CONNAUGHT
LABORATORIES, INC.
A PASTEUR MÉRIEUX COMPANY
ROUTE 611, P.O. BOX 187, SWIFTWATER, PA 18370
GEOFFREY G. PETERSON
DIRECTOR OF GOVERNMENT AFFAIRS
AND PUBLIC POLICY
1401 EYE STREET, N.W., SUITE 200
WASHINGTON, DC 20005
202 • 898 • 3193 FAX 202 • 371 • 1107

GEOFFREY G. PETERSON

Jennifer

Thanks for taking the time to meet with me. I look forward to working with you to solve both our problem and yours.

Perhaps there is something we can do quietly through Bunyea on the mandatory state purchase this year that wouldn't open this up into a big political issue. Perhaps combining that with some Clinton initiative focussing on the so-called 15 pockets of need could be sold as a refinement to the program without going thru the controversy of hearings, investigations + Republican grandstanding. Just thinking out loud. I look forward to hearing from you

Jeff

CONNAUGHT
LABORATORIES, INC.
A PASTEUR MERIEUX COMPANY

Fact Sheet

The Company

• Connaught Laboratories, Inc. (CLI) is a leading developer and manufacturer of vaccines and other biological products. The company is dedicated to the prevention and treatment of important diseases throughout the world.

• Connaught Laboratories, Inc. is a subsidiary of Connaught Laboratories Ltd., of Toronto, Canada, a member of the Pasteur Merieux Serums & Vaccins (PMsv) family of companies. Rhone Poulenc, based in Paris France, owns Institut Merieux, the parent organization of PMsv.

• A Connaught/Merck partnership accelerates development of products that combine a number of antigens to protect children against many common diseases with a single shot.

Products

• Connaught Laboratories, Inc. provides the broadest range of human vaccines and biologicals commercially available from any single U.S. company. It is a leading supplier of vaccines for children and adults, including DTP, polio, Japanese encephalitis, yellow fever, meningococcal, *Haemophilus influenzae* type b, rabies, influenza and typhoid fever vaccines. Pasteur Merieux Serum & Vaccins S.A. provides the largest selection of vaccines and biologicals commercially available in the world.

• CLI was the first company in the world to receive FDA approval to study a vaccine to prevent Lyme disease in humans. Connaught's Lyme Disease vaccine Phase 3 efficacy trials involving more than 10,000 volunteers are well underway.

-more-

TELEPHONE: 717 • 839 • 7187
TELECOPIER: 717 • 839 • 7235
ROUTE 611, P.O. BOX 187, SWIFTWATER, PENNSYLVANIA 18370-0187
CABLE ADDRESS: CONNAUGHT SWUD

1401 EYE STREET, NW, SUITE 200, WASHINGTON, DC 20005
TELEPHONE: 202 • 898 • 3193
TELECOPIER: 202 • 371 • 1107

CLI Fact Sheet -2-

History

• CLI's Swiftwater, PA site has been home to vaccine companies for nearly 100 years.

• Connaught Laboratories, Ltd. acquired the Swiftwater site from the Salk Institute in 1978, thereby establishing CLI.

• Pasteur Merieux Serums & Vaccins, S.A. acquired CLL and CLI in 1989.

People

• CLI employs more than 600 people. Approximately 500 employees are based in Swiftwater. More than 100 Biological Product Specialists bring the latest product information to health professionals throughout the country. Since vaccine production is seasonal, temporary workers also assist the company during peak manufacturing times.

• Employees with diverse backgrounds help develop, manufacture and distribute Connaught's products. Types of employees include health professionals (physicians, nurses), regulatory specialists, biochemists, production specialists, administrative staff, engineers, Quality Assurance experts and sales and marketing representatives.

Community Partnerships

• Community Partnerships are valued highly by Connaught.

• The company continually seeks new opportunities to support the community with people, programs and financial contributions. Emphasis is placed on programs to improve education, health and the environment.

• Education has always been a high CLI priority. Community education is supported through scholarships, internships, and speaking engagements.

• Connaught employees are encouraged to support the community by getting involved in a Speakers Bureau, volunteering to help local organizations and participating on a Community Relations Team that guides these activities.

Mary Ann Chafee 1/26

Vaccine at no cost for Medicaid populations for docs
CDC price important. Merk replacement programs.
Problems in Medicaid — shown by diagnostic studies —
coverage worse in private doctors offices. ↳ David Wood did study for L.A.
$30 M to do demos to focus on high risk areas —
Bumpers

Universal purchase — if move to 70-80%, concern.
Problem for Bumpers. Danforth was more interested
Mercer report - lost $s to R&D.
But doesn't sound like huge concern

Continued guar. for Medicaid $ more generous reimb.
for docs — states buy at public price for Med.
So free up $

Capped entitlement — but carrots to make sure they
spend it.
Formula based on # of kids at whatever poverty
level. This is what we buy, and this is
what you can buy above that.

States don't have any way of knowing what they need.
Limitation on amount of vaccine.
States shld pick up cost of delivery.
Flex. for states to work out replacement programs
~~for~~ w/ manufacturers.
WIC vouchers - Bumpers likes - must implement in
every WIC clinic

Georgia - clinic audit - perf. data on individual providers

Distribution
- replacement
- tap into fed. distribution contract

Vaccine cos. worried about block grants.

Bill Corr Questions

① State entitlement for vaccine purchase - spent only in context of state plan that addresses 317 and VFC
② universal purchase caps
③ explicit limit on % of CDC purchase

NGA

Roundtable at WH 9:30 - 11:30 Monday
Potus address to plenary session 11:15 Tuesday

4:00 Monday
List of issues/timeline/who will talk to whom & when

Marg Ann Chafee

HOW WE CAN FIX THE VFC PROGRAM

- Reallocate funds that would be spent on more federal vaccine to activities we know will address the high-risk population.

- Amend OBRA as follows:

  Strike authority to purchase vaccine under VFC and use savings ($150M to $200M per year) to fund a capped entitlement for immunization grants to states.

  Half of each year's funds would be allocated to states based on need; the remaining half would be allocated to states based on performance (immunization coverage rates).

  States could use entitlement funds for any "infrastructure" activity: registries, expanding clinic hours and clinic personnel, tracking systems, parent and provider education.

  Include provision for "Medicaid replacement" to ensure that all vaccine for Medicaid children is purchased at the public price.

  Grandfather universal purchase states to ensure that such states can continue to buy all vaccine at the public price.

- The current 317 program would continue in place with all children eligible for free vaccine in all public clinics and health departments.

- The political questions can be answered as follows:

  The VFC program is being redesigned because, thanks to better data collection and evidence from studies of high-risk children, we now have a much better understanding of the problem.

  We haven't faltered in our commitment to ensure that all our children are protected from preventable disease -- we are all willing to spend money on the problem, we are just targeting our efforts more effectively.

  The VFC program is only one part of the President's Childhood Immunization Initiative -- all other parts of the CII will stay in place.

  The President could take the lead on this -- Bumpers and Danforth will carry it as an amendment to health care reform, and credit will be given to the Administration for its foresight in refining this one component of the CII.

TO: Hillary Rodham Clinton
FROM: Jennifer Klein
RE: Call to Senator Bumpers
DATE: 12/28/95

Here are some talking points for a call to Senator Bumpers. I would recommend that you make the call on Friday, December 29. Melanne will be seeing Senator Bumpers over the weekend, so if you let her know if you've reached him she will follow up. He can be reached at 224-4734.

The purpose of the call is to begin a process to work with him on changing the Vaccines for Children program while ensuring that it guarantees immunizations to needy children. We also plan to work with Senator Breaux and Congressmen Waxman and Dingell. While the vaccine manufacturers and Republicans are continuing to push for repeal, four of the five reconciliation bills (Daschle, Breaux/Chafee, Coalition Democrats and ours) leave the program in place. (I'm not convinced, though, that this means too much. The Daschle and Breaux/Chafee bills simply did not address VFC.)

I would recommend that you make the following points:

- I know that you have had concerns from the beginning about the VFC program.

- I also know that you and I both want to make sure that kids get the vaccines they need. I think the best way to do that is to protect assured funding for immunizations for children.

- We have made clear that we oppose repeal of the VFC program. We would, however, like to work with you on some significant changes to VFC. We have done a good deal of thinking about changes that would address the concerns that you and others have raised -- like giving states more flexibility to tailor the program to different needs and situations -- while ensuring that the cost of vaccine does not prevent children from getting immunized.

- Melanne Verveer and Jennifer Klein would be happy to work with your staff.

I have also attached a memo outlining options for the Vaccines for Children program that Secretary Shalala sent to Leon. Option 3 is the most likely to appeal to Bumpers. Leon has not made any decision on the memo, but based on my discussions with John Angell, I think he would agree with option 3.

cc: Melanne Verveer

~~CONFIDENTIAL~~

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

DRAFT

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

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

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

OPTIONS:

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

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

OPTION #1: RETAIN THE VFC PROGRAM

PROS:

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

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

CONS:

* Opponents will insist on changes in VFC.

* The VFC will continue to be controversial with Congress.

~~CONFIDENTIAL~~ DRAFT

* Vaccine companies will continue to attack the program claiming it erodes the private market.

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

PROS:

* Retains most important feature of VFC - guaranteed vaccine for most needy children.

* Addresses vaccine company concerns with regard to market stability.

CONS:

* Increases cost to states to continue their current VFC programs - although we believe state health officials are prepared to accept higher costs to eliminate controversy about the program.

* Vaccine companies would continue to oppose VFC due to fear of future governmental restrictions to assure entitlement costs do not grow excessively.

* Opponents will not view as adequate compromise.

OPTION #3: Significantly modify the VFC program making it a state entitlement. Option 3 would entitle the states to receive sufficient funds to purchase all necessary childhood vaccines for all children in families below a certain percent of poverty level. States would receive funds only if they enter into a performance partnership agreement which would specify the state's plan (including its use of Section 317 appropriated funds for immunization) for reaching the 1996 and 2000 immunization goals. States would be limited in the volume of vaccine that could be purchased through CDC. In effect, states would design their own immunization programs with technical assistance from CDC.

But
1. Manuf. nervous about block grant -- use §317 $ for purchase at low price?
2. Jurisdiction for this program?
3. O.K. on ending univ. purchase
4. Keep public purchase low enough? 60-65%
5. Fit w/ Medicaid replacement?
6. Include WIC demonstration

PROS:

* Retains most important feature of VFC -- guaranteed vaccine for most needy children.

* Could garner support from key Democratic supporters and states.

Funding path for VFC?

~~CONFIDENTIAL~~ **DRAFT**

* May not be opposed by vaccine companies

* By removing individual entitlement could improve opportunity to reach compromise with Congressional Republicans. Program would still accomplish President's objectives.

CONS:

* Pediatricians and other advocacy groups supporting an individual entitlement may oppose, especially because it sets precedent for rest of Medicaid.

* Increases cost to states to continue their current efforts -- although we believe state health officials are prepared to accept higher costs to eliminate controversy about the program.

HOW TO PROCEED:

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

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

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

IMMEDIATE
OFFICE OF THE ASSISTANT SECRETARY
FOR HEALTH

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

FAX: (202) 690-6960
PHONE: (202) 690-7694

HEALTH "FAX"

TO:	FROM:
Jennifer Klein	Bill Corr

FAX NUMBER: 456-2878

MESSAGE:

PLEASE CALL: PTS _____ ASK FOR _____

IF ANY PROBLEMS WITH TRANSMISSION

NUMBER OF PAGES 2 (NOT COUNTING COVER PAGE)

501-664-1156
301-229-4906

TALKING POINTS FOR CONVERSATION WITH SENATOR BUMPERS

* I would like to talk with you about the Vaccine for Children Program (VFC). I hope this will be the first of several discussions.

* As you know, the Administration has taken a firm position on retaining the Medicaid entitlement. In stating our position, we have made clear that the VFC program should not be repealed. We were pleased to see that the budget proposal from the Blue Dog Democrats also does not repeal the VFC.

(JENNIFER: WE ARE STILL CHECKING ON SENATE PROPOSALS)

* I want you to know that while we are vigorously opposing repeal, we would like to work with you to see if we can agree on some significant changes in the VFC. Our goal in making these changes would be to avoid in the future the disagreements and controversies that have surrounded the VFC.

* We have done a great deal of thinking about potential changes. I believe we could develop a proposal with you that would be widely accepted by other Members and interested parties.

* I believe we can meet your concerns with the VFC while accomplishing our goal of a nation-wide immunization effort with assured funding for necessary vaccines for needy children.

Q. Our immunization coverage rates for two-year old children are now at historic highs. What role did the Vaccine for Children Program play is our current rates?

A. The VFC plays an essential role in our current childhood immunization system. Unfortunately, the impact of the VFC on immunization rates has not yet been recorded.

Our immunization goal is for children to have all their shots by age two. Our survey, therefore, questions the immunization status of two year old children (the actual survey questions the status of children 19 to 35 months old). Our most recent survey covers calendar year 1994. Since the VFC began in October, 1994, the 1994 immunization rates include only a few children who may have received one of their recommended shots with VFC purchased vaccine.

Even so, there is much to say about the essential role the VFC plays in our current immunization system.

* By providing guaranteed funding for all necessary vaccines for virtually all needy children, and by assuring that important future vaccines are automatically included, the VFC is a critical component of a nation-wide immunization system and infrastructure that will enable us to keep our rates at high levels. Without the organized system, our country could easily slip back into the same complacency that resulted in the measles epidemic of 1989 - 1991.

* We know that millions of children who are poor and on Medicaid or uninsured or who are American Indian or Alaskan Natives have received tens of millions of doses of childhood vaccines paid for through the VFC.

* The VFC has paved the way for an enduring partnership between private physicians and public health. This new relationship will have a lasting effect on our ability to assure that all children are protected against vaccine preventable diseases.

* The VFC has already made it possible for several new immunizations to be added to our childhood schedule (for example, Hepatitis B for adolescents and varicella), and for a substantial increase in the number of children who receive a second dose of measles vaccine. These additions are evidence of the commitment embodied in the VFC that all necessary childhood vaccines will be available to all needy children.

CLOSE HOLD

January 3, 1996

Health Division

Office of Management and Budget
Executive Office of the President
Washington, DC 20503

Please route to:

Richard Turman
Mark Miller
Barry Clendenin
Nancy-Ann Min

BC

Decision needed	___
Please sign	___
Per your request	X
Please comment	___
For your information	___

With informational copies for:

HPS Chron, HD Chron

Subject: Answering Your Questions on VFC Repeal

From: Gordon Agress and Nikki Highsmith

Phone: 202/395-4926
Fax: 202/395-3910
Room: #7026

Attached please find our memo answering your questions on State purchase rights and Section 317 funding levels in the event of VFC repeal. We have structured the memo to answer your two questions and placed other information in Appendices. The first appendix addresses the possibility that States may shift payment of Medicaid children's immunization from Medicaid to Section 317, and the second appendix shows several possible compromise positions on VFC short of full repeal.

Attachment

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

JAN 3 1996

Memo To: Nancy-Ann Min

Through: Barry Clendenin BC
Richard Turman
Mark Miller

Subject: Impact of VFC Repeal on State Purchase Rights and Section 317 Funding Levels

From: Gordon Agress and Nikki Highsmith

You asked us, if VFC is repealed: 1) "What to do about State access to the contract price for vaccine?"; and, 2) "What is the proper level for Section 317 vaccine purchase?" In short, we suggest:

> Answer 1: Getting States purchase rights to as much contract-price vaccine as possible, probably by using some version of the Breaux formula; and, grandfathering universal purchase States.
>
> Answer 2: Funding Section 317 vaccine purchase at $205 to $227 million in BA in FY 1997 to cover HHS estimates of uninsured and underinsured children losing Federal entitlement to immunization in VFC repeal. Estimates for any given year would depend on the date and conditions of VFC repeal.

The most recent data available show immunization rates in 1994 approaching the Administration's goals of 90% immunization of two-year olds with the initial and most crucial doses of vaccine. In that same year, States had less access to the contract price for vaccine than suggested in Answer 1 above, and Section 317 had funding comparable to that suggested in Answer 2. Thus the above suggestions will make Federal immunization programs even stronger than they were in 1994 when those high immunization rates were recorded.

(HD staff note that if the repeal of VFC results in State Medicaid programs paying some portion of the costs of immunizing Medicaid children (as opposed to VFC's 100% Federal payment), States will have an incentive to shift the cost of immunizing those children to Section 317 -- which is also 100% Federally funded. *Such potential cost shifting is the basis for manufacturers' concerns and the Breaux formula, and could increase the demand for Section 317 funds.* We recommend considering reducing this incentive to shift by requiring States to contribute to Section 317 vaccine purchase costs as they do for Medicaid [or some variation thereof]. However, States are likely to object, since Section 317 has never been subject to such a match. For simplicity, this memo assumes no match; however, the attached Appendix One provides our analysis and recommendation on shifting and a State match.)

Your questions probably require different answers in scenarios short of full VFC repeal, since State Medicaid programs could bear fewer costs if some portion of VFC is retained. For example, scaling VFC back to coverage of only Medicaid children while retaining 100% Federal payment of these children's immunization would substantially reduce States' concerns about access to contract price vaccine while increasing demand for Section 317 vaccine purchase funding. *For simplicity, this memo assumes full repeal of VFC.* The attached grid (please see Appendix Two) outlines potential compromises short of full VFC repeal.

Question #1: **VFC Repeal Imposes New Costs on States**

For States, one of VFC's key features is its 100% Federal payment for the immunization of Medicaid children. Repeal of VFC would restore State matching payments for Medicaid children and repeal their right to purchase vaccine at the discounted CDC contract price -- imposing new costs on States and raising the price they pay for vaccine at the same time. States would prefer to retain VFC's purchase rights to minimize these new costs while manufacturers prefer to minimize the amount of vaccine sold at the discounted price.

Senator Breaux compromised with manufacturers to achieve some State purchase rights for Medicaid children. The Breaux amendment to the Senate reconciliation bill allowed States to purchase vaccine at the contract price for their Medicaid children, adjusted by the assumption that 75% of Section 317 funds paid for Medicaid immunizations.[1] Staff from the Association of State and Territorial Health Officers (ASTHO) told HD staff that manufacturers were willing in principle to sell States vaccines for Medicaid children at the contract price. Manufacturers wanted the limitations in the Breaux amendment, because allowing States to buy contract price vaccine for all of their Medicaid children -- without adjustment for Medicaid children immunized under Section 317 -- would allow States to purchase more vaccine at the contract price than they actually need to immunize Medicaid children. ASTHO staff say that the Breaux amendment's assumption that 75% of Section 317 funds covers Medicaid children is too high, and that the adjustment should be 25%. HD staff know of no data to evaluate these numbers.

Recommendation, Question #1: **We recommend using some variation of the Breaux formula to obtain the best deal (e.g. as much vaccine at the contract price as possible) you can on State purchase rights for Medicaid children.** Without better information, HD staff cannot say what the right number is. We recommend that a compromise include provisions to ensure the development of better information -- States should report enrollment of Medicaid children, how many of these children were immunized on Medicaid, and how many children were immunized on Section 317. Purchase rights should be adjusted annually for these levels. HD staff also suggest seeking to grandfather the contract price purchase rights of the existing 15 universal purchase States now purchasing at the contract price. (Please see Appendix One for recommendations on preventing such shifting in the first place.)

---

[1] The amendment was dropped in conference and was not included in the vetoed reconciliation bill.

Question #2: Section 317 Funding Levels

Estimates of Section 317 funding levels in the event of VFC repeal depend on what policy the Administration pursues. They are also complicated by poor data about which groups are currently immunized under Section 317 and uncertainty about the effective date of any VFC repeal. We lay out three general options below. For simplicity, HD staff estimates are for FY 1997, assuming that this could be the first full program year, after VFC has been fully phased out; we used data from FY 1994 and FY 1995. These estimates will change as we obtain new data from HHS. Estimates for any given fiscal year would also depend on when VFC was repealed and how it was phased out.

Estimate 1 funds Section 317 to cover uninsured and underinsured children, the groups most affected by VFC repeal (Medicaid children would retain the Federal entitlement). Covering the uninsured and the underinsured that were covered by VFC in FY 1995 would require roughly $205-$227 million for vaccine purchase after adjustment for new vaccines (for a detailed analysis of this estimate, please see Appendix Three; for comparison with other estimates, see table at right). Estimate 2 simply adjusts FY 1994 appropriations for new vaccines, which would result in a level of $234 million in FY 1997. Estimate 3 uses HHS' informal estimate that Section 317 will require $317 million in vaccine purchase funds without VFC. (However, HHS staff have discussed neither what assumptions they made, nor what fiscal year they have in mind.)

Section 317 Vaccine Purchase: Estimates of Funding Levels After VFC Repeal
(dollars in millions)

FY 1995 BA	$152
FY 1996 (Likely) BA	$152
FY 1997 BA:	
Estimate 1: Cover VFC's uninsured and underinsured	$205-227
Estimate 2: Restoration of FY 1994 Levels	$234
Estimate 3: HHS Estimate	$317

Recommendation, Question #2: **We recommend planning for $205-$227 million for Section 317 vaccine purchase in FY 1997 if VFC is repealed, while we work with HHS to develop more robust estimates.** This would require $54-76 million over the Likely Level for FY 1996 and the RMO recommendation for FY 1997. These funds could be taken from the immunization Performance Partnership Grant and the "other" Section 317 grants which grew substantially after VFC was enacted and Section 317 funding for vaccine purchase was reduced (see Appendix Four). We are seeking more information to improve these estimates. (Please note that if States shift Medicaid children to Section 317, the requirements for Section 317 would rise above HD staff estimates. Please see Appendix One for our analysis and recommendations on shifting.)

Attachment

Appendix One -- Reducing Incentives to Shift Payments from Medicaid to Section 317

There is some evidence that, prior to VFC, States shifted payment for Medicaid children's immunization to Section 317 because a State match was required under Medicaid and States paid nothing under Section 317.[2] **Any repeal or amendment of VFC will restore this incentive.**

Such shifting:

- Reduces manufacturers' willingness to sell States contract price vaccine for Medicaid, since it confirms their suspicion that States actually need less vaccine for their Medicaid population that (question #1).
- Increases the demand for Section 317 funding; the estimates above do not account for shifting and would have to be revised upwards to do so (question #2).
- Reduces the amount of Section 317 funding available for uninsured and underinsured children.
- Shifts payment for immunization of Medicaid children from a mandatory source to a discretionary source. While Medicaid may be capped in some form, the proposals' caps provide for some growth; most proposals for discretionary caps assume no growth or annual reductions.

The incentive to shift could be reduced by requiring States to contribute to Section 317 vaccine purchases as they do to the Medicaid program, using similar rates as used for Medicaid.[3] This would impose new costs on some States, and would change the culture of Section 317, which traditionally has provided vaccine for any child appearing at a public clinic. However, HD staff analysis shows that States are already spending about as much of their own funds on vaccine as they would contribute at Medicaid FMAP rates. (Please see the attached table. Assuming States contributed according to the FY 1995 Medicaid FMAP, 32 grantees' FY 1995 expenditures would be an average of $211 thousand *below* their required contribution, and 23 grantees *exceeded* their requirement by an average of $321 thousand.) Vaccine purchased with State contributions could still be distributed through private providers or State clinics, as the States preferred. Even with State contributions, State public health clinics could continue to immunize all children who come to clinics, but would have to determine whether a child's immunization should be billed to Medicaid or Section 317. Such a requirement would seek to

---

[2] We note that ASTHO staff agree that some portion of Section 317 funding went to Medicaid children, though it says the proportion shifted was lower than Senator Breaux and the manufacturers thought (ASTHO says that 26.8% were shifted, while Sen. Breaux and the manufacturers compromised at 75%). South Carolina immunization officials say that Medicaid savings from VFC implementation were surprisingly low, even though State immunization rates were quite high. This suggests that while South Carolina's Medicaid children were immunized, their immunizations were paid for by some source other than South Carolina's Medicaid program.

The incentive to shift prior to VFC was exacerbated because Medicaid purchased vaccine at the undiscounted catalog price; however, the incentive to shift children so as to pay nothing rather than pay some cost will exist even if that cost is reduced by access to the contract price.

[3] The authorizing language in Section 317 of the Public Health Service Act contains nothing inconsistent with such a requirement, and some provisions that could be interpreted as allowing it; it is possible that such a requirement could be established without amendment to the legal authority in Section 317.

preserve Section 317 funds for uninsured children and focus the program's vaccine purchases on those children who have no other public recourse.

We suggest pursuing this possibility, since it reduces the difficulties addressed in question #1 about purchase rights and question #2 about Section 317 funding levels.

Analysis of Potential State Contributions to Section 317

This table shows State contributions if States matched Section 317 funds as they do Medicaid expenditures, and compares those contributions with current State purchases of vaccine with their own funds.

That comparison shows that States are already spending most of what they would have to contribute if Section 317 were to have a matching requirement -- and that many States' purchases currently exceed their contribution under such a requirement.

Column 1 shows actual State purchase of vaccine with their own funds in FY 1995. Vaccine was distributed through private providers and clinics.
Column 2 shows States' purchases of vaccine with Section 317 funds in FY 1995. Vaccine was distributed through clinics.
Column 3 shows total State purchases with Section 317 and State funds; no VFC purchases are included (i.e. sums Columns 1 and 2)
Column 4 shows the rate of State contributions to Medicaid (i.e. the inverse of the FMAP).
Column 5 shows how much a State could be required to contribute if Section 317 had a contribution requirement and they had to to pay using FMAP rates (shown in column 4) and they received the same volume of 317 vaccine using FY 1995
Column 6 compares the State contributions in column 5 with States' actual expenditures in FY 1995 (i.e. subtracts Column 5 from Column 1), and shows that while on average States currently spend more than they would be required to contribute if Section 317 had a match, some States would have to spend somewhat more than they do now.

Source: HHS Data

Dollars in thousands

	FY 1995 actual				HD Staff Analysis of State Contributions	
	State Purchases	317 Purchases	Total Non-VFC Purchases, Section 317 and State Funds	State Rate of Contribution to Medicaid (per FMAP)	State share of total purchase at Medicaid matching rates	State Share over/under State purchases in FY 1995
	(Column 1)	(Column 2)	(Column 3)	(Column 4)	(Column 5)	(Column 6)
Total	**$66,726**	**$82,278**	**$149,004**		**$63,318**	**$3,408**
Alabama	$630	$2,980	$3,610	29.55%	$1,067	-$437
Alaska	$19	$810	$829	50.00%	$414	-$395
Arizona	$1,154	$1,817	$2,971	33.60%	$998	$155
Arkansas	$729	$1,108	$1,837	26.25%	$482	$247
AS		$68	$68	37.13%	$25	-$25
California	$1,955	$3,172	$5,127	50.00%	$2,563	-$609
Colorado	$912	$853	$1,765	46.90%	$828	$84
Connecticut	$3,905	$227	$4,132	50.00%	$2,066	$1,839
D.C.	$71	$43	$114	50.00%	$114	-$43
Delaware		$238	$238	50.00%	$119	-$119
Florida	$1,950	$6,292	$8,241	43.72%	$3,603	-$1,653
Georgia	$2,940	$2,856	$5,796	37.77%	$2,189	$751
GU		$161	$161	50.00%	$80	-$80
Hawaii		$174	$174	50.00%	$87	-$87
Idaho	$595	$1,163	$1,758	29.86%	$525	$70
Illinois	$5,339	$1,848	$7,186	50.00%	$3,593	$1,746
Indiana	$240	$2,033	$2,273	36.97%	$840	-$600
Iowa	$713	$270	$983	37.38%	$367	$346
Kansas	$1,266	$2,106	$3,372	41.10%	$1,386	-$120
Kentucky	$25	$2,196	$2,221	30.42%	$676	-$651
LA		$807	$807	27.35%	$221	-$221
Maine	$113	$690	$804	36.70%	$295	-$182
Maryland	$341	$2,367	$2,708	50.00%	$1,354	-$1,013
Massachusetts	$1,844	$2,862	$4,706	50.00%	$2,353	-$509

Michigan	$1,068	$3,918	$4,985	43.16%	$2,152	-$1,084
Minn		$1,439	$1,439	45.73%	$658	-$658
Mississippi	$1,979	$265	$2,244	21.42%	$481	$1,498
Missouri	$2,775	$1,890	$4,666	40.15%	$1,873	$902
Montana		$800	$800	29.19%	$234	-$234
Nebraska	$264	$1,125	$1,388	39.60%	$550	-$286
Nevada	$1,704	$23	$1,727	50.00%	$864	$840
New Hampshire	$662	$707	$1,369	50.00%	$684	-$23
New Jersey	$127	$1,804	$1,931	50.00%	$966	-$838
New Mexico	$940	$1,507	$2,446	26.69%	$653	$287
New York St	$6,231	$2,293	$8,524	50.00%	$4,262	$1,969
North Carolina	$4,183	$1,442	$5,624	35.29%	$1,985	$2,198
North Dakota	$590	$0	$590	31.27%	$184	$405
Ohio	$5,538	$1,885	$7,423	39.31%	$2,918	$2,620
OK		$1,115	$1,115	29.95%	$334	-$334
OR		$804	$804	37.64%	$303	-$303
Pennsylvania	$236	$1,434	$1,669	45.73%	$763	-$528
Puerto Rico	$907	$1,040	$1,947	50.00%	$973	-$67
Rhode Island	$496	$850	$1,346	44.51%	$599	-$103
South Carolina	$1,909	$1,350	$3,259	29.29%	$955	$954
South Dakota	$372	$904	$1,276	31.94%	$407	-$36
Tennessee	$1,022	$1,215	$2,237	33.48%	$749	$273
Texas	$3,667	$3,828	$7,495	36.69%	$2,750	$917
Utah	$843	$1,400	$2,243	26.52%	$595	$248
Vermont	$215	$540	$756	39.18%	$296	-$81
Virgnia	$1,315	$764	$2,080	50.00%	$1,040	$275
VI		$177	$177	50.00%	$88	-$88
Washington State	$2,459	$2,860	$5,319	48.03%	$2,555	-$96
West Virginia	$335	$696	$1,031	25.40%	$262	$73
Wisconsin	$2,138	$2,872	$5,010	40.19%	$2,014	$125
Wyoming	$16	$427	$442	37.13%	$164	-$149

Appendix Two: Potential Fallback Options Short of VFC Repeal

Potential Fallback Options for VFC in Medicaid Reform	
Medicaid	**317 Discretionary**
Current Policy: 1) Retain VFC as a 100% Federally funded program at current law levels - either under the POTUS plan or a block grant. Retain State's access to contract price for immunizations.	1) Retain 317 funding at current law levels.
Middle Position: 2) Retain VFC as a 100% Federally funded program - either under a per capita cap or a block grant; however, reduce current law spending by scaling back VFC to only cover Medicaid children (i.e. do not provide coverage to uninsured and underinsured children).	2) Increase Section 317 funding to cover uninsured and underinsured children. State access to contract price for Medicaid children not an issue for States; attempt to grandfather universal purchase States' option to purchase vaccine at contract price.
If VFC Disappeared: 3) Under a block grant approach, require States to provide matching payments for immunizations. Only cover Medicaid eligible children.	3) Obtain as much access to contract price as possible for States. Increase Section 317 funding for uninsured and underinsured children. Possibly, use administrative mechanisms and State matching payments for 317 to reduce States' incentive to shift Medicaid children to 317 discretionary program.

Appendix Three: Detail of Estimate 1 of Section 317 Vaccine Purchase after VFC is Fully Phased Out

Generating Estimate 1 for Section 317 funding after VFC repeal (dollars in millions)	
Estimated Section 317 outlays on vaccine purchase, FY 1995	$ 82
VFC outlays on vaccine purchase, FY 1995	*$ 214*
*Uninsured children as % of total VFC Population**	*35%*
*Underinsured as % of total VFC Population**	*11%*
Total percentage of VFC population losing coverage in repeal	*46%*
VFC outlays on children losing coverage (obtained by multiplying percentage by VFC spending on vaccine purchase)	$ 98
Total outlays on vaccine purchase, through Section 317 and by VFC on children losing coverage	$ 180
5% adjustment for possible weaknesses in data on VFC population	+/-$9
Estimate of Section 317 outlays after full phase out of VFC Repeal, but using the current vaccine schedule	$ 171-189
Adjustment for New Vaccines**	20%
Estimate of Section 317 outlays after full phase out of VFC, adjusted for new vaccines	**$205-227**
FY95 Appropriation (budget authority)	$ 152
Increase over FY 1995 Appropriation	$ 54-76
* HHS estimates based on rough State reports.	
** As estimated by CDC staff.	

Medicaid Am. Indian

or 96

This estimate is based on rough outlay data for VFC and Section 317, since outlays are the only VFC data that are available. They generate an outlay estimate of $205-227 million when VFC repeal is fully phased in. Since we would need that much budget authority in some previous years to generate these outlays, and discretionary programs are appropriated in budget authority, for simplicity's sake we have assumed Section 317 would need $205-227 million in budget authority in FY 1997 under this set of assumptions, though in the first years we could actually make do with somewhat less than that since outlays lag budget authority. After transforming the outlay estimates into budget authority and comparing that budget authority with the FY 1995 appropriated level for vaccine purchase (which is also the FY 1996 Likely Level and the FY 1997 RMO recommendation), we find funding is not far off -- only about $54-76 million would be needed under this estimate.

Appendix Four: Immunizations Funding Table

Mandatory and Discretionary CDC Funding for Immunizations
(dollars in millions)

	FY 1993	FY 1994	FY 1995	FY 1996 Likely	FY 1996 *Request*	*FY 1997 RMO Rec*
Discretionary:						
Infrastructure	45	163	141	141	*0*	*0*
Vaccine Purchase	191	187	152*	152*	*166*	*152*
Performance Partnership Grant	0		0	0	*177*	*177*
Other	105	178	170	170	*145*	*136*
Total Discretionary	341	528	464	464	*488*	*464*
Mandatory:						
VFC		85	457	457	*457*	*457*
Medicaid	170	200				
Total Mandatory		285	457	457	457	457
Total	**511**	**813**	**921**	**921**	**945**	**922**

* Reflects Congressional appropriation. In FY 1995 CDC spent $82 million on discretionary vaccine purchase. Congress allowed CDC to shift up to $66 million to other activities if not needed for vaccine purchase. Similar flexibility is expected in FY 1996.

Fallback

205 - 227

150

110

RDD registries Polio eradication

922 - amt of uninsured/underinsured