How to limit eligibility?

- We buy 60%.
- We buy at CDC price (for VFC eligible). Then negotiate for price for public health clinic. (10-15%)
- They are prepared to pay more for the additional 10-15% in order to keep entitlement
- If need more than 60% to cover VFC, then we have to pay on sliding scale price.

→ Can we entitle a block grant?

Immunization Funding -- All Public Sources

(Dollars in Millions)

	FY 93	FY 94	FY 95	FY 96 1/
CDC:				
Vaccine Purchase	$193	$196	$152	$166
Infrastructure	$45	$163	$142	$142
Other 3/	$103	$169	$170	$170
Subtotal, CDC Immunization	$341	$528	$464	$478
Medicaid:				
Federal Vaccine Purchase	$130	$155	2/	--
Federal Vaccine Administration	$40	$45	$50	$60
Subtotal, Federal Share	$170	$200	$50	$60
State Vaccine Purchase	$97	$115	--	--
State Vaccine Administration	$30	$34	$37	$45
Subtotal, State Share	$127	$149	$37	$45
VFC:				
Vaccine Purchase	--	--	$339	$328
Distribution	--	--	$20	$20
Ordering	--	--	$8	$8
Operations	--	--	$9	$10
Subtotal, VFC	--	--	$377	$365
TOTAL, PUBLIC IMMUNIZATION	$638	$877	$928	$948
Vaccine Purchase (Non-Add)	$420	$466	$491	$494

1/ Reflects 50 percent Federal excise tax savings (-$25 M discretionary; -$47 entitlement) proposed in the FY 1996 President's Budget.

2/ Not available. 12 Month extension of Medicaid coverage is included within the current VFC estimate and will be available at a later date.

3/ Increase from FY 93 to FY 94 is primarily grants for surveillance and response, tracking systems, enhanced efforts in Global polio eradication, and other activities to improve immunization levels.

19-Jun-95

Jan. '94 (state data) 42% Med; 15% unins; 1% AI/En; 1% underinsured = 59% at FQHCs

23% are underin → 15% (of these) go to public health clinics → 50 covered by §317

Questions:

- Breakdown of eligibility → how to get to 60-65% of market e.g. by category, by age?
  - ↓ if so, which categories?
- Structure
  - How to protect some purchase for imm. in medical home?
- Ways to link to other programs e.g. WIC
- Breakdown of funding -- how much $ in VFC v. other CII programs.

- What would happen to §317 with repeal of VFC? Needs to be reauth. this year, but discret. - could be used for purchase or infrastructure

---

States concerned about our walking away.

↳ We **need** them.

Rest is univ. purchase: 80%
Currently, buying 60%

under §317, pay capped price $ states have right to buy more. Before, under 317 → neg.

Vaccines for Children Program

1. Communications Strategy

Do we continue to defend the program? If so, how? (Clearly our approach depends on our longer term strategy.)

- State support (ASTHO, Governors)
- Group support (American Academy of Pediatrics, Children's Defense Fund)

2. Legislative Strategy

- Do we work with the manufacturers to come up with a compromise we can live with? What is the process for doing that?
- Do we work with the hill? Waxman? Wyden John Bryant What to do about Bumpers?

3. Policy Decisions

What kind of solution can we live with?

The two major concerns:

(1) VFC is an entitlement out of control

We can cap the growth of the program in several ways:

(a) By limiting eligibility

- Eliminate categories of eligibility
- Cap grants to states and allow states to determine eligibility

(b) By limiting state optional purchase (either completely or on a sliding scale)

(c) By limiting coverage of new vaccines

(2) VFC doesn't address the real problems/cost is not a barrier

- We can continue to argue that cost is one proven barrier and that we are addressing other barriers as well in other parts of the Childhood Immunization Initiative.

- Alternatively, we can provide flexibility to states and allow them to use funding for initiatives other than vaccine purchase (e.g., outreach, expanded clinic hours).

(3) Linking to other Federal programs → e.g. WIC

DIVISION OF COMMUNITY PEDIATRICS
DEPARTMENT OF PEDIATRICS
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IRWIN REDLENER, M.D., F.A.A.P.
DIRECTOR, DIVISION OF COMMUNITY PEDIATRICS
DIRECTOR, NEW YORK CHILDREN'S HEALTH PROJECT

DETERMINED TO BE AN
ADMINISTRATIVE MARKING
INITIALS: MA DATE: 4-24-14

~~CONFIDENTIAL~~

FAX TRANSMITTAL SHEET

TO: MRS. CLINTON

FROM: Irwin REDLENER

FAX #: (202) 456-2878

DATE: 6/26/95

Number of pages including cover sheet: 2

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

Additional comments:

MEMORANDUM

TO: Hillary Rodham Clinton

FR: Irwin Redlener, M.D.

DT: 26 June, 1995

RE: VACCINE FOR CHILDREN PROGRAM

Hillary, I am very distressed about recent stories on VFC, particularly the Pear piece on the GAO report as well as the Goldberg op-ed, etc. There have been all kinds of ways to make this program a winner, control the story and have VFC turn out to be a significantly positive accomplishment for children and for the administration.

As you know, I have been concerned about aspects of the program since the beginning and have gotten absolutely no where in getting myself heard other than to have my judgement and/or loyalty questioned. But, the last thing you and the President need from people like me is to hear what people think you want to hear.

In my opinion, you have been repeatedly ill-advised on VFC and other issues around health care. This has been the case for more than two years and it is a source a profound frustration. I hope it is not necessary for me to tell you that I am making this statement with nothing but the greatest respect for you and the President and a deep commitment to the goals which you have espoused from the beginning.

I believe there is much to be salvaged functionally and politically around the concept of getting all American children immunized; this includes attention to infrastructure for poor families as well as relieving the cost burden for the middle class.

There is much that can and should be done now around VFC and a number of health related issues more generally. I sent Melanne a memo a few weeks ago which included recommendations for beginning to deal with the medical community and some basic health issues right now. Even without proposing anything resembling major health reform before 1996, I believe there are a number of dramatic and important steps that can and should be undertaken over the next few months.

In any case, I would be happy to discuss any of this with you and would be available at any time.

Please give my best to the President.

Immunization Funding -- All Public Sources

(Dollars in Millions)

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CDC:				
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3/ Increase from FY 93 to FY 94 is primarily grants for surveillance and response, tracking systems, enhanced efforts in Global polio eradication, and other activities to improve immunization levels.

20-Jun-95

plus about 109 million each year in state vaccine purchase

THE WHITE HOUSE

WASHINGTON

June 26, 1995

MEMORANDUM FOR: Harold Ickes

FROM: Jeremy Ben-Ami

SUBJECT: Immunization Program

Attached are talking points from HHS on the Vaccines for Children (VFC) program. The following is an overview of the issue.

Background on VFC: VFC provides an entitlement to free vaccine for the following categories of children:

- Children on Medicaid: These children were always entitled to free vaccine. The major difference under VFC is that costs that were formerly shared between the Federal government and the states are now paid entirely by us. This has not succeeded in immunizing more children, but has given the states a major fiscal stake in preserving the program. We have letters of endorsement from Governors Engler, Dean, and Carnahan. Much of VFC's cost is simply the transfer of these costs from Medicaid to VFC.

- Uninsured children: These children are entitled to free vaccine if (1) their doctors sign up to be a VFC provider; or (2) they go to a public health clinic. Prior to VFC they could receive free vaccine at public clinics under a pre-existing (non-entitlement) program.

- Children whose insurance does not cover immunization: These children are entitled to free vaccine if they get their shots at a federally qualified health center.

Reasons for Opposition to VFC:

Vaccine Manufacturers' Profits: The government has the right to purchase vaccine for the VFC program at below-market prices, which is why the drug companies oppose the program so vigorously. Prior to VFC, CDC had negotiated a lower price with vaccine manufacturers for the 50% of the market that CDC purchased at that time. When the VFC legislation passed, it automatically extended this lower price to all vaccine purchase under VFC, even though the government's share of the market was projected to grow to 70-80%. In some cases, the discrepancy between the CDC price and the market price is very significant. The manufacturers allege that the resulting revenue drop will significantly limit their research into new vaccines.

VFC also gave states the right to purchase vaccine for all children in the state at the low CDC price. Few have taken advantage of this option, but it has particularly enraged the drug companies.

How to Target Under-immunized Children: VFC's main advantage is that uninsured children can receive shots at their private doctors' offices, rather than having to make an extra trip to a public health clinic. It is common for private physicians to send uninsured children to clinics for their shots because they are free in that setting. However, often these children do not make it to the clinic, resulting in missed opportunities for immunization.

Critics like Senator Bumpers say that the children most likely to be behind on their shots are seen regularly by public clinics and private doctors, and that they miss their shots not because of cost but because their parents are not aware of the immunization schedule (which is quite complex), or because the parents are not well-organized or responsible enough to see to it that the vaccinations take place. These critics point to the fact that almost all children get their shots by age 6, when they must have them in order to start school. They would prefer to focus on enhancing public clinic outreach to these families rather than creating a new child entitlement.

Our response is that we agree that cost is not the only barrier, which is why VFC is just one of five parts of the Childhood Immunization Initiative. Other components include grants to states and localities to expand public clinic services, a community-based outreach effort to educate parents and providers, and better detection of vaccination levels and outbreaks of infection.

Options: Staff from the Domestic Policy Council and the First Lady's office have developed some options for modifying the program's structure and eligibility; they have been discussed with HHS and OMB. We are planning to convene a meeting with the chief of staff very soon to decide on our legislative strategy, including how strenuously to defend the program's current structure.

The likelihood that Medicaid will be block granted means that the program won't survive in its current form. If Medicaid is block granted, the best outcome would be to structure the vaccine program as "entitled" grants to states for immunization. Key questions are whether to let states decide which children they will serve, or to cut back explicitly on which children are eligible for the program. We could respond as we have in the Medicaid block grant debate, by fighting Congress's proposals but laying out our priorities and offering to work with them on changes to the program.

In the meantime, we have more information on the program if you need it.

cc: Erskine Bowles
Alice Rivlin
Mike McCurry
Doug Sosnik
Marcia Hale
Melanne Verveer
Carol Rasco

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.

Questions and Answers on the VFC Program
6/26/95

Q: The GAO has challenged CDC's assertion that the cost of vaccines is a barrier to childhood immunization. Is cost a barrier or not?

A: Cost is a barrier because it contributes to delays in achieving full immunization of preschool children with today's vaccines. The cost of the complete vaccine series has increased ten-fold in the past 12 years. Since parents must pay about $270 in vaccine costs and an additional amount in administration fees for the series, those without adequate insurance may not seek immunizations from their private doctors, but from public health clinics where vaccine is free or available at nominal cost. Having to make extra visits to public clinics can result in delays and missed opportunities for immunization.

Numerous surveys of practitioners and health departments have also documented increased referrals of patients from their primary care providers to public clinics, with cost as the most important reason cited. A 1992 American Academy of Pediatrics study revealed that 55 percent of pediatricians refer some or all or their patients to a public provider for immunizations. A 1992 North Carolina survey showed that 93 percent of physicians referred patients to health departments for immunizations, and states such as New York have showed similar trends.

Q: The GAO has recommended that the VFC program should be targeted to certain population groups and areas referred to as "pockets of need." Doesn't this make sense?

A: We believe, and Congress has agreed, that the proper goal of Federal immunization efforts is to raise immunization levels throughout the nation, and to put in place a sustainable system that will ensure that immunization rates remain high. The GAO conclusion assumes that "general immunization rates" are not now a problem and will not be a problem in the future.

While child immunization rates have improved since the 1989-1991 measles epidemic, VFC is a key part of a national strategy to reach the one million American children under two who are unvaccinated against one or more deadly diseases. A 1993 survey found that 28 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 40 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.

Q: Does the Administration oppose folding the Vaccines for Children (VFC) program into a block grant?

A: The Clinton Administration has a very simple goal -- to improve preschool immunization rates. Since taking office, the President has lead an aggressive campaign to reach that goal, and we have made great progress. But we believe that our current investment in children's immunizations must be maintained. Childhood immunizations are one of the most cost-effective public health investments we can make -- they save lives and they save money. To take just one example, for every dollar spent on the measles/mumps/rubella vaccine, we save $21 in health care costs.

We are more than willing to work with Congress to make changes to improve the VFC program. But we are not willing to watch as Congress slashes funding for childhood immunizations in just one more shortsighted attempt to cut the budget.

Q: Is the Administration's position that VFC must remain an entitlement?

A: Our position is clear. We believe that the federal budget should be balanced, but in a way that makes sense. The President has laid out a proposal that retains coverage under Medicaid while reducing spending and giving states more flexibility. Medicaid is a critical health care program; it can certainly be improved,but not by cutting it dramatically to balance the budget. The same applies to VFC. If we can improve the way we are going about our childhood immunization efforts, we're certainly willing to work on it. But we must maintain poor and uninsured children's access to life saving and cost-effective vaccines.

VACCINES FOR CHILDREN PROGRAM OPTIONS

Options

In order to address criticisms made of the program, a variety of changes could be made. These options generally fall into two categories:

- limiting the program's scope (by tightening eligibility requirements or limiting immunization venues) and
- altering the program's administrative structure (by capping expenditures or allowing alternative uses of funds).

Criticism: **The federal government will eventually purchase so much vaccine at reduced rates that manufacturers will be driven out of business.**

Background:

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

Possible Solutions:

- ***Limit the categories of eligible children***

  Uninsured children

  Impact on children: Uninsured children may be the neediest with regard to immunization. Prior to VFC uninsured children could get immunized at public clinics, and they still can. VFC would allow those children who have a private physician to receive all their well-child care from a single provider. However, it is unclear whether private doctors will accept uninsured children even if the doctors receive free vaccine for them.

  Impact on manufacturers: Manufacturers are likely to be pleased if uninsured children were dropped from the program because it would reduce the growth of the public share of the market.

  Impact on states: State funds would not be affected by dropping uninsured children from the program because public clinics are also federally funded.

Medicaid-eligible children

Impact on children: Children covered by Medicaid received free vaccine before the VFC program and could again if they were to be dropped from VFC.

Impact on manufacturers: The manufacturers would be particularly pleased if Medicaid-eligible children were covered under Medicaid rather than VFC because under Medicaid they are paid catalog price rather than the low federal price.

Impact on states: Since VFC eliminated the states' share of immunization costs for Medicaid-eligible children, states now expect the federal government to pay the total cost. The states are the strongest supporters of the VFC program and are likely to object to absorbing their Medicaid matching share. Some states (including Texas) have used their Medicaid savings to expand immunization programs.

- ***Limit service venues***

Free vaccines for children at federally qualified health centers (FQHCs) could be eliminated from VFC. This part of the program has been severely criticized because it does not prevent wealthy children whose insurance does not cover immunizations from getting free vaccine at these clinics. In reality, however, underinsured children of wealthy families do not seek care at these clinics so it would have little impact on them. The poor children who rely on FQHCs would remain eligible for free vaccinations under other immunization programs.

There has been some discussion of federal legislation mandating that all insurance policies cover immunizations for children, which would eliminate the category of underinsured children. But it is unlikely that such legislation would be enacted.

Manufacturers are likely to be pleased by a limitation on the scope of the program that might curtail the growth of the public share of the market.

- ***Freeze or eliminate state purchasing options***

Optional state vaccine purchases for all children in the state could be frozen or states could be allowed to purchase vaccine on a sliding scale basis at a higher price. This would go a long way toward appeasing the manufacturers. States may complain about losing optional purchase (although no new states have indicated interest in taking advantage of it).

Criticism: **The program could become an out-of-control entitlement expenditure.**

Background:

Since the VFC program operates as an entitlement, there is no mechanism to control its cost. Some are afraid it could lead to exorbitant expenditures.

Possible Solution:

- ***Maintain the individual entitlement but cap total purchase***

  If Medicaid is not block granted, we could maintain the individual entitlement but cap total federal vaccine purchase. This option does not really address questions about how best to allocate immunization dollars. It does prevent the program from becoming another "out-of-control" entitlement, as some have charged.

Criticism: **The neediest children aren't reached.**

Background:

Critics of the VFC program have charged that -- by focusing resources on getting free vaccine to children in doctors' offices -- the program does not address the most significant barriers to immunization and does not help the neediest children, who are rarely seen by private doctors. They argue that cost is not a significant barrier to immunization, and therefore providing free or cheap vaccine will do little to increase immunization rates.

Possible Solutions:

- ***Allow state flexibility***

  If Medicaid is block granted, we could provide "entitled" grants to states for immunization. States could either be required to use the funds for vaccine purchase or could be allowed to spend the money as they saw fit (e.g., infrastructure or outreach rather than purchase). States would be required to demonstrate that eligible children -- not just a minimum number of children -- were being immunized.

- ***Add new features to the program***

  We could add new features to the program, like "parental responsibility" -- by requiring that welfare parents show proof of immunization in order to receive benefits. Using this strategy, programs in cities, including Chicago, New York and Dallas, as well as in states, most notably Maryland, have shown an increase in immunization rates among poor children of 40 to 80 percent. Alternatively, outreach requirements might be added to ensure that parents are aware that their children can receive free immunization.

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

27-Jun-1995 02:36pm

TO: (See Below)

FROM: Diana M. Fortuna
Domestic Policy Council

SUBJECT: Tomorrow on immunization

Apparently there will be another development on immunization tomorrow.

The VFC law says that new vaccines will be automatically added to the entitlement whenever the ACIP (Advisory Committee on Immunization Practices) adds one to its recommended schedule. Tomorrow they will (almost certainly) vote to add varicella, the new chicken pox vaccine.

ACIP is some sort of advisory council to CDC, and is composed of a bunch of doctors/professors; pharmaceutical manufacturers (!), and HHS PHS-types.

It was kind of a given that they would recommend this, because the new vaccine is presumably a good thing. However, it may well raise cries that VFC is out-of-control cost-wise, because we have handed over the purse-strings to these non- or pseudo-governmental bodies.

We don't know what the cost will be because there is no price negotiated yet between Merck and CDC. (Given the fact that the VFC law locked in low prices for all the other vaccines, we can expect Merck to be pretty aggressive in negotiating a price.) We also don't know what children they will recommend it for. But HHS says it could costs somewhere between $35 and $500 million.

Jen Klein and I agree that our response should center on the benefits of the vaccine and less so on the merits of the VFC program, especially since we don't meet till Thursday to discuss where we go from here on the program.

Melissa Skolfield of HHS is working with our press office on how to respond to this, and will send over talking points.

Distribution:

TO: Carol H. Rasco
TO: Jeremy D. Benami

CC: Virginia M. Terzano
CC: Richard L. Siewert
CC: Janet Murguia
CC: Emily Bromberg
CC: John C. Angell
CC: Nancy-Ann E. Min
CC: Douglas B. Sosnik
CC: Jennifer L. Klein

VACCINES FOR CHILDREN PROGRAM OPTION

Decisions about the Vaccines for Children (VFC) program must address: (1) possible changes in eligibility; and (2) options for restructuring the program.

(1) Eligibility

To reach agreement with the vaccine manufacturers, it is probably necessary to reduce public purchase of vaccine by limiting eligibility. VFC currently covers children who are Medicaid-eligible (37-38 percent of the program), uninsured (10-15 percent), Indian (1 percent), and underinsured if they are immunized at a federally qualified health center (FQHC) (8 percent). ---- States also have taken advantage of the option to purchase vaccine at the low federal price for all children in their state (raising the percentage of vaccine purchased at the public price to -- percent).

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

In order to address these concerns, we could:

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

  - Uninsured children

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

  - Medicaid-eligible children

    Children covered by Medicaid received free vaccine before the VFC program through the section 317 program. It would seem logical to eliminate eligibility for these children under VFC and leave them to Medicaid. However, states now expect the federal government to pay the total cost. Since the states are the strongest supporters of the VFC program, it would be difficult to ask them to absorb half of the costs again and to end state optional purchase (as discussed below).

- Eliminate eligibility for children served at FQHCs.
  - Federally qualified health clinics will continue to immunize the children they serve. This part of the program has been severely criticized because it does not prevent wealthy children whose insurance does not cover immunizations from getting free vaccine at these clinics. In reality, however, underinsured children of wealthy families do not seek care at these clinics. Eliminating this category of eligibility therefore allows us to avoid the charge that the program serves those who can afford vaccine while catching the needy children who are actually served by FQHCs. [Is this fair?]
  - In addition, there has been some discussion of federal legislation mandating that all insurance policies cover immunizations for children. [Comment on likelihood of this.] This would obviously eliminate the category of underinsured children.
- Freeze state optional purchase or allow states to purchase vaccine for all children in the state at a higher price that is higher than the Federal price based on a sliding scale.

FIGURE OUT 317!!!!

(2) Structure

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

Options:

- If Medicaid is not block granted: maintain the individual entitlement but cap it. [Or is it enough to limit categories?] This option does not really address questions about how best to allocate immunization dollars. It does prevent the program from becoming "another out of control" entitlement, as some have charged.
- If Medicaid is block granted: provide entitled grants to states for immunization. States could either be required to use the funds for vaccine purchase or could be allowed to spend the money as they saw fit (e.g., infrastructure rather than purchase). In either case, states would be required to demonstrate that *eligible* children -- not just a minimum level of children -- were being immunized.

Outstanding Issues:

- Should we add new features to the program, like "parental responsibility" -- by requiring that welfare parents show proof of immunization in order to receive benefits? Programs in cities, including Chicago, New York and Dallas, as well as in states, most notably Maryland, have shown an increase in immunization among poor children by 20-80 percent. } where #?

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

delete per Carol

VACCINES FOR CHILDREN PROGRAM OPTION

Decisions about the Vaccines for Children (VFC) program must address: (1) possible changes in eligibility; and (2) options for restructuring the program.

(1) Eligibility

To reach agreement with the vaccine manufacturers, it is probably necessary to reduce public purchase of vaccine by limiting eligibility. VFC currently covers children who are Medicaid-eligible (37-38 percent of the program), uninsured (10-15 percent), Indian (1 percent), and underinsured if they are immunized at a federally qualified health center (FQHC) (8 percent). States also have taken advantage of the option to purchase vaccine at the low federal price for all children in their state, ~~raising the percentage of vaccine purchased at the public price to -- percent~~.

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

In order to address these concerns, we could:

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

- Uninsured children

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

- Medicaid-eligible children

  Children covered by Medicaid received free vaccine before the VFC program through the ~~section 317 program~~. It would seem logical to eliminate eligibility for these children under VFC and leave them to Medicaid. However, states now expect the federal government to pay the total cost. Since the states are the strongest supporters of the VFC program, it would be difficult to ask them to absorb ~~half of~~ the costs again and to end state optional purchase (as discussed below).

- Eliminate eligibility for children served at FQHCs.

- Federally qualified health clinics will continue to immunize the children they serve. This part of the program has been severely criticized because it does not prevent wealthy children whose insurance does not cover immunizations from getting free vaccine at these clinics. In reality, however, underinsured children of wealthy families do not seek care at these clinics. Eliminating this category of eligibility therefore allows us to avoid the charge that the program serves those who can afford vaccine while catching the needy children who are actually served by FQHCs. ~~[Is this fair?]~~

In addition, there has been some discussion of federal legislation mandating that all insurance policies cover immunizations for children. ~~[Comment on likelihood of this.]~~ This would obviously eliminate the category of underinsured children.

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

~~FIGURE OUT 317!!!!~~

(2) Structure

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

Options:

- If Medicaid is not block granted: maintain the individual entitlement but cap it. ~~[Or is it enough to limit categories?]~~ This option does not really address questions about how best to allocate immunization dollars. It does prevent the program from becoming "another out of control" entitlement, as some have charged.

- If Medicaid is block granted: provide entitled grants to states for immunization. States could either be required to use the funds for vaccine purchase or could be allowed to spend the money as they saw fit (e.g., infrastructure rather than purchase). In either case, states would be required to demonstrate that *eligible* children -- not just a minimum level of children -- were being immunized.

Bumpers bog on this.
Shalala indicated no problem w/ this.

Outstanding Issues:

- Should we add new features to the program, like "parental responsibility" -- by requiring that welfare parents show proof of immunization in order to receive benefits? Programs in cities, including Chicago, New York and Dallas, as well as in states, most notably Maryland, have shown an increase in immunization among poor children by 40-80 percent.

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

HIP-POCKET OPTION

Options to scale back the number of children covered:

To reach an agreement with the manufacturers, it would probably be necessary to cap public purchase at some level.

The public share is projected to grow under VFC from 50-55% to 75-80%, or even higher if many more states were to take advantage of the option for universal purchase.

Manufacturers have talked about capping public purchase at 60%. This is probably too low to accomplish most of our objectives.

Here are the 4 types of kids VFC covers, and options for change.

- Medicaid: These kids were always covered, but reverting to pre-VFC would cost states a lot of money.

- Uninsured: This is the most important group to preserve.

- Underinsured: Could these children be covered by legislation mandating that insurance policies cover immunization? There are indications that such legislation could succeed.

- Insured in states with universal purchase: States would object to freezing the number of states that can take advantage of this option. It's not clear how many really want to take advantage. Another option here would be requiring states that take advantage of this option to pay a higher price for vaccine based on a sliding scale.

Take out of options.

Question: should we revisit the feature of VFC that automatically adds new vaccines to the program when the ACIP endorses them?

(Also, the 317 program continues to serve children, but it is not clear how the children it serves are distinct from VFC kids.)

Options to change the structure of the program:

If Medicaid is block granted:

- our best option with VFC would be a block grant within a block grant

If Medicaid is not block granted:

- Capped entitlement: most obvious alternative
- State flexibility option: Is it possible to offer states two or three different models to choose from? They could use funds either to purchase vaccine as part of an entitlement, or to strengthen infrastructure, whether through clinic hours, mobile vans, etc. In either case, states would have to demonstrate that eligible children are being immunized.
- Means-tested entitlement

Note: In June, there will be a hearing in the House

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FROM: GREGORY LAWLER

DATE: APRIL 5, 1995

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VACCINE FOR CHILDREN

Facts according to GEL

The current federal funding for vaccine purchase is:

Year	317	VFC
FY96	$165 Million	$412 Million (may require another $100 Million)

In addition, there is another $176 Million under the 317 program for infrastructure funding. The total of both programs for vaccine purchase and infrastructure is $753 Million, and the total funding for both programs is $891 Million. [I think the additional $138 Million must be for CDC vaccine activity other than purchase and infrastructure, but not sure.] Attached is a sheet describing the funding history, I hope accurately.

CDC's best guess about the population reached with free vaccines, based on state estimates from January 1994, for the birth cohort under 1 (4.1 million kids) is:

- 37-38% will receive under Medicaid eligible;
- 10-15% will receive as uninsured;
- 8% will receive as underinsured at FQHC's;
- 1% will receive as Indians.

Between 56% and 62% of the 4.1 million 1 year olds will receive free vaccines.

This compares to the pre-VFC world where Medicaid kids were covered, and the 317 program was spending $30-40 Million more per year on free vaccines.

[My stupid math tells me the following -- medicaid kids are covered either way; the rest, 21.5% of 4.1 million kids or 880,000; the average per child cost of vaccine under VFC is $170 [58.5% of 4.1 million = 2.4 million; $420 Million for 2.4 millon kids = $170]; 880,000 kids at $170 each is $150 Million.]

The only two categories that are different than the pre-VFC world are the uninsured, who can now receive in private docs office, and Indians. Everyone always got free vaccines at FQHC's.

The other obvious difference from the pre-VFC world is the state option to purchase at the contract price. I haven't seen any figures on this, but it makes sense that the volume of state purchase would increase.

New Program

% increase = CPI

Here is how a new program might work:

o states would receive entitled funds (no need for appropriation) based on the following formula - number of Medicaid kids, Indians, uninsured as a % of the national total.

# of kids in state / # of kids in country X FY96 budget request

o the funds available that the formula would be applied against would be the ~~FY95 appropriation~~ FY96 budget request, but in no event less than the cost of vaccines for Medicaid kids (even if new, expensive vaccines are introduced).

o states would be required to cover vaccines for Medicaid kids, either under Medicaid or a separate vaccine program.

o states could use the services of CDC to purchase and deliver vaccines, at the option of the state.

o there would continue to be a federal contract price for the 317 program and states would be entitled to purchase at that price for Medicaid kids, uninsured and Indians.

o there would be no state option to purchase at the federal contract price beyond Medicaid kids, uninsured and Indians.

Are universal state purchasing at K price. for all kids? What do we do ~~this~~ about this?

o states might or might not be allowed to use the federal funds for infrastructure or education, as long as the obligation to cover Medicaid kids was fulfilled.

o the 317 program would remain, as today, subject to appropriations.

What about other nonuniv. states that are doing more? • What are they doing? • At K price?

o new vaccines would have a negotiated price, as today, and would be used to automatically increase any state entitlement for Medicaid kids, if such new vaccines were approved. (I don't know how you make this automatic, since it could be very expensive and unknown. An AID's vaccine would be fabulous, but at $500 per for 1.5 million Medicaid kids, it's $750 Million. Who gets to decide that, and other less expensive vaccines, like the new combinations that cost $250 per kid?)

You know the general arguments for and against this kind of

approach. The best I can say for it is that it protects the entitlement approach, requiring states to cover and freeing state Medicaid money for other things. The only category that is eliminated directly is the underinsured at FQHC's and they should get covered by 317, although there will be a battle over that appropriation.

On the other side, it uses the appropriation to limit the program to somewhat the same market as before.

I don't know what the CDF, every child needs a medical home, reaction would be.

Please call me after you have read this masterly missive.

IMMUNIZATION FUNDING HISTORY

Total Federal Immunization Funding (combined 317 and VFC funding)

	Total Funding	Vaccine and Related Costs	Infrastructure Funding
FY 92	$296,159,000	$158,104,805	$ 45,407,931
FY 93	$341,081,000	$182,000,000	$ 45,000,000
FY 94	$628,003,695	$269,063,389	$162,511,000
FY 95	$870,541,719	$534,638,688	$176,700,000
FY 96	$691,018,000*	$577,700,000	$176,700,000

* Since the release of the FY 96 budget, the Advisory Committee on Immunization Practices has recommended the addition of new vaccines or doses of existing vaccines to the list of products to be purchased through the VFC program. The additional estimated cost to the VFC program is approximately $100 million annually. Therefore, the total combined immunization spending may be closer to $991 million.

Section 317 Program

	Total Funding	Vaccine Purchase Funding	Infrastructure Funding
FY 92	$296,159,000	$158,104,805	$ 45,407,931
FY 93	$341,081,000	$182,000,000	$ 45,000,000
FY 94	$528,143,000	$193,000,000	$162,511,000
FY 95	$465,591,000	$149,000,000	$176,700,000
FY 96	$478,818,000	$165,500,000	$176,700,000

Vaccines for Children Program

	Total Funding	Vaccine Purchase	Ordering/ Distribution
FY 94	$ 79,860,695	$ 76,063,189	$ 3,797,306
FY 95	$404,950,719	$385,638,688	$ 19,312,031
FY 96	$412,200,000**	$412,200,000	

** The addition of new vaccines to the VFC program may increase the annual cost by $100 million. The VFC cost for FY 96 may be closer to $512 million.

DRAFT

NATIONAL IMMUNIZATION POLICY FOR POOR CHILDREN

BACKGROUND--VFC PROGRAM

Congress approved the Vaccines For Children program in 1993 as part of the Omnibus Budget Reconciliation Act. Under the Act, children ages 0-18 are entitled to receive federally-supplied vaccine. Eligible children include those under Medicaid, American Indians, children without health insurance, and those with insurance but without coverage for childhood vaccines.

The VFC program was created by Congress with these goals:

- Increase America's low pre-school immunization rate from 50% to 90% by year 2000.
- Reduce inappropriate referrals of children from private doctors to public clinics solely to receive vaccinations.
- Ensure that all children, regardless of economic means, are able to receive traditional and future vaccines.

The Vaccines For Children program has been criticized for the following reasons:

- Wastes scarce federal resources on a broad new entitlement with no means test, when the greatest problem with under immunization lies with the poor, to whom free vaccine was already available through Medicaid and public health clinics.
- Focuses inappropriately on the cost of vaccine as the principle reason for under immunization, meanwhile neglecting to address education, outreach and lack of parental knowledge and personal responsibility as underlying causes.
- VFC intrudes unnecessarily into the private marketplace, posing harm to manufacturers of vaccine by limiting pricing for an increasing amount of the total market.
- Automatic addition of new vaccines to the list of covered shots to which beneficiaries are entitled by CDC's Advisory Council on Immunization Practices allows for unbridled growth in federal spending beyond the control of the federal government.

PROPOSED VFC REFORM PLAN

The following proposal would address the above concerns and seek to improve national immunization policy by providing incentives to improve vaccination rates among the poorest populations, where there is greatest risk for underimmunization. This plan would also retain key policies under VFC beneficial to achieving a strong federal role in vaccine policy :

- **Reform VFC by limiting eligibility only to the Medicaid, and American Indian and Alaskan Native populations, which would cover about 70% of all children presently elibigle for VFC.**

- **Improve vaccination rates among the poor by requiring proof of immunization as a condition of welfare/WIC payment receipt.**

- **Assure appropriate national vaccine policy by maintaining federal purchase according to CDC/ACIP immunization guidelines.**

- **Introduce fiscal accountability to ACIP vaccine recommendations by requiring congressional review.**

- **Maintain competition in public vaccine purchasing by retaining multiple contracting requirements for the CDC.**

1. **Federally Purchased Vaccines Should Be Limited to Medicaid-Eligible, American Indian and Alaskan Native Children, Up to Age 18, Targeting Only Truly Needy Children**

Last year, about 42% of all children up to age 18 were eligible for Medicaid (an additional 1% are American Indian and Alaskan natives). Seventy percent (70%) of all children eligible for VFC were also eligible for Medicaid. By limiting VFC to these children, **this centrally managed and monitored program will be targeted to those children with the greatest need and with the lowest rates of immunization.**

By limiting the program to low-income, Medicaid children, improper encroachment into the private marketplace will be eliminated. Presently the program covers the uninsured and underinsured, regardless of income. Underinsured eligibles can include the children of insured workers whose plans do not include well-baby care, a practice of many Fortune 500 companies. Also, some states have adopted the VFC option to purchase vaccine at CDC prices for all children in the state, even those with existing private coverage for immunizations. **This proposal would eliminate the optional authority for states to purchase vaccine under the CDC contract for populations beyond Medicaid-eligibles.**

2. **Increase Immunization Rates Among the Poor by Instituting "Parental Responsibility" Requirements**

Federal policy should focus on achieving full immunization among the most high risk populations.

Several cities, including Chicago, New York, and Dallas, and states, notably Maryland, have instituted requirements that welfare parents show proof of immunization prior to receipt of benefits. In the three cities cited, this requirement has been implemented at WIC sites, where parents are given only one months' supply of WIC vouchers, as opposed to the usual two months supply, unless a parent can show proof of immunization. **Within two years, these programs have shown an increase in immunization among poor children by 40-80%.**

3. **Infectious Agents Do Not Respect State Borders: Maintain a Strong Federal Role in National Vaccine Policy**

In the modern era, it is no longer rational for our national vaccine policy to be the summation of the decisions of the individual States. We need a national vaccine policy, especially targeted to poor, high-risk populations, to ensure that infectious childhood diseases are eradicated. Epidemics of measles, hepatitis A, pertussis, etc. occur as multi-state or national problems, and are not isolated to individual States. VFC provides a strong federal vaccination policy by providing that all entitled children receive the latest, futuristic vaccines recommended by CDC's Advisory Council on Immunization Practices (ACIP). If VFC were wholly repealed, vaccine policy would revert entirely back to the States, with each State making individual decisions on vaccines coverage and schedules.

Further, VFC guarantees that the poorest, most high-risk kids in our society, will get new vaccines just as quickly as more fortunate kids with private coverage. If VFC were repealed, or vaccine coverage authority turned back to the states, some Medicaid or state programs might not have the resources to provide coverage for all vaccines.

4. **Limit Current ACIP Authority Under VFC**

Although centralized authority over appropriate immunization schedules is in the national interest, The ACIP's power to automatically increase federal spending on new vaccines poses major cost concerns.

This issue can be addressed simply by requiring that the ACIP submit recommendations to Congress for their review and approval within 90 days, or ACIP recommendations will be deemed approved. This will allow for the Congress to weigh critical budgetary concerns versus health policy concerns of adding innovative vaccines to VFC schedules.

5. **Maintain Centralized, Multiple-Award Federal Contracting for Public Sector Vaccine Purchasing**

Centralized, multiple-award federal contracting assures manufacturers of a stable public marketplace. Should Congress turn vaccine purchase over to the states, there is concern that each state could institute its own purchasing process, creating a confusing array of systems with low price being the only factor considered.

Winner-take-all contracting on a state-by-state basis will reduce the price of vaccines to a very low, commodity level. As with the infant formula business under the WIC program, which employs state-by-state competitive bidding, competition and innovation could virtually disappear. Driving manufacturer to provide vaccine to so broad a public market at very low cost, while saving money for states in the short term, would prove to be detrimental in the long term, as manufacturers would have lower incentive and resources to invest in innovative vaccines. **Manufacturers presently have the incentive to invest in the development of combination vaccines, which will ultimately drive down the cost of health care. Together with the introduction of new vaccines, such as for Lyme disease, herpes and chicken pox, futuristic vaccines will reduce overall health care costs in the long term.**

DRAFT

BACKGROUND ON THE VACCINES FOR CHILDREN PROGRAM

The following aspects of U.S. vaccine policy and the vaccine marketplace, as well as its history, should be considered by Congress as it seeks to reopen the debate over the Vaccines For Children Program.

VFC

The Vaccines for Children Program was created by Congress with the following primary goals:

- Increase America's low pre-school vaccination rate from 50% to 90% by the year 2000. Congress recognized that that prevention is the best health policy and the best economic policy.

- Reduce the inappropriate referral of children from their private physicians to public clinics solely to receive vaccinations. This practice fragments pediatric care.

- Ensure that all children, regardless of economic means, are able to receive traditional and future vaccines.

VFC was enacted as part of the Omnibus Budget Reconciliation Act of 1993. Under the Act, the following children (age 0-18) became entitled to receive federally-supplied vaccines:

- Medicaid-eligible children
- American Indians
- Children who do not have insurance
- Children who have insurance, but lack coverage for childhood vaccines, provided that vaccines are received through a federally-qualified health center or rural health clinic.

VFC began operations on October 1, 1994. The program is administered by the State health departments and the federal Center for Disease Control and Prevention, an agency within the U.S. Public Health Service. Under VFC, vaccine is distributed mainly through private physicians, who are charged with establishing eligibility for the program. the States are now in the process of enrolling private physicians across the United States.

A National Vaccine Program is Decisively Cost-Beneficial

Several studies have shown that spending on childhood vaccination is unequivocally cost-beneficial. Dollars spent on childhood vaccination are returned through the prevention of clinical epidemics and sporadic cases; ie., through saved costs in years of productive life lost and medical costs in curative medicine, hospitalizations, and the prevention of chronic immunizable diseases.

Notably, the major vaccine manufacturers are now developing combination vaccines, with the ultimate goal of combining most or all childhood immunizations into far fewer shots than the 16 shots presently recommended by age two. Combination vaccines should have a significant effect on health care costs and immunization rates by dramatically reducing the number of doctor visits and individual shots needed to reach full immunization.

VFC Assures Poor Kids Access to Futuristic Vaccines

Because VFC entitles eligible children to a schedule of shots recommended by a CDC panel of experts in the vaccine field (the Advisory Council on Immunization Practices--ACIP), VFC guarantees that the poorest kids in society will get new vaccines just as quickly as more fortunate kids with private insurance. If VFC were repealed, the states may not be able to include all vaccines as part of the Medicaid programs, due to the budgetary constraints virtually all states are now facing.

VFC Centralized, Multiple Contracting is Beneficial to Vaccine Manufacturers, and Should Not Be Reversed

Although there are a number of promising innovative vaccine products currently under development for the U.S. market place, the number of companies competing in this market place has dwindled radically over the past 10 to 15 year. A number of factors have contributed to driving the large majority of traditional pharmaceutical companies out of the U.S. vaccine marketplace since the early 1980s, including: liability costs; relatively low level of profitability relative to other pharmaceutical products; rising R&D costs; and the rising share of the public market. In the 1970s, many large pharmaceutical companies participated in the vaccine market, including Pfizer, Lilly, and Burroughs Wellcome. However, today there are only four companies competing in the U.S. market--Merck, Lederle, Connaught and SmithKline Beecham.

Studies have shown that the dramatic rise over the past 10 years in the public purchase of vaccines may have contributed to driving out competition in the U.S. market. Further, prior to the Vaccines for Children program, the CDC vaccine purchase program awarded contracts to only one manufacturer of each of the childhood vaccines--and the pre-VFC public purchase accounted for about 50% of the total market for each of the vaccines. This made it virtually impossible for a manufacturer wishing to introduce a new version of an existing vaccine to gain market share.

VFC implemented an important policy which will enhance competition: VFC ended CDC winner-take-all contracting, and instituted a policy of multiple awards. Any manufacturer willing to bid for the public purchase will be assured of at least a portion of the VFC market. Together with the entitlement aspect of VFC, this important policy has incented manufacturers to develop innovative versions of existing vaccines, such as acellular pertussis and IPV, to develop combination vaccines, and to develop brand new vaccines, such as for hepatitis A, chicken pox, Lyme disease, and herpes.

<u>VFC Vaccine Purchase Dollars Are Significantly Offset From Other State and Federal Vaccine Programs</u>

In its first year, FY 1995, VFC's vaccine purchase estimate is $422 million. At first glance, this looks like a large increase in federal vaccine purchase spending over premious outlays for CDC Section 317 spending (about $193 million in FY 1993). But it is important to remember that two large federal vaccine purchase programs, Medicaid and the Indian Health Service, were generally superseded by VFC. And CDC Section 317 spending can be reduced by VFC.

Section 317 spending for vaccine purchase in FY95 will be $45-110 million less than in FY94. Federal Medcaid spending will be reduced by as much as $165 million. Indian Health Service spending will be cut by up to $8 million. Of the estmated $422 million in spending by VFC for vaccine purchase in FY95, an estmated 40-65% is accounted for by offsets from other federal programs.

Finally, VFC also represents an assumption by the federal government of about $110 million in vaccine purchase formerly made by the States.

<u>States Favor VFC</u>

Most states favor VFC, because it enables them to divert state immunization resources away from vaccine purchase toward vaccine delivery and infrastructure, which are crucial in their effort to raise America's pre-school vaccination rate. VFC also gives States quicker, more efficient access to newer, high tech vaccines like acellular pertussis, hepatitis A, and varicella (chicken pox) vaccines.

Viruses Do Not Respect State Boarders: A Federal Government Role in Vaccine Policy Making Is Good Public Policy

Under our constitutional system of federalism, jurisdiction over public health matters resides with the states. However, in the modern vaccine era beginning with Salk, the states have recognized that heterogeneous policy making at the state level is insufficient to protect their own populations against vaccine-preventable diseases. Nearly every State, for example, routinely adopts *in toto* the recommendations of the federal Advisory Council on Immunization Practices, the central policy making body.

Vaccine-preventable diseases do not respect state boarders. With modern interstate transportation and shipping practices, viruses responsible for vaccine preventable diseases move easily and rapidly between states. The 1989-90 measles epidemic occurred on a national basis, quickly sweeping across entire regions of the United States. Currently, a large epidemic of hepatitis A underway in Memphis, Tennessee, has spilled over into nearby Arkansas and Mississippi.

By statute under VFC, the ACIP determines which childhood vaccines, doses, schedules, etc., shall be covered under the entitlement. Although States are represented on the ACIP through individual members and professional groups, and they rarely, if ever, object to ACIP policies. However, if VFC were repealed or relegated to State block grants, ACIP's ability to set national vaccination policy would be weakened in that many States may not have the resources to ensure coverage for new, innovative vaccines. This would be particularly harmful for the [illegible], which have recently been approved by the FDA.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

MAY - 9 1995

MAY 8 1995

MEMORANDUM FOR THE CHIEF OF STAFF

FROM: ALICE M. RIVLIN

SUBJECT: Senator Packwood and the Vaccine for Children (VFC) Program

Background

Senator Packwood has recently taken an active interest in the Administration's Vaccine for Children (VFC) program; he held oversight hearings on the program last Thursday in the Finance Committee. In general, the hearing went well for us. While Packwood appeared critical of the entitlement nature of VFC, he mostly focused on policy issues rather than political criticism. However, he did work to establish that vaccine cost may not be the key factor in parents' failure to get children immunized, and asserted that the program has cost three and a half times more than the original estimates. (We believe the ratio is much smaller; it appears that the VFC program is now spending about one and a half times what the discretionary immunizations program would have spent, net of Medicaid dollars).

Your meeting this week with the Senator to discuss welfare reform offers an opportunity to let him know we want to work with him.

Points That Can Be Made to Senator Packwood

- We appreciate his focusing last Thursday's hearing on vaccine <u>policy</u>, not politics. We know he made an effort to give the VFC program a fair hearing, which we appreciate.

- The President's goal has always been to increase immunization rates. We are within striking distance of our goal to get 90% of 2-year olds immunized by end of 1996.

- We want to work with him if he needs to achieve savings or otherwise modify VFC.

Possible Compromise

One way to maintain the VFC program while producing savings and resolving a key concern of vaccine manufacturers would be to make VFC a capped entitlement beginning in FY 1998. We can argue that the program should be maintained at its current growth rate through FY 1996 in order to meet our immunizations goal, but that we are willing to consider freezing its size after FY 1997.

Assuming that VFC became a capped entitlement in FY 1997 with spending frozen at FY 1996 levels for the period from FY 1997 through FY 2000, there would be mandatory savings of more than $350 million.

Vaccine manufacturers have communicated informally that they would be supportive of a capped entitlement for VFC; what they resent the most about the program is that they see the proportion of vaccine purchased by the Federal Government (at a lower than market price dictated by law) continuing to grow.

Please let me know if we can provide you with other information on this.

DRAFT

Memorandum For The Chief of Staff

From: Nancy-Ann Min

Subject: Vaccines For Children Program

This memorandum responds to your request for some ideas about how to protect the goals of the Administration's Vaccines For Children (VFC) program, which we expect to be under attack again this year. We tried to look at the VFC program from the perspective of the Administration's success in protecting the school lunch program, and have identified some options to focus the VFC program and address its critics while still retaining its advantages. While the goal of immunizing children has almost universal support -- as does the goal of providing lunches to poor children -- some aspects of the VFC program can be assailed by critics as a bureaucratic morass. This memorandum outlines the background and current status of VFC, lists criticisms of the program, and discusses options that might be acceptable to us if the Republicans attack it.[1]

Description of VFC and CDC's Section 317 Immunization Programs

VFC is a mandatory program to provide Federally-purchased vaccines free of charge to Medicaid, uninsured and underinsured children. Health care providers enrolled in the program provide vaccines to Medicaid and uninsured children; underinsured children (i.e., those whose health insurance does not cover immunizations) can receive free vaccine in Federally Qualified Health Centers (e.g., community and migrant health centers). Private providers may charge administration fees, which are covered by Medicaid for Medicaid beneficiaries.

CDC also supports immunizations under Section 317 of the Public Health Act, funded by discretionary appropriations. Section 317 provides funds for the purchase of vaccines for children in public clinics and for State education, outreach, and tracking efforts. Prior to VFC, these "317" programs and Medicaid coverage of vaccines constituted the Federal Government's immunization efforts (Table 1 displays immunization programs before and after VFC.)

Immunization Spending, FY 1993 -- FY 1996
(dollars in millions, BA)

	FY 1993	FY 1994	FY 1995	FY 1996 Budget
Mandatory:				
Medicaid	*170*	*200*		
VFC		*81*	*377*	*365*
Total Mandatory	170	281	377	365
Discretionary (Section 317)	341	528	465	479
Total, All Spending	**511**	**809**	**842**	**844**

[1] We have attached a description of the Administration's original vaccine proposal from 1993.

Table 1: Immunizations Before and After VFC

Summary of VFC Changes:

- **For Uninsured Children, Free Vaccine Is Available in Doctor's Offices (Instead of Just In Clinics)**
- **For States, the Federal Government Now Pays 100% of Vaccine Cost for Medicaid Children (Rather Than Just Federal Match)**
- **For Medicaid and Underinsured Children, Not Much Has Changed**

Beneficiary or Target Group	**Before VFC** (prior to October 1, 1994)	**After VFC** (after October 1, 1994)
Medicaid Children	Vaccinated in doctor's office and by other Medicaid providers; Vaccines and administration fees paid for by **Federal Medicaid Payments** and State Medicaid matching payments	Where VFC is available: Vaccinated in doctor's office; vaccine paid for by **Vaccines For Children**; administration paid for by State and **Federal Medicaid payments** Where VFC is not available: Vaccinated in doctor's office; Vaccines and administration paid for by **Federal Medicaid Payments** and State Medicaid matching payments until October 1, 1995
Uninsured Children	Vaccinated in public clinic; Vaccines and administration **paid for by Section 317** and State Funds or, Vaccinated in doctor's office, paid for by parents	Where VFC Is Available: Vaccinated in doctor's office; vaccine paid for by **Vaccines For Children**: administration paid for by parents Where VFC is not Available: Vaccinated in public clinic; vaccines paid for **VFC,** administration paid for by Section 317 or State Funds or, Vaccinated in doctor's office, paid for by parents
Underinsured Children	Vaccinated in public clinic; Vaccines and administration paid for by **Section 317** and State Funds or, Vaccinated in doctor's office, paid for by parents	Vaccinated in public clinic; Vaccines and administration paid for by **Section 317** or State Funds or, Vaccinated in doctor's office, paid for by parents or, vaccinated in Federally Qualified Health Center (FQHC): vaccine paid for VFC, administration paid by ???
Insured Children	Vaccination obtained in public clinics; Vaccines and administration paid for by **Section 317** and State Funds or, vaccination obtained in doctors office, vaccination and administration paid for by insurance company	Vaccination obtained in public clinics; Vaccines and administration paid for by **Section 317** and State Funds or, vaccination obtained in doctor's office, vaccination and administration paid for by insurance company

Funding Sources: Federal Payments: **include Medicaid and VFC (entitlement spending) and Section 317 (discretionary appropriation)**
State Payments: **include** Medicaid matching payments, and other State budget resources
Private Sector: include insurance, out-of-pocket expenditures, and payment foregone by providers

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After VFC, the main changes were that 1) free vaccines for all uninsured children became an entitlement; 2) free vaccines were provided to private doctors (not just public clinics), and 3) States could choose to purchase vaccine for all children at the CDC price, i.e. lower than what the States had been paying.

Impact of the VFC Program

VFC passed in OBRA '93, and took effect on October 1, 1994. We can report that:

- VFC vaccine is available in all public clinics;
- currently 36 States are delivering vaccine to private providers and eight more plan to begin such delivery by the end of the year. Only four States (CO, LA, NE, and PA) do not plan to develop delivery systems, and HHS is now considering options to serve them;
- 21,000 private provider sites (with roughly 2.3 providers in each site) have enrolled. This rough estimate of 40,000 to 50,000 providers falls short of the 70,000 to 80,000 providers that HHS reported last summer would be enrolled by the end of FY 1995; and
- based on data for the first quarter of 1994, we are within reach of the Administration's goal of immunizing 90% of all two year olds for each antigen by 1996. (See Table 2 for more details). Rates do not distinguish among Medicaid, uninsured, underinsured, and insured children.

As shown in Table 1, VFC produces winners and losers. VFC most benefits uninsured children who can now receive free vaccine in their doctors' offices, -- previously, they were vaccinated free of charge only in State clinics.[2] VFC also represents a savings to State governments, since they used to pay between 22 and 50% of the cost of vaccination of Medicaid children (i.e., their Medicaid "match"), and now pay nothing.

Critics Focus on the Implementation Problems and Cost

Critics do not question the goal of immunizing children or even of raising immunization rates among two-year olds to levels currently held among five-year olds (which are over 95%). Instead, they have emphasized:

Delivery system: Critics have focussed on the program's difficulties in establishing a national delivery system (i.e., the GSA warehouse proposal).

Cost: Critics argue that the program's focus on vaccines' cost misses the real causes of low immunization rates (they argue, and some medical journal articles suggest, that non-cost barriers to immunization -- such as provider and parent knowledge -- are also important factors).

[2] Since many of these children may receive their care primarily in clinics, this benefit may be more perceived than real.

Table 2: Where We Stand in Relation to Our Goals

		1992	1993				1994	Goals	
		Whole year	1st Half	3rd Q	4th Q	Annual	First Quarter	1996	2000
Diphtheria/TetanusPertussis (DTP	3+	83%	87%	90%	88%	88%	**87%**	**90%**	90%
DTP	4+	59%	71%	75%	72%	72%	67%		90%
Oral Polio Vaccine (OPV)	3+	72%	78%	80%	79%	79%	**76%**	**90%**	90%
Hemophilus influenza b	3+	28%	50%	60%	58%	55%	**71%**	**90%**	90%
Measles Containing Vaccines (MCV)		83%	81%	86%	87%	84%	90%		
Hepatitis B	3+		13%	16%	23%		**26%**	**70%**	90%
3 DTP/3 Polio/1 MCV		69%	72%	79%	74%		76%		
4 DTP/3 Polio/1 MCV		55%	65%	72%	66%	67%	66%	-	90%

1) Data from the National Health Interview Survey. Data for the 2nd quarter of 1994 will be available in May.

2) This vaccine was only recently introduced, which accounts for its relatively low rate and for the lower goal (70%) in 1996.

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High Federal Expense: Some (including Labor/HHS Appropriations Chairman Porter and Senator Bumpers) also argue that the program is more expensive than necessary. Federal immunization costs are expected to rise from $511 million in FY 1993 to an estimated $842 million in FY 1995 (an increase of 65%; see funding table on page 1).

Uncontrollable Costs: Finally, they contend that the program's costs are uncontrollable because new vaccines could be added whenever CDC's Advisory Committee on Immunization Practices (ACIP) recommends that VFC cover them.

Capped Price: The price of all vaccines purchased is set at the CDC negotiated contract price in 1993, and can only increase by the CPI-U each consecutive year. Vaccine manufacturers claim that they cannot supply the amount of vaccines needed for all VFC eligible children at the capped price because they no longer have enough non-Federal clients to whom they can shift the costs. They also argue that they will have lower profit margins, reducing their ability and incentive to invest in research and development of new vaccines.

Other Manufacturers' Complaints: Some vaccine manufacturers contend that the Federal Government has cornered the vaccine market. HHS estimates that, at full implementation, discount purchases will account for 80% of all vaccines purchased, up from 50% before VFC.[3]

Of the four major vaccine manufacturers, only one -- Smith Kline -- has supported VFC. The others have impeded VFC implementation with lengthy delivery contract negotiations, raising issues that suggested that they did not ever intend to sign contracts. Further, HHS could only negotiate a vaccine purchase contract with Lederle for oral polio vaccine (OPV) that limits the number of doses purchased at the Federal price to 11 million, when the normal amount of OPV used in a year is 15 million doses.

Packages of Options

The VFC program as it finally emerged from Congress had 2 main problems: 1) it is more complicated than the previous system; and 2) it left us vulnerable to the charge that we were paying for shots for Donald Trump's children. We have identified some options that could address these problems. These options can be "packaged" in a variety of ways. Which package we choose depends on how we want to balance the goals of immunizing children, targeting Federal funds where they are most needed, and maintaining consistency with previous immunization policy (especially given the States' investment in VFC).

Congress may choose not to terminate the VFC program entirely, given the controversy over the rescission of funding for the school lunch program, but there are indications that members may seek savings by targeting VFC more narrowly or placing it in a Medicaid block grant. Given this

[3] OBRA 93 required that the Federal Government purchase all vaccines for the VFC at the CDC discount price, and authorized States to purchase vaccine from manufacturers at the discounted price. Before OBRA '93, some States said they wanted to purchase vaccines for all children in their State but were prevented from doing so because they had to pay a higher price.

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political context, we have constructed the two illustrative packages of options shown below. They have not yet been looked at by HCFA's actuaries; we will consult with them as soon as we can. The contents are summarized in a table on page 6.

Package A: Retain VFC Program as Entitlement, But Means-Test It

Critics have claimed that even wealthy children could receive federally-funded vaccines through the VFC program if their parents chose not to obtain insurance.[4] These criticisms can be met by targeting the program to low-income children. Eligibility for VFC could be changed to include only children whose families have incomes at or below some percentage of the Federal poverty level. VFC could be made a capped entitlement.

In addition to limiting eligibility, other changes could be proposed to satisfy the program's critics:

1. The current price cap for federal vaccine purchase could be removed or modified to include allowances for manufacturers' delivery, research and development, and a return on investment.[5]

2. States would not be able to increase the quantity of vaccine they purchase at the discounted CDC contract price.[6] (This addresses another concern of manufacturers, who fear further shrinkage of the non-contract market.)

3. States would be required to use some Section 317 funds to implement clinic assessments of immunization programs, which have demonstrated success with raising immunization rates in States. (This responds to Senator Bumpers' belief that clinic assessments are one of the best tools for getting more children immunized.)

4. States would accelerate immunization linkages to WIC or other Federal programs for low-income families.

5. The VFC statute would be changed so that it would no longer automatically cover new vaccinations recommended by ACIP. This would reduce growth in program costs and allow for greater certainty in predicting future VFC costs. (Some of the manufacturers actually like this aspect of VFC, because it puts additional Federal funds in their pockets automatically if they develop a new vaccine -- so this could be a bargaining chip with them if we approach them to get their agreement.)

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[4] The truth is that any child -- no matter what his parents' income -- could have gotten free immunization before if he went to a public health clinic. But by creating a new open-ended entitlement, VFC has highlighted this feature.

[5] It is unclear what effect the removal of the price cap would have on the budget. Scoreable federal costs would result from a change in law which raised the amount of the acceptable yearly increase in discount prices. A removal of the price cap would be more difficult to score, given the uncertainty that surrounds contract negotiations.

[6] States that currently have universal vaccine purchase would be grandfathered.

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Package B: Change VFC to Discretionary Program

This option would transform the VFC program by folding it back into Medicaid and CDC's discretionary immunizations program, which would be expanded to better serve the uninsured. Mandatory funds from VFC would be transferred into this discretionary program. Consistent with the "performance partnerships" created to consolidate PHS activities in the President's FY96 Budget, incentive grants to States would be awarded on the basis of immunization rates among uninsured children. This package would also reform the price cap, restrict State purchases at the discount price, encourage linkages, and require clinic assessments. It could also allow states to dispense vaccines through physicians offices, preserving one of the innovations of VFC.

Medicaid coverage for vaccines for Medicaid children would be simply reinstated. All States would be allowed to run "Medicaid replacement" programs for vaccine. These programs allowed States through a Medicaid waiver to buy vaccine for Medicaid children at the CDC negotiated price, which is an aspect of VFC they have liked.[7] The Federal match for vaccination could remain at something like VFC's 100%, since dropping it back to pre-VFC match rates could cost the States a lot.[8]

This proposal could be designed to avoid a net PAYGO effect. The amount of funds transferred to the discretionary program for uninsured children could equal the estimated mandatory savings from eliminating the VFC program, offset by the increased Federal Medicaid costs caused by reinstating Medicaid coverage and removing the price cap. We compare these two packages in the chart below.

[7] Senator Bumpers proposed this option as an alternative to several Congressional committees' proposals during the OBRA 93 debate.

[8] The Federal match for Medicaid family planning services provides a precedent for enhanced match rates -- currently, the match for family planning is set at 90%.

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	Package A: Retain VFC Program as Entitlement, But Means-Test It	Package B: Change VFC to Discretionary Program
Description	• Retain and means-test VFC • Eliminate or reform price cap • Limit States' ability to purchase vaccine at the discounted price • Require states to perform clinic assessment • Encourage linkages • Eliminate automatic coverage of new vaccines • Turn into a capped entitlement	• Transform portion of VFC into discretionary program targeting uninsured in performance measures; • Restore Medicaid coverage of vaccines for Medicaid children • Allow Medicaid replacement programs • Eliminate or reform price cap • Limit States' ability to purchase vaccine at the discounted price • Require states to perform clinic assessment • Encourage linkages and parental responsibility • Eliminate automatic coverage of new vaccines • Allow access to vaccine through physician offices
Pros:	• Limits eligibility to "needy" children • Reduces federal costs • Addresses vaccine companies' concerns over price cap and increased discount purchases • Encourages use proven techniques to raise immunization rates • Capped entitlement, as opposed to open-ended entitlement	• Targets Federal dollars on uninsured children • Maintains Federal coverage of vaccines for Medicaid children • Reduces federal costs ——→ ? • Addresses vaccine companies' concerns over price cap and increased discount purchases • Encourages use proven techniques to raise immunization rates
Cons:	• Means-testing will add complexity to States and providers who administer the program. Although it could be accomplished very simply, like the school lunch program, providers are already unhappy with the current VFC administrative burden. • Will result in higher contract prices • Limits States' access to the discount price	• Collecting data on uninsured will be costly • Will result in higher contract prices • Immunization policy loses continuity of the single VFC program • Limits States' access to the discount price

but also removes price cap — costs more

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Conclusion

Package A would focus eligibility for VFC to include only children whose families have incomes at or below some percentage of the Federal poverty level, and make it a capped entitlement. The price cap could be adjusted, clinic assessments could be encouraged, immunization linkages could be increased, some manufacturers' concerns could be addressed, and Federal financial exposure could be limited.

Package B eliminates the VFC program as an open-ended entitlement and moves the responsibility for immunizing uninsured children to the states through Federal discretionary funds. It reinstates Medicaid coverage of vaccines through Medicaid replacement programs. This option maintains the focus on uninsured children, the major beneficiary of VFC. It could allow states to distribute Partnership vaccine through physicians' offices. Through the "performance partnership" concept, it also makes States accountable for the immunization funds they receive, controls Federal costs, addresses some of the manufacturers' concerns, and increases the attention of program managers on the real problem of immunizations for uninsured children.

We believe both options could be crafted so as to be scored by CBO as budget neutral, though we still need to work with the actuaries to get that all nailed down. Both options address many of the criticisms of VFC by moving us away from a system where HHS and the states are preoccupied with worries about how to ship particular doses of vaccines that are purchased at Federally-controlled prices. (We don't set the price of lima beans used in school lunches -- or arrange for their delivery to every school). Either option could help to make the VFC program more like the school lunch program, and thus less vulnerable politically.

Which types of packages we choose to accept depends on how strongly we want to fight to retain the expanded entitlement status of VFC. Please let us know how you would like to proceed.

cc: Alice Rivlin

Administration's Initial Proposal on Immunizations

The Administration's original proposal, submitted to Congress on April 1, 1993, provided for the purchase of vaccine for all children and the development of State vaccine registries (a good idea that proved controversial because conservative groups raised privacy concerns). **The proposal did not cap the price of vaccine, but directed the Secretary to consider a variety of factors, including delivery, profit, and future research and development in negotiating the prices of vaccines.** A key objection to VFC is its impact on the future development of vaccines. The proposal did not identify a funding source for the program.

The proposal's elements included:

- Authority for the Secretary to purchase vaccines for children;
- Vaccine contract price to be negotiated by HHS considering R&D, production, distribution, marketing, profit levels to encourage future investment, maintaining outbreak capacity, and whatever the Secretary determines to be relevant (cost to include shipping and distribution; not to be charged to States);
- Vaccine to be distributed to providers in States with registry programs (available in a variety of clinics in those without);
- Providers may charge for administration, but not the cost of vaccine (must also report vaccination to State or Federal registry);
- Authority for the Secretary to develop a tracking registry. In States without registries, the Secretary will notify parents that children require vaccinations;
- Authority for the Secretary to make grants to States for tracking registries
  - -- State registries to be operational by October 1, 1996,
  - -- registry information to be confidential,
  - -- parents must provide a Social Security number to receive free vaccine;
- State Medicaid programs to cover vaccinations for Medicaid children;
- Funds to come out of special trust fund, funded by revenue to be identified in health care reform;
- Program sunsets with passage of health care reform; and
- Mandatory funding for purchase, discretionary for registries.