

CHILDHOOD IMMUNIZATION INITIATIVE

**Briefing for the First Lady
March 20, 1995**

- I. The Childhood Immunization Initiative--An Overview**
- II. Progress to Date**
- III. Current Issues**
 - o Vaccine Delivery Contracts**
 - o Upcoming GAO Report on Vaccines for Children Program**
 - o Federal Vaccine Pricing**
 - o Oral Polio Vaccine--Federal Contract Issues**
 - o Congressional Issues**

April 20, 1995

IMMUNIZATION EVENT
AT MARY'S CENTER FOR MATERNAL AND CHILD CARE

DATE: Friday, April 21
TIME: 10:00 am
LOCATION: Mary's Center for Maternal
and Child Care
FROM: Liz Bowyer, Jennifer Klein

I. PURPOSE

To promote the importance of early immunization and recognize National Infant Immunization Week by visiting Mary's Center for Maternal and Child Care with Secretary Shalala, Dr. Henry Foster and Eleanor Holmes Norton.

II. BACKGROUND

This visit to Mary's Center, a maternal and pediatric health clinic in Adams Morgan, will serve as the kick-off event for National Infant Immunization Week (April 22 - 29). Your visit will include a tour of the center's immunization facilities and a roundtable discussion with parents, Dr. Foster, Secretary Shalala and Eleanor Holmes Norton. The primary purpose of this event is to:

- Promote the importance of age-appropriate immunization (with a particular emphasis on parent education);
- Highlight a successful, community-based immunization effort in the District;
- Emphasize the Clinton Administration's commitment to children's health and the President's goal to eliminate vaccine-preventable diseases in children nationwide.

This event is also an opportunity to show the Administration's support for Dr. Foster before his nomination hearings begin on May 2nd. The event will allow the public to see Dr. Foster as a doctor and educator, participating in an initiative that he would be involved in as Surgeon General.

National Infant Immunization Week

As you know, President Clinton signed a proclamation recognizing National Infant Immunization Week at a Rose Garden ceremony last April, as part of the Administration's outreach campaign to promote early immunization.

The slogan of this year's National Infant Immunization Week is "At Least Eleven Shots by Two: How Sure Are You?". The week is built around a "seven days of immunization" theme, with each day aimed at encouraging a particular sector of society – including volunteer, community and business groups, religious and service organizations, schools, the media and others – to participate in community-based immunization efforts (see attached outline).

Mary's Center for Maternal and Child Care

Mary's Center provides a range of maternal and pediatric health services – including primary pediatric care, preventive health programs, family planning and midwifery-based prenatal care and deliveries – to a low-income, predominantly Hispanic population in Adams Morgan. Mary's Center has a reputation for providing high-quality, cost-effective care in an atmosphere that is sensitive to the cultural and linguistic needs of Spanish-speaking families.

According to the center, most clients have an annual income of \$18,000 or less, and at least 90% lack private health insurance or Medicaid coverage. In addition to health services, the center also provides various social services, including case management and referrals, and assistance in applying to Medicaid and other entitlement programs.

Immunization Efforts at Mary's Center

Mary's Center has an aggressive immunization program and has achieved remarkable success. The center has an immunization rate of 95%, as compared to a national average of 67% and a citywide rate of 45%. This success is due, in large part, to an approach to immunization that mirrors the Administration's goals in the VFC program – to immunize children where they get other health care services and when they come in for these services. Mary's Center checks a child's immunization record every time he or she enters the clinic – even if the scheduled appointment is for a prenatal visit for the child's mother – and immunizes the child then and there, if it is medically indicated.

Mary's Center is a private, non-profit health center that receives free vaccine from the District of Columbia through the VFC program. That means that the center is guaranteed a steady supply of federally purchased vaccine – even as D.C. faces a budget crisis and may be forced to cut essential services. In addition, the center participates in the computerized registry supported by the Administration's Childhood Immunization Initiative that allows any doctor across the country to access a child's immunization record (thereby ensuring that even if a family moves or loses a child's records, an accurate immunization record is available).

The center also uses a number of innovative strategies to educate parents about the importance of age-appropriate immunization and get children immunized. For example, the center congratulates parents whose children have received all recommended vaccines in a local Spanish-language newspaper.

Discussion

After a brief tour of the center's immunization facilities, you will proceed to a roundtable discussion with Dr. Foster, Secretary Shalala, Eleanor Holmes Norton and approximately eight mothers with small children. Maria Gomez, executive director of the center, will open up the discussion and introduce Dr. Foster. Each of you will make brief opening remarks, followed by a discussion with the parents, all of whom are regular clients at Mary's Center and have had their children immunized there. The remarks have been divided into the following topics:

Del. Norton: Brief remarks about Mary's Center

Dr. Foster: The importance of preventive health, particularly early immunization

Sec. Shalala: Overview of the Childhood Immunization Initiative and National Infant Immunization Week

HRC: The immunization effort as part of the Administration's larger commitment to investing in America's children

The discussion will focus on the importance of preventive health in general and immunization in particular. The parents will talk about the preventive and primary care services they have received at Mary's Center, and discuss barriers to proper immunization, including lack of parental education, language barriers, limited access to primary health care, overburdened public health clinics and inconvenient clinic hours.

III. PARTICIPANTS

Tour

HRC

Dr. Foster

Secretary Shalala

Del. Norton

Maria Gomez, executive director, Mary's Center

Discussion

Tour participants and approx. eight women (see attached list)

Note: The list currently includes 10 mothers, but will be narrowed down to about six or eight on Thursday night. A seating chart will be provided Friday morning.

Note: Secretary Shalala will be accompanied by her cousins, Hugh and Ellen Maher.

IV. SEQUENCE OF EVENTS

- HRC arrives and proceeds to tour of Mary's Center
- Maria Gomez gives overview of the Center's services in waiting area
- Maria Gomez escorts HRC, Sec. Shalala, Dr. Foster and Del. Norton from waiting area to immunization room
- Group views examining rooms and proceeds to conference room for discussion
- ~~HRC~~ intros Maria Gomez — Eleanor Holmes Norton
- Gomez gives brief welcoming remarks and intros Dr. Foster
- Dr. Foster gives brief remarks and intros Sec. Shalala
- Sec. Shalala gives brief remarks and intros HRC
- HRC gives brief remarks and opens discussion
- Discussion with parents
- Maria Gomez closes discussion
- HRC pauses for photo op with clinic staff upon departure

V. PRESS

Tour: Closed press

Discussion: Pool press

VI. REMARKS

Prepared by Lissa Muscatine.

POSSIBLE Q & A

Question: I've heard that the Clinton Administration's vaccine program isn't working. Why is that?

Answer: The Vaccines for Children Program -- which is only part of the Administration's effort to increase awareness about the importance of getting children immunized at the right ages and to improve immunization rates -- is actually providing the free vaccines to eligible children at Mary's Center. So far, about 13 million doses of vaccine have been shipped to States through the VFC program. Vaccine is being delivered to public providers in all States and to private offices in 35 States. And, while there are still private doctors who do not participate in the program, we are committed to getting a delivery system working for private doctors in the remaining states.

With this effort and the good work being done at health centers like this one, we can reach our goal of immunizing all of our nation's children by the age of two.

PROFILES OF DISCUSSION PARTICIPANTS

APRIL 21, 1995

A Latina young woman, **Maria Paz (Poz)** brings her four year old daughter, **Suleyma (Soolema)** Mary's Center for Pediatric care and is proud that Maria is fully immunized. Maria says that she loves gentle, personalized care and attention provided by the pediatric nursing staff, physician, physician's assistant and social worker. Suleyma is in pre-kindergarten at Emory school and Maria is a full-time loving mother.

Enrolled in Mary's Center's pediatric program, Jonathan Sun is the son of a Chinese couple studying in the United States. His mother, **Ruoli (Rooli)** is an engineer and his father, **Qingping (Chingping)** is a biochemistry graduate at American University.

A Latina woman, **Delmee Reys (Delmee Reyes)** has a five year old daughter, Diana, who routinely comes to Mary's Center for pediatric care, including well-baby visits and vaccinations. She loves that the Center is conveniently located in the neighborhood, the Spanish-speaking staff and her feeling of being able to freely express concerns and ask questions.

Originally from the United States, **Paula Yando (Yando)** just arrived in Washington D. C. one week before entering the prenatal program. Throughout her pregnancy, she held a job. Paula's husband participated actively in her prenatal care and now in health care and vaccinations for the baby which are provided through the pediatric program. They both hold jobs and share child care responsibilities.

Oscar Jiminez (Himinez) was born to **Melina Jiminez (Himinez)**, a bicultural (African Latino) when she was fourteen in 1990. Our pediatric social worker was able to secure child care for Oscar so that Melina could return to Upper Cardozo High School. Oscar is now five years old and doing well in school. The pediatric team continues to work with Melina to assist her in learning constructive methods of discipline for Oscar.

A Medicaid recipient, Brittany was born to **Helen Dye**, an African-American woman in 1989 and is presently enrolled in Mary's Center's pediatric program. During Brittany's last pediatric visit, her Denver screening and nutritional assessment yielded good results while her physical exam was completely normal. She is fully up to date on her immunizations and always looks forward to her visits with the pediatric assistants.

Aisha (Ayesha) Holgate is a sixteen year old African-American mother who delivered her baby through Mary's Center's adolescent program. Through her participation in the Latin American Youth

Center's Teen Parents Program, Aisha returned to high school and is now on the honor roll. Her baby continues to come to Mary's Center for preventive and primary pediatric care and is up to date on immunizations.

A married woman from the island of Dominica, **Curly Edwards** has two children born through Mary's Center's prenatal program and is the patient representative on Mary's Center Board of Directors. Curly's children love to come to Mary's Center, even on days when they receive their shots.

Maria Selces is a Bolivian child care worker who brings her young son to Mary's Center for pediatric care, including timely immunizations. Although separated, both father and mother share the care of the little boy.

Elba Varela and her husband, both Latino, delivered a healthy daughter through our prenatal program. During her second pregnancy, she was expecting Siamese twins and therefore was hospitalized at the University of Maryland in Baltimore until delivery. Post-delivery, her babies were surgically separated. The twins are now pediatric patients at Mary's Center.

Maria Ramirez gave birth on August 17, 1995.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and PreventionNational Infant Immunization Week
April 22-29, 1995**THE SEVEN DAYS OF IMMUNIZATION**
"At Least Eleven Shots by Two: How Sure are You?"

The immunization rates for children under two years of age are far too low, and all members of our communities can play a role in making sure that all of our youngest children are properly immunized. Thousands of lives are jeopardized by preventable diseases, and hundreds of thousands of dollars have been spent on the care of stricken children whose illnesses could have been avoided. National Infant Immunization Week (NIIW) offers an opportunity to reach audiences who can help make certain that our nation's children are fully immunized by the age of two.

The slogan for NIIW 1995 is "At Least Eleven Shots by Two: How Sure Are You?", supported by the theme: "We need you to get all our babies shots by two." This theme reinforces the need to get all members of our communities involved in appropriately immunizing our children. The "Seven Days of Immunization" provides a guideline for community activities during NIIW. Each of the seven days focuses on a particular sector of the community and helps to demonstrate that everyone can play a role in making certain that all of our children are protected against vaccine-preventable diseases.

April 22 and 23 - Religious Leaders Lead the Way

Religious leaders play an important role in the community and reach a loyal audience every week. By incorporating immunization messages into their weekly service, religious leaders can potentially affect a large audience.

April 24 - Elected Officials Voice Their Support

Elected officials, such as governors, mayors, members of Congress, state legislators, and city council members, have the ability to reach and mobilize broad cross-sections of the population. On this day, elected officials could highlight the importance of disease prevention and identify childhood immunization goals for their respective state, district or city. Their participation can illustrate the entire community's commitment to our youngest children, and reinforce the message that disease prevention can be measured in both economic terms and health benefits.

April 25 - Community Partnerships: A Key Element

Public-private partnerships, including health care providers, community-based organizations, businesses, civic and service groups, the media and numerous others, play crucial roles in state and community-based immunization efforts. This day of the week provides an opportunity to

highlight some of these pre-existing partnerships. Through the attention focused on the partnership activities, it is hoped that new partners will be encouraged to join these efforts.

April 26 - Disease Prevention: The Children's Perspective

For this day of the week, we are suggesting use of a school setting to focus on children's understanding of disease prevention. Teachers and children can provide a direct link to parents and younger siblings. The days' activities present an opportunity for teachers and children to educate parents and peers. As a long-term benefit, schools may incorporate disease prevention education as an ongoing part of their curriculum.

April 27 - Provider Spotlight: Innovative Strategies

Health care providers play the central role in immunizing children. In addition to administering vaccine, many health care providers participate in community-based partnerships and undertake innovative efforts to increase immunization coverage rates. These efforts include extending office hours to accommodate working parents, making reminder phone calls, and auditing their own patient records to check the immunization status of all children under their care. This day of the week provides an opportunity to acknowledge these activities and encourage others to adopt similar efforts.

April 28 - Childhood Immunization Across the Nation

One barrier to raising childhood immunization rates is the public's lack of awareness that the problem is so serious and wide-spread. Friday's activities are designed to demonstrate that under-immunization is a national issue that affects all of us. In addition, this day's activities provides an opportunity to highlight the different strategies used by states and communities to address the under-immunization problem.

April 29 - Community Mobilization: Reaching out for Children

Having built up momentum throughout the week, the final day of NIIW will focus on bringing together existing partners for a "grand finale" event - highlighting the fact that everyone has a role to play in raising immunization rates. One suggested activity includes volunteers, community groups and health care providers combining forces to organize phone banks or canvassing efforts to reach as many parents as possible to discuss the importance and specific timing of the necessary immunizations. Reminding parents of the specific timing for needed immunization has proven to be an effective method for raising infant immunization rates. The community mobilization activities provide a vehicle to recognize existing efforts, recruit more volunteers to these pre-existing efforts, increase public awareness, highlight effective ways to raise immunization rates, and possibly make the reminder/recall effort an ongoing activity in the community.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

Childhood Immunization Suggested Talking Points

Vaccines are the most powerful and cost-effective way to prevent nine infectious diseases.

- Childhood vaccines prevent nine infectious diseases: polio, measles, diphtheria, mumps, pertussis (whooping cough), rubella (German measles), tetanus, hepatitis-B, and Hib (the most common cause of spinal meningitis).
- More than \$21 are saved for every dollar spent on the measles/mumps/rubella vaccine. \$29 are saved for every dollar spent on the diphtheria/tetanus/pertussis vaccine and over \$6 are saved for every dollar spent on the polio vaccine.
- Failure to immunize children on time led to the 1989-1991 measles epidemic causing over 55,000 cases, 11,000 hospitalizations and 136 deaths -- over 60 of these deaths were children under two years of age. Various studies indicate that the measles outbreak resulted in over \$150 million in direct medical costs.

A third of America's youngest children are under-immunized.

- 33 percent of two year-old children are under-immunized, and in some cities and urban areas over 50 percent are not fully immunized.
- To be fully immunized, children should receive 80 percent of their vaccinations (between 11 and 15 doses) by age two. This is the period when a child is most vulnerable to contracting these diseases. Receiving all needed doses requires about five visits to a health care provider.

Parents understand the importance of childhood immunizations, but are unaware when the shots should be administered.

- Parents generally understand the importance of immunization and are aware that their children must be fully immunized before they enter school; but, they often do not realize that 80 percent of immunizations should be administered before the child's second birthday.
- Studies show that many parents who thought their children were fully immunized were mistaken. Parents need to help assure their child is immunized by keeping a current immunization record, bringing it to every health care visit and asking the health care providers to make sure their child is fully immunized.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention**The Childhood Immunization Initiative**

Ensuring that our youngest children are safe from vaccine-preventable diseases is the mission of the Childhood Immunization Initiative (CII). In the United States, more than 96 percent of children are fully vaccinated when they enter kindergarten. However, only 67 percent of 2-year-old children are fully immunized, and it is during the first two years of a child's life that 80 percent of vaccine doses (11-15 doses) should be administered. Although immunization levels for 1993 were the highest levels ever recorded, about two million 2-year-old children were still inadequately protected against vaccine-preventable diseases.

Recognizing the need to protect our youngest children, the Childhood Immunization Initiative was launched. The CII is a comprehensive effort to:

- eliminate most childhood vaccine preventable diseases
- increase vaccination levels for 2 year olds to at least 90 percent for the initial and most critical doses by 1996
- establish a sustainable system to ensure that at least 90 percent of all 2 year olds receive the full series of vaccines by the year 2000 and beyond

The CII is designed to marshal and coordinate efforts of the public and private sectors, healthcare professionals and volunteer organizations. The CII includes the following five broad areas:

Improve the Quality and Quantity of Vaccination Delivery Services

In October 1993, \$129 million (\$83 million in new federal resources) was provided to states and large local health departments, based on plans they developed, to improve and expand existing immunization services. These resources are being used at the discretion of each area to contend with the immunization barriers that the local community faces, such as expanding immunization clinic hours to make it easier for working parents to take children to visit a health care provider.

Reduce Vaccine Costs for Parents

In October 1994, the Vaccines for Children (VFC) Program was initiated. This program is designed to (1) reach more children with free vaccine than ever before and (2) allow more parents to receive free vaccine for their children at a private healthcare provider. The VFC program means that cost will no longer be a barrier for our neediest children and parents can obtain these vaccinations at the provider of their choice.

Increase Community Participation, Education and Partnerships

The National Outreach Program strives to (1) increase awareness concerning age-appropriate immunization (an awareness that 80 percent of all immunizations should be administered before a child's second birthday; that waiting until school age is insufficient protection) and (2) establish and reinforce community-based immunization efforts. Through regional meetings and outreach staff working at the state and local level, the Centers for Disease Control and Prevention (CDC) has helped bring together and encourage all sectors of society -- including volunteer, community and business groups, religious and service organizations, schools, the media and other public or private organizations -- to participate in long-term community-based immunization efforts. CDC activities also encourage healthcare providers to check their patient's immunization records and use every opportunity to vaccinate children who are not up-to-date.

Improve Systems to Monitor Diseases and Vaccinations

CDC has expanded its ability to assess immunization rates at the local, state and national levels in order to pinpoint which populations are not receiving the benefits of infant vaccination. The ability to monitor immunization coverage levels using local, state and national data allows targeted interventions to be put in place quickly. Evaluating the outcome of federal and state programs addresses an essential component of the CII, which is to focus accountability for program results.

Concurrently, a surveillance network to look out for cases of vaccine-preventable disease and rapidly report them is also being intensified. Looking for cases -- even rare cases -- of vaccine-preventable diseases will help public health providers take fast action to prevent widespread outbreaks of disease. Epidemics begin in populations with low immunization levels. Finding pockets of low immunization today helps health care providers target efforts to prevent tomorrow's epidemic.

Improve Vaccines and Vaccine Use

CII emphasizes the development and licensure of new, safer, and more effective vaccines, including combination vaccines to help simplify the vaccination schedule. Improved vaccines mean children are better protected from disease earlier in life. The CII has already helped unify the childhood immunization schedule, through close collaboration between CDC, the Advisory Committee on Immunization Practices (ACIP), and major health care provider organizations. CII also supports applied research into new vaccines to reduce the number of shots children must receive. Although vaccines are very safe and effective, CDC is working with states and selected healthcare provider institutions to improve monitoring of vaccine safety and to evaluate the role vaccines may play in rare adverse events following inoculation.

To: Sen
From: Melanne

AMERICAN HOME PRODUCTS CORPORATION

FIVE GIRALDA FARMS

MADISON, N.J. 07940

(201) 660-5008

JOHN R. STAFFORD
CHAIRMAN, PRESIDENT AND
CHIEF EXECUTIVE OFFICER

May 16, 1995

Mrs. Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mrs. Clinton:

Thank you very much for meeting with us on May 5th to discuss our concerns regarding erosion of the private market for childhood vaccines as a result of the Vaccines for Children (VFC) program. We hope that the meeting represents the beginning of a constructive dialogue.

First, we would like to respond to the question we were not able to answer adequately at the meeting: what is the Medicare reimbursement methodology for influenza vaccine, and why is that methodology less problematic for industry than the VFC's? In Medicare, in contrast to the VFC program, our company sells no vaccine directly to the government. Instead, we sell to physicians at trade price with no difference in price between vaccine that ultimately is received by Medicare beneficiaries and that received by others. The physicians who purchase our vaccines are reimbursed for them by Medicare, private insurance or self-payment by the patient, as the case may be. When Medicare reimburses physicians for influenza vaccine, payment is made pursuant to Part B--i.e., charge-based--methodology except that, unlike most Part B items or services, the influenza vaccine is reimbursed 100% without deductibles or coinsurance. Thus, Medicare pays market price for influenza vaccine in sharp contrast to the deep discounts and frozen prices characterizing the VFC program. We understand that Medicare's reimbursement policy for influenza vaccine was established based on the demonstrable cost-effectiveness of the vaccine.

Second, you asked for suggestions that might promote the idea of a medical home for children better than the purchase-oriented VFC program. Here we have no original ideas, but we can share some that have come from experts in the field:

- Some experts, including the Institute of Medicine, suggest a system of bonus payments to physicians who have fully immunized their patients, an approach that has been successful in England (Senator Bumpers has express interest in such bonus payments as a means of avoiding missed opportunities for immunization);
- Dr. Irwin Redlener urged at the recent Finance Committee hearing that any physician receiving free vaccine be required to take every Medicaid and uninsured child who presents at his or her office;
- In Maryland, the Aid to Families with Dependent Children (AFDC) program has developed a series of penalties and rewards related to the immunization status of children, with resulting impressive increases in immunization rates; and
- A program previously considered by the Centers for Disease Control and Prevention (CDC) would provide "one-stop shopping" for federal benefits and require coordination of AFDC, WIC and food stamps benefits with immunization status.
- The States of Georgia and Mississippi and the City of San Antonio have significantly improved immunization rates through techniques such as auditing providers to determine which practices require correction and following the immunization status of individual children through computerized tracking systems.

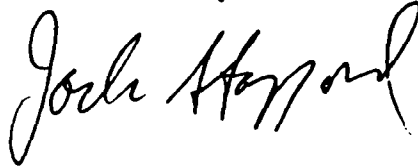
We share your goal of protecting all of America's children from disease through timely immunization, but we believe that this goal can be better achieved by restoring a balance in federal funding between vaccine purchase and delivery infrastructure. Such balance would have the additional benefit of supporting a vibrant research-intensive American vaccine industry. By virtue of American research investment, *Hemophilus influenzae* type b (Hib) meningitis, with an annual price tag of \$2.5 billion, has been practically eradicated. If industry continues to invest in research and development, we will do the same for otitis media, infant diarrhea and pneumonia. Research will also make possible the combining of numerous antigens into a single injection, thus reducing cost and trauma as well as enhancing immunization compliance.

However, our research and development effort cannot be sustained if the federal government remains the dominant purchaser. In considering possible revisions to the VFC program, we are urging that equivalency be reinstated between the public and private sectors, with government purchases limited to no more than 50% of the total market. Only in this fashion will vaccines be able to attract capital and inspire investor confidence to enable research and development to continue.

We appreciate your time and your willingness to hear our views on this issue of critical importance for the health of America's children, both present and future.

Again, my personal thanks for the meeting.

Sincerely,

A handwritten signature in black ink, appearing to read "Josh Hays". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

JRS:MH

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
PHONE: (202) 690-7694

HEALTH "FAX"



~~CONFIDENTIAL~~

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: AD DATE: 08/26/15
2014-0536-S

TO:

Jennifer Klein

FROM:

Bill Corr

FAX NUMBER: _____

MESSAGE:

*Please call and let me
know when you receive this!*
Carol

PLEASE CALL: FTS _____ ASK FOR _____

IF ANY PROBLEMS WITH TRANSMISSION

NUMBER OF PAGES 3 (NOT COUNTING COVER PAGE)

~~CONFIDENTIAL~~

DRAFT

MEMORANDUM FOR THE HONORABLE LEON PANETTA

This memorandum describes several options for addressing the Congressional challenges to the Vaccine for Children (VFC) program.

As you know, the VFC program provides all necessary childhood vaccines to four groups of entitled children: Medicaid eligible, American Indians and Alaskan Natives, uninsured, and underinsured (if they are served by a Federally Qualified Health Center).

Both House and Senate reconciliation bills repeal the VFC program. Both bills would include in each state's "Medigrant" the amount of federal Medicaid funds that were spent in the state in FY 1994 (prior to VFC). The use of FY 1994 as the base reduces federal funds for childhood vaccine purchase by approximately \$200 million each year during the period FY 1996 through FY 2002. The bills also include a requirement that each state cover immunizations (as selected by the state) for children made eligible by the state.

OPTIONS:

The VFC is a critical part of the President's Childhood Immunization Initiative (CII) because it provides the funds to purchase vaccine for low-income and, otherwise, needy children. (The other four parts of the CII are infrastructure support, education and outreach, monitoring and research on better vaccines.) Without adequate funds for vaccine purchase, it is unrealistic to expect the CII to reach its immunization goals for 1996 and 2000.

We need to develop a strategy to assure the continued availability of needed vaccine. Here are three options that will accomplish this objective, with the pros and cons of each.

OPTION #1: RETAIN THE VFC PROGRAM

PROS:

- * The VFC has been implemented and is doing well. The VFC is in public health departments in every state and in private doctors' offices in 42 states.

DRAFT

Page 2 - The Honorable Leon Panetta

- * The VFC is not purchasing the large quantities of vaccine initially projected by the states; therefore, VFC costs are lower and the impact on vaccine companies is less than they claim.

CONS:

- * Opponents will insist on changes in VFC.
- * The VFC will continue to be controversial with Congress.
- * Vaccine companies will continue to attack the program claiming it erodes the private market.

OPTION #2: Significantly modify the VFC program while retaining the individual entitlement. Changes would (1) establish a limit on the total amount of vaccine CDC could purchase from vaccine companies -- thereby guaranteeing the size and stability of the private vaccine market; (2) eliminate coverage for underinsured; (3) eliminate authority of states to become universal purchase by buying additional vaccine at capped price; and (4) if necessary, eliminate current price caps on older but most critical vaccines (OPV, MMR, DPT).

PROS:

- * Retains most important feature of VFC - guaranteed vaccine for most needy children.
- * Addresses vaccine company concerns with regard to market stability.

CONS:

- * Increases cost to states to continue their current VFC programs - although we believe state health officials are prepared to accept higher costs to eliminate controversy about the program.
- * Vaccine companies would continue to oppose VFC due to fear of future governmental restrictions to assure entitlement costs do not grow excessively.
- * Opponents will not view as adequate compromise.

OPTION #3: Significantly modify the VFC program making it a state entitlement. Option 3 would entitle the states to receive sufficient funds to purchase all necessary childhood vaccines for all children in families below a certain percent of poverty level. States would receive funds only if they enter into a performance partnership agreement which would specify the state's

185% of pov = 47% of birth cohort

DRAFT

Page 3 - The Honorable Leon Panetta

plan (including its use of Section 317 appropriated funds for immunization) for reaching the 1996 and 2000 immunization goals. States would be limited in the volume of vaccine that could be purchased through CDC. In effect, states would design their own immunization programs with technical assistance from CDC.

PROS:

- * Retains most important feature of VFC -- guaranteed vaccine for most needy children.
- * Could garner support from key Democratic supporters and states.
- * May not be opposed by vaccine companies
- * By removing individual entitlement could improve opportunity to reach compromise with Congressional Republicans. Program would still accomplish President's objectives.

CONS:

- * Pediatricians and other advocacy groups supporting an individual entitlement may oppose, especially because it sets precedent for rest of Medicaid.
- * Increases cost to states to continue their current efforts -- although we believe state health officials are prepared to accept higher costs to eliminate controversy about the program.

Does not
retain
purchase
element of
program?

HOW TO PROCEED:

Given the pending Congressional action, the VFC will be a major factor in reconciliation negotiations between the Administration and Congress.

Prior to engaging in any negotiation with Congressional Republicans, we should develop an Administration position through discussions with key Senate and House Democratic supporters -- Senators Bumpers and Breaux and Congressmen Waxman and Dingell. Those discussions would strengthen our position in negotiations with Congressional Republicans and assure the support of these key Democratic allies for our implementation of the program that results.

I recommend that we select a preferred option and immediately begin discussions with these key Democrats.

Donna E. Shalala

cc: Carol Rasco

MEMORANDUM



Children's Defense Fund

TO: Carol Rasco
FROM: ~~Marla~~ Wright Edelman
DATE: July 31, 1995

The next few weeks should determine whether the Vaccines for Children program (VFC) survives. As you know, VFC has taken a battering in hearings on the Hill and in the press in the last couple of months. I know that the Administration has been working hard to counter this campaign. At CDF we also have been working for VFC. Among other activities: we held a conference call with a dozen editorial boards two weeks ago; did the Diane Rehm show; placed an op-ed in the New York Daily News; have been talking to ASTHO about state activities; and have been making a number of Hill visits.

I am desperately worried, however, that just at the time this program is beginning to produce real gains for children, we are entering a period of maximum danger for VFC. It is apparent that members of Congress hostile to the program--most but not all of them Republicans--will try in the context of Reconciliation to block grant, eliminate totally, or otherwise cut the heart out of the VFC program. I am concerned not only that we may not have enough support on the Hill to stop this, but that the Administration, with so much else (legitimately) on its platter in Reconciliation, may be unable to focus on VFC if it waits too long.

I hope, therefore, that the Administration can spend the next few weeks before Reconciliation heats up, both accelerating the campaign for the program (using the growing evidence of its positive impact at the state level), and conceptualizing and getting agreement on a possible compromise that would preserve all of the most essential parts of VFC (including purchase of vaccines for private doctors to dispense to Medicaid and uninsured children) yet also produce support before mark-up among some of the current Democratic, Republican, press and corporate critics. We have specific thoughts on some approaches that we very much want to share in the days ahead.

VFC is simply too important a program for children to let it disappear from sight in the huge political storms we all expect this fall. When Medicaid heats up in September, it will be harder for any of us to focus adequately on the VFC piece. By resolving as many issues as possible now, the Administration would be in a better position to lead on this issue in September, and to slow the momentum of the VFC opponents.

CDF stands ready to work with you to preserve VFC.

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

15-Aug-1995 10:22am

TO: Jennifer L. Klein

FROM: Diana M. Fortuna
 Domestic Policy Council

SUBJECT: Here's the revised memo that went to Carol FYI

August 15, 1995

MEMORANDUM FOR THE PRESIDENT

FROM: Carol Rasco

SUBJECT: Immunization Program

You had asked where we are on the Vaccines for Children (VFC) program.

Background: As you know, VFC is part of the Childhood Immunization Initiative, and provides a Federal entitlement to vaccine for uninsured and Medicaid-eligible children, as well as underinsured children served at federal clinics. It uses 100% Federal funds to purchase vaccine for participating providers, including private physicians who enroll in the program.

Critics (especially Senator Bumpers) charge that VFC is misguided because cost is not a significant barrier to immunization. They argue that free vaccine has long been available at public clinics, and that VFC funds would be better spent on shoring up these clinics. We have responded that the high cost of vaccines leads private physicians to refer children to public clinics, leading to missed opportunities for immunization. Critics also charge that VFC is not well run, with problems delivering vaccine and ensuring accountability for vaccine purchase.

Drug companies vigorously oppose VFC because it gives HHS the right to purchase vaccine at below-market prices. Prior to VFC, the industry negotiated a low price with HHS for the 50% of the market that HHS then purchased. Under VFC, HHS's share of the market would grow to 70-80% at that same low price. In some

cases, the discrepancy between the HHS price and the market price is very significant. Manufacturers allege that the loss in revenue will significantly limit research into new vaccines.

States tend to support VFC because it eliminated the state share of Medicaid for vaccine purchases.

Strategy: In the fall, the manufacturers and certain members of Congress will attempt to eliminate the program. Rather than an outright repeal, they are more likely to try to fold it into a Medicaid block grant.

Therefore, we have developed a two-part strategy. The first part is to continue to support the program publicly. To that end, HHS is working in concert with the American Academy of Pediatrics, state health officials, and the Children's Defense Fund to get

out the word that VFC is a valuable program that is filling a critical need. Second, we are preparing a compromise that we could back on in the fall, with two key goals in mind. First, we will have to limit public purchase of vaccine in some fashion. This is critical to the manufacturers, but it means that VFC would serve fewer children. Second, we will make it a priority to preserve some part of the purchase program, even though we might restructure VFC as entitled grants to states.

The Children's Defense Fund has expressed an interest in working with us on this strategy. Our support for any compromise must be unveiled delicately so that we do not alienate our allies, particularly the states.

From a legislative standpoint, we expect to fare better in the Senate than in the House. We plan to reach out cautiously to the more reasonable drug companies and to key members of Congress to discuss the outlines of a potential compromise. We are also working to develop a strategy to approach Senator Bumpers.

cc: Leon Panetta
Alice Rivlin
Melanne Verveer
Pat Griffin
Marcia Hale

TO: Hillary Rodham Clinton
Melanne Verveer
FROM: Jennifer Klein
DATE: 6/14/95
RE: Immunization

I know that we are all overwhelmed by the budget roll-out, but I wanted to lay out an immunization option for you.

I also wanted to let you know that there is a hearing on the VFC program scheduled for tomorrow in the House Commerce Committee. The hearing will focus primarily on the GAO Report, which will be released at the hearing. David Satcher's testimony provides an excellent response. We also have the same process in place to generate support as we did for the Senate hearing, but this one is expected to be tougher.

VACCINES FOR CHILDREN PROGRAM OPTION

Decisions about the Vaccines for Children (VFC) program must address: (A) possible changes in eligibility; and (B) options for restructuring the program.

(A) Eligibility

To reach agreement with the vaccine manufacturers, it is probably necessary to reduce public purchase of vaccine by limiting eligibility. VFC currently covers children who are Medicaid-eligible, uninsured, Indian, and underinsured if they are immunized at a federally qualified health center (FQHC). In addition, states use section 317 (of Medicaid) to buy vaccine for underinsured children who are immunized at public health clinics. Fourteen states also have taken advantage of the option to purchase vaccine at the low federal price for all children in their state.

The public market for vaccine could grow under VFC from about 50 percent (the current market share for CDC purchased vaccine) to as much as 80 percent (if more states take advantage of the option to purchase vaccine for all children in a state). The manufacturers claim that they will be unable to stay in the vaccine business and continue to do research if they are paid the public price for so large a share of the market. While American Home Products and other manufacturers have said publicly that they can afford to be paid the low public price for only 50 percent of the market, privately they have acknowledged that they would accept as high as 60 percent.

In order to address these concerns, we could:

(1) Limit eligibility to uninsured, Medicaid-eligible and Indian children.

- Uninsured children

Most people agree that it is important to preserve coverage for the neediest children -- the uninsured. However, prior to VFC these children could get immunized at public clinics, and they still can. It is not clear that they will be seen by private doctors even if the doctors receive free vaccine for them, so the charge that VFC is not reaching our neediest children may be most true of this category.

- Medicaid-eligible children

Children covered by Medicaid received free vaccine before the VFC program through the Medicaid section 317 program. It would seem logical to eliminate eligibility for these children under VFC and leave them to Medicaid. The manufacturers would be particularly pleased

because under Medicaid they are paid catalog price rather than the low VFC price.

However, states now expect the federal government to pay the total cost. Some states (including Texas) have used their Medicaid savings to expand immunization programs. Since the states are the strongest supporters of the VFC program, it would be difficult to ask them to absorb their Medicaid matching share of the costs again.

(2) Eliminate eligibility for children served at FQHCs.

- Federally qualified health clinics will continue to immunize the children they serve. This part of the program has been severely criticized because it does not prevent wealthy children whose insurance does not cover immunizations from getting free vaccine at these clinics. In reality, however, underinsured children of wealthy families do not seek care at these clinics. Eliminating this category of eligibility therefore allows us to avoid the charge that the program serves those who can afford vaccine while catching the needy children who are actually served by FQHCs.
- In addition, there has been some discussion of federal legislation mandating that all insurance policies cover immunizations for children. This would obviously eliminate the category of underinsured children, but it is probably unlikely.

(3) Freeze state optional purchase or allow states to purchase vaccine for all children in the state at a price that is higher than the Federal price based on a sliding scale.

- This would go a long way toward appeasing the manufacturers. However, states may complain about losing optional purchase (although no new states have indicated interest in taking advantage of it).

(B) Structure

As the Congress considers significant structural changes to Medicaid, we must also address the structure of the VFC program. In addition, critics of the VFC program have charged that -- by focusing resources on getting free vaccine to children in doctors' offices -- the program does not address the most significant barriers to immunization and does not help the neediest children (who are rarely seen by private doctors).

- If Medicaid is not block granted, we could maintain the individual entitlement but

cap total purchase. This option does not really address questions about how best to allocate immunization dollars. It does prevent the program from becoming "another out of control" entitlement, as some have charged.

- If Medicaid is block granted, we could provide "entitled" grants to states for immunization. States could either be required to use the funds for vaccine purchase or could be allowed to spend the money as they saw fit (e.g., infrastructure rather than purchase). In either case, states would be required to demonstrate that *eligible* children -- not just a minimum number of children -- were being immunized.
- In either case, we could add new features to the program, like "parental responsibility" -- by requiring that welfare parents show proof of immunization in order to receive benefits. Programs in cities, including Chicago, New York and Dallas, as well as in states, most notably Maryland, have shown an increase in immunization rates among poor children of 40 to 80 percent.

- Should we limit the ability of the CDC's Advisory Council on Immunization Practices (ACIP) to add new vaccines to the VFC program?

AMERICAN HOME PRODUCTS CORPORATION

FIVE GIRALDA FARMS

MADISON, N.J. 07940

(201) 660-5008

JOHN R. STAFFORD
CHAIRMAN, PRESIDENT AND
CHIEF EXECUTIVE OFFICER

January 25, 1995

Mrs. Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mrs. Clinton:

Let me thank you once again for being so generous with your time to help the New York United Cerebral Palsy. As you know the dinner was a great success, obviously, in large part, due to your presence. On a personal note, Mrs. Stafford and I enjoyed being with you, and I especially appreciated the chance to talk a bit of shop during dinner. I do hope you and your family come back to Martha's Vineyard where, as I'm sure you know, you are very welcome.

With your permission I would like to reiterate some of the points we discussed concerning the impact of the Administration's Vaccines for Children (VFC) program. As I told you, American Home Products' recent acquisition of American Cyanamid included its vaccine division, Lederle-Praxis Biologicals (LPB). At present, only two major vaccine manufacturers are American-based, but American research, including substantial contributions by LPB, has led the world in vaccine innovation.

With the advent of biotechnology, many more new vaccines are now feasible. Our company introduced three new vaccine products during the first four years of the decade, including a vaccine to prevent bacterial meningitis in infants, a less reactive version of pertussis vaccine to address parent concerns about side-effects, and a new combination vaccine that halved the number of injections necessary to protect against four major childhood diseases. These are products that would not have been possible just a few years ago without the benefit of biotechnology; other vaccines in our pipeline have the capacity to revolutionize disease prevention and to save billions in medical and other costs.

Vaccine innovation, however, is currently at risk in the United States because of the VFC program. The legislation permits essentially unlimited purchases of childhood vaccines by state and federal governments at extremely low, statutorily-fixed prices. If not amended

substantially to limit public purchases, the VFC program will completely destroy our private market, which is the sole source of revenue supporting its research and development efforts.

Even prior to enactment of VFC, the economics of the vaccine business were extremely difficult. (A principal reason why only two U.S. based companies are in the vaccine business.) In fact, American Home Products made a decision several years ago not to remain in the childhood vaccine market, at least in part, because of concerns over excessive government purchases. With the LPB acquisition we are once again in a position which requires us to assess this market. Our greatest concern is the ability to continue the outstanding research program of LPB.

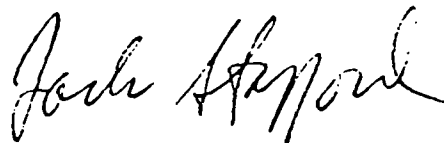
I shared with you the exciting prospect of a vaccine to protect children against otitis media (chronic ear infection that can cause deafness), which is the single largest reason for infant pediatric visits. Obviously, this product offers the potential of tremendous savings for the nation. Without substantial capital investment and continued clinical research, however, LPB will not be able to move this vaccine from the product pipeline into pediatricians' offices. Already LPB officials tell me that progress toward approval of the otitis media vaccine has been delayed by a year or more by uncertainties engendered by the VFC program. This is understandable because uncertainty is the absolute enemy of stable investment. But the loss to the country, in terms of both unnecessary illness and lost opportunities for savings, from just one year of delay is a tragedy.

I would like to request a meeting with you and the White House staff to discuss how the VFC program might be revised to support our shared goal of improved childhood immunization without undermining vaccine research and development. We can, no doubt, provide for today's needy children without depriving tomorrow's children of the promise of greatly enhanced prevention and freedom from disease through new vaccines.

Of course, I would also welcome an opportunity to discuss other areas of the pharmaceutical and biotechnology research-based industries if you or your staff should desire to do so.

Thank you again for the opportunity to be with you at last week's dinner, and I look forward to continuing our dialogue in a meeting anytime at your convenience.

Sincerely,

A handwritten signature in dark ink, appearing to read "Jack Harkness", written in a cursive style.

JRS:MH

TO: Hillary Rodham Clinton
FROM: Jennifer Klein
DATE: 5/4/95
RE: Meeting with Jack Stafford

Background for Meeting

On Friday, May 5 at 10:00 a.m., you are meeting with Jack Stafford, the Chairman, President and CEO of American Home Products. Mr. Stafford will be accompanied by Dr. Ran Saldarini, the President of Wyeth-Lederle Vaccines and Pediatrics, and Leo Jardot, Vice President for Government Relations of American Home Products.

As you may remember, Stafford wrote in January asking for a meeting to discuss his concerns about the VFC program. (See attached letter.) American Home owns Lederle, which produces oral polio vaccine and other vaccines. (See attached list of vaccines and description of Lederle's vaccine business.) Their major concern is that prices under VFC are too low, and that the VFC program will force them to curtail research or even leave the vaccine market. Lederle is in a more difficult than other manufacturers because they agreed to sell oral polio vaccine at a severe discount (\$2 a dose rather than the private market price of \$10). However, they do sell other vaccines to the program at more reasonable rates.

Incidentally, Lederle has threatened to leave the vaccine market many times (long before VFC). In fact, the Vaccine Compensation Act of 1986 -- that provided no fault compensation for children injured by vaccines -- was passed in response to Lederle's concerns.

I have also heard that Lederle is circulating a proposal that would fold VFC funds into block grants to states to be used for immunization efforts (but not necessarily for vaccine purchase). The funds would be a capped entitlement to states. States would be held responsible for ensuring that eligible children received immunizations. As I have noted before, I do not think this would be a terrible outcome (especially in the context of overall Medicaid block grants). However, Lederle has also noted that eligibility under the program is too broad. The proposal might therefore eliminate eligibility for uninsured children. I would recommend that we oppose this part of the proposal. In addition, I do not think that we should signal interest in any proposal now. Instead, we need to continue to fight for the program.

Beyond expressing their concerns, Stafford plans to tell you that he wants to work together to fix the VFC program. He may even outline their proposal. As you know, they expect you only to listen and do not anticipate any commitment. You might explain that while you have heard that there have been discussions about changes to the program and that we want to work with them, this program is extremely important to you and the President.

Immunization Hearing

The immunization hearing today actually went well. Senator Breaux was very positive (Mack did speak with him this morning), and Packwood was more positive than expected. Moseley-Braun gave very strong support. Moynihan was quite critical despite the assurances we had heard from his staff. However, his "facts" (e.g., "We don't have a problem in New York because New York has provided free vaccine for over a century.") were contradicted by the New York State First Deputy Commissioner of Health -- who testified that only 58% of two year olds in New York are adequately immunized and that VFC has been essential in improving immunization efforts in the state.

The basic question at the hearing was whether the cost of vaccine is a barrier to childhood immunization. The basic message from all witnesses was that cost is a factor, and that there are other important barriers (like the lack of access to health care and inadequate funding for infrastructure) as well. The more negative witnesses concluded that the VFC dollars would be better spent on infrastructure. The more positive witnesses said that this program is an important part of the effort to improve childhood immunization levels. Several witnesses (obviously including Satcher) pointed out that VFC is just one part of the Administration's investment in improving immunization rates.

Bliley has also asked for a hearing on the VFC program. This hearing will be less balanced.

cc: Melanne Verveer

AMERICAN HOME PRODUCTS CORPORATION

FIVE GIRALDA FARMS

MADISON, N.J. 07940

(201) 660-5008

JOHN R. STAFFORD
CHAIRMAN, PRESIDENT AND
CHIEF EXECUTIVE OFFICER

January 25, 1995

Mrs. Hillary Rodham Clinton
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Mrs. Clinton:

Let me thank you once again for being so generous with your time to help the New York United Cerebral Palsy. As you know the dinner was a great success, obviously, in large part, due to your presence. On a personal note, Mrs. Stafford and I enjoyed being with you, and I especially appreciated the chance to talk a bit of shop during dinner. I do hope you and your family come back to Martha's Vineyard where, as I'm sure you know, you are very welcome.

With your permission I would like to reiterate some of the points we discussed concerning the impact of the Administration's Vaccines for Children (VFC) program. As I told you, American Home Products' recent acquisition of American Cyanamid included its vaccine division, Lederle-Praxis Biologicals (LPB). At present, only two major vaccine manufacturers are American-based, but American research, including substantial contributions by LPB, has led the world in vaccine innovation.

With the advent of biotechnology, many more new vaccines are now feasible. Our company introduced three new vaccine products during the first four years of the decade, including a vaccine to prevent bacterial meningitis in infants, a less reactive version of pertussis vaccine to address parent concerns about side-effects, and a new combination vaccine that halved the number of injections necessary to protect against four major childhood diseases. These are products that would not have been possible just a few years ago without the benefit of biotechnology; other vaccines in our pipeline have the capacity to revolutionize disease prevention and to save billions in medical and other costs.

Vaccine innovation, however, is currently at risk in the United States because of the VFC program. The legislation permits essentially unlimited purchases of childhood vaccines by state and federal governments at extremely low, statutorily-fixed prices. If not amended

substantially to limit public purchases, the VFC program will completely destroy our private market, which is the sole source of revenue supporting its research and development efforts.

Even prior to enactment of VFC, the economics of the vaccine business were extremely difficult. (A principal reason why only two U.S. based companies are in the vaccine business.) In fact, American Home Products made a decision several years ago not to remain in the childhood vaccine market, at least in part, because of concerns over excessive government purchases. With the LPB acquisition we are once again in a position which requires us to assess this market. Our greatest concern is the ability to continue the outstanding research program of LPB.

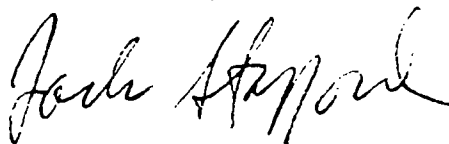
I shared with you the exciting prospect of a vaccine to protect children against otitis media (chronic ear infection that can cause deafness), which is the single largest reason for infant pediatric visits. Obviously, this product offers the potential of tremendous savings for the nation. Without substantial capital investment and continued clinical research, however, LPB will not be able to move this vaccine from the product pipeline into pediatricians' offices. Already LPB officials tell me that progress toward approval of the otitis media vaccine has been delayed by a year or more by uncertainties engendered by the VFC program. This is understandable because uncertainty is the absolute enemy of stable investment. But the loss to the country, in terms of both unnecessary illness and lost opportunities for savings, from just one year of delay is a tragedy.

I would like to request a meeting with you and the White House staff to discuss how the VFC program might be revised to support our shared goal of improved childhood immunization without undermining vaccine research and development. We can, no doubt, provide for today's needy children without depriving tomorrow's children of the promise of greatly enhanced prevention and freedom from disease through new vaccines.

Of course, I would also welcome an opportunity to discuss other areas of the pharmaceutical and biotechnology research-based industries if you or your staff should desire to do so.

Thank you again for the opportunity to be with you at last week's dinner, and I look forward to continuing our dialogue in a meeting anytime at your convenience.

Sincerely,

A handwritten signature in dark ink, appearing to read "Jack Steppard". The signature is fluid and cursive, with the first name "Jack" being more prominent and the last name "Steppard" following in a similar style.

JRS:MH

**Major Childhood Vaccines and Who Markets Them
In the United States**

Lederle (American Home Products):

oral polio vaccine (OPV)
diphtheria/tetanus/pertussis (DTP) combination
Haemophilus influenzae type b (Hib) [HbOC]
DTP/Hib combination (TETRAMUNE™)
acellular pertussis combined with diphtheria/tetanus (DTaP)

Merck

measles/mumps/rubella (MMR)
Hib vaccine [PRP-OMP]
hepatitis B [Hep B]
varicella, or chicken pox, vaccine

Connaught (Pasteur-Merieux Connaught)

inactivated polio vaccine (IPV)
DTP vaccine
Hib vaccine [PRP-D]
DTP and Hib vaccines mixed [PRP-T]

SmithKline Beecham

hep B vaccine

**American Home Products
Lederle Vaccines**

- American Home Products (AHP) has long been a leader in production of pharmaceuticals, but in recent years has also made substantial investments in biotechnology. With its purchase of a majority interest in Genetics Institute, AHP has become the second largest investor in biotechnology research among U.S. companies.
- Last year AHP also acquired American Cyanamid and its Lederle vaccine business. Lederle is the largest U.S. manufacturer of childhood vaccines.
- AHP had a long history in the vaccine business, dating back to 1882, but had steadily decreased its involvement in childhood vaccine manufacturing and research as a result of liability concerns.
- With the acquisition of the Lederle vaccine business, AHP now has a substantial product line of childhood vaccines with a number more in various stages of development.
- At present, AHP, through Lederle, markets the following major vaccines for children:
 - oral polio vaccine (OPV);
 - diphtheria/tetanus/pertussis (DTP) combination;
 - Haemophilus influenzae type b (Hib);
 - DTP/Hib combination (TETRAMUNE™); and
 - acellular pertussis combined with diphtheria/tetanus (DTaP).
- Lederle OPV is responsible for eradicating polio in the U.S. Several decades ago, there were a number of OPV manufacturers, but all others left the market for reasons of liability or low profit margin. Lederle stayed the course, and the Lederle formulation of OPV is used to break epidemics of polio when they occur in Africa, Asia or the Middle East.
- Like OPV, the Lederle DTP vaccine is considered the "gold standard" worldwide. As with OPV, Lederle stayed in the U.S. DTP market when other manufacturers -- especially those from foreign countries -- left the market (and then returned when the liability crisis abated).
- In 1990, Lederle became the first company to obtain approval of a new biologically engineered vaccine to protect against Haemophilus influenzae type b (Hib) in infants. So-called Hib disease caused meningitis that left thousands of

children dead, thousands of children deaf (including the current Miss America) and thousands mentally retarded. It was in fact the greatest single source of non-congenital mental retardation in the U.S. CDC estimated the total U.S. cost of Hib disease at \$2.5 billion annually. Less than two years after introduction of that vaccine, Hib disease had almost been eradicated.

- In 1991, Lederle introduced a new acellular pertussis version of DTP to address concerns of parents and pediatricians about possible adverse reactions to whole cell pertussis. This vaccine had been designated the number one priority for vaccine development by the Public Health Service, and Lederle rose to that challenge.
- In 1993, Lederle was the first company successfully to combine DTP and Hib vaccine, thus reducing by half the number of injections required to protect against four major childhood diseases. The Lederle vaccine remains to this day the only one that comes already mixed and ready to use in a single vial.
- Lederle vaccine research leads the world in vaccine innovation. Among the products in Lederle's pipeline are vaccines to protect against severe infant diarrhea caused by rotavirus, otitis media (acute ear infection) caused by pneumococcal bacteria and infant pneumonia caused by respiratory syncytial virus.

TO: Hillary Rodham Clinton
FROM: Jennifer Klein *J.K.*
DATE: 5/2/95
RE: Immunization

On Thursday, the Senate Finance Committee will hold a hearing on the Vaccines for Children (VFC) Program. The witnesses will be: Dr. David Satcher from the CDC, a representative from GAO, representatives from the New York State and Mississippi Departments of Health, Irwin Redlener, and Dr. David Wood (a pediatrician from Cedars-Sinai Medical Center).

As I know more, I will give you summaries of the expected testimony from each witness and information about advocacy groups' and States' plans for publicly supporting the program on Thursday. I am working with CDC on Satcher's testimony (especially to add good, hard facts about the success of the program and the rest of the Childhood Immunization Initiative).

About Irwin . . . I have no idea why he is testifying, and -- after calming myself down when I found out today -- I spoke with him. As you know, he was critical of the program last month at an AEI conference. On Thursday, he will say that he supports the VFC program. However, he plans to raise four concerns (which he will describe as issues that must be addressed to ensure the continuing success of the program). They are: (1) more funding must be allocated for infrastructure development; (2) VFC should better target children without "medical homes"; (3) private providers should not be required to serve all eligible children; and (4) maintenance of effort provisions should be put in place so that VFC does not act as a disincentive for insurance companies to cover immunization. I don't have any problem with his raising (3) and (4). I told him that (1) and (2) are dangerous points because they can so easily be used to argue that this money should be spent elsewhere. My sense is that he will make all of these points but he will emphasize that it is important to fix these problems, not to repeal the program. I will be in touch with him again tomorrow.

I am attaching the memo that Leon mentioned to you last week. The memo provides two alternatives for addressing the problems in VFC; one would make the program a means-tested, capped entitlement and the other would change VFC to a discretionary program. Both options would eliminate the cap on the price of vaccine under the program and would limit the ability of states to buy vaccine at the low federal rate.

I am also attaching a (not public) proposal by SmithKline. As you can see, they would (among other things) also reform VFC by limiting eligibility.

The Children's Health Fund

Board of Directors

Paul Simon
Co-Founder

Irwin Redlener, MD
Co-Founder, President

Robert F. Tannenhauser, Esq.
Chairman

Jeffrey S. Maurer, Esq.
Treasurer

Karen B. Redlener
Secretary

Ann Druyan
Fred Francis
Steven J. Green
Dan Klores
Robert C. Osborne
Marvin S. Rosen
Ray Schulte
Nancy Waldbaum

Corporate Council

David R. Bethune
Chairman

Senator John D. Rockefeller IV
Honorary Co-Chairman

Senator Christopher S. Bond
Honorary Co-Chairman

Joe Boyd
Robert Essner
Gordon Douglas, Jr., MD
Edward V. Fritzky
Thomas Kalinske
Gerald M. Levin
James W. McLane
Don Panoz
Ronald J. Saldarini, PhD
Hiroshi Shikata
Robert Wallach
David Williams

Advisory Board

Paul Simon
Chairman

Ron Anderson, MD
Ron Berger
Senator Bill Bradley
Neil Braun
Michael I. Cohen, MD
Hon. David N. Dinkins
Senator Christopher J. Dodd
Esther R. Dyer
Dick Ebersol
Honorable Mike Espy
Patrick Ewing
Zachary Fisher
Herbert B. Fixler, Esq.
Spencer Foreman, MD
H. Jack Geiger, MD
Rod Gilbert
Paul A. Goldner
Robert J. Haggerty, MD
Dave Herman
Gloria Janata
Samuel A. Keesal, Jr., Esq.
Joel Lamstein
Don Mattingly
Jewell Jackson McCabe
Bill McIntosh
Paul Metselaar
Senator George J. Mitchell
Billie Heller Monness
Jane Pauley
Steven Ricchetti
Senator John D. Rockefeller IV
Carl Sagan
Susan Saint James
Susan Taylor
Joseph W. Werthammer, MD
Senator Harris Wofford
Ronald Wolfgang

April 7, 1995

Jerry Klepner
Assistant Secretary for Legislation
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Jerry:

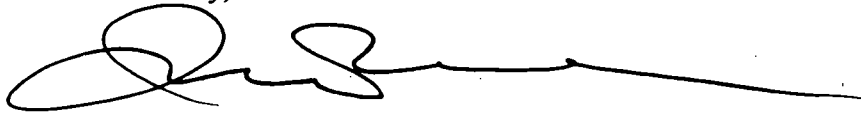
Thank you for a very informative and productive meeting regarding the Vaccines for Children program.

As was discussed, The Children's Health Fund strongly supports Vaccines for Children, particularly in its capacity to provide medically underserved children with access to critical immunization services. As you know, we continue to have concerns regarding certain program provisions. We feel that these can be addressed through modification of VFC to ensure the following:

- o allocation of sufficient funding for infrastructure development and support to facilitate adequate provision of services in medically underserved communities
- o funding for vaccine purchase be targeted to address the immunization crisis in disadvantaged communities
- o private providers participating in VFC serve as access points for **all** medically underserved children in need of immunizations
- o maintenance of effort provisions be put in place to ensure that VFC does not act as a disincentive for insurance companies to provide coverage for immunization

The Children's Health Fund mission has always been that medical care for children works best within the medical home context. Vaccines for Children must strive to meet that threshold. We look forward to working with HHS to make VFC work to improve the level of childhood immunization within that framework. Please let us know how we can be of assistance.

Sincerely,



Irwin Redlener, MD
Director, Division of Community Pediatrics
Associate Professor of Pediatrics,
Albert Einstein College of Medicine - Montefiore Medical Center

THE WHITE HOUSE

WASHINGTON

May 3, 1995

MEMORANDUM FOR LEON PANETTA

FROM: Diana Fortuna *DF*
Domestic Policy Council

SUBJECT: Hearing Tomorrow on Vaccines for Children Program

In Carol Rasco's absence, I wanted to make sure you were aware of tomorrow's Senate Finance hearing on the Vaccines for Children (VFC) program. We became aware of the hearing this week, but we are working with OMB and HHS to try to ensure that it goes well.

The Administration's witness is Dr. David Satcher, Director of CDC. Dr. Satcher's draft testimony has problems that we and OMB are working to address. It needs to explain better how the program will help us reach our immunization goals; demonstrate that we have adequate protections against over-ordering of vaccines and fraud; and show progress on getting vaccine delivered to private providers in all 50 states.

Also testifying are GAO, the states of Mississippi and New York, Dr. Irwin Redlener of the Children's Health Fund, and David Wood of Cedars-Sinai Medical Center. We have heard that Senator Packwood wants to make this a balanced hearing; the list of witnesses could certainly be worse than this. We believe New York State will be positive, and we are trying to ascertain the positions of the other witnesses. We have spoken to Dr. Redlener, who has been critical of VFC for not doing more, to explain that attacking the program in this setting will not help our immunization efforts. GAO will be under pressure to reveal its findings, which were not expected for another couple of months.

At the hearing, HHS is planning to release letters of support for VFC from several organizations, including the Association of State and Territorial Health Officials, the Children's Defense Fund, the American Academy of Pediatrics, the State Medicaid Directors, and possibly SmithKline. In addition, HHS is working with Democratic Senators to help them defend the program. Senator Breaux has been particularly helpful, although apparently he could use some encouragement.

cc: Carol Rasco
Mark Gearan
Pat Griffin
Alice Rivlin
Melanne Verveer

TO: Hillary Rodham Clinton
FROM: Jennifer Klein
DATE: 4/11/95
RE: Immunization Meeting

As you know, on Monday HHS ended negotiations for delivery contracts with the vaccine manufacturers. Leon and Carol have called a meeting to discuss our plan for dealing with the "cut-off" as well as our longer term strategy.

The agenda for the meeting includes: (1) plans for defending the program (i.e., State and provider support); (2) plans for fixing the problems (i.e., new delivery contracts, provider accountability, manufacturers concerns about price); and (3) legislative strategy.

HHS continues to believe that, although the manufacturers are publicly asking for repeal, the Members will be unwilling to repeal the program and that we should continue to defend it as is. While I agree that we should continue to defend the program, I think that the following questions should be addressed internally: (1) Are there changes to the VFC program that we might accept (i.e., should we and can we reach a settlement with the manufacturers and the Hill)?; and (2) Assuming that the discussion of Medicaid block grants continues, will VFC be preserved as a separate program and, if not, how can we protect immunizations for children?

I have attached the memo that you received this weekend about the cut-off.

THE WHITE HOUSE

WASHINGTON

April 7, 1995

MEMORANDUM FOR LEON PANETTA

FROM: Carol Rasco 
SUBJECT: Cut-off of Negotiations in Vaccine Program

HHS has just informed us that the Centers for Disease Control cut off negotiations today with the vaccine manufacturers to add delivery of vaccine to their existing vaccine purchase contracts. HHS tells us that the Procurement Integrity Act prevented them from informing us of this action in advance. The letters to the manufacturers formally announcing the end of the negotiations were put in the mail today, which allows HHS to divulge details of the negotiations. They plan to make this information public on Monday; they have informed no one else today. As you know, HHS indicated earlier that the negotiations were not going well, and we had assumed this cut-off was a possibility.

Background: As you know, the Vaccines for Children (VFC) program entitles children who are uninsured, on Medicaid, or treated at public clinics to immunization by providing free vaccine to private and public sector providers who enroll in the program. From the beginning of VFC, delivering vaccine to private physicians has been a stumbling block. Currently this problem prevents the program from operating in the private sector in 14 states. HHS has encouraged states to deliver the vaccine, and 35 are now doing so, with the remainder expected to join over the next year or so. To fill the gap in the meantime, CDC began negotiations with the vaccine manufacturers in September to amend their existing contracts for vaccine purchase by adding delivery. According to HHS, the manufacturers were unreasonable during the negotiations.

The rationale for cancelling the negotiations is that -- since these were to be amendments to contracts that begin expiring on June 29, and the companies say it would take up to three months to get the system up and running -- it is now too late for them to be of any use. CDC now proposes to seek bids from contractors other than the manufacturers.

Next Steps: On Monday, HHS plans to alert the manufacturers, the states, the Hill, GAO, and other interested parties. HHS will also talk to the AP on the theory that this is less risky than letting the manufacturers shape the story. HHS hopes to persuade the manufacturers to react in a measured way to the announcement, but it is quite possible that the companies will use this as an opportunity to criticize HHS for continuing to run the VFC program ineptly. If this happens, HHS would criticize one or two

of the manufacturers for being particularly unreasonable during the negotiations.

Obviously this could easily raise questions on the Hill about the future of the program. The manufacturers are still calling for repeal of the entire program, although privately they are probably interested in compromise.

Following a meeting I had with Tom Downey and his client (Merck) yesterday, I have serious concerns about whether this program will survive. I believe you need to convene a meeting very early next week with our communications staff, legislative affairs, DPC, and whoever else is appropriate.

cc: Hillary Rodham Clinton

draft 4/10/95 noon

Dear Colleague:

I write to update you on the status of the efforts by the Centers for Disease Control and Prevention (CDC) to negotiate delivery contracts with vaccine manufacturers for the Vaccines for Children (VFC) program for those states that do not wish to deliver vaccines to public and/or private providers themselves. For several reasons, which I will explain, CDC is canceling the solicitation for these delivery contracts with the vaccine manufacturers. This does not affect the vaccine purchase contracts that remain in effect.

As part of the VFC legislation enacted by Congress, CDC has sought to establish a vaccine distribution system for those states which choose not to deliver vaccine to all providers. In early September 1994, CDC contacted the four major vaccine companies--Connaught; Lederle-Praxis; Merck, Sharp, and Dohme; and SmithKline Beecham--and asked them to consider adding private provider delivery to their existing vaccine purchase contracts. Following these discussions, we issued written "Requests for Proposals" (RFP) on September 15-16, 1994. Based on discussions with the companies in September, it was anticipated that vaccine deliveries could begin in December 1994.

Although negotiations for vaccine delivery immediately got underway with all four vaccine companies, we have been unable to

reach signed contracts with all of the manufacturers. CDC has now made the decision to discontinue its current efforts to establish a vaccine distribution system for FY 1995 for the following reasons:

1. An effective distribution system requires CDC to have delivery contracts with all four vaccine companies. Although we have reached final agreement with one company, we have no realistic expectation of final agreements with all four companies in time to deliver vaccine under the current vaccine purchase contracts.
2. Even if delivery contracts with all vaccine companies were signed this month, we estimate that at least three additional months would be required before all manufacturers would have in place the necessary mechanisms to begin receiving electronic orders for vaccine. Because our current vaccine purchase contracts are due to expire as early as June 29, 1995, new delivery arrangements made through modifications of these contracts could not be made before some of the vaccine purchase contracts expire.
3. As of March 30, 1995, thirty-five States have informed CDC that they are delivering vaccine to all enrolled public and private providers who request vaccine. Each of the fourteen remaining states has reported to CDC

that they are planning to deliver vaccine to all providers in the future. Ten of the fourteen reported that they would begin providing vaccine to private providers this year. The remaining four plan to deliver to private providers as soon in 1996 as feasible. (Alaska is not participating in the VFC program.)

4. Under these developing circumstances, it would be difficult for CDC to guarantee the manufacturers the minimum number of deliveries that are specified in the RFPs, given the decreasing number of states that are requesting direct vaccine delivery to providers.

The cancellation of the delivery contract solicitation does not alter CDC's commitment to the establishment of a delivery system for those states which do not wish to deliver vaccine themselves. CDC's ability to serve those states, however, is affected by the fact that so few states now want CDC's assistance with delivery. Under these new circumstances, consultation by CDC with states, including state health departments and immunization program directors, vaccine manufacturers, private provider organizations, commercial distributors and other interested parties will help determine the most efficacious way to deliver vaccine in those states.

During the period of negotiations with vaccine manufacturers, CDC

continued to explore options for a long term vaccine distribution system that could become effective in FY 1996. We have been working with Logistics Management Institute (LMI) to explore possible alternatives. As we consult with you and others, I am confident that LMI's work will be an important resource in these discussions.

Finally, I want to express my appreciation to you for your support and cooperation during this period of implementation of the Vaccines for Children program. As we all know, the start up of a new and important public health effort is a complex undertaking, and we have made great progress since October 1. Together we can be proud of the many considerable accomplishments we have achieved so far. I look forward to continued progress during our deliberations regarding vaccine delivery. Soon, CDC will be seeking your participation. I hope you will assist us in this effort.

Sincerely,

David Satcher, M.D.

draft 4/7/95 8:30 am

Letter to companies:

We have been unable to reach agreements with all manufacturers on modifications to current vaccine purchase contracts that would provide for vaccine delivery to private providers. For the following reasons, we have decided we will no longer pursue these modifications:

--As of March 30, 1995, thirty-five states have informed CDC that they are delivering vaccine to all enrolled public and private providers who request vaccine. All of the remaining 14 states have reported to CDC that they are planning to deliver vaccine to all providers in the future. Ten of the fourteen reported they would provide vaccine to private providers during 1995. The remaining four plan to deliver to private providers some time in 1996. (Alaska is not participating in the VFC program.)

--An effective distribution system requires CDC to have delivery contracts with all four vaccine companies. We have reached full agreement with one company; but we have no realistic expectation of final agreements with all four companies in time to deliver vaccine under the current vaccine purchase contracts.

--Even if delivery contracts with all vaccine companies were signed this month, distribution could not begin until approximately June 1995, and at least one company may require what we would estimate to be three months to establish the necessary mechanisms to begin receiving electronic orders for vaccine. Because our current vaccine purchase contracts are due to expire as early as June 29, 1995, the new delivery arrangements made under these contracts would be in effect for as little as a month.

--Under the present circumstances, it would be difficult for CDC to guarantee a minimum number of deliveries, given the decreasing number of states that are requesting direct vaccine delivery to providers.

We appreciate your submission of proposals for these services and your willingness to work with us to establish provider deliveries.

Sincerely yours,

Mary Ann Bryant

TO: Hillary Rodham Clinton
FROM: Jennifer Klein J.K.
DATE: 1/25/95
RE: Vaccines for Children Program

This memorandum briefly describes the background of the Vaccines for Children (VFC) program, outlines the program's problems, and proposes a set of next steps to address these problems.

The VFC program was designed to reduce the costs for families of immunizing their children and to improve immunization rates and continuity of care by enabling private physicians to provide free vaccine rather than refer children to public clinics. (Increasing numbers of physicians have been referring children to public clinics and health departments for their immunizations because of the rising costs of purchasing vaccine at retail price. These referrals often result in missed immunizations and breaks in continuity of care.)

As you know, the VFC program has been vigorously opposed by vaccine manufacturers and Democratic and Republican Members of Congress, plagued by serious implementation problems, and attacked by the press. As you also know, the VFC program is part of the Administration's Childhood Immunization Initiative, which includes other (widely supported and quite successful) activities to improve the public immunization delivery infrastructure in States and local communities and to educate providers and parents about the importance of age appropriate immunization.

Background

The Program as Proposed. The Administration originally proposed a federally-funded entitlement program to immunize all children in the United States. Vaccine was to be purchased by the Federal government at prices negotiated with vaccine manufacturers and distributed free of charge to private physicians and public clinics. The Administration did not identify a source of financing for this new entitlement program.

The Program as Passed by Congress. The VFC program passed by Congress created an entitlement program under which the Federal government purchases sufficient vaccine to immunize only specified categories of children -- Medicaid beneficiaries, Indian children, uninsured children, and some underinsured children. (Underinsured children -- defined as children who have health insurance that does not cover immunizations -- are eligible to receive free vaccine if they are immunized at a federally qualified health center or a rural health clinic.) The Federal government pays a statutorily set price that is deeply discounted below the private market price. States may also purchase vaccine at this price for children who are not eligible for the VFC program (known as the State optional purchase provision).

Problems and Proposed Solutions

1. Implementation

Problems. One of the biggest problems with the program has been the failure to set up a workable delivery system. HHS interpreted an ambiguity in the law as prohibiting the Secretary from entering into contracts with manufacturers to deliver their own vaccine. HHS refused offers by Congress to clarify the legislative confusion and instead chose to set up a Federal delivery system. The resulting GSA warehouse was criticized as both unsafe and inefficient from the outset and finally was closed. As a result, while almost two-thirds of the States have arranged for their own distribution systems, in the remaining States no VFC vaccine is being distributed.

In addition, physicians have been over-ordering free vaccine. This is most likely due to their inability to estimate accurately how many of their patients are eligible for the program. However, manufacturers have begun charging that the program is riddled with fraudulent doctors who get free vaccine, bill their patients for the retail price, and pocket the money.

Proposed Solutions. The General Accounting Office is expected to issue a report in the next few weeks exposing this "fraudulent provider" problem. We can act before the report is issued to put in place an accountability system to ensure that physicians and clinics order VFC vaccine only for eligible children.

In addition, over the next few months, we can negotiate with manufacturers to pay for delivery of vaccine at or near market rates. HHS is currently negotiating with manufacturers to deliver vaccine under the Medicaid program; it is possible that the manufacturers would be willing to extend any agreement to the VFC program. (However, because all negotiations are confidential, we do not know what, if any, agreement has been reached.)

2. Price Discount

Problems. In order to meet budget reconciliation requirements, Congress abandoned the Administration's initial plan to negotiate prices with the vaccine industry each year. Congress instead imposed a statutorily set, deeply discounted price equal to the price that the manufacturers had agreed to accept in the early 1980s for vaccine purchased by the Centers for Disease Control (with an adjustment for inflation). Since the 1980s, the market share of vaccine sold at the CDC price has been 50 percent. The manufacturers estimate that with the VFC program in place (including State optional purchase) they will now be forced to sell 80 percent of vaccine at a discount. This will reduce their profit margins significantly and, they claim, will therefore slow new vaccine research and compromise their

ability to continue to produce vaccine.

The attached chart compares vaccine prices in the private sector with prices under the VFC program.

Proposed Solutions. We can ease the strain on manufacturers by reaching a legislative settlement to end State optional purchase (i.e., prevent new States from purchasing vaccine at the VFC discounted prices for non-VFC eligible children in their States). We may also consider offering to manufacturers a price they consider "fairer" (i.e., closer to market) for vaccine purchased for the VFC program. However, this second step may not be necessary and will obviously have cost implications.

Incidentally, while these issues are real, much of the manufacturers' hostility stems from the extreme ill will that has developed between the industry and HHS. Even if we do not address all of their complaints, it would be useful if you and/or Carol met with the manufacturers to hear their concerns.

3. Perception of the Program

Opposition to the program by Members and in the press has been highly visible. The program has been attacked as yet another Clinton Administration "big government" solution -- a government takeover of the private sector's system of vaccine delivery. The original Administration proposal (which would have provided free vaccine to all children in the United States) was also criticized because taxpayer dollars would have been used to buy vaccine for children whose families could easily afford to pay for it. These perceptions are particularly damaging because there is little data showing that providing free vaccine increases age appropriate immunization.

Proposed Solutions. While some Members and manufacturers have called for the repeal of the VFC program, there is growing pressure to leave it in place. States support VFC because their Medicaid programs -- which in the past purchased vaccines -- now receive free vaccine from the Federal government. Many have already spent this windfall. As early as the fall of 1993, some Republican Senators opposed elimination of the VFC program because of concern about their home States' budgets. We should enlist and publicize the support of Governors, State Medicaid directors and State health officers in the coming weeks.

Finally, while much of the damage has already been done, negative perceptions have been severely aggravated by the real failings of the VFC program. Addressing the implementation and price issues quickly will go a long way toward improving the public view of the program. This memorandum outlines possible first steps to solve these problems. I would be happy to discuss these in more detail.

cc: Melanne Verveer

**CURRENT VACCINE PRICES
FEDERAL CONTRACT AND PRIVATE SECTOR
OCTOBER, 1994***

Vaccine or product**	Centers for Disease Control (Federal Contract): Cost per dose	Private sector: cost per dose	Centers for Disease Control (Federal contract): Cost for vaccines recommended from birth to age two.†	Private sector: Cost for vaccines recommended from birth to age two.
Oral Polio Vaccine (OPV)	\$ 2.21	\$ 10.47	\$ 6.63 (3 doses)	\$ 31.41 (3 doses)
Diphtheria-Tetanus-Pertussis (DTP)	\$ 5.96	\$ 10.10	\$ 23.84†† (4 doses)	\$ 40.40†† (4 doses)
Measles-Mumps-Rubella (MMR)	\$ 15.71	\$ 25.87	\$ 15.71 (1 dose)	\$ 25.87 (1 dose)
<i>Haemophilus influenzae</i> type B (HIB)	\$ 4.17	\$ 15.13	\$ 12.51 - \$ 16.68 (3-4 doses, depending on vaccine types)	\$ 45.39 - \$ 60.52 (3-4 doses depending on vaccine type)
Hepatitis B (Hep B, HBV)	\$ 7.09	\$ 16.17	\$ 21.27 (3 doses)	\$ 48.51 (3 doses)

* Based on information from the Centers for Disease Control and Prevention, U.S. Public Health Service

** Certain vaccines, such as those for high-risk patients, are not shown

† Vaccine doses are as recommended by the American Academy of Pediatrics (AAP) and the federal Advisory Committee on Immunization Practices (ACIP). Doses are to be administered at specified intervals, from birth through 18 months of age. Additional doses are recommended by ages 4 years to 6 years, before a child enters school, as follows: OPV (fourth dose); DTP (fifth dose††); MMR (second dose recommended by ACIP; AAP recommends second dose by age 12, preferably before entry to middle school or junior high).

†† Fourth and fifth doses may be Diphtheria-Tetanus-acellular pertussis (DTaP), at per-dose cost of \$ 9.81 (CDC) or \$16.09 (Private sector).

March 16, 1995

MEMORANDUM TO HILLARY RODHAM CLINTON
CAROL H. RASCO
MELANNE VERVEER

FROM: JENNIFER KLEIN

SUBJECT: Vaccines for Children Program

In preparation for our meeting on Monday, this memorandum identifies three important problems with the Vaccines for Children (VFC) program. They are: (1) the lack of a delivery system in 13 states; (2) the provider accountability problem; and (3) the claim by manufacturers that they will not be able to produce vaccine if they continue to be paid such a low price for so large a share of the vaccine market.

1. The Delivery System Problem

Problem: Thirteen states do not have systems in place to deliver vaccine. HHS is attempting to negotiate with the vaccine manufacturers for delivery contracts for these states. However -- although publicly HHS continues to say that the negotiations are continuing -- it seems unlikely that HHS will reach agreement with the manufacturers.

HHS Rationale: HHS says that, because all contract negotiations are confidential, they can not tell us why the contracts are not in place -- although they continue to blame the manufacturers who, at this point, want repeal of the program.

Unanswered Questions:

- (1) Does HHS *know* that they will be unable to reach agreement with the manufacturers?
- (2) What is HHS's plan for delivery if they are unable to sign contracts with the manufacturers?
- (3) Do these delivery problems affect the Medicaid (section 317) vaccine program in any way?

2. The Accountability Problem

Problem: GAO is expected to release a report criticizing the VFC program at the end of March. The most damaging claim in the report will be that physicians are over-ordering free vaccine. The GAO report will recommend that only "dose-by-dose accounting" will ensure that only eligible children are receiving free vaccine.

HHS Rationale: HHS says that they have a good accountability system in place that does not overburden physicians (but admittedly may not catch all over-ordering). They say that GAO's approach is too burdensome and that they would rather allow over-ordering than deny any eligible child vaccine.

Unanswered Questions:

- (1) CDC is studying other ways to monitor ordering. Their studies will not be complete until June. Why are they *studying* alternatives rather than making changes *now*?
- (2) What can be done before the report is issued?

Possible Solutions: Whether GAO is right or not, the report will be powerful ammunition for opponents of the VFC program. HHS's rhetoric about erring on the side of protecting eligible children will fall flat. At the very least, before the report is issued, we can get physician groups to voice their support for the approaches CDC is studying. We could also act now (even as an interim measure) to limit the amount of vaccine that private physicians can order unless they demonstrate that they serve a greater number of eligible children.

3. The Price Problem

Problem: Manufacturers claim that because the vaccine prices set in the statute are so low, the VFC program will compromise their ability to do research and produce vaccine. The manufacturers are particularly unhappy because the VFC program allows states to purchase vaccine at the low VFC prices for children in their states who are not eligible for the VFC program (the so-called "state optional purchase" provision). The manufacturers estimate that with this provision in place they will be forced to sell 80 percent of vaccine at a discount.

HHS Rationale: Bill Corr has pointed out that the prices set by statute do not cover new vaccines or new combinations of vaccines. That means that those manufacturers who are currently developing new vaccines will be paid a negotiated, rather than a capped, rate. (For example, the Advisory Council on Immunization Practices recently added three vaccines to the recommended schedule; these vaccines are not subject to the cap.)

Unanswered Questions:

- (1) Are the manufacturers claims fair?
- (2) Is there anything we can do to satisfy them? Do we think they will be satisfied if states are no longer allowed to purchase vaccine at the low rates set in the statute? Will they settle for anything short of repeal?

Possible Solutions: We could negotiate with states and manufacturers to end state optional purchase. Bill Corr told us (*very* confidentially) that HHS is close to reaching a legislative settlement to do this.

We are raising these issues in large part to see what can be done to strengthen the program so that when the fight to repeal it begins we are defending a defensible program. We should, therefore, also ask HHS to fill us in on any discussions they are having on the Hill and get their sense of when the real push for repeal will begin.

TO: Hillary Rodham Clinton
FROM: Jennifer Klein
DATE: 3/1/95
RE: Immunization Update

Here is a short report on the conference call that Melanne and I had with Phil Lee and Bill Corr. We raised what we see as the three most important problems with the program. They are: (1) the lack of a delivery system in 13 States; (2) the provider accountability problem; and (3) the claim (that you heard from John Stafford of American Home Products) by manufacturers that they will not be able to produce vaccine if they continue to be paid such a low price for so large a share of the vaccine market.

Melanne and I concluded that while there is not much to be done about the delivery system problem (beyond a herculean effort to get contracts in place and to encourage States to set up delivery systems), we can take immediate steps to improve accountability and relieve the manufacturers concerns about price.

Problems

1. The Delivery System Problem

HHS continues to negotiate with manufacturers for delivery of vaccine in the 13 States without their own delivery systems. Because all contract negotiations are confidential, Phil Lee and Bill Corr could not tell us why the contracts are not in place -- except to say that it is of course difficult to reach agreement with manufacturers who, at this point, are pushing for repeal of the program.

Bill did mention, however, that seven of the 13 States are beginning work on their own delivery systems. Melanne and I suggested that HHS help these States in any way it can.

2. The Accountability Problem

GAO is expected to release their report criticizing the VFC program at the end of March. The most damaging claim in the report will be that physicians are over-ordering free vaccine. (The data shows over-ordering -- although it is not clear whether physicians are ordering wrong or simply reporting the amount they are ordering wrong.) The GAO report will recommend that only dose-by-dose accounting will ensure that only eligible children are receiving free vaccine.

The current VFC accountability system was designed to monitor vaccine ordering without burdening physicians. (The overwhelming sense was that private physicians would not participate in the program if it required significant paperwork.) Physicians must place a brief form in a child's medical record to verify that the child is eligible (and are subject to

audit at any time). The States are also required to submit accountability plans that may go beyond the Federal requirements.

Because physicians have been over-ordering vaccine, CDC is currently studying other ways to monitor ordering. They are considering two approaches: (1) requiring that physicians complete an audit when ordering new vaccine; and (2) taking a snapshot of the amount of vaccine that a physician needs in one month to estimate year-long need. However, these studies will not be complete until June.

At the very least, before the report is issued, we can get physician groups to voice their support for the approaches CDC is testing. We could also act now to place an upper limit on the amount of vaccine that private physicians can order (i.e., no more than a proportion of their practice that is equal the proportion of eligible children in the State). Physicians who need to order more vaccine could demonstrate that they serve a greater number of eligible children.

3. The Price Problem

The Statutorily Set Price. As I noted in my first memo, manufacturers claim that because the vaccine prices set in the statute are so low, the VFC program will compromise their ability to do research and produce vaccine. Bill Corr pointed out that the prices set by statute do not cover new vaccines or new combinations of vaccines. That means that those manufacturers who are currently developing new vaccines are guaranteed a market for those vaccines because of the VFC program and will be paid a negotiated, rather than a capped, rate. (For example, the Advisory Council on Immunization Practices recently added three vaccines to the recommended schedule; these vaccines are not subject to the cap.)

I understand that John Stafford shared with you his concerns about the low price set by statute. Unfortunately, the fact that the price cap does not apply to new vaccines is not helpful to Lederle (the vaccine company owned by American Home Products); Lederle produces only one vaccine (which *is* subject to the cap), and the company has no plans to develop other vaccines.

State Optional Purchase. As you may remember, the manufacturers are particularly unhappy because the VFC program allows States to purchase vaccine at VFC discounted prices for children in their States who are not eligible for the VFC program (the so-called "State optional purchase" provision). The manufacturers estimate that with this provision in place they will be forced to sell 80 percent of vaccine at a discount.

Bill Corr told us that HHS is close to reaching a legislative settlement to end State optional purchase. This could dramatically improve our relationship with the manufacturers and might induce them to sign delivery contracts in the States without systems in place.

Other Issues

1. One piece of good news. The Morbidity and Mortality Weekly Report recently

published the attached study demonstrating that significant numbers of primary care physicians in New York refer children to clinics and health departments for vaccination and cite the cost to their patients as a "very important" reason for doing so. The editorial note on the study states that "VFC has allowed New York to increase provision of vaccine to more children in primary-care settings where they first seek care." This evidence will be helpful in refuting the expected charge in the GAO report that cost is not a barrier to immunization. More can be done to encourage State health departments and pediatricians participating in VFC to be more vocal in their support for the program.

2. Melanne and I think it would be worthwhile for you to meet with John Stafford to hear his concerns. You might get a sense from him about how satisfied the manufacturers would be if we ended the state option to purchase vaccine at the discounted statutory price.

cc: Melanne Verveer

TO: Melanne
FROM: Jen
DATE: 2/2/95

I decided that the memo sounded too "directive" with the suggested solutions included. Here (next to the bullets in his memo and written in bold) are some proposals/questions you could raise with Phil Lee in conversation.

- We do not have a workable delivery system in place. The GSA warehouse was criticized as both unsafe and inefficient from the outset. Since it closed, no new system has been implemented (e.g., delivery contracts with the manufacturers). As a result, almost two-thirds of the States have arranged for their own distribution systems, while in the remaining States no VFC vaccine is being distributed.

How are we progressing in finding alternative delivery methods?

- Physicians have been over-ordering free vaccine. I have been told that this is most likely due to an inability to estimate accurately how many of their patients are eligible for the program. However, manufacturers have begun charging that the program is riddled with fraudulent doctors who get free vaccine, bill their patients for the retail price, and pocket the money. I have heard that the General Accounting Office is expected to issue a report in the next few weeks exposing this "fraudulent provider" problem.

Can we act before the report is issued to put in place an accountability system (that is not burdensome) to ensure that physicians and clinics order VFC vaccine only for eligible children?

- According to the manufacturers, the price set in the statute is quite low. Because such a large share of the market now pays this low price (especially given the State optional purchase provision), the manufacturers claim that their profit margins will be reduced significantly and their ability to do new vaccine research will end.

Should we agree to end State optional purchase? Will this satisfy them -- or do we need to talk about offering a price that is closer to market?

In addition, States support VFC because they now receive free vaccine from the Federal government. Some have already spent this windfall. You might suggest to Phil Lee that we enlist and publicize the support of Governors, State Medicaid directors and State health officers in the coming weeks.

CONFIDENTIAL

TO: Phil Lee
FROM: Melanne Verveer
DATE: 2/2/95

Per our conversation, here are the concerns about the Vaccines for Children Program that I have heard from various sources.

- We do not have a workable delivery system in place. The GSA warehouse was criticized as both unsafe and inefficient from the outset. Since it closed, no new system has been implemented (e.g., delivery contracts with the manufacturers). As a result, almost two-thirds of the States have arranged for their own distribution systems, while in the remaining States no VFC vaccine is being distributed.
- Physicians have been over-ordering free vaccine. I have been told that this is most likely due to an inability to estimate accurately how many of their patients are eligible for the program. However, manufacturers have begun charging that the program is riddled with fraudulent doctors who get free vaccine, bill their patients for the retail price, and pocket the money. I have heard that the General Accounting Office is expected to issue a report in the next few weeks exposing this "fraudulent provider" problem.
- According to the manufacturers, the price set in the statute is quite low. Because such a large share of the market now pays this low price (especially given the State optional purchase provision), the manufacturers claim that their profit margins will be reduced significantly and their ability to do new vaccine research will end.

I'm sure that none of these issues come as a surprise to you. I will call in a few days to talk more about this.