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

04-May-1995 12:00pm

TO: (See Below)

FROM: Gordon P. Agress
Office of Mgmt and Budget, HD

SUBJECT: VFC Hearing

In today's oversight hearing, Senator Packwood took more interest in VFC policy than in implementation. He focused on the effect of vaccine cost on immunization rates, and seemed skeptical that it was very important.

GAO reported that there is no evidence that cost is a major barrier (but took pains to avoid saying it is not); CDC argued that cost drove referrals, leading to missed opportunities.

Senators Mosely-Braun and Breaux focused on the importance of prevention and the money saved by proper vaccination.

At one point GAO said CDC had agreed with their findings, citing agreement on GAO's assessment of some diagnostic studies. When Sen. Packwood followed up, Dr. Satcher noted that CDC might agree narrowly that a particular study did not identify cost as a barrier, without agreeing generally to a conclusion on the larger question of the importance of cost. I thought his answer ended that line of inquiry very effectively.

I will provide more details later.

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

04-May-1995 06:25pm

TO: (See Below)

FROM: Gordon P. Agress
Office of Mgmt and Budget, HD

SUBJECT: Senate Finance Hearing on VFC

The Senate Finance Committee today held oversight hearings on the Vaccines For Children program. Chairman Packwood opened by saying the program cost three and a half times the original estimates; that cost of vaccine didn't seem to be the reason immunization rates are low; and that he wasn't sure we needed this program. He said he had called the hearings to examine the real barriers to immunization. Other Senators attending included Moynihan, Simpson, Mosely-Braun, and Breaux. GAO and CDC testified first, followed by representatives from Mississippi, New York and the Children's Health Fund. A wire service summary is attached.

GAO testified that there is no evidence that cost of vaccine is a barrier to immunization. CDC argued that cost of vaccine does cause referrals to public clinics and so contributes to missed opportunities and low immunization rates, and that cost is one of many barriers the Administration is trying to address. Sen. Packwood didn't seem to think cost was an important barrier, and Sen. Moynihan questioned the role of a Federal entitlement for immunization. Sens. Mosely-Braun and Breaux argued that vaccination is cost-effective, and that the focus should be on the costs avoided. Details follow.

GAO -- No Evidence Cost Is a Barrier

GAO testified that it had found no conclusive evidence that cost was a barrier to immunization. GAO took pains throughout the hearing to note that it was not saying that cost was not a barrier -- just that there is no evidence that it is. GAO said it based its work on CDC studies. GAO said that other factors, such as clinic access, provider and parent knowledge, and missed opportunities, were major barriers.

CDC -- Cost Is One of Many Barriers

CDC Director Satcher argued that cost was one of many barriers to immunization, and that the Administration's immunization initiative had components to address all of these. He noted that cost drove physician referrals of patients to clinics, and that

these referrals increased the likelihood of missed opportunities and quoted a Journal of Pediatrics article that 93% of physicians said that cost drove referral. He noted that there are many barriers to immunizations, and that immunization programs attempted to address all of them.

Do CDC and GAO Agree?

At one point, GAO said that CDC had agreed that there was no evidence that cost was a barrier to immunization. Senator Packwood followed up on this point aggressively, asking who GAO spoke with and that they come to the table -- the persons involved were not at the hearing. The chairman continued to press until Dr. Satcher noted that while CDC staff might have agreed that a particular study did not provide evidence that cost was a barrier, that was not a conclusion on the general importance of cost. Sen. Packwood let it go at that.

Sen Packwood -- If Cost is a Barrier, Why Are Some Immunization Rates High?

Sen. Packwood noted that immunization rates for three doses of DTP are much higher (20 percentage points) than for those for four doses, and asked why. Dr. Satcher argued that parents forgot their appointments for the fourth shot, which occurred later in the baby's life. Sen. Packwood asked if cost wasn't a barrier to the first three doses, why was it a barrier for the fourth? CDC reiterated that cost was a barrier, among several others. Sen. Packwood asked if cost was a barrier to immunization for preschoolers, whose immunization rates are around 95%. Dr. Satcher said he could not comment on why parents immunized children at five rather than two, but that it was important for health reasons to immunize two-year olds.

Sens. Braun and Breaux: Vaccination Saves Money, Focus on Costs Avoided

Sen. Mosely-Braun said it was difficult to document savings, but asked that CDC provide information about the amount of money saved by not having to react to disease outbreaks that were avoided by proper immunization. Dr. Satcher said the World Health Organization estimated eradicating polio would save $3 billion annually, and that polio eradication would save the U.S. $230 million a year. He said numerous studies showed the cost-effectiveness of vaccinations. Sen. Mosely-Braun said that it was important to remember these savings when discussing cost and immunizations.

Sen. Breaux agreed, and said that the focus should not be on cost as a determinant of immunization rates but on the cost of not immunizing children. He asked CDC what the cost would be if VFC had not immunized children, and how many children VFC had immunized that would not have otherwise been immunized. CDC replied that it was impossible to know that number, and Sen.

Packwood interrupted to note that as the program had begun only seven months ago it was hard to judge its impact yet.

Sen Moynihan: Why Involve the Feds?

Senator Moynihan said as the Congress worked on $500 billion in deficit reduction in 1993, the Administration said that it needed a new entitlement for vaccinations. This surprised him, as New York already had free vaccine, and Rostenkowski told him Chicago had it too, and he didn't understand why the Federal government would involve itself in something the municipalities had been doing for a century. He said he hoped we would get away from simple answers to complex behavioral problems. Dr. Satcher said that CDC was also trying to address behavioral issues with its educational campaigns and efforts to improve access to clinics and tracking systems.

Sen. Simpson: Do People Fear Needles?

Sen. Simpson suggested that low immunization rates in inner cities were caused by an association of needles not with medicines but with drugs. CDC staff replied that studies showed that only a very small percentage of parents don't want their children immunized, and that most of those cited religious reasons. He also noted that he had not come across such a perception in his work in clinics.

Other Witnesses

State health officials and the president of the Children's Health Fund criticized the program for offering free vaccination to children with health insurance but without coverage for vaccination only in Federally Qualified Health Centers. They said these are not always convenient. A State health official from Mississippi suggested rethinking the program and letting the States have more latitude, but the others said the program should be left as is and its problems fixed.

Distribution:

TO: Nancy-Ann E. Min

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

04-May-1995 03:24pm

TO: Gordon P. Agress

FROM: William L. Dorotinsky
Office of Mgmt and Budget, HD

SUBJECT: VACCINE PROGRAM FACES PROBLEMS OF MISSED OPPORTUNITIES

Date: 05/04/95 Time: 14:31

Vaccine Program Faces Problems of Missed Opportunities

WASHINGTON (AP) As many as 2 million American children under the age of 2 don't have all the vaccinations they need because of problems ranging from missed opportunities at the doctor's office to inadequate services for the poor, experts told a Senate panel on Thursday.

Even with the 7-month-old government Vaccine For Children Program, which provides free vaccines for uninsured, underinsured, Medicaid-eligible, and some minorities, many children still fall through the cracks, said Dr. David Satcher, director of the Centers For Disease Control and Prevention.

Dr. F.E. Thompson Jr. of the Mississippi Health Department told the Senate Finance Committee that physicians often do not check on whether their young patients have been vaccinated.

''A policy of stick 'em while you got 'em is critical,'' Thompson said.

Finding ways to track the children in their complicated schedules of immunizations is key, said Thompson, whose state just set up a computerized tracking system.

Many unimmunized children are the nation's very poorest. Often no one knows they don't have the shots since they have no central place where all their health care needs are met, said Dr. Irwin Redlener, president of the Children's Health Fund, a foundation which tries to establish comprehensive pediatric programs for some of the nation's neediest.

''These kids that we're dealing with are sick, they're extraordinarily disadvantaged, they're suffering terribly and they are not immunized,'' said Redlener.

''The kind of health care we're interested in for children is a comprehensive, continuity-based, organized system where the health provider becomes the medical home'' for the child, Redlener said.

The government vaccine program will help, the health officials said. But there is one key problem: Underinsured children whose families have insurance that doesn't cover immunization are

required under the program to go to specific federally qualified health clinics, not their own doctors or state health departments.

Such clinics ''are generally located in poor, inner-city or rural areas, relatively inaccessible to the large percentage of middle-class families that will fall into this category,'' said David Wood, a pediatrician practicing in an inner-city clinic in Los Angeles.

Thompson suggested the panel rethink the entire government program, and consider letting the states arrange vaccines themselves.

But others said the program must stay, just with glitches fixed.

''Our job now is to make the adjustments in an important program that will permit it to function with maximal impact and in the spirit intended by its original drafters,'' said Redlener.

APNP-05-04-95 1432EDT

The Children's Health Fund

FAX TRANSMITTAL SHEET

TO: Pam Cicetti

FROM: Irwin Redlener, MD

FAX #: (202) 456-~~2878~~ 1715

DATE: 5/4/95

Number of pages including cover sheet: 6

If there is any problem regarding this transmittal, please call Kathryn Sanders at 212-535-9707. Thank you.

Additional comments:

Pam -
Thanks a lot - please
pass on to Mrs. Clinton.
Best regards
Irwin Redlener
(also to Jennifer)

The Children's Health Fund

May 4, 1995

First Lady Hillary Rodham Clinton
The White House
Washington, DC 20500

Dear Hillary:

I hope this finds you well. I look forward to seeing you later this month.

This morning I had an opportunity to testify before the Senate Finance Committee on the Vaccine for Children program. This has been a difficult issue for me on a number of levels which I have shared with Donna Shalala, her staff and others. I have been, as constructively as possible, trying to clarify my own perspective on immunization which differs from the current operational perspective of VFC.

In essence, while the cost of vaccine may be a problem for some working-poor families, the more intractable issues around underimmunization have to do with the millions of children who do not have a medical home or any regular source of health care where immunizations can be administered and tracked. I testified before Senator Packwood's committee as a strong supporter of the VFC, but in a modified form with several key changes which I believe are essential.

By the way, my written testimony had already received fairly negative feedback from folks in the administration; and, ironically a very negative reaction from some of our very large funders within the vaccine manufacturing industry. My assessment of the hearing was that Senator Packwood--and others--are looking to take VFC down for a variety of reasons, not the least of which is plain old politics.

What I am concerned about, however, is that there is a legitimate case to be made for de-emphasizing the focus on vaccine purchase. There ought to be a redirecting of resources toward solving some of the more challenging aspects of ensuring a medical home for children who are profoundly medically underserved and at greatest risk for underimmunization.

Here's my strategic suggestion:

I think the administration should declare a victory in "Phase I" of the VFC program. In many cases, the availability of subsidized vaccine has helped families for whom affordability was a problem. **We should now move to "Phase II" of the VFC program which would:**

- move more VFC money to infrastructure and resource development;

- suggest that states devise ways to require all family health insurance policies to cover recommended childhood vaccines;

- attempt to close loopholes which currently permit states to use public resources for supplying vaccine to insured or well- off families; and,

- encourage and support innovative ways of really reaching underserved populations.

Such a "Phase II" approach could have a number of major beneficial results. For one thing, we would really begin maximizing resources to get to the kids who most need assistance. In addition, it would pre-emptively neutralize the biggest and most legitimate argument made by opponents of VFC. Finally, it would put the administration out front on this issue.

I would be happy to provide you with some additional information on this matter. Perhaps a "Phase II" approach would be helpful in cooling things down, moving the program forward and gaining some new allies in the process.

Best regards,

Irwin Redlener, MD

IR: kms

enclosure

The Children's Health Fund

March 24, 1995

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Shalala:

It was good to see you earlier this week at the White House. I want to take this opportunity to review our position on national immunization strategies.

My observations and concerns on this matter in general and the VFC program in particular are based on nearly 25 years of experience in caring for some of the most disadvantaged and medically underserved children in the country. At this time, we are running the country's largest health care program for homeless children here in New York, in addition to intensive medical services for children in South Central LA, Anacostia in D.C., south Florida, Newark, rural Mississippi, West Virginia, Dallas and the South Bronx.

Immunization status in children is, of course, a determinant of vulnerability to vaccine preventable disease. But from the public health and policy perspectives, immunization status is one of the better markers of accessibility to good quality primary care in children. This is a key concept: children who have "medical home" type comprehensive, continuity-driven health care have an excellent chance of being up to date in their immunization schedule.

Conversely, the most important reason why millions of children are behind in their immunizations, from my point of view, is that they do not have a regular source of medical home type pediatric care. Isolated, categorical programs to vaccinate children without attending to their source of on-going care problems either (1) fail to provide a way of sustaining immunization levels or (2) do not reach the most vulnerable and intractably unimmunized populations.

I have been arguing this point for years with many people in government, including my friend Walter Orenstein at the CDC. Isolated immunization programs may actually reduce the incentive for parents to identify and utilize a pediatric medical home for their children, thus depriving those kids of a variety of other necessary health care services.

The VFC program is a concept which has become, in my judgement, increasingly irrelevant to the extraordinary needs of children most likely to be partially or totally unimmunized. The VFC program does nothing for my patients who, until they get into a medical home relationship, have as much as a 90% chance of being behind in their shots. This is true for homeless kids in New York and children living in rural isolation and poverty in the Mississippi delta.

VFC helps parents who are, for the most part, already in private pediatric practices, but without insurance coverage for vaccines. What does the program do for the five to ten million children who simply have no doctor? These are the children about whom I am most desperately worried.

My point is that if we have money to improve immunization rates, let's use as much of that as possible to give children access to complete health services. It is health care, not vaccines, that should be guaranteed for children by government.

Many states are taking advantage of provisions in the VFC program, and are doing so in ways which represent a gold mine for insurance companies. The latter are "off the hook" in terms of covering vaccine since it will simply be paid for by the government, irrespective of family financial status.

Donna, I am deeply worried that VFC is a program in trouble. Some of the criticism is legitimate; some is politically driven and dangerous. I think, however, that the program can be fixed to do what was intended without some of the flaws currently inherent in its design.

I am hoping that our meetings with you and/or your staff will allow us to suggest some possible mechanisms to fix VFC in ways that will keep all of us who care about children on the same wavelength.

Sincerely,

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

DEPARTMENT OF HEALTH & HUMAN SERVICES Chief of Staff

Washington D.C. 20201

FACSIMILE

DATE 5/4

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

Jen - looks like

Diana Fortuna

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

Melissa S is on the case - see p 2. -Diana

Tiep Hoang

RECIPIENT'S FAX NUMBER: ( ) 456-7028

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 9

COMMENTS.

Karen - FYI.

5/3

NOTE TO JAKE SIEWERT --

As discussed, Dr. Satcher and Dr. Orenstein will be testifying on the VFC program tomorrow -- I'm planning to wrote up some talking points after we get final clearance on their remarks from OMB.

In the meantime, I've attached some "generic" VFC talking points, and some of the supportive letters we've solicited from the American Academy of Pediatrics and the March of Dimes. We plan to distribute these to reporters tomorrow, along with the testimony and the child immunization fact sheet.

Please share these with Ginny, and let me know if you need anything else.

Melissa

Talking points - Vaccines for Children

The Vaccines for Children program is an important part of the broader Childhood Immunization Initiative. The CII includes five key strategies to improve preschool vaccination rates. These include improving the quality and quantity of vaccination delivery services; reducing vaccine costs; increasing awareness, community participation and partnerships; improving the monitoring of disease and vaccination coverage; and improving vaccines and vaccine use.

Improving preschool immunization rates is one of the Clinton Administration's highest priorities. Since taking office, the Clinton Administration has doubled funding, and guaranteed funds for new vaccines. Legislation to launch a new Childhood Immunization Initiative was introduced soon after President Clinton's inauguration. A specific goal was set for 1996: increasing vaccination levels for two-year-old children to 90 percent for the most critical doses. And a new program to provide free vaccines to millions of poor and uninsured children was instituted.

While child immunization rates have improved since the 1989-1991 measles epidemic, VFC is a key part of the national strategy to reach the one million American children who are not fully vaccinated by age two. A 1993 survey found that 33 percent of pre-school children (average age 27 months) had not received a full series of the three most critical vaccines (MMR, DTP and polio). About 45 percent had not received the HIB vaccine, which protects children against bacterial meningitis; and 84 percent had not been vaccinated against Hepatitis B, which causes liver disease.

As an integral part of the CII, the Vaccines for Children program focuses on making free vaccines more widely available, reducing costs and missed opportunities for immunization. In the past ten years, immunization costs have increased ten-fold: the private cost of a full series of immunizations increased from about $27 in 1983 to $270 in 1994. A Spring 1992 survey by the American Academy of Pediatrics showed that 43 percent of pediatricians had increased their referrals to public clinics for vaccinations in the preceding ten years, primarily because of costs.

Under the VFC program, vaccines will be provided free to children who are enrolled in Medicaid or uninsured, and to native Americans and Alaskan natives. That means that physicians will no longer have to refer uninsured children to public clinics, a common practice that means missed opportunities for immunizations and fragmented care. And parents can choose which provider makes the most sense for their child, because the difference in price between the two settings ($270 and $129) won't be a factor.

This will make a tremendous difference for nine million uninsured American children. While Medicaid recipients can receive free vaccines under current law, working families have not had the same guarantee. Under VFC, more than one million infants and toddlers without insurance will now be guaranteed free vaccines, and their parents will pay only a modest administration fee. And because ten percent of all American children don't have health insurance, VFC will also help millions more older children who need follow-up vaccines at age four and fifteen.

Under VFC, every eligible child will receive vaccinations, even if parents cannot afford to pay the administration fee. Private doctors will continue to serve their regular patients, even if the parent or guardian cannot afford to pay the administration fee. Other needy children will not be charged a fee in public clinics.

In addition, VFC will provide free vaccines to children with limited insurance in rural health clinics and Federally Qualified Health Centers. In these settings, additional children whose insurance plans don't cover vaccinations will continue to be eligible for free vaccines.

Funds for new vaccines will automatically be provided. Under VFC, new childhood vaccines recommended by a federal advisory committee will automatically be purchased by the federal government and provided free to eligible children -- and budget constraints will never again limit or delay federal purchase of new vaccines.

States will be able to save money by ordering vaccines at the lower, government price. Because VFC will lower states' Medicaid costs for vaccines, these savings can be used to keep clinics open longer, or take other measures to increase immunization rates. And more states will be guaranteed the lower CDC price for the vaccines they do purchase.

Child immunization protects children and saves money. For example, every dollar spent on the MMR (measles/mumps/rubella) vaccine saves $21 in potential health care costs. For the DTP (diphtheria/tetanus/pertussis) vaccine, the cost-benefit ratio is 30 to 1. And for polio, it's 6 to 1.

March of Dimes
Birth Defects Foundation
National Government Affairs Office
1901 L Street N.W., Suite 350
Washington DC 20036
Telephone 202 659 1600
FAX 202 296 2964

May 3, 1995

The Honorable Bob Packwood, Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Mr. Chairman:

It is my understanding that the U.S. Congress is reviewing the effectiveness of the Vaccines for Children Program. The March of Dimes has particular interest in this program because our mission is to improve the health of babies by preventing birth defects and infant mortality. Timely childhood immunizations can do both. Our history includes efforts to prevent polio, as well as to eliminate rubella and the serious birth defect congenital rubella syndrome. We also believe no babies should die of measles -- as many did in the 1990-91 epidemic.

When fully implemented, the Vaccines for Children Program would ensure that poor and uninsured children have financial access to all necessary vaccines. While rates of childhood immunization for individual vaccines have improved over the last few years, only two-thirds of children are fully immunized (4 DTP, 3 polio and 1 MMR) by their second birthday.

The Federal childhood vaccine program funded through appropriations for local health departments has long fallen short of the need. For example, before the Vaccines for Children Program was initiated, the federal distribution for the Hib meningitis vaccine was inadequate for three years after it was put on the market. Health departments had to ration the vaccine, rather than protect all children.

The shortfall in public funds was related to steady increases in the price of vaccines. At the same time, many uninsured working families paid double the public price for vaccines in private physicians offices. When they could not afford these prices, such families were sent to the already burdened health department clinics. The Vaccines for Children Program can help families receive affordable immunization services from their private pediatricians.

The Vaccines for Children Program can both save money for federal and state government and target needed immunizations to children who are uninsured and whose families cannot afford the out of pocket costs for vaccines. The Vaccines for Children Program provides relief to states, who can reallocate public health dollars for outreach, education and services. The federal law also correctly protects states' rights to purchase vaccines for all children at the Federal price.

It is important to remember that the Vaccines for Children Program was developed as a bipartisan compromise, including elements from the original Clinton Administration plan, as well as from bills introduced by Democratic and Republican Senators in the 103rd Congress (S.733 and S.732 introduced by Senators Reigle and Kennedy; and S.886 introduced by Senators Danforth, Kassebaum, Durenberger, Gregg and Bond).

As president of the March of Dimes, I urge you to work for continuation of the Vaccines for Children Program so that the goal of immunizing all our nation's children with age-appropriate vaccines can be reached by the Year 2000.

Sincerely,

Jennifer House

Dr. Jennifer L. Howse
President

American Academy of Pediatrics

Department of Government Liaison
American Academy of Pediatrics
The Homer Building
601 Thirteenth Street, NW
Suite 400 North
Washington, DC 20005
202/347-8600
800/336-5475
Fax 202/393-6137

May 1, 1995

David Satcher, M.D.
Director, Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30333

Dear Dr. Satcher:

The American Academy of Pediatrics, and, more importantly, the families we serve, urge your continued support for the Vaccine for Children (VFC) Program. Although the program is only in its infancy (8 months) and has had more than its share of growing pains, over 36 states have a complete program, with the remaining in various stages of development.

Until all children and adolescents have financial access to comprehensive health care, the VFC program provides an important remedy for obstacles to our nation's immunization initiative in 4 important areas:

1) it provides immunizations for the increasing number of children in working,middle-class families where dependent coverage is either not covered or dropped;
2) it assures that all eligible children will receive the benefits of newly recommended vaccines for school entry, thus strengthening immunity levels of the community;
3) it gives states the option to purchase additional vaccines to cover the so-called underinsured children who have typical insurance policies which don't include immunizations; and
4) it allows Medicaid and native American families to receive immunizations in a medical home.

The VFC Program is an integral part of this nation's goal of protecting its youngest citizens from the ravages of vaccine-preventable diseases. It must be viewed within the context of all other public and private health initiatives, each contributing an important element. A premature halt to the VFC Program in the absence of universal access to health care including immunizations, would leave many children in limbo and vulnerable to disease.

The VFC Program is deserving of your support.

Sincerely yours,

George D. Comerci, MD

George D. Comerci, M.D.
President

American Academy of Pediatrics
601 Thirteenth Street, N.W.
Suite 400 North
Washington, DC 20005

News Release

CONTACT: Marjorie Tharp
800/336-5475
202/347-8600

FOR RELEASE: May 3, 1995

BUDGET PROCESS THREATENS VACCINE PROGRAM

Washington, D.C. -- The American Academy of Pediatrics (AAP) is urging Congress to maintain federal funding for the Vaccines for Children (VFC) program, which provides free vaccine to children meeting certain requirements.

"Americans want fiscal responsibility," AAP President George Comeri, M.D., said, "and in this case, the economic sense comes from investing money in a preventive service now to avoid higher health care costs later."

The Senate Finance Committee will review the VFC program tomorrow, 9:30 a.m., 215 Dirksen, to determine whether funding should be cut or eliminated so that the savings can be used towards balancing the budget.

The VFC program, just 8 months old, guarantees free vaccine to children age 18 or younger who are Medicaid eligible, uninsured or Native American. Underinsured children are eligible if they receive care at a federally qualified health center.

According to the AAP, the VFC program addresses most of the barriers some parents faced in delaying their child's immunizations, such as:

- offering free immunizations for children in working, middle-class families where dependent coverage is either not included or has been dropped;

-more-

VFC PROGRAM
2-2-2

- providing states the option to purchase additional vaccines at a reduced price to cover underinsured children whose insurance doesn't include immunizations;
- allowing Medicaid and Native American families to receive immunizations in a medical home.
- assuring that all eligible children will receive the benefits of newly recommended vaccines for school entry, causing immunity levels in the community to strengthen.

"The truth is that medical science has done such a fantastic job of virtually eliminating these infectious diseases," Dr. Comerci said. "People have forgotten what it was like when diphtheria, polio and other contagious diseases were common.

"Clearly, vaccine manufacturers have shared in this success story. We must ensure that they are able to continue their research and development of new and better vaccines.

"But make no doubt about it, we still need the government's financial support for the VFC program to guarantee that our children, and subsequently the communities they live in, are free of preventable diseases.

"Immunizing children is a public health issue. Until all children and adolescents have financial access to comprehensive health care, the VFC program must remain intact."

The VFC program was appropriated $348 million for fiscal year 1995. President Clinton's fiscal year 1996 budget proposes $365 million.

# # #

The American Academy of Pediatrics is an organization of 49,000 pediatricians dedicated to the health, safety and well-being of infants, children, adolescents and young adults.

The George Washington University
WASHINGTON DC

CENTER FOR HEALTH POLICY RESEARCH

May 4, 1995

The Honorable John D. (Jay) Rockefeller IV
United States Senate

Dear Senator Rockefeller,

We are writing in response to your request for further information about our recent study, *Universal Childhood Vaccine Distribution: The Experience of Twelve States*. This study is the first comprehensive study of state universal vaccine distribution programs. It analyzes the 12 state universal pediatric vaccine procurement and distribution programs which were in effect during the 1993-94 time period.[1] The study has been cited by Dr. Irwin Redlener in testimony prepared for the Senate Finance Committee's hearing today on the Vaccines for Children (VFC) program. In his testimony Dr. Redlener states that our study "verifies" that the "VFC in its current form does not confront the factors responsible for severe under-immunization in the millions of children who have no regular source of care".

We would like to take this opportunity to clarify our findings. We request that both this letter and the full study (a summary version of which was sent to more than 250 state policy makers) be included in today's hearing record.

Study findings. As part of the study we conducted extensive interviews with state officials responsible for the administration of their state's childhood immunization programs. We found as follows:

- As Dr. Redlener notes, virtually all states with universal vaccine procurement and distribution programs continue to report barriers to childhood immunization that arise from factors other than the lack of availability of low cost vaccine. The only exception is Vermont, which has been able to provide a medical care home to nearly all children. Officials in that state reported that because vaccines are distributed free of charge to all pediatric providers, children are routinely immunized as part of their ongoing health care. Data available at the time our study showed that Vermont had the highest rate of childhood immunization among the universal states.

[1] Of the 12 states with universal programs that we studied, four are represented on the Finance Committee (Rhode Island, Wyoming, South Dakota and Alaska). Additionally, since October 1, 1994, five states and the Commonwealth of Puerto Rico have instituted universal vaccine purchasing and distribution systems. Of these, two (North Dakota and Illinois) are represented on the Finance Committee.

2021 K STREET, N.W., SUITE 800 • WASHINGTON, DC 20052 • (202) 296-6922 • FAX (202) 785-0114

However, state officials also uniformly reported that the universal availability of free vaccine was an essential component of their childhood immunization improvement efforts (Rosenbaum and Wehr, p. 73). Officials considered the availability of free vaccines to both publicly funded and office-based providers as a basic building block for all state pediatric immunization improvement efforts. State initiatives include both the expansion of the public administration infrastructure for children without health care homes, as well as efforts to improve the performance of office-based primary care providers in order to reduce the problem of "missed opportunities". According to the officials whom we interviewed, the problem of "missed opportunities" emerged as second most commonly reported barrier after inadequate pediatric primary care services for underserved children (Appendix 16, table 12).

It is our understanding that the fundamental purpose of the VFC program is to ensure that in all states there is a sufficient supply of affordable vaccine at least for Medicaid-enrolled, uninsured, Indian, and medically underserved children cared for at rural and urban health clinics. In this sense, the VFC program acts as a companion to other federal immunization initiatives including initiatives to improve infrastructure which are carried out by the CDC with appropriated funds. Were VFC funds to be reduced or eliminated, it would appear that the CDC would be forced to withdraw some or most funding for infrastructure improvements in order to once again buy vaccines for many of these children.

The task of improving childhood immunization levels a three-part undertaking. All three parts are of equal importance. One part is ensuring the availability of a sufficient and stable vaccine supply. Another is improving vaccination practices among providers. According to national statistics provide half of all care received by low income children is furnished by office-based physicians. The final task is the development of a strong publicly funded preventive health care infrastructure for children without a health care home. We believe that all three activities are essential. Given the enormous cost-effectiveness of pediatric immunization according to innumerable studies, we would recommend that the nation invest in all three legs.

Sincerely,

Sara Rosenbaum
Co-Director

Elizabeth Wehr
Research Associate

cc: The Honorable Bob Packwood
The Honorable Daniel Patrick Moynihan

STATEMENT

PRESENTED BY

LLOYD F. NOVICK, M.D., M.P.H.

FIRST DEPUTY COMMISSIONER

NEW YORK STATE DEPARTMENT OF HEALTH

HEARING BEFORE

THE SENATE FINANCE COMMITTEE

UNITED STATES SENATE
ON
THE VACCINES FOR CHILDREN PROGRAM

THURSDAY, MAY 4, 1995

ROOM 215

DIRKSEN SENATE OFFICE BUILDING

WASHINGTON, D.C.

Statement by Lloyd F. Novick M.D., M.P.H., First Deputy Commissioner, New York State Department of Health.

Good morning. My name is Lloyd Novick and I am the First Deputy Commissioner of the New York State Department of Health. I am here on behalf of Dr. Barbara DeBuono, Commissioner, New York State Department of Health, who serves on the Advisory Committee on Immunization Practices to the United States Public Health Service. I am pleased to have the opportunity today to present to the Committee New York's experience with the Vaccines for Children program (VFC). Since its inception a little over six months ago, VFC has become an important link in the chain of our efforts in New York to improve the vaccination status of our children and, ultimately, to prevent unnecessary illness and death in these, our most vulnerable citizens.

We at the state level have designed a unique system which successfully serves children in New York. In our state, we have invented a vaccine distribution system which allows children to be vaccinated by their own pediatrician or family doctor, thus preserving continuity of care.

States should have the opportunity to design their own programs, and the federal government should continue to support state programs that have demonstrated track records of success. States can benefit from both federal assistance and flexibility in the design and implementation of programs of this type. I strongly recommend to you this morning that you continue to provide support for immunization of children to achieve our goal to eliminate vaccine-preventable diseases in this country. States need both federal assistance and flexibility in the design and implementation of programs of this type.

In recent years, New York children have suffered because vaccine preventable diseases were not prevented. In 1990 and

1991, we had the largest measles outbreak in recent memory with almost 5,000 confirmed cases and 24 deaths. In 1993 and 1994, we had the highest rates of pertussis, or whooping cough, in over a decade. The root of the problem is poor vaccination levels in preschool children. In New York, we have only recently achieved the level of 58% of two year olds up-to-date for the basic series of vaccines.

We take a very aggressive approach to childhood vaccination in New York. We adopted a routine 2-dose measles vaccination schedule before the rest of the nation. We were among the first states to require screening of pregnant women for hepatitis B and treatment of at-risk newborn babies, and we are the first to require routine hepatitis B immunization for entry into school.

The National Vaccine Advisory Committee's "Measles White Paper" in 1991 spelled out the barriers to timely preschool immunization. These run the gamut from educating and motivating parents to get their children vaccinated and making preventive health services available, to ensuring that these services are actually provided including ensuring that vaccines are available. We will not succeed by removing only one or two of these barriers; all are critical links in the chain leading to the goal of full vaccination coverage. In New York, we have aggressively attacked these barriers on all fronts, as outlined in the attachments to my testimony.

The focus of many of our efforts to improve vaccination status is the concept of a "medical home" for each child: a health care provider who the family can know and trust, and who is able to provide vaccinations and other preventive health services.

The Vaccine program is an important link in our efforts to build a partnership for immunization between public health and

the medical care community in New York. This partnership is vital because between two-thirds and three quarters of children in New York receive their routine medical care in the private and voluntary sector and not in public health department clinics. This is in sharp contrast to the situation our colleagues face in Mississippi and some other states where the vast majority of vaccinations are given in public health clinics. No amount of effort directed at the public health clinics in New York will solve our immunization problems because that is not where most children are vaccinated.

Despite the problems you may have read about in the newspaper with the federal VFC vaccine warehouse, New York's VFC program began on time last October and has grown rapidly into a major success. We have enrolled over 2,800 physicians and 478 health facilities including 95% of major Medicaid fee-for-service billers. We have shipped over 2.8 million doses of vaccine. We have begun a media campaign informing parents of the program highlighted by a television spot by the Harlem Globe Trotters.

Have we had problems? That goes without saying in a program of this magnitude. Overall, there have been remarkably few problems.

Have physicians embraced the program? The enrollment numbers speak for themselves. A recent satisfaction survey of 55 enrolled physician practices showed good acceptance of the program.

Will immunization levels improve as a result of VFC? Again, I believe the answer is yes, although the impact of VFC will be hard to separate from that of all of our other efforts.

There are a number of ways that we can already measure the impact of VFC in New York. First, we view VFC as more than a

vaccine distribution program and are already using it to educate enrolled providers on good vaccination practices. We have also taken steps to protect VFC vaccines by supplying many enrolled providers with continuous temperature recording thermometers. We have also seen a tremendous demand for hepatitis B vaccine suggesting that VFC has helped to speed acceptance of this vaccine. Steps like this will be increasingly important as new vaccines, like the chickenpox vaccine which requires lower storage temperatures and different handling practices than other vaccines, are introduced. We are coordinating VFC with immunization registry development and should be able to use the registry as an accountability tool in the future. We have also seen a tremendous demand for hepatitis B vaccine suggesting that VFC has helped to speed acceptance of this vaccine for routine use.

Finally, and most significantly, we have preliminary evidence that referrals for vaccination to public health clinics have declined dramatically. Data on vaccine usage from the first 37 counties for which they are available indicate an average 30% drop in vaccine administered in county health department clinics in December 1994 - February 1995, compared with the same time period in 1994. If this trend continues and is seen in other counties, it will provide significant evidence suggesting that VFC has reduced some referrals to public health department clinics.

I want to conclude by reiterating our support for federal immunization assistance in New York. The program is up and running in New York and is working well as an important link to improving our commitment to immunization for the sake of our children's health.

Thank you, and I would be glad to answer any questions.

NEW YORK VACCINES FOR CHILDREN (NY VFC)

STATUS REPORT

APRIL 1995

NEW YORK VACCINES FOR CHILDREN (NY VFC)
STATUS REPORT - APRIL, 1995

The 1993 Omnibus Budget Reconciliation Act created a new Federal vaccine entitlement program for children under the age of 19. This program is known as the Vaccines for Children Program, commonly called VFC. In New York, local funds are used to expand the program to include other categories of children.

Eligibility

A child meets federal VFC eligibility requirements in one of the following ways:

- as a Medicaid recipient,
- by not having insurance,
- being underinsured and visiting a Federal qualified health center,
- being an American Indian/Alaskan native.

New York VFC eligibility includes:

- underinsured children in any medical setting other than FQHCs.
- nonfederal eligible patients served at a local health department.

Doses Distributed

New York State and New York City implemented NY VFC and began enrolling providers in July 1994. On September 15, 1994, NY VFC was distributing vaccine to participating providers and facilities. Since October 1, 1994, the effective date for the program, free vaccine has been available to participating physicians and facilities in New York State for VFC eligible children. From September 15, 1994 NY VFC has shipped approximately 2.8M doses from the NYC DoH, NYSDoH depots and from the NYSDoH contracted distribution vendor. Combined federal VFC dollars for New York State and New York City equal approximately $30.5 million in calendar year 1995.

Provider Enrollment

As of April 27, 1995 a total of 2,836 physicians and 478 facilities have enrolled in the VFC program. The attached maps show physician and facility enrollment by county. NY VFC staff compared 1993 Medicaid billing information related to child vaccinations with our provider information. 2,160 providers billed Medicaid for childhood vaccinations in 1993. Of these billers, 1,482 are currently enrolled in the NY VFC. Of the 163 physicians who billed Medicaid for more than 1,000 immunizations in 1993, 95% are currently enrolled in NY VFC.

Patient Eligibility Estimates

In order to enroll in NY VFC each provider must estimate their patient population by eligibility category. The current summary of the provider profiles estimates of their patient eligibility status is compared to the statewide VFC eligibility estimates below

Provider Profiles		Statewide Eligibility Estimate
41%	Medicaid recipients	51%
15%	Uninsured	12%
1%	American Indian/Alaskan Native	.3%
1%	Underinsured served at a Federally Qualified Health Center	.3%
13%	Underinsured not federally qualified and served in a public clinic	10%
29%	Fully insured - not covered by VFC.	28%

Recruitment of Providers

NY VFC is recruiting physicians on an on-going basis. The following describe some of our efforts:

- at the request of District II of the AAP and the Preferred Providers and Children (PPAC) Advisory Committee we developed a question and answer form to respond to the most commonly expressed concerns about VFC,
- NY VFC recruitment advertisements have been published in professional newsletters,
- a second NY VFC recruitment mailing was sent to 4,034 non enrolled physicians (some of which may not be in active primary care practice) in January 1995,
- a mailing will be sent to members of the District II AAP who are not enrolled in NY VFC.

Consumer Campaign

- posters and pamphlets for waiting rooms and consumers are being distributed to inform consumers of this program.
- a public service announcements featuring the Harlem Globetrotters is being distributed to radio and television stations statewide.

VFC and Provider Referral Practices

One of the goals of the VFC Program is to eliminate the need for private physicians and other providers to refer their patients without adequate health insurance for immunization to public clinics. Encouraging the immunization by primary care providers of children in their "medical home" has been identified as a way to substantially reduce the "missed opportunities" that often result in delays in immunizing children. A random sample survey of NYS pediatricians and family physicians was conducted in 1993 to determine vaccination practices. Fifty percent of physicians stated that they referred all or some of their patients elsewhere for vaccinations. Eighty-eight percent of physicians who referred

patients for vaccinations indicated financial hardship to be a very important reason for referral. Fifty-four percent of physicians responding to the survey indicated that some or all of the costs of childhood vaccinations should be underwritten by government. (Refer to MD survey for referral information). Preliminary data from a number of county public clinics in New York State indicates that the number of children being referred to their clinics for immunizations has decreased since the implementation of the program (a decrease of 45% of vaccines were administered in the 5 public clinics for which we have data from similar time period BEFORE VFC & AFTER VFC implemented). This trend is expected to continue, thereby increasing the number of children who are immunized on time while visiting their primary care physician.

Less than 20% of all two year old children in New York State are served by public clinics. The vast majority of children are served by the private medical community. It is clear that the best route to increasing the number of children who are immunized on time is to forge a public/private partnership to address this issue. Without the active participation of private sector providers, any effort to improve the immunization levels in New York State will fall short of it's goal. The New York Vaccines for Children represents the best hope thus far for achieving an effective partnership in pursuit of our goal.

Satisfaction Survey

In order to monitor the level of satisfaction with the NY VFC Program we have developed a survey instrument which is used by Department of Health field staff when contacting participating providers. This "satisfaction survey" (see attached questionnaire) enables providers to describe their experiences with the program in a way that will both help identify aspects of the program that are effective or need to be improved and to ask physicians if they think the program will help their patients. The most recent survey conducted included 55 private physicians practices representing 181 individual physicians and 36 facilities (hospitals and clinics). Of those polled 87% of physicians and 77% of facilities indicated that the program's vaccine ordering system is convenient to use and a large majority felt that the operators reached through the toll-free number were knowledgeable and helpful. Survey responders also indicated that vaccines were received in a timely fashion and in good condition. Significantly, 89% of physicians polled stated that they felt that the VFC program was beneficial for their patients and 58% concluded that the enhanced vaccine administration reimbursement through VFC provided an incentive to serve Medicaid enrolled children. Ongoing use of the survey will allow the program's administrators to see "how they are doing" and to respond quickly to participant's problems. Complete results of the most recent survey are represented on the attached sheet entitled "VFC Satisfaction Survey".

Vaccine Accountability

From the inception of the VFC Program it has been our intention to provide accountability systems that both represent responsible oversight of public funds and minimize provider burden. This is in part because State purchased vaccines are also being distributed in the system for which we need to maintain accountability. The specific issues that we want to be able to account for are proper vaccine handling to

minimize waste, appropriate use of specific funds by eligibility criteria and a decrease in patient referral practices away from the "medical home". The following systems currently are or will be implemented in New York State to assure VFC accountability:

- Pilot State working with CDC to develop accounting problems from doctor's offices that are not overly burdensome.
- Using vaccine ordering records to compare "orders" to "provider profiles" to determine if profiles should be amended. In most instances providers over estimated the number of children they serve. Ordering practices can be used to adjust the profiles.
- From aggregated provider profile information determine if patient status percentages are in accordance with the state population profiles. This has been done periodically and percentages are in line with previous statewide estimates.
- Review vaccine orders to determine that providers are not ordering vaccines in excess (three month supply) of their patient estimates. Specific vaccines such as pediatric DT and adult Hep B will have special edits attached to ensure that vaccines are not used beyond the CDC or NYS established policies.
- Periodically cross reference vaccine administration billing information from Medicaid with vaccine ordering and profile information from the same physician.
- Conduct random educational/technical assistance visits to providers to make available vaccine storage and safeguarding information as well as other pertinent issues about vaccine scheduling, contraindications, school immunization requirements etc.
- Conduct "spot checks" record reviews among providers whose ordering patterns/amounts are considered to be outside the norm of other similarly sized providers.
- Conduct periodic random audits of facility providers to review record keeping, vaccine handling and verification of provider profile information.
- Continue annual local health unit visits to review vaccine storage/handling and implementation of Standards of Pediatric Immunization Practices.
- Record instances of vaccine loss by provider name/site. Ensure those sites receive additional information/tips on vaccine safeguarding. If vaccine loss occurs frequently, make site visit or remove from NY VFC program.
- Determine through phone call or mail survey what vaccine safeguarding systems/policies are in place in sites where large quantities of vaccines are

maintained. As resources permit, provide those sites with temperature monitoring devices, model protocols,"day-glo"stickers to be placed on outlets and refrigerator, etc.

- Compare aggregate and individual vaccine orders by types of vaccines requested to determine if the "expected" ratio of vaccines appear. (example 5 DTP, 4 OPV, 3 Hep B, 3 Hib, and 2 MMR). Significant deviations from the expected ratio will serve as one means to select sites for office reviews.

Evaluation

The overall success of the NY VFC Program will be measured in a number of ways. We plan to continue to encourage recruitment of providers particularly those providing services to large numbers of eligible children; we will continue to assess immunization levels of two year olds both on a statewide basis as well as for selected subgroups of children; and we will monitor whether or not the NY VFC decreases the patient referral of children from their primary care provider to the local public health clinic as reported by physicians in a 1993 survey. The following are specific examples of plans to evaluate the program.

- Compare vaccine usage data of local health units from equivalent periods from prior to VFC and after implementation to determine if the program has resulted in decreased referrals to public clinics.
- Review Medicaid immunization claims by provider to determine enrollment in NY VFC.
- Continue statewide retrospective immunization survey levels of two year olds.
- Review immunization status of patients in VFC provider offices through the peer review project.

NEW YORK STATE IMMUNIZATION INITIATIVES

1989-1994

New York State Immunization Initiatives, 1989-1994

The period 1989 to the present has been a time of intense activity for the New York State Department of Health (NYSDOH) Immunization Program. The highlights have been efforts to fight the measles epidemic and to improve immunization levels in preschool age children through reduction of barriers to immunization, taking advantage of every opportunity for immunization, outreach to high-risk communities, and development of a vaccine ordering and distribution system for all health care providers. As examples of the degree of activity, doses of vaccine administered through the program have increased over 400 percent from 250,000 doses (1987) to 1,250,000 doses projected in 1994 and vaccine expenditures by the program have increased from approximately $1.5 million in 1986 to over $18 million projected in 1994.

The period has seen five major additions to the Public Health Law (PHL) affecting immunizations (mandatory perinatal hepatitis B screening, college immunization requirement, Haemophilus influenzae type b (Hib) day-care requirement, hepatitis B school requirement and insurance-mandated coverage for immunization), five major amendments to state regulations (those related to PHL changes plus two-dose measles requirements for kindergarten and health care workers) and three statements of departmental policy in the form of Health Series Memoranda affecting hospitals and other regulated facilities. Valid contraindications to immunization, outbreak control guidelines and required screening and provision of immunizations in health care facilities.

A timeline of highlights of immunization activities over the past four years follows:

1. February - June, 1989. Widespread measles outbreaks affecting 12 colleges and nine secondary schools with 91 cases and over 50,000 doses of measles-mumps-rubella (MMR) used in outbreak control. Total outbreak control costs exceed $1 million.

2. April, 1989. NYSDOH recommends routine two-dose measles immunization in advance of national advisory groups.

3. June, 1989. PHL 2165 mandates that all post-secondary students in the state provide proof of immunity to measles, mumps and rubella in order to attend college.

4. May, 1990. PHL 2500-e mandates screening of all pregnant women for hepatitis B and treatment of all exposed newborn infants.

5. June, 1990. Measles epidemic begins in New York City (NYC) and surrounding counties.

6. July, 1990. Amendment to PHL 2164 mandates Hib immunization for all children less than age five years attending child day care, nursery school or pre-kindergarten programs.

7. September - November, 1990. WIC immunization initiative in NYC in response to the measles epidemic. Ninety-five thousand four hundred fifteen children in over 100 WIC clinics had measles immunization status screened, 8,394 (8.8 percent) needed measles immunization and were known vaccinated as a result of WIC efforts (3,132 - 37 percent) or referred for immunization.

8. September - November, 1990. Hospital immunization initiative in New York City. Over 40,000 doses of MMR vaccine were distributed to 42 hospitals for use in nontraditional settings such as emergency departments in accordance with Public Health Law 2805-h requiring hospitals to screen and make available immunizations to all patients under their care less than 18 years old. Vaccine shortages were identified in some facilities as a barrier to immunization.

9. January, 1991. Statewide policy adopted to screen immunization status in all children attending WIC and vaccinate or refer those needing immunizations. WIC medical referral form updated to include dates of receipt of all vaccines.

10. April - November, 1991. Study of strategies to achieve immunization through WIC participation, funded by the Centers for Disease Control and Prevention (CDC) Infant Immunization Initiative grant. Attempted to give MMR to eligible children at six NYC WIC sites by escort to nearby pediatric clinic (two sites), triage to monthly WIC check pick-up until proof of MMR provided (two sites) or referral for immunization without other incentive (two sites). Six thousand children enrolled, 13 percent were eligible for measles immunization, and immunization was achieved in 79 percent (escort), 79 percent (check triage) and 35 percent (referral) by the end of the study period.

11. May, 1991. NYSDOH and NYCDOH successfully request an additional $1 million from CDC to address vaccine shortages in the NYC Health and Hospitals corporation facilities.

12. June, 1991. NYSDOH sponsors a one-day conference in NYC for hospital directors of pediatrics to discuss removing barriers to immunization within the health care system and encouraging provision of immunizations in nontraditional settings like emergency departments in accordance with PHL 2805-h. Notables attend such as Dr. Saul Krugman, professor emeritus at New York Univeraity and Dr. Walter Orenstein, director of immunization at CDC.

13. June, 1991. Informal telephone survey conducted of pediatric directors by DOH professional staff to elucidate barriers to immunization activities in hospitals. Salient responses include: high cost of vaccines in private sector and lack of specific reimbursement for vaccines in clinics and emergency departments, lack of primary care slots resulting in long waits for appointments, and reluctance to provide immunizations outside the primary care setting (e.g., emergency departments).

14. June, 1991. Section 405.3 of state regulations amended to require all workers in regulated health care facilities to provide proof of immunity to measles including two doses of measles vaccine. This was in response to widespread nosocomial measles outbreaks involving hospital staff: In 1990, 19 hospitals reported a total of 74 nosocomial measles cases, 26 involving staff. Four patients died who acquired measles in the hospital. Fifty-two hospitals were required by the State to adopt nosocomial outbreak control measures because of measles exposure. Over 22 hospital worker cases reported in 1991 including job titles ranging from pediatric neurosurgeon to housekeeper.

15. August - October, 1991. NYSDOH and New York State Department of Social Services (NYSDSS) conduct an immunization campaign in NYC using community-based organizations (CBOs) to outreach to high-risk, hard-to-reach populations such as minorities and illegal immigrants. In all, 31 CBOs participated and 77 clinics were held at various neighborhood sites, four Income Maintenance Centers and three NYS Housing Authority locations. Five thousand six hundred and five persons were immunized, 1,101 (18 percent) in the target preschool age groups (under five years old).

16. December, 1991. NYSDOH hosts a statewide Immunization Retreat involving representatives of local health departments, State agencies including the Departments of Social Services and Insurance, hospital and professional organizations, physician groups including FPAC providers, the pharmaceutical industry and CDC. The agenda involves universal provision of vaccine by the public sector, but discussion quickly focuses on the need for a written, comprehensive state immunization plan. The key components of the plan are discussed.

17. March, 1992. Health Series Memorandum establishing measles outbreak control policies in health care facilities is published.

18. April, 1992. Health Series Memorandum concerning state policy on valid and invalid contraindication to vaccination is published.

19. January, 1992. State Immunization Plan (later termed Immunization Action Plan) is developed and over 20 individuals or organizations representing health care providers, State/local adjunct health agencies, voluntary associations, child health advocates are enlisted to become coalition members to improve immunization levels of New York State's 0-2 year children.

20. December, 1992. NYSDOH hosts a National WIC/Immunization Conference in NYC attended by WIC and Immunization staff from each state and U.S. territory. Mrs. Cuomo was the Keynote Speaker.

21. April, 1992. One million two hundred fifty thousand dollars of NYS Public Health Campaign (PHC) funds are directed to immunization initiatives. Two hundred fifty thousand dollars of State funds are matched with Federal funds to create a total of $400,000 to support 11 community-based organization in NYC's highest risk neighborhood

to identify underimmunized children and to link them to primary care services. Seven local health units receive PHC funds to expand their clinic service hours, dates and locations to better serve underimmunized children.

22. February, 1993. Health Series Memorandum detailing requirements of Public Health Law 2305-h to screen and immunize, as appropriate, each child under 18 years of age who presents to a health care facility.

23. April, 1993. A random survey of 1,137 licensed pediatricians and family-practice physicians in New York were surveyed about vaccination practices. The responses from this survey provided information regarding adherence to the Standards for Pediatric Immunization Practices, physician attitudes about DOH Immunization initiatives such as vaccine availability and the development of a statewide immunization registry.

24. June - October, 1993. NYSDOH and DSS conduct a pilot study designed to access children under six years of age who receive AFDC benefits and review their immunization status. Three models are piloted in three locations in NYC. The study revealed that the children are both poorly immunized and receptive to the design of the project. The immunization levels of the children less than two years of age ranged between 20-30 percent and over 80 percent of the families brought the immunization records to the AFDC recertification site as requested. As a result, additional State-funded projects are underway in AFDC sites around NYS (see NBA below).

25. September, 1993 - The Immunization Program developed a PSA to encourage immunization of children by the age of two which features the entertainer Shari Lewis and her puppet Lamb Chop. This PSA is colorful and entertaining and portrays Shari Lewis and Lamb Chop in a birthday party celebration setting with balloons, streamers and a birthday cake. A humorous dialogue takes place between the two which informs parents of the need to complete a child's immunization series by their second birthday. When this PSA was distributed to TV stations statewide, the Growing Up Healthy Hotline experienced an increase in calls requesting information on immunizations.

26. 1993. Historic low point for measles incidence in NYS and nation.

27. 1993. Passage of Child Health Insurance Reform Bill mandating that regulated insurance companies in NYS cover routine pediatric primary care including immunizations (effective April 1, 1994).

28. 1994. The NYS DOH Immunization Program established contracts with the nineteen federally funded community health centers in NYS (exclusive of NYC). Each CHC was asked to perform two specific tasks: the first is to perform an assessment of the immunization status of children two years of age served at their centers; the second is to identify barriers that may exist in their practices that may be contributing to underimmunization. The goal of the

Program is to ensure that each of these CHC's institutionalize the process of assessing the immunization status of children two years of age and to identify and eliminate barriers that exist preventing children from being fully immunized.

29. April, 1994. Nineteen Neighborhood Based Alliances (NBA) receive State PHC funding to hire, train, and place outreach workers at local DSS AFDC sites to screen immunization levels and ensure lead poisoning tests are conducted for children less than six years of age. The outreach workers are responsible for referring and following up on children who are behind in their immunizations or who have not been tested for lead poisoning.

30. June, 1994. Immunization legislation passes which includes hepatitis B immunization requirement for school attendance (first State in the nations to do so), broadens the definition of who is eligible to consent for the immunization of a child to include adult family members other than the parent, and allows pilot testing to determine the feasibility of a statewide immunization registry.

31. October, 1994. Implementation of the New York Vaccines for Children Program (NY VFC). A Federal vaccine entitlement program for Medicaid and underinsured children is implemented at the State level and expanded with State and City funds to cover underinsured children and all patients seen at local health departments. An estimated 5,000 private physicians could benefit from the program by receiving vaccines at no charge to provide to their eligible patients. Parents who cannot afford the high cost of immunization will not have to be referred from providers to their local health unit for one aspect of their child's primary health care needs.

32. October 1994 - The Immunization Program sponsored a statewide conference entitled "Immunization in the Era of Health Care Reform" which occurred at the Mohonk Mountain House, New Paltz, New York. This one and one-half day conference was co-sponsored by the Medical Society of the State of New York, the New York State Academy of Family Physicians, the American Academy of Pediatrics and the New York State Association of County Health Officials. This program was designed to bring together physicians from the private sector to discuss the challenges of modern immunization practices in the delivery of primary care. Physicians attending this conference gained an in-depth understanding of the regulatory and clinical strategies designed to increase the immunization status of children by the age of two.

33. October 1994 - Since 1993, local health units have received funding for local Immunization Action Plans (IAP). To date, 70 new clinic sites have been added operating an additional 10,000 hours including 2,000 evening and 500 weekend hours. More than 1,000 outreach activities and 800 educational events have been conducted.

34. December, 1994 - The Immunization Program developed an educational campaign entitled "Kindergarten Registration" to assist in meeting the national goal of ensuring that more than 90% of New York's

two-year old children are adequately immunized by the year 2000. The objective of this educational campaign is to increase parent's awareness of the importance of age appropriate immunizations during kindergarten registration. The focus of this campaign is on the immunization status of younger siblings. The material to be handed out and discussed by the school nurse includes a parent flyer, story/coloring book and a stick-on-badge. The campaign was piloted throughout New York State during 1994 and is scheduled for implementation during the 1995-96 school year.

35. Spring, 1995. Three sites were selected for pilot school based adolescent Hepatitis B initiatives. Rural, suburban and urban based schools were selected by three county health departments to implement an educational and Immunization Hepatitis B pilot. School based clinics and referrals to healthcare providers will be measured to determine the best means to ensure adequate immunization coverage for adolescents. The pilots will take place in the fall of 1995.

PHYSICIAN VACCINATION REFERRAL PRACTICES AND VACCINES FOR CHILDREN

NEW YORK, 1994

Health Objectives for the Nation

Physician Vaccination Referral Practices and Vaccines for Children — New York, 1994

Although vaccinations are among the most effective preventive public health measures available, many children are not appropriately vaccinated on time (*1*). One identified barrier to timely vaccination is referral by primary-care physicians of children to other medical settings for vaccination (*2*). This report summarizes a survey by the New York State Department of Health of vaccination referral practices among New York physicians and describes the implementation in New York of Vaccines for Children (VFC), a national program making federally purchased vaccines available at no cost to health-care providers for administration to eligible children (*3*).

During April 1993, a random sample of 1137 licensed pediatricians and family practice physicians (total n=5392) in New York were surveyed by mail about vaccination practices. Of 752 (66%) responses, 502 (67%) were from actively practicing primary-care physicians. Of these, 250 (50%) referred all or some of their patients elsewhere for vaccinations. Of referring physicians, 228 (91%) referred patients to a local health department clinic; 169 (66%) had increased the number of patient referrals during 1983–1993, while seven (3%) had decreased referrals. In addition, 63 (25%) reported the number of well-child visits had decreased during 1983–1993, while five (2%) reported increases during that time. Reasons for referral were provided by 246 of the 250 referring physicians (Table 1) and rated as "very important", "somewhat important", or "not important". Financial hardship was "very important" reason for 217 (88%) of those surveyed; the lack of vaccination coverage by private insurance was "very important" for 132 (54%). Physicians also were asked whether the government should underwrite the cost of mandatory vaccinations. Overall, 409 (89%) respondents indicated that some or all of the costs of childhood vaccination should be underwritten.

Since October 1, 1994, free vaccine has been available at all participating providers in New York through VFC. Categories of federally eligible children include those aged <19 years on Medicaid, uninsured, underinsured who visited federally qualified health centers, and American Indian/Alaskan Native children. New York also extended eligibility to include underinsured children in any medical setting and any nonfederally eligible child served at a local health department.

Medical-care providers were recruited for VFC through articles published in professional organization newsletters and by mailing of registration packets to licensed pediatricians, family physicians, osteopathic physicians, and medical facilities. As of December 27, 1994, a total of 1378 physician practices in New York (including 1972 individual physicians and 382 health-care facilities) were participating in VFC.

To determine the extent of enrollment by Medicaid providers, the list of VFC enrollees was compared to a list of providers who billed Medicaid for childhood vaccines during federal fiscal year 1993. Of 2169 physicians who billed Medicaid for childhood vaccines in 1993, 1213 (56%) had enrolled. Among the 186 physicians submitting a minimum of 1000 claims for individual vaccines, 143 (86%) had enrolled, while 553 (68%) of 956 physicians not yet enrolled had submitted fewer than 50 claims.

Vaccines for Children — Continued

In September 1994, the New York State Department of Health conducted a telephone survey of health-care providers who had returned registration forms and declined participation in the program to determine reasons for nonparticipation and to guide future recruitment efforts. Of the 41 physicians who had declined, 29 (71%) were contacted. Of these, five (17%) were retired, five (17%) did not accept patients aged <19 years, six (21%) were subspecialists or in academic medicine and did not provide vaccinations, six (21%) indicated that most of their patients would not be eligible, and one (3%) had multiple reasons for not registering; six (21%) with patients who could benefit from VFC agreed to register as a result of the phone call.

From September 15, 1994, (the first date vaccines could be ordered) through December 27, 1994, a minimum of 2,496,000 doses of vaccine had been ordered and more than 2,456,000 doses were shipped to VFC participants. The average time between placement of orders and receipt of vaccine by providers was 1 week.

Reported by: HG Ciofalo, MD, GA Bunn, DR Lynch, SC Meldrum, MS, GS Birkhead, MD, New York State Dept of Health. S Friedman, MD, N Jentusky, MPH, D Morse, MD, State Epidemiologist, New York City Dept of Health. EE Schulte, MD, Albany Medical Center, Albany, New York. National Immunization Program, CDC.

Editorial Note: In the United States, coverage rates for vaccinating preschool-aged children against vaccine-preventable diseases are among the lowest in the world (*reference*). In New York, only 53% of 2-year-olds during 1989 were appropriately vaccinated with the recommended vaccines (*4*). Important barriers to timely vaccination include the high costs of vaccines and the referral of children from the private sector to the public sector, which delays vaccination. This report demonstrates that vaccination referrals, in part attributable to high vaccine costs, are common among New York primary-care providers. Implementation of VFC is expected to reduce these barriers.

TABLE 1. Importance of reasons for vaccination referral by physicians* — New York, 1993

Reason	Very important		Somewhat important		Not important	
	No.	(%)	No.	(%)	No.	(%)
Financial hardship for patient	217	(88)	14	(6)	15	(6)
Private insurance not covering vaccinations†	152	(54)	56	(23)	96	(24)
Free vaccine to physicians discontinued by health department§	110	(45)	34	(14)	102	(41)
High vaccine purchase price for physician	94	(38)	56	(23)	96	(39)
Insufficient Medicaid reimbursement	74	(30)	43	(17)	129	(52)
Vaccine availability	38	(15)	42	(17)	168	(68)
Vaccine-related liability	24	(10)	31	(13)	191	(78)

* N=248 of 250 physicians who reported referring patients elsewhere for vaccinations.
† As of April 1994, all New York State-regulated major medical health insurance policies, exclusive to self-insured entities, were required to cover all childhood vaccinations.
§ New York State Department of Health discontinued distribution of free vaccine to any physician through county health departments in 1988.
Source: New York State Department of Health

Vaccines for Children — Continued

The actual number of VFC participants in New York probably is underestimated because many physicians work in facilities or in group practices where only the physician-in-chief is registered in the program. In addition, the impact of the program on vaccination coverage and overall occurrence of vaccine-preventable diseases cannot be determined yet. However, VFC has allowed New York to increase provision of vaccine to more children, and in states where vaccines have been made available for all children, vaccination rates of preschoolers are approximately 10% higher than the national average (AG Hollmann, University of Miami, unpublished data, 1993).

The Childhood Immunization Initiative has designated vaccination of preschool-aged children a national priority and has established a year 2000 goal of vaccinating at least 90% of children by age 2 years with the recommended number of doses of diphtheria and tetanus toxoids and pertussis, polio, *Haemophilus influenzae* type b, hepatitis B, measles, mumps, and rubella vaccine. VFC and elimination of barriers to vaccination are integral parts of this initiative and will assist physicians and other health-care providers in reaching this goal.

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3. CDC. Vaccines for Children program, 1994. MMWR 1994;43:705–9.
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Current Trends

Proportionate Mortality from Pulmonary Tuberculosis Associated With Occupations — 28 States, 1979–1990

The risk for occupational exposure to tuberculosis (TB) is increased among health-care and other workers exposed to persons with active TB, workers exposed to silica or other agents that increase susceptibility to TB, and workers in occupations associated with low socioeconomic status (SES). Accurate estimates of and surveillance for occupationally acquired TB are limited because most reports of incident TB cases lack occupational data. Although occupation is routinely recorded on death certificates, this information is not routinely coded and entered into vital statistics data files. To identify occupations associated with increased risk for TB mortality, CDC's National Institute for Occupational Safety and Health (NIOSH) used data from the National Occupational Mortality Surveillance (NOMS) database* to conduct a proportionate

*Through a collaborative project with NIOSH, the National Cancer Institute, and CDC's National Center for Health Statistics, the following 28 states have contributed occupation-coded death certificate data to NOMS for one or more years between 1979 and 1990: Alaska, California, Colorado, Georgia, Idaho, Indiana, Kansas, Kentucky, Maine, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, Utah, Vermont, Washington, West Virginia, and Wisconsin.

TO: Hillary Rodham Clinton
FROM: Jennifer Klein
DATE: 5/3/95
RE: Immunization Hearing

A brief update on my progress on the immunization hearing that will be held tomorrow before the Senate Finance Committee:

1. **Testimony.** As I wrote last night, the witnesses are: Dr. David Satcher from the CDC, a representative from GAO, representatives from the New York State and Mississippi Departments of Health, Irwin and Dr. David Wood (a pediatrician from Cedars-Sinai Medical Center).

   Here are the highlights of the testimony:

   - Satcher's testimony provides a strong defense of the program as well as solid analysis of the problems he was asked to address. He will also emphasize that VFC is only one part of the Childhood Immunization Initiative (which also includes investments in infrastructure and efforts to raise awareness about the importance of age-appropriate immunization).

   - Irwin's testimony is slightly better than it looked last night, but will still be very damaging. The other physician's written testimony discusses immunization rates and barriers to immunization and does not address problems in the VFC program specifically.

   - The State Health Officer from Mississippi will testify that cost and availability of vaccine are not problems in Mississippi. He will talk about the success they have had immunizing children at public clinics. The representative from New York will testify that, in New York, studies have found that cost is a problem and that the VFC program has substantially improved New York's ability to immunize children.

2. **Members.** In addition to the supportive Democrats on the Committee who will be at the hearing (Rockefeller, Graham, Pryor (who is trying to come), Moynihan and Moseley-Braun), we expect that Senator Breaux will be very helpful. As of this evening, Mack McLarty was supposed to call Breaux to thank him for his support.

3. **Groups and Governors Support.** We have letters of support for VFC that will be submitted for the record from: the Association of State and Territorial Health Officers, SmithKline, the American Academy of Pediatrics, the Children's Defense Fund, the March of Dimes and the American Public Welfare Association. These groups have been very active on the hill in preparation for the hearing.

As you know, we also have letters of support from Governors Engler, Dean, Sundquist and Carnahan.

We will continue to work with the groups and the governors. Unfortunately, we were unable to get support on the record from the Medicaid directors or the National Governors Association.

Senator Rockefeller will submit a letter from Sara Rosenbaum clarifying the findings of her recent study of the 12 universal purchase states. The study found that while barriers to immunization still exist in those states, the states have had tremendous success in increasing immunization rates because they provide free vaccine. Irwin uses the study incorrectly in his testimony by concluding that the study shows that: "VFC, in its current form, does not confront the factors responsible for severe underimmunization in the millions of children who have no regular place for health care. These are the children who really need assistance in getting and sustaining up-to-date immunizations."

4. **Press.** Finally, I have our press office and the HHS press office ready to field any calls.

Assuring that the Budgetary and Health Care Challenges that Confront the Nation are Evaluated Fairly and Equitably

WHEREAS the Congress is beginning a historical debate about changes in the Medicare and Medicaid programs at the same time the delegates of the White House Conference on Aging are meeting to develop aging and health policy recommendations for the Nation;

WHEREAS the health care cost and coverage shortcomings of the Nation continue to go unaddressed;

WHEREAS the need for health reform, deficit reduction and assuring the solvency of the Medicare Trust Fund are inextricably intertwined;

WHEREAS Democratic and Republican Members of Congress joined together before the Conference to express their support for the Medicare program and the need to strengthen it;

WHEREAS the President of the United States addressed the delegates of the White House Conference on Aging to further illustrate his commitment to and support for the Medicare and Medicaid programs, as well as to challenge the delegates to come together on a multi-generational, bipartisan basis to address the real problems facing this Nation.

THEREFORE, BE IT RESOLVED by the White House Conference on Aging that we should respond to our Government's challenge to help develop sound health and budget policy by recommending that any major proposal affecting the Medicare and Medicaid programs should only be considered in the context of broad-based health reform and should adhere to the following principles:

Proposals should above all not take our system backwards by reducing coverage for health care and long-term care, and should be designed to expand coverage and increase long-term care options;

Older Americans should be provided more choices for alternative health plans, but no proposal should have the effect of financially coercing beneficiaries into plans that do not guarantee access to their own doctors.

Quality must not be undermined by proposals to cut the Medicare and Medicaid programs;

Proposals should not produce cost increases to beneficiaries that make health care unaffordable;

Arbitrary deficit reduction targets should not be the driving force behind reform, but rather deficit reduction should be a logical outgrowth of sound health policy reforms; and

Savings from proposals that cut the Medicare and Medicaid programs must not be used to pay for tax cuts for our most well off citizens.

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TESTIMONY TO
THE UNITED STATES SENATE COMMITTEE ON FINANCE
CHAIRMAN, HONORABLE BOB PACKWOOD

MAY 4, 1995

IMMUNIZING AMERICA'S MEDICALLY UNDERSERVED CHILDREN: MEDICAL HOMES AND THE VACCINE FOR CHILDREN PROGRAM

By:

Irwin Redlener, M.D., F.A.A.P.
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Testimony - 5/4/95
Irwin Redlener, M.D.
Senate Finance Committee

Chairman Packwood, members of the committee, I am here to support the Vaccines for Children Program - but qualify this support based upon certain concerns which must be addressed by introducing a few important modifications. In general I am suggesting three over-arching goals for the program:

1. As increasing attention is paid to budget deficits and state versus federal control of public programs, we need to protect the integrity of the VFC program and health care access for children. The national agenda for children should not be undermined by multiple state interpretations of what America's children need. And, VFC should not be endangered by limitations related to possible fundamental changes in Medicaid structure.

2. We must safeguard against unanticipated consequences of the program as it is currently organized - including the use of precious resources in ways which will not accomplish the goals of VFC in the most efficient manner possible.

3. Conversely, we need to maximize all available resources -including those provided through VFC - so that the program targets the children most in need with expenditures targeted to address their specific barriers to health care and immunizations.

I am Dr. Irwin Redlener, director of community pediatrics and associate professor of pediatrics at the Montefiore Medical Center and Albert Einstein College of Medicine in New York. I have had some 25 years experience in delivering health care and developing programs for disadvantaged children.

I am also president of the Children's Health Fund, a foundation responsible for establishing comprehensive pediatric programs for some of the most medically underserved children in the nation, including the children of homeless, migrant and otherwise severely disadvantaged families in a wide range of communities.

Children's Health Fund programs operate in New York City; Newark, New Jersey; Dallas, Texas; rural Mississippi; West Virginia; South Florida; South Central Los Angeles; and Washington, D.C. These programs have, to date, provided nearly 180,000 medical primary health care encounters to our designated target populations.

The projects included within our network take children who have had very little organized, quality health care and provide them with care that is delivered by medical teams who are committed to quality and continuity.

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Senate Finance Committee

We ascribe to a notion that the care all children receive should be the kind of care we expect for our own children. This care should be comprehensive, preventive and organized. Immunizations should be administered at a place where the rest of their health care is delivered; where follow-up vaccinations and follow-up for medical problems can be tracked and managed. Where, if needed, specialty care and hospital care can be coordinated and ensured.

Pediatricians refer to this kind of care as being provided in a "medical home." It is the appropriate way to do what's right. It's what all children deserve to have.

Children without a medical home may get health care, but it is the worst kind of episodic, fragmented and expensive medical attention in emergency rooms and drop-in clinics. This kind of care typically entails little or no follow-up; and, it often does not happen until illness has progressed too far.

In other words, medically homeless children get the wrong kind of care, in the wrong places, at the wrong time. It is precisely these children, without regular, dependable access to primary care that are most likely to be underimmunized.

Conversely, the most important piece of evidence that a child is medically underserved is **underimmunization.**

In fact, our programs provide medical care to some of the most medically underserved children in the United States. For the homeless and extremely indigent children cared for by our flagship mobile unit program, the New York Children's Health Project, the immunization rates are devastating:

Some 90% of our pediatric patients, on their first visit to our program are behind in - or cannot document - their routine immunizations.

This is an extraordinary indictment of the health care system for indigent children and is, to our knowledge, one of the absolute worst immunization situations in the United States.

Actually, in all of our sites, rural and urban, immunization rates are terrifyingly low and, importantly, reflective of the sorry state of the child health safety net in the United States. It is my opinion, that because of factors ranging from lack of health insurance to severe maldistribution of health professionals, **at least 15 million children under the age of 18 years lack appropriate access to appropriate health care.**

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Senate Finance Committee

I need to emphasize this reality: in terms of the most significant causes for the nation's problems around immunizing our children, the cost of vaccine is not the major factor. **Rather, it is lack of access to a medical home type of health care relationship and the absence of a functioning child health care safety net in this country which are overwhelmingly responsible for our seeming inability to consistently protect our children through on-time immunizations.**

The Vaccine for Children Program (VFC) is clearly based on an essential and laudable principle that all children need to be immunized in an appropriate and timely manner. Our country cannot afford otherwise. President Clinton and his entire administration are committed to this goal and it needs to be achieved.

We are, therefore, strong supporters of the VFC but have insisted that it be modified in several important ways in order to enhance the program's ability to improve the nation's childhood immunization rates.

Modifications are necessary because of certain problems and issues which have become apparent as the program unfolds.

I would like to share with you my four principal concerns and specific recommendations to re-shape VFC:

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Concern #1

George Washington University's Center for Health Policy Research recently reported a study of immunization issues in 12 states where there is universal purchase of vaccine for all children. In these states, cost - associated barriers have been effectively dealt with as factors in underimmunization.

However, this study verifies our clinical experience in providing immunizations and primary care to underserved children around the U.S.: **VFC, in its current form, does not confront the factors responsible for severe underimmunization in the millions of children who have no regular place for health care.** These are the children who really need assistance in getting and sustaining up-to-date immunizations. They need medical homes.

You might look at the issue in this way: underimmunization is a symptom of lack of access to relevant pediatric health care. The real "treatment" for this problem is guaranteeing access to

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comprehensive health care where immunizations can be given over time and on-schedule.

For the 15 million medically underserved children in the United States the total amount of funds including the VFC program, Section 317 and other public sector initiatives is insufficient to meet existing needs. However, right now I am concerned that the relationship between funds spent on vaccine purchase versus new health provider capacity for disadvantaged children is not in appropriate balance.

Recommendation:

Congress needs to safeguard the total expenditure for vaccine-related programs so as not to jeopardize the long-term national agenda for children. **But, tax dollars should not be used to purchase or subsidize vaccines for families with sufficient income or insurance coverage.** These dollars should be re-directed to providing access to health care for as many medically underserved children as possible. **This means support for infrastructure that is, new capacity to provide comprehensive, primary health care. Such investments will help public sector provider systems become more consistent with the medical home model. At the same time, we need to ensure that funds to provide vaccines are always sufficient to meet the needs of the children identified as "at risk."**

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Concern #2:

The VFC purchase and distribution plan helps families who have a regular source of health care - pediatrician, family physician, clinic, etc. - but cannot afford or are not covered for vaccines in that setting. Some are directed to use public health clinics, thereby fragmenting care. Studies have shown that VFC can help many of these families. **But under current VFC guidelines, there is insufficient monitoring and oversight of under what circumstances and for how long these families would be eligible for free or subsidized vaccine. In addition, certain VFC provisions permit states to inappropriately use public funds to provide vaccines for insured or non-needy children.**

Recommendation

VFC should not offer opportunities for states to use limited public

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resources to provide free or subsidized vaccines to non-needy or insured patients. In addition, VFC funds should only provide vaccine to families until Medicaid or private insurance coverage is obtained.

Concern #3

The VFC program is, of course, a great assistance to private physicians and their patients since it eliminates the need to utilize public clinics for vaccinations. Yet, although the private practitioner benefits from the VFC as a government subsidy, **private doctors may still refuse to provide subsidized vaccine, or any health care, to Medicaid or low-income patients - precisely the children who are most in need.**

Recommendation

Physicians or clinics participating in any aspect of VFC should be required to accept children covered by Medicaid, children who are uninsured or those who are otherwise unable to obtain appropriate health care.

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Concern #4

Many insurance companies do not include immunizations in their family coverage. Companies may surmise that responsibility for the cost of vaccines will simply be assumed by a tax-supported program.

Recommendation

All insurance policies covering families, whether fee-for-service or capitated premium based, should be required to include all recommended vaccines for children.

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Members of the Committee:

As I stated earlier children need real medical homes. If every child in this country had a medical

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home, we would not have the unconscionably low immunization rates we experience in rural and urban areas around the country.

We need VFC. But it must be modified so that it can really take on and solve one of the most important challenges of our time.

Finally, it is my hope - and that of virtually every health professional and provider organization - that we can find a way to make sure that every child in the United States has access to appropriate and essential health care.

At the end of the day, it is health care, not vaccines, that should be guaranteed for children by government.

I know that the President and the Administration are deeply committed to VFC and access to health care for the nation's children.

Our job now is to make the adjustments in an important program that will permit it to function with maximal impact and in the spirit intended by its original drafters. In this day and age, where ever more children are vulnerable, endangered and facing an uncertain future, making VFC as effective as it can possibly be is the least we should do.

Thank you.

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TESTIMONY FOR THE SENATE FINANCE COMMITTEE.
MAY 4, 1995

Thank you Mr. Chairman for the opportunity to address you today on this important topic. My name is Dr. David Wood. I am a pediatrician practicing in an inner city clinic in Los Angeles called Para Las Americas. I am also a Assistant Professor of Pediatrics at UCLA at a health services researcher at RAND and Cedars-Sinai Medical Center in Los Angeles. I am the principal investigator on a CDC funded research project to diagnose the causes of under immunization in Los Angeles. The research team is composed of health sociologists, maternal child health experts, economists and statisticians from UCLA School of Public Health and Dept. of Sociology and RAND, Santa Monica, CA.

The major points I would like to make today are:

1. There continues to be a significant percentage of children who are under-immunized in this country, especially in poor, urban populations. A sustained and coordinated effort is needed by government and the private health care system to raise immunization rates and keep them high.

2. According to current research, the interventions most likely to make significant gains in immunization rates are those focused on the delivery and financing systems for well child care and immunizations. The primary goals of the interventions should be to; 1) increase the access for all children to timely well child visits for all preschool children; 2) increase financial incentives and reduce administrative barriers for well child care and immunizations for both providers and parents; and 3) improve the quality of well child care and immunization delivery by utilizing all opportunities to delivery the appropriate immunizations. Due to the complexity of the child health care delivery and financing systems, the accomplishment of these goals may require substantially different approaches for different health sectors.

A significant under-immunization problem still exists.

While surveys of immunization coverage conducted by the Centers of Disease Control and Prevention (National Health Interview Survey) have shown increasing rates of immunization coverage for the population as a whole, disparities in coverage persist.[1] Poor children, those from traditionally underserved minority groups, and those who live in urban areas are significantly less likely to be immunized than the general population. When these risk factors converge, as they do in many inner city areas, immunization rates are much lower than for other parts of the US. According to our data in Los Angeles, at 3 months only 70% of Latino and 51% of African Americans had received their first immunizations and by 24 months only 42% of Latino children and 25% of African American children were fully immunized.

However, these demographic indicators identify not only people-groups but also the health delivery systems that serve them. Research clearly demonstrates that the problem lies in these health delivery and financing systems. While we do know that variation exists in parental knowledge of immunizations and motivation to seek immunizations, parents of both immunized and unimmunized children are equally likely to value immunizations, believe in the seriousness of vaccine preventable disease and believe in their efficacy.[2,3] The data suggest that children are immunized not because of their parents' belief or motivation, instead parents rather passively follow the advice and direction of their doctors. Again, problems in the child health delivery and financing system are largely responsible for the under-immunization of preschool children in the US.

Moreover, rather than blame parents it is important to search for new methods to empower families to increase demand for immunizations with their providers, especially among particularly high risk populations. Health passports, distributed widely in Utah and recently instituted in California and case-management demonstration projects are all important pieces to the puzzle of more actively involving parents in the delivery of immunizations. These efforts need to be sustained long-term, and they must be coordinated with other educational efforts in WIC and other programs.

Where do we need to intervene?

It is imperative that we make the existing health delivery and health financing system improve its efficiency at delivering immunizations to young children. An important first step in this process is to promote timely entry into the well child and immunization system. We must reach the mothers before they give birth. Several studies have found that timely receipt of the first set of immunizations is related to receipt of prenatal care, early education at WIC visits during prenatal care, and receiving the appointment for the first well child visit.[4] Prenatal care provides a crucial bridge for a smooth and timely entrance to a series of recommended health maintenance visits. Increasing the connectedness between prenatal care and early well child care can be accomplished by 1) increasing access to prenatal care for poor, inner city families, 2) expanding access to WIC and other prenatal care education programs (such as California's Perinatal Case-management Program (CPSP) and 3) insuring the connection to a primary provider for the newborn with an appointment before leaving the hospital.

Making the well child and immunization delivery system work.

The American Academy of Pediatrics and EPSDT recommend 7-9 well child visits during the first two years of life, most of which correspond with the schedule for immunizations. Half of all

vaccines delivered in the public clinics in Los Angeles and almost all of the vaccines delivered in private doctors' offices occur during well child visits. However, in many areas the majority children receive less than adequate numbers of well child visits during the first two years of life, as few as two or three.[5] Moreover, even among those that receive adequate numbers of well child visits only approximately half receive the recommended vaccinations. Why isn't the health care system delivering these important services to our Nations' children?

To answer that question one must examine our complex child health delivery and financing system in several discreet sectors; 1) Medicaid fee-for-service, 2) Medicaid capitated systems, 3) private health insurance fee-for-service, 4) private capitated systems and 5) and the uninsured and the systems of care they access. Each of these sectors has a unique set of incentives and disincentives for the delivery of well child care and immunizations. I will examine the barriers to well child care and immunizations and potential interventions to raise immunization rates within each of these sectors.

Medicaid Fee-for-service.

Medicaid and EPSDT are the primary financing systems for well child care and immunizations for approximately 25% of America's children. In our study we found that African American children with Medicaid insurance were only one-fourth as likely to be fully immunized by 24 months as African American children with private insurance.[6] A 1990 American Academy of Pediatrics study of preventive services use by California Medicaid children found that only 20%-30% received preventive EPSDT services in the prior year.[7] Children on Medicaid are much less likely to have had a preventive health examination in the past year than privately insured children.[8]

Why is Medicaid so ineffective at promoting timely well child care and immunizations? The answer is primarily that Medicaid does not adequately reimburse providers for the services. Under Medicaid fee-for-services, reimbursement rates for well child care and immunizations are notoriously low and payments are often delayed.[9] State reimbursement rates to private providers for a vaccine and its administration average approximately one-half of the UCR for these services. Compared to UCR fees, the typical Medicaid program underpays physicians $40 to $60 per well child visit (physical examination and immunization administration). Medicaid payment rates for these services have eroded badly over the past decade as States have been slow to review and raise payment schedules. California has not raised the immunization administration fee in over a decade.[10]

As a result of these poor reimbursement rates providers are either neglecting to provide these services to their Medicaid patients as compulsively as recommended or they are increasingly referring patients to the public sector for these services. Under either

scenario, fewer and fewer children are receiving timely well child care and immunizations under the current Medicaid fee-for-service system.

Recommendation. Reimbursement rates for well child care and immunizations under Medicaid must be increased in order to promote their timely delivery. A state or federal based bulk vaccine purchase program is one vehicle to accomplish this. It has the substantial advantage of being cost-neutral. Under Medicaid fee-for-service programs, physicians purchase vaccine at the catalogue price and States reimburse providers for the catalogue price of a vaccine, approximately double the cost of the bulk purchased vaccine.[11] The substantial savings accrued under bulk purchase can be invested in increasing the administrative fees to providers. This approach was suggested by a California nonpartisan task force report in 1992.[12]

Thus, under a bulk purchase program positive incentives to private providers include relieving them of carrying the substantial cost of a vaccine supply, and raising reimbursement rates for vaccine administration. In States that already bulk purchase and distribute vaccine this approach has been successfully at increasing providers willingness to administer vaccine and reduce referrals to the public clinics.[13] Important factors in the success of a bulk purchase program are that; 1) the distribution system be efficient, and 2) providers not be overly burdened with eligibility determinations nor vaccine use reporting. The California Vaccines for Children has recently instituted a bulk purchase program with a private pharmaceutical distributor that appears to be user friendly and makes minimal paperwork demands on providers.

An alternative approach is to simply raise Medicaid fee-for-services reimbursement fees to providers for well child visits and for the administration of immunizations. However, this approach would entail substantial increases in costs in the Medicaid program.

Medicaid Managed Care.

We found the lowest immunization rates in the inner city of Los Angeles among children enrolled in Medicaid managed care.[14] Of children in HMOs only 33% were UTD. Between 1987 and 1992 states' total enrollment in Medicaid managed care more than doubled.[15] In December of this year approximately 2.5 million California Medicaid recipients will be switched from Medicaid fee-for-service to Medicaid Managed care.[16] The few studies that have examined Medicaid managed care indicate that it may or may not increase access to routine preventive services.[17] In some settings, access to well child care and immunizations may even deteriorate.

Private managed care premiums are established based on the cost of providing a determined set of benefits. Medicaid managed care benefits are set by federal regulation and are generally broader

than those provided in the private sector. In order to reduce costs, however, States set Medicaid capitation rates based capitation rates not on the costs of providing the benefit package but on a reduced percentage of expenditures in the Medicaid fee-for-service program. Moreover, to the extent that Medicaid programs are already among the lowest paying third-party payers, further discounting rates in managed care can leave providers without sufficient funds to provide needed care and may dramatically increase the incentive to under-serve.[18] Routine preventive services such as well child care and immunizations comprise a significant proportion of the capitated reimbursement during the first two years of life (after birth related health expenses), and they may be easy targets for under-service by plans.

Health Maintenance Organizations under managed care capitated contracts traditionally have actively promoted preventive services as a means to prevent more costly events in the future, such as a hospitalization for a measles infection. Indeed, Kaiser and other HMOs serving the middle class have some of the highest immunization rates in the Nation. However, under Medicaid managed care the incentive to provide preventive services is largely eroded by the extreme instability of the enrolled population. It is estimated that 10% of Medicaid AFDC enrollees loose Medicaid coverage each year.[19] When they regain coverage after of period of months, they are likely to join a different health plan, causing dramatic populations shifts among managed care plan. One managed care medical director characterized the problem in the following terms; "If our plan expends significant resources to bring children that are behind, up-to-date on their immunizations, which we do, we are doing the work the previous plan should have done, and we are saving money for the next plan in which the child will enroll six months from now"[20]

Recommendations. The Federal and State governments must structure the Medicaid managed care programs such that all children have access to well child care and immunizations according to the EPSDT guidelines. States should set Medicaid managed care capitation rates to insure that there are adequate resources to provide the mandated services at high quality. States must provide adequate oversight to Medicaid managed care plans. The Federal Health Care Financing Administration strongly criticized the State of California for its near complete lack of oversight of early experiments with Medicaid managed care.[21] Many abuses of Medicaid managed care resulted, including very low immunization rates in inner-city Los Angeles.

To increase the effectiveness of States' oversight of Medicaid managed care plans delivery of preventive services, States should requiring plans to report encounter based data on EPSDT services, including immunizations and population based immunization rates.. In the fall California passed legislation requiring this kind of reporting of all Medicaid managed care plans. To put teeth into the oversight process, States should provide financial incentives

to plans for raising immunization rates and providing other EPSDT services according to the guidelines as well as penalize plans that do not perform well. This program could be financed in part from the savings accrued from a vaccine bulk purchase program similar to the Vaccines for Children program.

Private Insurance system.

Approximately 60% of US children are covered by employee based private insurance.[22] A 1989 by the Health Insurance Association of America Survey found that only 45% of conventional employment based insurance plans covered basic childhood immunizations.[23] Health maintenance organizations provide much better coverage of well-child care, with 98% paying for immunizations.[24] Many states, including California, have passed laws in recent years to require employer based health plans to cover immunizations. However, up to 60% of employer self-insured health plans are exempt from state regulation under the Employer Retirement Income Security Act (ERISA) of 1974.[25] The combined effect of the lack of coverage in private insurance and rising vaccine costs and rising administration costs for providers has placed a significant economic burden on families. Rather than pay these costs, up to $500 dollars for the cost of the full set of childhood immunizations and their administration,[26] many families are opting to refuse immunizations at the private providers office. More and more private providers are referring families to the public clinics for immunizations, overwhelmingly citing cost of the vaccine to families as the primary reason.[27] This shift from the private to public sector has placed increase strain on an already overburdened public sector. Moreover, the added transportation and time costs will likely discourage many families from obtaining immunizations in a timely fashion.

Recommendation. The Vaccine for Children program makes provision for children with health insurance that does not cover immunizations, however, the program as designed also prevents them from receiving the immunizations at their private provider's office. Under the VFC program, children in this category can receive free vaccine ONLY at Federally Qualified Health Centers (FQHCs). FQHCs are generally located in poor, inner-city or rural areas, relatively inaccessible to the large percentage of middle class families that will fall into this category. Moreover, no provision in made in the VFC program to increase the capacity of FQHCs to handle the increase demand for well child care and immunizations.

A more rational approach would be to amend ERISA to give states the authority to mandate employer self-insured health plans to cover child preventive health services. This may not be politically feasible at this time. However, there are two private sector trends may reduce the children who have insurance but no coverage for immunizations. First, various forms of managed care plans, such as Preferred-Provider-Organizations, are rapidly replacing classic fee-for-service indemnity plans and a growing

percentage of these managed care plans cover child immunizations and well child care. Secondly, employer purchasing cooperatives are increasingly demanding outcomes based reporting or health report cards from health plans. All of these health report cards include child immunization coverage levels as one indicator of the quality of care provided within plans. In order to optimize quality ratings, more and more plans are voluntarily covering immunizations and well child care for children.

Uninsured Children.

Almost 15% of US children lack any form of health insurance. In our studies, lack of insurance is an important predictor of under immunization. Uninsured Latino children were only half as likely to be fully immunized by 24 months as privately insured Latino children.[28] There are two fairly distinct groups among the uninsured; the poor and the non-poor (the later is the larger group). The poor, uninsured are the traditional users of public clinics, which have become even more overburdened by the increasing numbers of referrals of privately and publicly insured children. While in our studies over half of poor, uninsured children utilized public health clinics for well child care and immunizations, almost 40% sought care at private providers offices. This number is certainly higher among non-poor, uninsured children. Families of non-poor, uninsured children face similar financial barriers to receipt of immunizations at their private doctor's office as we describe for insured but uncovered children. Many will seek free immunizations rather than pay the high cost of receiving the immunizations in the private sector.

Poor, uninsured families should qualify for EPSDT payment programs for well child care and immunizations at a private doctors office. The California EPSDT program covers children in families with incomes of up to 200% of the poverty line (approximately $28,000 annual salary for a family of 4). However, the California EPSDT program only reaches 30% of eligible poor children with well child or immunization services.[29] Few providers accept EPSDT clients due to low reimbursement rates, late payments, frequent and often capricious denial of claims and burdensome paperwork requirements. the billing requirements of EPSDT are also a significant barrier to physicians. EPSDT in California does not utilize standard CPT or ICD9 billing codes and therefore is not accessible to most office computer billing software.

The Vaccines for Children program allows provider to administer vaccine received at no cost to poor or non-poor, uninsured children. Providers are allowed to charge up to a $15 administration fee for each vaccine. Subtracting the cost of the vaccine product, the cost of immunizations for the parent will decline at least 40%. Some providers may reduce their administrative fee for uninsured families, further reducing the families' financial burden. This may allow many non-poor families to receive immunizations from their private providers.

For poor, uninsured populations eligible for EPSDT, the VFC program or similar bulk purchase program will strengthen the EPSDT program's financial incentive to providers by relieving them of the cost of advance purchase of vaccine and by increasing the vaccine administration fee (in California the fee is projected to rise from its current rate of $4.52 per vaccine to approximately $7.50 per vaccine). This may induce many more providers to participate in the EPSDT program or accept more EPSDT clients.

Recommendations. The VFC program could strengthen its provisions for uninsured children by reimbursing providers for both the cost of vaccine and its administration. This would eliminate the financial barrier to immunizations for uninsured children. However, since immunizations are generally delivered in private offices only accompanied by a full physical exam, the cost of the visit would still be born by the families. The EPSDT program will be significantly strengthened by the VFC program or a similar bulk purchase program. In order to induce the maximum number of providers into the program, EPSDT program should also dramatically reduce the paper work burden to providers though the institution of a simple, electronic billing capabilities similar to Medicaid or other health insurance, utilizing standard CPT and ICD9 codes.

The last major factor contributing to the low immunizations rates is an issue of quality, generally unrelated to the structure of health delivery systems or health financing systems. In many well child and other health care visits, children fail to receive the immunizations that are due. This is referred to as a missed opportunity to vaccinate. Missed opportunities to vaccinate are responsible for approximately 50% of the delay in immunization receipt.[30]
Children coming into public and private offices for well child care fail to receive the needed immunization at approximately 40% well child visits and at the vast majority of illness visits..[31] Studies have shown that even when children receive adequate number and timing of well child care visits, immunizations may not be received, resulting in significant delays in the receipt of immunizations.[32]

Why do providers miss so many opportunities to vaccinate? Data indicate that physicians and nurses do not adequately understand the immunization schedule.[33]. In our chart abstraction study nurses accurately assessed immunizations needed only 27% of the time. Secondly, providers have misunderstandings of what constitutes a contraindication to vaccinate a child, so that they frequently defer immunizations inappropriately.[34]

Recommendations. The CDC and the professional societies have already taken a number of positive steps to address the epidemic problem of failure to give the appropriate immunizations at a health visit. The AAP and the ACIP recently jointly published a simplified immunization schedule, making it easier for providers

to understand the schedule and assess a child's need for immunizations.[35] In addition, the CDC has published and disseminated the Pediatric Standards for Immunization Practices, which explicitly refute many commonly held misinterpretations of contraindications, and clearly delineate the true contraindications for each vaccine. These true contraindications are in fact, rare.[36]

The Standards need to be disseminated more widely and more clearly adhered to by providers in both the public and private clinical setting. In addition, education efforts for providers should be intensified to raise the knowledge level of providers on immunization practice. However, it is unlikely that simply making information available to providers will change their beliefs or their behavior.[37] Studies indicate that the dissemination of practice guidelines or clinical recommendations may not change provider beliefs or cause behavior to conform to the new recommendations.[38] Incorporating provider education on guidelines into an ongoing, active process of quality improvement would greatly increase the chances of successful adoption of clinical guidelines.[39] This includes, but is not limited to, active participation by providers in the construction and measurement of outcomes (e.g., immunization levels and rates of missed opportunities to vaccinate) in their own practices, and the institution of an evaluation and feedback process to measure the impact of policy changes. The American Academy of Pediatrics has produced simple but effective materials for providers to apply Quality Improvement principles to their delivery of childhood immunizations.[40] The CDC, through local health departments and Immunization Action Plans, should provide the technical leadership to institute the quality improvement processes in the public and private provider organizations. In order to do this in a cost effective manner our nation must invest in an automated data system that tracks immunizations and other important quality indicators on all children.

Conclusions

Immunizations rates remain dangerously low in the many areas in the United States, providing a potential reservoir of susceptible for disease epidemics. Our child health delivery and health financing systems are complex and interventions must be tailored to the specific delivery/financing system. It is imperative to assure that adequate financial incentives are built in to induce physicians to administer immunizations under all public and private health care delivery and financing systems. In Fee-for-service systems adequate first dollar coverage for well child care and immunizations must be provided at reimbursement levels adequate to cover provider costs and to induce them to participate vigorously in the delivery of these essential services. Managed care plans should be monitored carefully and performance based incentives should be built into capitation rates based on their documented well child care and immunization performance standards. High risk, poor and inner-city populations may continue to be

largely dependent on the public sector and may be more costly to immunize. Adequate support for basic public health infrastructure is crucial to the provision of high quality services to these populations and the prevention of future epidemics.

Thank you, Mr. Chairman for the opportunity to speak to your committee today.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR LEGISLATION
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PHONE: 690-7450 **FAX:** 690-8425

FROM: **TO:** Jennifer Klein

Department of Health and Human Services

Bridgett Taylor
Associate Director (Health)

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DATE: 5/3/95

PAGES: _____
(INCLUDING COVER)

Jennifer --

The outside groups which we have contacted are:

1. The Association of State and Territorial Health Officers.
2. The Academy of Pediatricians
3. The Children's Defense Fund
4. March of Dimes
5. The American Public Welfare Association
6. National Governors Association
7. Smith Klein (Vaccine Manufacturer)

All of these groups except for NGA agreed to do letters for the record. I will send you copies as they arrive. APWA's and Smith Klein's might not make it before the hearing, but they will get them in before the record closes.

The members we expect to be at the hearing tomorrow are:

Senator Moynihan
Senator Breaux
Senator Graham
Senator Pryor (maybe)
Senator Rockefeller
Senator Moseley-Braun
Senator Packwood
Senator Chafee
Senator Simpson

I left a message for Marsha Hobes in Intergovernmental and she hasn't returned my call. Our people in public affairs will contact Jake Seaword.

One additional piece of information on American Home Products. They are apparently floating an alternative to the VFC which they are saying will provide states with more flexibility. I've heard is similar to a block grant.

Let me know if you need anything else.

Bridgett

American Academy of Pediatrics
601 Thirteenth Street, N.W.
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News Release

CONTACT: Marjorie Tharp
800/336-5475
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FOR RELEASE: May 3, 1995

BUDGET PROCESS THREATENS VACCINE PROGRAM

Washington, D.C. -- The American Academy of Pediatrics (AAP) is urging Congress to maintain federal funding for the Vaccines for Children (VFC) program, which provides free vaccine to children meeting certain requirements.

"Americans want fiscal responsibility," AAP President George Comerci, M.D., said, "and in this case, the economic sense comes from investing money in a preventive service now to avoid higher health care costs later."

The Senate Finance Committee will review the VFC program tomorrow, 9:30 a.m., 215 Dirksen, to determine whether funding should be cut or eliminated so that the savings can be used towards balancing the budget.

The VFC program, just 8 months old, guarantees free vaccine to children age 18 or younger who are Medicaid eligible, uninsured or Native American. Underinsured children are eligible if they receive care at a federally qualified health center.

According to the AAP, the VFC program addresses most of the barriers some parents faced in delaying their child's immunizations, such as:

- offering free immunizations for children in working, middle-class families where dependent coverage is either not included or has been dropped;

-more-

VFC PROGRAM
2-2-2

- providing states the option to purchase additional vaccines at a reduced price to cover underinsured children whose insurance doesn't include immunizations;
- allowing Medicaid and Native American families to receive immunizations in a medical home.
- assuring that all eligible children will receive the benefits of newly recommended vaccines for school entry, causing immunity levels in the community to strengthen.

"The truth is that medical science has done such a fantastic job of virtually eliminating these infectious diseases," Dr. Comerci said. "People have forgotten what it was like when diphtheria, polio and other contagious diseases were common.

"Clearly, vaccine manufacturers have shared in this success story. We must ensure that they are able to continue their research and development of new and better vaccines.

"But make no doubt about it, we still need the government's financial support for the VFC program to guarantee that our children, and subsequently the communities they live in, are free of preventable diseases.

"Immunizing children is a public health issue. Until all children and adolescents have financial access to comprehensive health care, the VFC program must remain intact."

The VFC program was appropriated $348 million for fiscal year 1995. President Clinton's fiscal year 1996 budget proposes $365 million.

# # #

The American Academy of Pediatrics is an organization of 49,000 pediatricians dedicated to the health, safety and well-being of infants, children, adolescents and young adults.

American Academy of Pediatrics

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May 1, 1995

David Satcher, M.D.
Director, Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30333

Dear Dr. Satcher:

The American Academy of Pediatrics, and, more importantly, the families we serve, urge your continued support for the Vaccine for Children (VFC) Program. Although the program is only in its infancy (8 months) and has had more than its share of growing pains, over 36 states have a complete program, with the remaining in various stages of development.

Until all children and adolescents have financial access to comprehensive health care, the VFC program provides an important remedy for obstacles to our nation's immunization initiative in 4 important areas:

1) it provides immunizations for the increasing number of children in working, middle-class families where dependent coverage is either not covered or dropped;
2) it assures that all eligible children will receive the benefits of newly recommended vaccines for school entry, thus strengthening immunity levels of the community;
3) it gives states the option to purchase additional vaccines to cover the so-called underinsured children who have typical insurance policies which don't include immunizations; and
4) it allows Medicaid and native American families to receive immunizations in a medical home.

The VFC Program is an integral part of this nation's goal of protecting its youngest citizens from the ravages of vaccine-preventable diseases. It must be viewed within the context of all other public and private health initiatives, each contributing an important element. A premature halt to the VFC Program in the absence of universal access to health care including immunizations, would leave many children in limbo and vulnerable to disease.

The VFC Program is deserving of your support.

Sincerely yours,

George D Comerci MD

George D. Comerci, M.D.
President

March of Dimes
Birth Defects Foundation
National Government Affairs Office
1901 L Street N.W., Suite 260
Washington DC 20036
Telephone 202 659 1600
FAX 202 296 2964

May 3, 1995

The Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W. Room 615F
Washington, DC 20201

Dear Secretary Shalala:

It is my understanding that the U.S. Congress is reviewing the effectiveness of the Vaccines for Children Program. The March of Dimes has particular interest in this program because our mission is to improve the health of babies by preventing birth defects and infant mortality. Timely childhood immunizations can do both. Our history includes efforts to prevent polio, as well as to eliminate rubella and the serious birth defect congenital rubella syndrome. We also believe no babies should die of measles -- as many did in the 1990-91 epidemic.

When fully implemented, the Vaccines for Children Program would ensure that poor and uninsured children have financial access to all necessary vaccines. While rates of childhood immunization for individual vaccines have improved over the last few years, only two-thirds of children are fully immunized (4 DTP, 3 polio and 1 MMR) by their second birthday.

The Federal childhood vaccine program funded through appropriations for local health departments has long fallen short of the need. For example, before the Vaccines for Children Program was initiated, the federal distribution for the Hib meningitis vaccine was inadequate for three years after it was put on the market. Health departments had to ration the vaccine, rather than protect all children.

The shortfall in public funds was related to steady increases in the price of vaccines. At the same time, many uninsured working families paid double the public price for vaccines in private physicians offices. When they could not afford these prices, such families were sent to the already burdened health department clinics. The Vaccines for Children Program can help families receive affordable immunization services from their private pediatricians.

The Vaccines for Children Program can both save money for federal and state government and target needed immunizations to children who are uninsured and whose families cannot afford the out of pocket costs for vaccines. The Vaccines for Children Program provides relief to states, who can reallocate public health dollars for outreach, education and services. The federal law also correctly protects states' rights to purchase vaccines for all children at the Federal price.

It is important to remember that the Vaccines for Children Program was developed as a bipartisan compromise, including elements from the original Clinton Administration plan, as well as from bills introduced by Democratic and Republican Senators in the 103rd Congress (S.733 and S.732 introduced by Senators Reigle and Kennedy; and S.886 introduced by Senators Danforth, Kassebaum, Durenberger, Gregg and Bond).

As president of the March of Dimes, I urge you to work for continuation of the Vaccines for Children Program so that the goal of immunizing all our nation's children with age-appropriate vaccines can be reached by the Year 2000.

Sincerely,

Dr. Jennifer L. Howse
President

March of Dimes
Birth Defects Foundation
National Government Affairs Office
1801 L Street N.W., Suite 280
Washington DC 20036
Telephone 202 659 1600
FAX 202 296 2964

May 3, 1995

The Honorable Bob Packwood, Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Mr. Chairman:

It is my understanding that the U.S. Congress is reviewing the effectiveness of the Vaccines for Children Program. The March of Dimes has particular interest in this program because our mission is to improve the health of babies by preventing birth defects and infant mortality. Timely childhood immunizations can do both. Our history includes efforts to prevent polio, as well as to eliminate rubella and the serious birth defect congenital rubella syndrome. We also believe no babies should die of measles -- as many did in the 1990-91 epidemic.

When fully implemented, the Vaccines for Children Program would ensure that poor and uninsured children have financial access to all necessary vaccines. While rates of childhood immunization for individual vaccines have improved over the last few years, only two-thirds of children are fully immunized (4 DTP, 3 polio and 1 MMR) by their second birthday.

The Federal childhood vaccine program funded through appropriations for local health departments has long fallen short of the need. For example, before the Vaccines for Children Program was initiated, the federal distribution for the Hib meningitis vaccine was inadequate for three years after it was put on the market. Health departments had to ration the vaccine, rather than protect all children.

The shortfall in public funds was related to steady increases in the price of vaccines. At the same time, many uninsured working families paid double the public price for vaccines in private physicians offices. When they could not afford these prices, such families were sent to the already burdened health department clinics. The Vaccines for Children Program can help families receive affordable immunization services from their private pediatricians.

The Vaccines for Children Program can both save money for federal and state government and target needed immunizations to children who are uninsured and whose families cannot afford the out of pocket costs for vaccines. The Vaccines for Children Program provides relief to states, who can reallocate public health dollars for outreach, education and services. The federal law also correctly protects states' rights to purchase vaccines for all children at the Federal price.

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Sincerely,

Jennifer Howse

Dr. Jennifer L. Howse
President

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FAX 202 296 2964

May 3, 1995

The Honorable Daniel Patrick Moynihan
Ranking Minority Member
Committee on Finance
United States Senate
203 Hart Senate Office Building
Washington, DC 20510

Dear Senator Moynihan:

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Sincerely,

Jennifer House

Dr. Jennifer L. Howse
President

STATEMENT OF

F. E. THOMPSON, JR., M.D., M.P.H.

STATE HEALTH OFFICER
MISSISSIPPI STATE DEPARTMENT OF HEALTH

BEFORE THE

COMMITTEE ON FINANCE

OF THE

UNITED STATES SENATE

MAY 4, 1995

Mr. Chairman and members of the committee, I am F. E. Thompson, Jr., M.D., M.P.H., Director of the Mississippi State Department of Health. Prior to assuming my position as State Health Officer, I was State Epidemiologist and Chief of the Bureau of Preventive Health Services, which included our immunization program.

As a practicing public health professional with continued direct involvement in a statewide immunization program, I want to express my appreciation for the interest and support being given children's immunization by the President and the Congress. The increased resources already provided for childhood immunization are a clear indication of both the President's and the Congress's intent to protect our children against diseases no child should have.

CURRENT STATUS

Mississippi, a state with one of the lowest per capita incomes in the Nation, and one with limited public resources to address the prevention of disease, has achieved one of the highest immunization levels for its two year old children of any state. Compared to a national level of at most 71.6 percent of children who have completed their basic series of immunizations by the age of 27 months, Mississippi consistently documents approximately 76.1 percent of its 27 month old children having completed their basic series. One of our nine public health districts has already reached the goal of 90%, and two others are above 80%.

We know our immunization levels with confidence because we perform an annual statistically sound survey of two year old children's immunization levels. It is done using a probability sample selected from the entire birth cohort of two years prior to the year of study. The immunization records of the sample children are then located and examined so that we are able to demonstrate, with extraordinarily narrow confidence intervals, what our immunization levels actually are. Very few other jurisdictions perform such a statistically rigorous survey.

As depicted in Attachment 1, approximately 80 percent of Mississippi children receive all or most of their immunizations in health department clinics. Another five percent receive their immunizations in community health centers and other publicly funded clinics, and approximately 15 percent are immunized by private physicians. While we do not suggest that this is the best approach in every state or even in most states, it does demonstrate that immunization levels well above those found in most states can be achieved largely through public health clinics.

BARRIERS TO HIGHER IMMUNIZATION LEVELS

To achieve our goal of 90% completion by two years of age, we must look at the major barriers that have prevented higher levels of completion. The cost of vaccines has not been one of them. Mississippi's experience clearly demonstrates this. We have accomplished the high immunization levels we have, and can reach our 90% goal, without furnishing free vaccine to private providers. In analyzing the reasons why 24% of our two-year olds are not fully immunized, we have not found the availability of vaccine, or its cost, to be a significant barrier. MMR is currently the most expensive vaccine we give, yet in 1993, 86% of Mississippi children had received MMR by 27 months of age. Availability of vaccine is not the problem. Like all states, we purchase our public health vaccines through federal contracts at prices significantly below the retail prices paid by private providers. We have been able to provide immunizations to any child in Mississippi who wants to receive them through the health department at minimal charge ($5 per dose) for those who can afford it , and at no charge to those who cannot. We have had enough vaccine, and as long as new vaccines and cost increases are provided for, we will have.

The real barriers are (1) the complexity of the vaccine schedule, (2) our failure to track children's immunizations and remind parents of needed doses, (3) lack of accessibility of clinics and staff to give the vaccine, and (4) our missed opportunities to immunize many children we are already seeing. .

By addressing these real barriers and developing activities to get vaccine out of bottles and into children, such as reminder notices, outreach, checking records, and better clinic hours, one of our public health districts raised completion levels for all two-year olds from 58% to 80% in one year, without doing anything about the cost of vaccine.

The two most important barriers are actions not taken: Failure to track children's immunizations and missed opportunities. Overcoming these two barriers would take us to our national goal of 90% of children complete by age two.

Failure to Track Children's Immunizations

Because the immunization schedule for children is complex and requires at least 4 to 5 visits to complete, parents need help in knowing what shots their child needs, and in remembering when the next ones are due. Immunization tracking systems or "registries" can provide that help.

Mississippi has just implemented a computerized immunization tracking system or registry. Its purpose is twofold. First, it makes available immunization records of children to health care providers who see that child so that they can assess the child's immunization status and provide any needed immunizations. Secondly, and much more importantly, a registry allows us to track children's immunizations. We can then send notices to parents of immunizations about to be due, send additional notices to parents whose children fail to be immunized by a scheduled time, and identify children who are falling too far behind in immunizations so that we can make phone calls or home visits to get them back on schedule and protected.

Recalling children is a critical element in increasing immunization coverage. As noted in Attachment 2, in 1993, although only 76 percent of Mississippi two year olds were fully immunized by their 27th month, another 16 percent needed only one more visit to a clinic to complete their series. If we could have recalled these youngsters just once, we would already have reached the 90 percent goal. We can do so if we

develop tracking systems that allow us to identify and recall them.

Missed Opportunities

The other major area of emphasis is to avoid missed opportunities to immunize children. Missed opportunities fall into two main categories: 1) times when the child is seen in a clinic for other services and immunizations are due according to the schedule but the schedule is not checked and the child leaves without being immunized; 2) times when the child presents in the clinic for an immunization or for another service when the immunization is due and the provider realizes an immunization is due, but defers the immunization for inappropriate reason, such as "being on antibiotics" or a minor upper respiratory infection or any of numerous "false" contraindications that do not really preclude immunizations.

At one of our largest Health Department clinics we found that 50 percent of children being seen in that clinic had completed their basic series by 19 months of age, but if all opportunities to immunize had been taken and none missed, the percentage would have been 67 percent. This is illustrated in Attachment 3.

We have made it our policy in the Department of Health's clinics to assess a child's immunization status on every encounter for any of our clinic services and to "stick 'em while you got 'em" if any immunizations are due. Minimizing or eliminating missed opportunities is critical to raising our nation's immunization levels.

IMPLEMENTATION OF THE VFC

The main problems encountered with implementation of the VFC in Mississippi have been the numerous changes in the program before it was implemented, the added responsibility of the Health Department for distributing the VFC vaccine to providers, and the lack of private provider participation. We sent out 1300 enrollment kits to providers; as of today, 77 private providers have signed up.

The main success has been that we have at least implemented the program. Also, in some states, state medicaid matching funds previously used to pay for vaccines which VFC now covers have been made available for other uses.

EFFECT OF THE VFC ON IMMUNIZATION LEVELS

Even as originally proposed, the VFC would have had little if any impact in raising our immunization levels. The cost of vaccine was not the problem in the first place, and making more vaccine available at public expense was not the solution. However, as originally proposed, the VFC was at best overkill, and at worst wasteful, spending a huge amount of money for a minimal impact on immunization levels. As it now exists, at least in some states, the VFC itself stands to become a major barrier to improving immunization levels, and is very likely to lower them.

The reason for this is the restriction of VFC vaccine use to Federally Qualified Health Centers (FQHC's) for "underinsured" children, those who have health insurance which does not cover vaccine. Such children are the majority of those we see in Health Department clinics, and in most private practices. In Mississippi, as seen in Attachment 4, 53% of children have insurance, but that insurance does not cover vaccine. If those children have a private doctor, that doctor cannot give them VFC vaccine; if they come to the Health Department, which has clinics in every county in the state, we can't give them VFC vaccine. Under the program as it now stands, their doctor, or the health department must send them to a FQHC or give them non-VFC vaccine. For the private doctor, this means charging the patient or absorbing the cost. For the health department it is far more serious.

Vaccine for Health Department clinics has long been purchased with funds provided through the CDC under section 317 of the Public Health Service Act. With the advent of the VFC, 317 funds to health departments have been reduced, on the theory that VFC will replace them. In 1993, Mississippi received $3.2 million in VFC funds; in 1994, we got $3.9 million; for 1995 our allocation is $1.7 million. Meanwhile, we

have $3 million for VFC, but we can't use that vaccine for most of the children we see. We cannot immunize half the children coming to us with the 317 dollars available. And they do come to us. They come for the WIC program; they come for well child care; they come for immunizations because our clinics are convenient. Under the VFC as it now stands, we will be faced with turning these youngsters away. Rather than avoiding missed opportunities, the VFC will create them, and multiply them.

The VFC as presently constituted threatens to result in a working, successful immunization system being dismantled. It is a major concern on our part that federal efforts to increase immunization levels do not tear apart a system which is working well and which, if continued and improved upon will take us to the 90% goal before many other states.

The restriction of VFC vaccine for the majority of children to FQHC's is the reason many of our private providers have chosen not to participate in the program. Citing the fact that well over half their patients have insurance that does not cover vaccine, they tell us that it just doesn't help them very much, and it's not worth the trouble.

RECOMMENDATIONS FOR CONGRESSIONAL ACTION

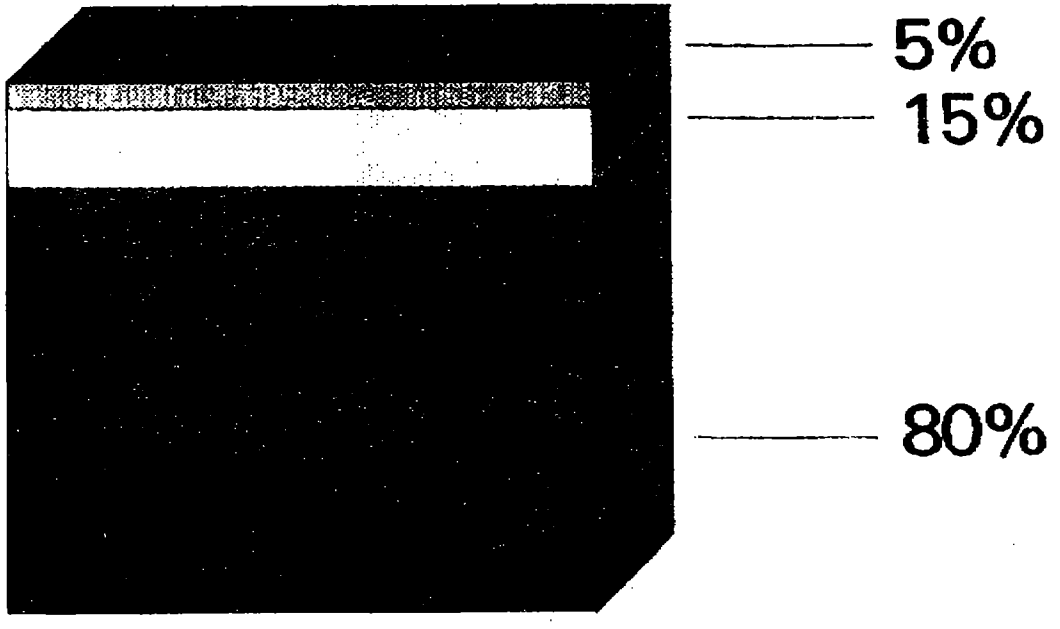
I recommend that this committee and the congress consider the wisdom of the VFC as a whole, in addition to examining the mechanics of its implementation and operation. If the VFC is to be left in place, I strongly urge this committee to recommend that the restriction of the use of VFC vaccine for underinsured children to FQHC's be removed. If it cannot be removed, at least extend the ability to give VFC vaccine to underinsured children to Health Departments. Otherwise the VFC, a well intentioned program, will do more harm than good.

Another critical action from our State's perspective is to restore funding of the 317 program to its pre-VFC levels. Finally, and also critical, if the VFC is left in place, any

changes made to it should preserve the ability of states to purchase vaccine at federal contract prices using state funds, at least for use in Health Department clinics. These two actions will at least insure that existing, working immunization programs are not impacted adversely.

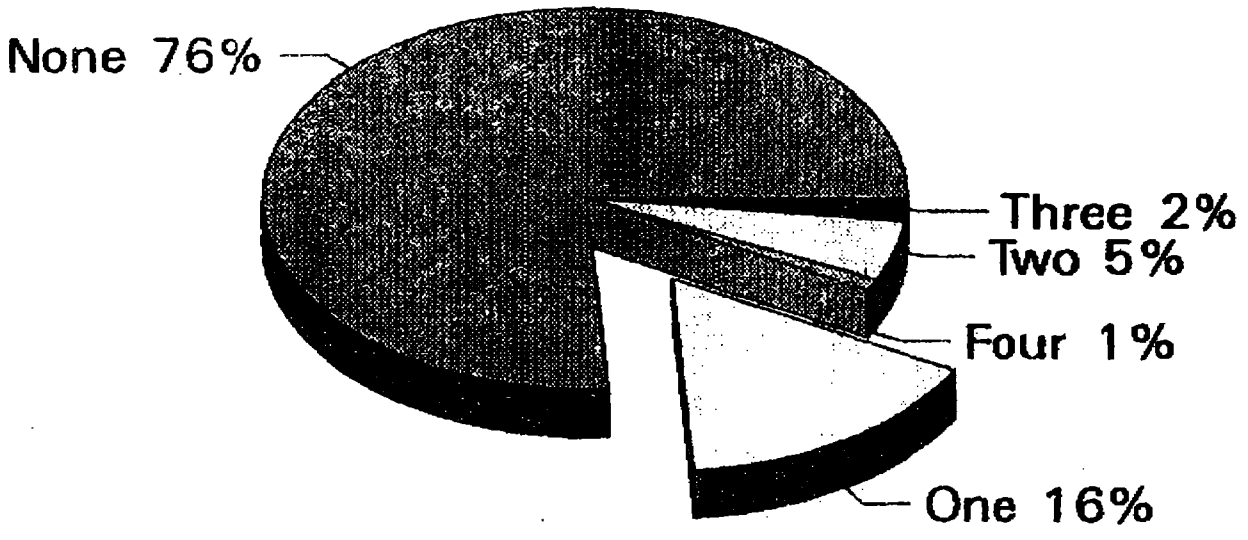
Source of Immunization

Mississippi, 1994



Attachment 1

Immunization Levels for Two-Year-Olds
by Number of Additional Visits Required to Complete
Mississippi, 1993



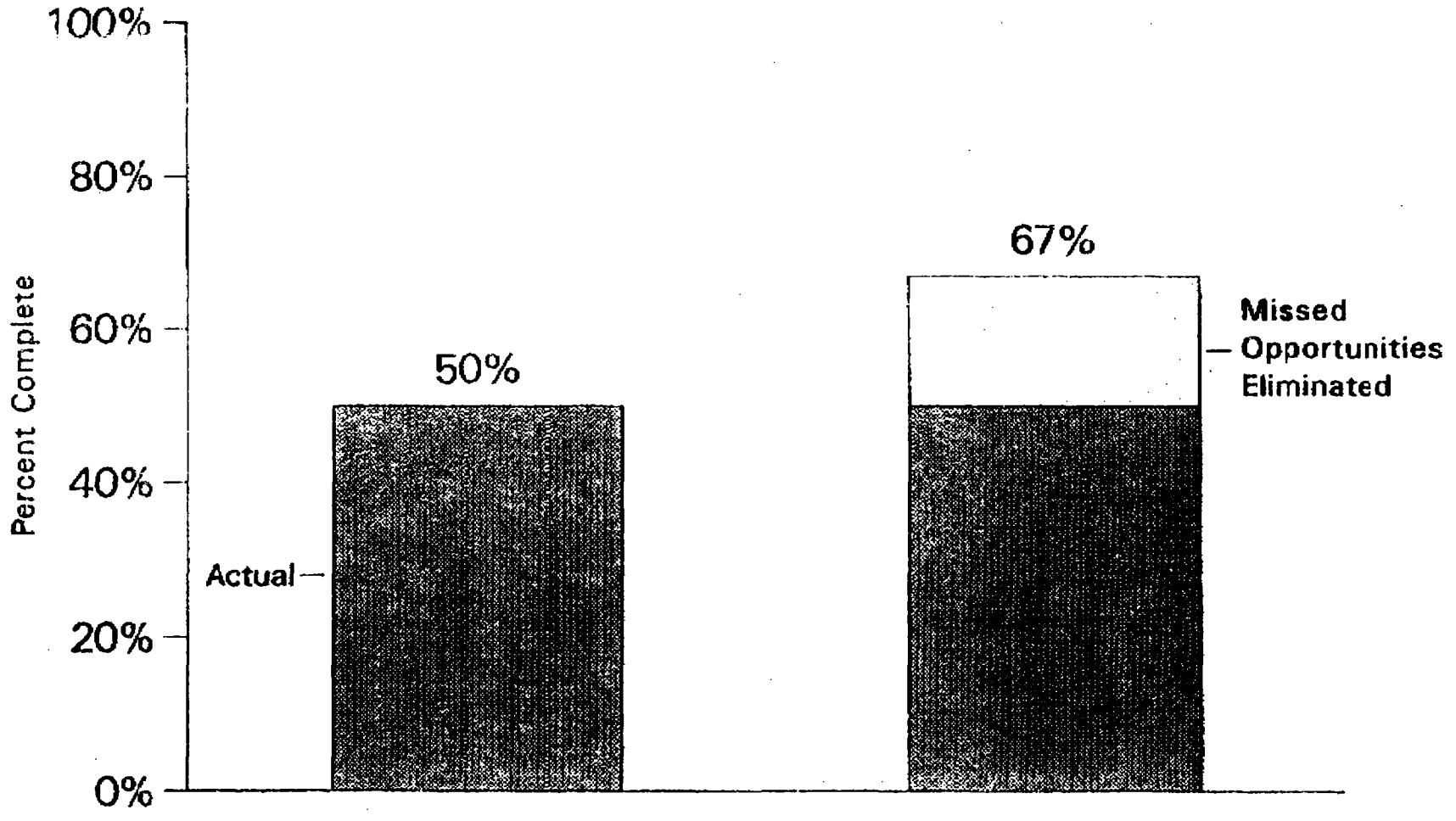
Source: Mississippi Immunization Survey of Two Year Olds

Attachment 2

HINDS COUNTY, MISSISSIPPI HEALTH DEPARTMENT CLINIC

Children Already Being Seen, 1993

19 Month Olds

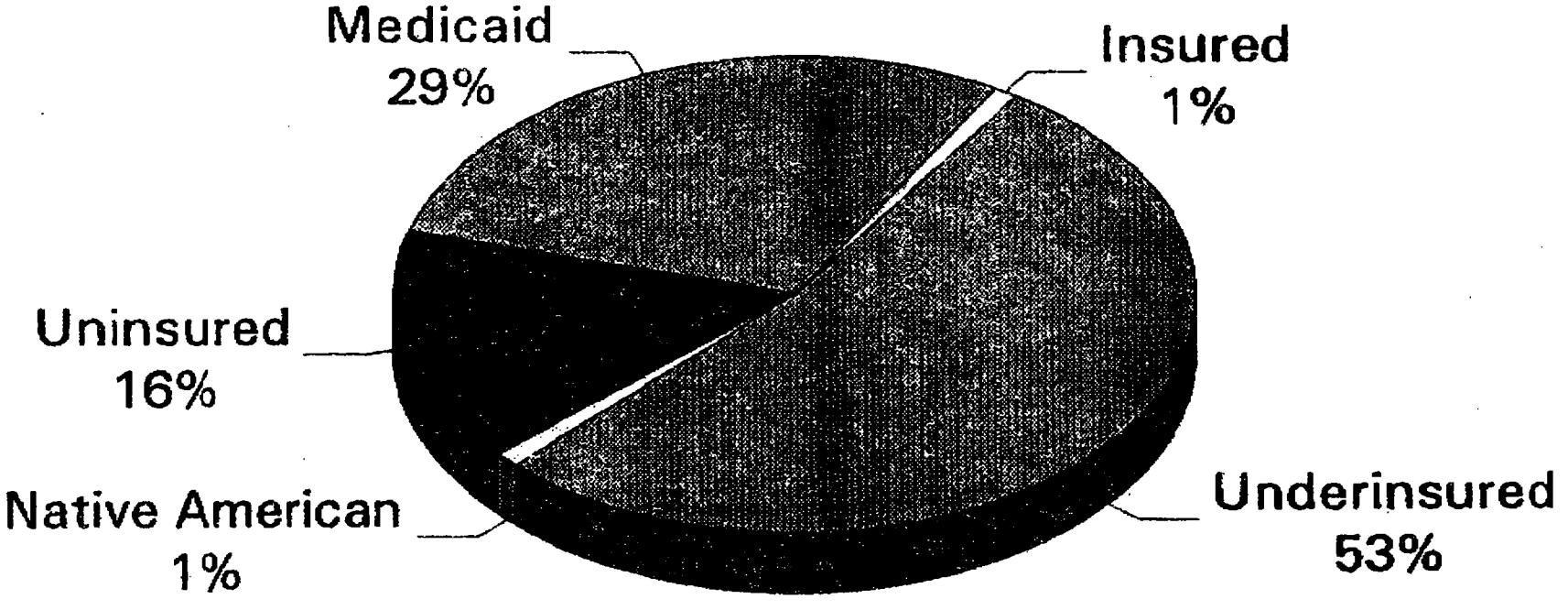


Source: Hinds County Health Department Clinic Audit, 1993

Attachment 3

Insurance Coverage

Mississippi, 1994



Source: Governor's Commission On Health Care Reform

Attachment 4

DRAFT - 6:10PM, 5/3/95 Doc. 51971

STATEMENT OF

DAVID SATCHER, M.D., Ph.D.

DIRECTOR

CENTERS FOR DISEASE CONTROL AND PREVENTION

BEFORE THE

COMMITTEE ON FINANCE

U. S. SENATE

MAY 4, 1995

Mr. Chairman, I am Dr. David Satcher, Director of the Centers for Disease Control and Prevention (CDC). I am accompanied by Dr. Walter Orenstein, Director of CDC's National Immunization Program.

Thank you for the opportunity to appear before this Committee to discuss childhood immunization. I am pleased to be here to tell you about the progress we have made since October 1 when the Vaccines for Children (VFC) Program became operational, according to law, and to clarify issues that have been raised in the process. Your letter asked that we bring you up-to-date on several issues, including successes and problems of VFC implementation, barriers to immunization, and impact of VFC on immunization rates.

IMPLEMENTATION OF THE VFC PROGRAM

The VFC Program began only 7 months ago. We have made significant progress.

- VFC is operating in all States.[1]

- Vaccine purchase contracts were signed with the manufacturers to provide vaccines for eligible children at

[1] Alaska, which already delivers vaccines to all providers in the State, is not participating in the VFC program. Alaska is able to use other Federal vaccine funds to purchase all vaccines for all children in the State.

discounted CDC contract prices for all vaccines routinely recommended for children.

- State Health Departments are rapidly enrolling public providers into the program. As of March, over 8,100 public sites, such as local public health departments, community health clinics, maternal and child health clinics, and public hospitals, in every State are participating in the program.

- Private providers are also being rapidly enrolled. As of March, over 21,000 private provider sites, many with multiple physicians per site, have enrolled so far. This is a 32 percent increase in private provider sites since the program began. We expect to increase the number of private providers enrolled as more States develop systems to deliver vaccine to private providers.

- The vaccine ordering system is working well. Over 1,700 bulk orders have been processed, totaling over $150 million in vaccine.

- Since October, over 13 million doses of children's vaccines have been shipped through the VFC program.

The good news is that we are making progress towards our goal of immunizing 90 percent of the nation's children against vaccine-preventable diseases. Our most recent immunization coverage information, from the first quarter of 1994, indicates that we are at record high levels of immunization coverage for two-year-old children. I believe if we stay focused, we will achieve our goal. → Imm. rates ↑

We still, however, have work to do. Our data tells us that about 600,000 to 2 million of our nation's children between 19 and 35 months of age still had not received recommended vaccinations against specific diseases. For example, about 2 million of these children had not received the full series of vaccinations. About 1.4 million of these children had not received necessary polio vaccinations. Table 1 presents these most recent vaccination levels and the associated estimates of children who have not received all recommended vaccines.

Table 1

Vaccination Levels and Estimated Numbers of Two Year Old* Children Not Fully Protected in the U.S., 1st Quarter 1994

Vaccine	Vaccination Levels (Percentages)	Estimated Numbers of Children Not Fully Protected
DTP 3+	87	800,000
DTP4	67	1,900,000
OPV 3	76	1,400,000
MMR	90	600,000
Hib 3+	71	1,700,000
4DTP/3OPV /1MMR	66	2,000,000

* Children 19-35 months old.

Note (1): A "+" next to a vaccine indicates 3 or more doses. For example, DTP 3+ is receipt of 3 or all 4 recommended DTP doses.

Note (2): Hepatitis B, although a recommended childhood vaccine, is not included in the table. The coverage for Hepatitis B was only 26%, leaving 4.3 million children not fully protected. However, many of these children were born before the Hepatitis B recommendations were in effect.

Recognizing that there are multiple barriers to childhood immunization, CDC and its State and other partners, developed a comprehensive approach to increase and sustain these percentages. The Childhood Immunization Initiative (CII) was launched in early 1994. CII includes five key strategies that will 1) improve the quality and quantity of vaccination delivery services, 2) reduce

vaccine costs for parents, 3) increase community participation, education, and partnerships, 4) improve the monitoring of disease and vaccination coverage, and 5) improve vaccines and vaccine use. The VFC Program, one component of the CII, was designed as one of these key strategies to address immunization barriers.

The VFC Program is important for several reasons, including

- allowing eligible children to obtain immunizations in their medical homes,
- providing greater access to vaccines, and
- forging public/private partnerships to get more children immunized.

Cost is a barrier that contributes to delays in achieving full immunization of preschool children with today's vaccines. The cost of the vaccine series has increased about 10 fold in the past 12 years. This is the result of more doses recommended for older vaccines, new vaccines added, excise taxes, and increases in the cost of the old vaccines. Regardless of the cause of the increased cost of the vaccine series, when parents must pay about $270 in vaccine costs and almost an equal amount in administration fees to have each child fully vaccinated, it stands to reason that parents without adequate insurance seek immunizations, not from their private doctor, but from public health clinics where the vaccine is free or available at nominal cost. Having to make the extra visits to these public clinics

can delay the timely immunization of children.

SUCCESSES AND PROBLEMS IN THE VFC PROGRAM

There have been many successes in the implementation of the VFC Program. Through the purchase of vaccines at discounted CDC contract prices, the VFC program helps assure cost savings to Medicaid. Before VFC, the cost of vaccines for most children on Medicaid was based on higher catalogue prices. VFC allows States to purchase their vaccines at discounted CDC contract prices without having to negotiate these prices directly with manufacturers. By shifting children on Medicaid from higher catalogue vaccine prices to lower CDC contract prices, millions of Federal and State taxpayer dollars will be saved. The catalogue price for the total series of vaccines is about $270, while the CDC price is about $130. California alone has estimated that it saves $40 million a year from the ability to purchase vaccines at the lower CDC contract price.

Transition ?

Of course, we know that addressing cost alone will not solve the underimmunization problem. It is clear only a comprehensive approach with interventions against multiple barriers is likely to raise and sustain immunization levels among preschool children in the U. S.

Transition ?

A cornerstone of the VFC Program is the forging of new

partnerships with private providers. Support from public and private medical communities at the National, State and local level have strengthened our efforts to immunize children.

Total Federal and State vaccine expenditures will not be much more when VFC is fully operational than what they were before. VFC allows us to buy more life-saving vaccine for about the same amount of money. This is because vaccine purchase under the "317" grant program has been significantly reduced Also, Medicaid vaccine (which makes up well over one-half of VFC vaccine) is now purchased at discounted CDC contract prices, rather than more expensive catalogue prices.

Most State Health Departments strongly support the VFC program and value its benefit to individual children and communities as a whole. Several States, including California, Georgia, Oregon, South Dakota and Rhode Island, have reported to the Association of State and Territorial Health Officials that, without the VFC program, their immunization efforts would suffer "catastrophic" consequences. Some States, such as Connecticut, Kentucky, Idaho, and Michigan, advised they would have to limit the availability of some vaccines, including the *Haemophilus Influenzae* type b and Hepatitis B vaccines, and South Carolina reported that immunization rates would plummet.

The major private physician associations and tens of thousands of

private physicians are supporting the VFC program. CDC has made it a priority to listen to these groups' views and develop an acceptable and workable program. It should also be remembered that not all private physicians, such as those that only serve children with insurance, would see a VFC benefit to their practices.

While some physicians remain skeptical, primarily because of the perceived paperwork burden, we expect continued increases in enrollment as more States establish delivery systems to private providers, and the facts about the operation and benefits of the VFC program become more recognized.

The VFC program has strengthened and institutionalized the partnership between public and private medical communities at the National, State, and local level. More than 30 private medical professional associations are working with us to implement the VFC program. These groups include the American Medical Association, the American Academy of Pediatrics (AAP), the American Academy of Family Physicians, the American Osteopathic Association, the National Medical Association, and the Interamerican College of Physicians and Surgeons. Dr. Frances Rushton, President, South Carolina Chapter, AAP, recently told my staff that the VFC partnership has been the single greatest public/private partnership effort in his medical career.

PROBLEMS IN THE VFC PROGRAM

The complex nature of the implementing legislation and the relatively short time allowed to kick-off the VFC program have complicated its implementation. I would like to address two issues: accountability systems and vaccine delivery to private providers in some States.

VFC Accountability Systems

GAO has expressed concern about accountability. Financial accountability is an essential component of the VFC program. States have primary responsibility for accounting for vaccine. States have over 10 years experience managing immunization programs and are in the best position to account for vaccines because of their knowledge of unique circumstances and provider practices.

It is crucial to maintain the right balance between effective accountability and provider participation. Private provider organizations have warned us that paperwork would keep physicians from enrolling. If providers had to report each immunization transaction, they would be burdened with filling out and sending in over 14 million pieces of paper a year. CDC has been reluctant to impose such bureaucratic accountability requirements. In building an effective accountability system, several activities are underway, including the development of

ID:

State accountability plans, monitoring orders, and the submission of three annually required forms. Overall, CDC feels it has instituted the appropriate balance between accountability and provider participation.

Vaccine Delivery to Private Physicians in Some States

CDC initially proposed distributing vaccine to private physicians in selected States through a national distribution center, as requested by most States. In September 1994, CDC began negotiations with vaccine manufacturers anticipating delivery to private physicians in December. On April 10, CDC had to discontinue these negotiations. Although final agreement was reached with one manufacturer, time was not available to reach agreements with remaining manufacturers. CDC is planning to meet with interested parties to determine how best to conduct vaccine delivery.

Despite this, VFC vaccine is being delivered to tens of thousands of public and private providers. Forty-nine States are delivering vaccines to public clinics, which account for about 50 percent of immunizations nationwide. As of March 30, 35 States had informed CDC they were delivering vaccine to enrolled private providers. At least 10 of the 14 remaining States reported they plan to begin delivering vaccine this year.

4 remaining states will set up delivery.

BARRIERS TO IMMUNIZATION

There are numerous risk factors for failure to vaccinate children on time which have been identified from research and from the experience of health professionals directly involved in providing vaccines to infants and children.

Recent studies are also emphasizing the crucial role of the provider in improving immunization coverage. Children are seeking health care, but that health care may not be translated into high immunization coverage. Based on a study of the immunization records of children in 5 public health clinics around the United States, the average number of visits during the first 2 years of life ranged from 5 to 15, yet coverage for the complete vaccination series ranged from only 18% to 61%. The number of health care contacts should have been adequate to provide all vaccinations needed in the first 2 years of life.

Providers have a crucial role in making sure all opportunities to vaccinate are taken, in reducing obstacles or barriers parents may face in getting their children vaccinated, and stimulating parents to return for immunization visits. The potential impact of taking advantage of all vaccination opportunities was studied in 4 inner cities. DTP-4 coverage could have improved from 8

percentage points in Los Angeles to 16 points in Baltimore.

Another serious barrier is the condition of the public health system. About 50% of immunizations in this country are given in public clinics. A variety of impediments exist to delivering vaccines in these public settings, including insufficient clinic staff, inconvenient clinic hours, or lack of recall systems. Also, vaccine cost, by increasing referrals from private to public providers, further stresses these delivery systems. Federal infrastructure grants address these problems. (See Table 2)

Table 2

Grant Funding for Infrastructure Enhancement (FY 93-FY 96)

($ in millions)

	FY 93 Approp.	FY 94 Approp.	FY 95 Approp.	FY 96 Estimate
Infrastructure	$45	$129	$108	$108
Incentives	$ 0	$33	$33	$33
TOTAL	$45	$162	$141	$141

That's why we've inc. funding Increase by 213% from 45 to 141

Immunization must be a shared responsibility of both providers and parents. Data from a variety of studies indicate the vast majority of parents want to immunize their children. But parents do not understand the complexity of the immunization schedule and the fact that more doses and visits are needed now, than when

they were children. Frequently, parents have believed that their children were fully immunized, when they were not. Through community outreach and education, parents need to understand that immunizing a child requires at least 5 visits to providers, and that they should have the immunization status of their child checked at every health care contact whether the child is ill or well.

With increasing numbers of available vaccines complicating the immunization schedule, parents and providers need help in keeping track. Computerized, State-based immunization registries, when operational, will remind parents when immunizations are due, or overdue, and assist providers in determining the immunization needs of their patients, old or new, at the time of each visit. Some States are now developing these systems. One example is Delaware, which has developed a statewide registry system for public and many private providers.

Again, aren't we funding this.

Numerous surveys of both practitioners and health departments have documented increasing referrals of patients from their primary care providers or medical homes to public clinics, with cost to the patient as the most important reason. A 1992 AAP study revealed 55 percent of pediatricians refer some or all of their patients for immunizations to a public provider. A 1992 North Carolina survey documented 93% of physicians referred patients to health departments for immunizations. A recent

survey of pediatricians and family practitioners in New York found that 50 percent referred all or some of their patients for vaccinations, generally to public health clinics. Finally, in a 1993 survey of 538 families attending public immunization clinics in California, Lieu and colleagues concluded that financing reform has the potential to improve vaccination rates, if it is combined with improved parent education, and reduced non-financial barriers to immunization.

Clearly, cost contributes to making immunization harder to obtain and plays a role in the delay in getting children fully immunized according to the recommended schedule.

IMPACT OF VFC ON IMMUNIZATION RATES

Childrens health will improve as a result of VFC. It will be difficult to document how the VFC program alone will increase immunization rates. In its July 1994 report on the VFC program, GAO documented that it will be extremely difficult to assess VFC's impact since VFC is only one of the CII's five components. CDC is currently developing an evaluation plan to attempt to address this issue, which we will provide this summer.

The VFC Program will definitely improve the health of our Nation's children, despite the difficulty of documenting increases in immunization rates directly related to VFC. ~~This is because the VFC program speeds up the provision of new and improved vaccines to eligible children. Some States would not be able to offer these new vaccines to children without VFC covering a substantial portion of the children in need. Also,~~ the VFC program allows eligible children to obtain immunization in their medical home where they can receive other components of health promotion and disease prevention.

CONCLUSION

Immunization represents one of the most, if not the most, cost-effective public health intervention. However, vaccines can only be as good as the system we have to make sure children in need get them when they need them. There is no magic bullet to solve the problem. No one approach, such as school laws, will suffice for the preschool population. We are close enough to our goals to be convinced we can reach them with intensified use of our current comprehensive strategy.

This nation has too often responded to crises rather than preventing them. We need a system that will assure that children born yesterday, today, and in the future will be vaccinated at the time in their lives when vaccines can prevent the greatest amount of disease. This system must function not only during and immediately after the threat of epidemic disease, such as occurred after the recent measles resurgence between 1989-1991; but, more importantly, the system must function during the period of absence of disease which often lasts for many years after an epidemic. Never again should epidemics be the primary motivation of immunization efforts.

The CII is designed to build this disease prevention system by enhancing vaccine delivery infrastructure, building partnerships, involving the community, establishing data systems to help

parents and providers remember when immunizations are due, and much more. If we are to prevent disease, we must build a system that has secure vaccine financing, not only for today's vaccines, but tomorrow's as well. VFC does that with the added benefit of returning children to their medical homes where they can get so many other preventive services, such as growth monitoring, screening for anemia, and much more. The VFC is a major step forward in improving the health of our children, and the CDC is committed to doing its best to fully implement the program to gain its full benefits.

TESTIMONY TO
THE UNITED STATES SENATE COMMITTEE ON FINANCE
CHAIRMAN, HONORABLE BOB PACKWOOD

MAY 4, 1995

THE CHALLENGE OF IMMUNIZING AMERICA'S CHILDREN:
MEDICAL HOMES AND THE VACCINE FOR CHILDREN PROGRAM

By:

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Irwin Redlener, M.D.
Senate Finance Committee

Chairman Packwood, members of the committee, I am here to support the Vaccines for Children Program - but qualify this support based upon certain concerns which must be addressed by introducing a few important modifications. In general I am suggesting three over-arching goals for the program:

1. As increasing attention is paid to budget deficits and state versus federal control of public programs, we need to protect the integrity of the VFC program and health care access for children. The national agenda for children should not be undermined by multiple state interpretations of what America's children need. And, VFC should not be endangered by limitations related to possible fundamental changes in Medicaid structure.

2. We must safeguard against unanticipated consequences of the program as it is currently organized - including the use of precious resources in ways which will not accomplish the goals of VFC in the most efficient manner possible.

3. Conversely, we need to maximize all available resources - including those provided through VFC - so that the program targets the children most in need with expenditures targeted to address their specific barriers to health care and immunizations.

I am Dr. Irwin Redlener, director of community pediatrics and associate professor of pediatrics at the Montefiore Medical Center and Albert Einstein College of Medicine in New York. I have had some 25 years experience in delivering health care and developing programs for disadvantaged children.

I am also president of the Children's Health Fund, a foundation responsible for establishing comprehensive pediatric programs for some of the most medically underserved children in the nation, including the children of homeless, migrant and otherwise severely disadvantaged families in a wide range of communities.

Children's Health Fund programs operate in New York City; Newark, New Jersey; Dallas, Texas; rural Mississippi; West Virginia; South Florida; South Central Los Angeles; and Washington, D.C. These programs have, to date, provided nearly 180,000 medical primary health care encounters to our designated target populations.

The projects included within our network take children who have had very little organized, quality health care and provide them with care that is delivered by medical teams who are committed to quality and continuity.

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We ascribe to a notion that the care all children receive should be the kind of care we expect for our own children. This care should be comprehensive, preventive and organized. Immunizations should be administered at a place where the rest of their health care is delivered; where follow-up vaccinations and follow-up for medical problems can be tracked and managed. Where, if needed, specialty care and hospital care can be coordinated and ensured.

Pediatricians refer to this kind of care as being provided in a "medical home." It is the appropriate way to do what's right. It's what all children deserve to have.

Children without a medical home may get health care, but it is the worst kind of episodic, fragmented and expensive medical attention in emergency rooms and drop-in clinics. This kind of care typically entails little or no follow-up; and, it often does not happen until illness has progressed too far.

In other words, medically homeless children get the wrong kind of care, in the wrong places, at the wrong time. It is precisely these children, without regular, dependable access to primary care that are most likely to be underimmunized.

Conversely, the most important piece of evidence that a child is medically underserved is **underimmunization.**

In fact, our programs provide medical care to some of the most medically underserved children in the United States. For the homeless and extremely indigent children cared for by our flagship mobile unit program, the New York Children's Health Project, the immunization rates are devastating:

Some 90% of our pediatric patients, on their first visit to our program are behind in - or cannot document - their routine immunizations.

This is an extraordinary indictment of the health care system for indigent children and is, to our knowledge, one of the absolute worst immunization situations in the United States.

Actually, in all of our sites, rural and urban, immunization rates are terrifyingly low and, importantly, reflective of the sorry state of the child health safety net in the United States. It is my opinion, that because of factors ranging from lack of health insurance to severe maldistribution of health professionals, **at least 15 million children under the age of 18 years lack**

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appropriate access to appropriate health care.

I need to emphasize this reality: in terms of the most significant causes for the nation's problems around immunizing our children, the cost of vaccine is not a major factor. **Rather, it is lack of access to a medical home type of health care relationship and the absence of a functioning child health care safety net in this country which are overwhelmingly responsible for our seeming inability to consistently protect our children through on-time immunizations.**

The Vaccine for Children Program (VFC) is clearly based on an essential and laudable principle that all children need to be immunized in an appropriate and timely manner. Our country cannot afford otherwise. President Clinton and his entire administration are committed to this goal and it needs to be achieved.

We are, therefore, strong supporters of the VFC but have insisted that it be modified in several important ways in order that there is some reasonable chance of the program realizing significant and sustained improvements in the nation's immunization completion rates.

Modifications are necessary because of certain problems and issues which have become apparent as the program unfolds.

I would like to share with you my four principal concerns and specific recommendations to re-shape VFC:

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Concern #1

George Washington University's Center for Health Policy Research recently reported a study of immunization issues in 12 states where there is universal purchase of vaccine for all children. In these states, cost has been eliminated as a factor in underimmunization.

However, this study verifies our clinical experience in providing immunizations and primary care to underserved children around the U.S.: **VFC does virtually nothing to increase immunization rates for the millions of children who have no regular place for health care.** These are the children who really need assistance in getting and sustaining up-to-date immunizations. They need medical homes.

You might look at the issue in this way: underimmunization is a

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symptom of lack of access to relevant pediatric health care. The real "treatment" for this problem is guaranteeing access to comprehensive health care where immunizations can be given over time and on-schedule.

kids without a medical home

Need to focus on infra for

For the 15 million medically underserved children in the United States the total amount of funds including the VFC program, Section 317 and other public sector initiatives is insufficient to meet existing needs. However, right now I am concerned that the relationship between funds spent on vaccine purchase versus new health provider capacity for disadvantaged children is not in appropriate balance.

Focus on what CII has done for infra.

Recommendation:

Congress needs to safeguard the total expenditure for vaccine-related programs so as not to jeopardize the long-term national agenda for children. **But, tax dollars should not be used to purchase or subsidize vaccines for families with sufficient income or insurance coverage.** These dollars should be re-directed to providing access to health care for as many medically underserved children as possible. **This means that what is really needed is money for infrastructure, that is, new capacity to provide comprehensive, primary health care - while ensuring that funds to provide vaccines are always sufficient to meet the needs of the children identified as "at risk."**

how does this fit w/ idea of medical home?

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2/3% from $45 to $141 - Fed spending increase.

Concern #2:

The VFC purchase and distribution plan helps families who have a regular source of health care - pediatrician, family physician, clinic, etc. - but cannot afford or are not covered for vaccines in that setting. Some are directed to use public health clinics, thereby fragmenting care. Studies have ~~shown that~~ VFC can help many of these families. **But under current VFC guidelines, there is no limit to or monitoring of under what ~~circumstances~~ and for how long these families would be eligible for free or subsidized vaccine. In addition, certain VFC provisions permit states to inappropriately use public funds to provide vaccines for insured or non-needy children.**

Dr. has to verify.

Are you making the GAO account. point?

what guidelines?

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Recommendation

VFC should **not offer opportunities for states to use limited public resources to provide free or subsidized vaccines to non-needy or insured patients.** In addition, VFC funds should **only provide vaccine to families until Medicaid or private insurance coverage is obtained.**

Concern #3

The VFC program is, of course, a great assistance to private physicians and their patients since it eliminates the need to utilize public clinics for vaccinations. Yet, although the private practitioner benefits from the VFC as a government subsidy, **private doctors may still refuse to provide subsidized vaccine, or any health care, to Medicaid or low-income patients - precisely the children who are most in need.**

Recommendation

Physicians or clinics participating in any aspect of VFC should be required to accept children covered by Medicaid, children who are uninsured or those who are otherwise unable to obtain appropriate health care.

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Concern #4

Again put in more positive terms. ~~Stark~~ We should req. Ins. Cos to cover.

The VFC program **discourages insurance companies from including immunizations in their family coverage.** Companies may surmise that responsibility for the cost of vaccines will simply be assumed by a tax-supported program.

Recommendation

All insurance policies covering families, whether fee-for-service or capitated premium based, should be required to include all recommended vaccines for children.

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Members of the Committee:

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As I stated earlier children need real medical homes. If every child in this country had a medical home, we would not have the unconscionably low immunization rates we experience in rural and urban areas around the country.

We need VFC. But it must be modified so that it can really take on and solve one of the most important challenges of our time.

Finally, it is my hope - and that of virtually every health professional and provider organization - that we can find a way to make sure that every child in the United States has access to appropriate and essential health care.

At the end of the day, it is health care, not vaccines, that should be guaranteed for children by government.

I know that know that the President and the Administration are deeply committed to VFC and access to health care for the nation's children.

Our job now is to make the adjustments in an important program that will permit it to function with maximal impact and in the spirit intended by its original drafters. In this day and age, where ever more children are vulnerable, endangered and facing an uncertain future, making VFC as effective as it can possibly be is the least we should do.

Thank you.

# # #

Name	Date
Eric Holder	6/16/2000

EA # 13533
NARA # 109.33