completed its review for state requests for the remaining funds and has submitted a recommendation for release of approximately \$6.5 million to address domestic violence, well water sampling, sealing of abandoned wells, and other relief activities.



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

17-Mar-1994 06:13pm

TO:            Rosalyn A. Miller  
FROM:          Carol H. Rasco  
                Economic and Domestic Policy  
SUBJECT:      RE: Immunization Briefing

*4/1/94 - 3:00-4:00?  
Staff?*

We need to talk early tomorrow about that week. I of course had originally thought I had asked that whole week be blocked when we wrote that M-M would be gone but I wouldn't think of changing the Heuman meeting after all the trouble in setting it so I have done some work to rearrange some personal plans. We do need to talk about possibility of dental appt. early in week as Dr. Petersen's office will be calling you...we can then look and see if anyone wants to do this immunization meeting another time.

THE WHITE HOUSE  
WASHINGTON

	Yes (Rep.)	NO
(Garnie 62329) McLarty		✓
(Missy 66798) Lader	?	Will call when she has answer
(Janice 66798) Lakes	?	David Levy w/call back
(Diana 62195) Mergen	?	Jody may attend - they w/call back
(Heather 67105) Stephanopoulos		NO OUT-OF-TOWN
(Scoop 62640) Mearns		NO OUT-OF-TOWN
(Jessica 67060) Hale	Keith Mason will be attending (will call back to confirm this)	
(Ruly 66455) Zerman	Wendy Nishikawa	
(Erin 62230) Giffen		NO - ON VACATION
(Laurie 66280) Varney	✓	
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*Wendy Nishikawa - Public Liaison*

THE WHITE HOUSE

WASHINGTON

March 14, 1994

MEMORANDUM FOR KEVIN THURM

FROM: Carol H. Rasco 

SUBJECT: Immunization Meeting

With the Vaccines for Children Program scheduled to go into effect in about 6 months, I would like to schedule a meeting at the White House to review the status of the following issues:

- the vaccine purchase contracts with the manufacturers
- the provider delivery system the Secretary will be using
- instructions to state Medicaid agencies regarding provider outreach and enrollment, state obligations with respect to ordering vaccines for participating providers, and conditions under which FFP is available for these activities as part of states' overall EPSDT program
- eligibility standards for children
- instructions to state health agencies and other agencies regarding supplemental vaccine purchasing
- special outreach efforts aimed at uninsured, underinsured and Indian children
- special outreach efforts aimed at enrolling providers
- any other matters related to the implementation of the program

As I understand it, CDC now has lead responsibility for this program; if at all possible, I would like to have personnel from Atlanta at the meeting along with other appropriate senior PHS staff. I also think that because HCFA in many ways will continue to play a pivotal role, senior staff from that agency also should be present.

I particularly want to know if any problems in implementation have come up, what they are, and how they are being resolved.

I have asked Rosalyn Miller in my office to expect a call from you so that mutually agreeable dates can be explored. If HHS wishes to prepare background briefing materials, I would welcome them.

THE WHITE HOUSE

WASHINGTON

March 31, 1994

MEMORANDUM FOR JUDY SPANGLER *nam*  
FROM: Rosalyn Miller (x62216)  
SUBJECT: Calligraphy Request

As discussed, these are the names for which I will need tent cards before 10:00 a.m. tomorrow:

Kevin Thurm  
Jo Ivey Boufford  
William Corr  
David Satcher  
Walter Ornstein  
Richard Leach  
Sally R. Richardson  
Jerry Klepner  
Nancy-Ann Min  
Keith Mason  
Jennifer Klein  
Sheryl Dicker  
Wendy Nishikawa

Health Care Financing Administration  
Center for Disease Control  
Office of Intergovernmental Affairs  
Office of Cabinet Affairs  
Office of Public Liaison