

SB
SmithKline Beecham
Pharmaceuticals

Jean-Pierre Garnier, Ph.D.
President-North America

March 15, 1993

Roz
Were you able to
reach them to
say Shalala
is handling?

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

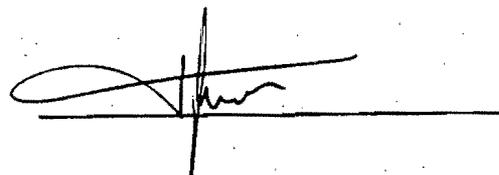
Dear Ms. Rasco:

On February 15, I had the pleasure of meeting with you as part of a group of four executives representing the vaccine providers in the United States. Following our meeting, I joined these same executives in a March 1 meeting with Secretary Shalala and her senior staff, to discuss the Administration's childhood vaccines initiatives.

SmithKline Beecham is in agreement with your stated goals to immunize America's children. We have very carefully crafted a proposal which we believe meets those goals. In addition to the infrastructure requirements for better delivery of vaccines, we have addressed the need to provide all public programs for the needy including Medicaid with the CDC bid price on an apportioned basis. We feel that our proposal strikes the balance between providing our government and its programs with the lowest price on vaccines, while at the same time preserving a private market, which will allow for companies to stay in the vaccine business and continue their search for new and better vaccines. I presented a working draft of this proposal to Secretary Shalala's senior staff at a private meeting on March 4, and I would like to have an opportunity to present it to you at your earliest possible convenience.

I am enclosing an executive summary as well as a more detailed description of the recommendations that we have made to HHS. I believe that a short presentation of this proposal would prove very useful to your efforts in crafting a childhood vaccine program.

Sincerely,



FEDERAL IMMUNIZATION PROPOSAL

Executive Summary

- 1. Require all states to provide Medicaid coverage to all children whose family income is 185 percent of the poverty level and require states to cover the physician's follow-up office visit needed to complete immunizations.**
- 2. Avail the CDC price to Medicaid from all manufacturers who are awarded the CDC bid as long as CDC bid quantity includes the needs of Medicaid programs. In order to ensure the pricing stability of the market place, the Vaccine Injury Compensation Fund should be restored.**
- 3. Replace the CDC winner-take-all system with an "apportioned" bidding system which would allocate a share of the bid to all bidders but favoring the lowest bidder.**
- 4. Devise a variety of ways of availing vaccines to Medicaid programs at the CDC price. The current proposal of a "free replacement program" may be of limited utility towards enhancing vaccination rates.**
- 5. Require all private insurers to provide coverage of all AAP recommended childhood immunizations in their plans and make preventive care services, including immunizations, part of basic health care benefits in any plan that is adopted to provide universal health care coverage. Preserve the private sector of the vaccine market.**
- 6. Simplify the regulatory approval process for vaccines, particularly the new combination products, with clearer guidelines and expedited approval.**
- 7. Require a multi-pronged approach to improve access, outreach, education and delivery of immunizations, including a national immunization tracking and surveillance registry.**

FEDERAL IMMUNIZATION PROPOSAL

PRINCIPLES FOR A FEDERAL IMMUNIZATION PROGRAM

The following principles should guide the development of a federal plan to increase childhood immunization rates:

Principle 1: Elimination of Financial Barriers to Immunization

Clearly, the families of some children face financial barriers to immunization and these should be addressed through a combination of private and public approaches. Government health programs that serve needy children should be able to purchase vaccines from manufacturers at the lowest prices.

Principle 2: Preservation of Healthy Private Market

A private market for vaccines must be preserved to support research and development of future vaccine products. This includes retaining and expanding the role of private insurance for immunizations as well as streamlining the regulatory processes that approve new vaccine products.

Principle 3: Guaranteed Participation in Public Market

All vaccine manufacturers should be allowed to participate in a competitive federally administered program to purchase vaccines on behalf of all government programs. A winner-take-all system extended to an expanded public market would drive most companies out of the vaccine business and make it virtually impossible for new entrants to compete, eliminating competition (thus driving up prices in the long run) and severely hampering innovation.

Principle 4: Improved Access, Outreach, and Restoring Liability Protection

Experts agree that improved access and outreach are critical to increasing this nation's childhood immunization rates, and universal purchase of vaccines alone will be insufficient to increase vaccination rates. Furthermore, tort reform in the long run and restoration of the Vaccine Injury Compensation Fund immediately will go a long way towards containing the cost of vaccines, more so than universal purchase.

RECOMMENDATIONS

Issue 1: Elimination of Financial Barriers

One reason for low immunization rates is lack of Medicaid coverage for children whose parents don't meet poverty guidelines and don't have health insurance.

Recommendation:

Require all states to provide Medicaid coverage to all children whose family income is 185 percent of the poverty level and require states to cover the physician's follow-up office visit needed to complete immunizations.

Rationale:

Currently, Medicaid coverage for childhood vaccines is relatively good, primarily because the EPSDT program requires states to provide all medically necessary immunizations to the categorically needy. The problem is that eligibility guidelines can vary by state. For example, all states now cover children up to age 6 from families with incomes at 133 percent of poverty level. But some states raise the eligibility level to 185 percent of poverty. Mandating Medicaid eligibility for all children up to 185 percent of poverty level would guarantee that almost 3 million more children would be eligible for Medicaid coverage and immunizations, according to Bureau of the Census poverty statistics.

In addition, most experts agree that inadequate reimbursement levels provide strong disincentive to physicians to immunize Medicaid patients. Many states provide no payment for follow-up visits required to complete the immunization schedule. Requiring coverage of these visits should provide enough additional reimbursement so that physicians don't turn eligible children who need immunizations away.

RECOMMENDATIONS

Issue 2: Availability of Vaccines to the Needy

All government health programs serving needy children should be able to purchase vaccines at the CDC prices as long as such demand has been represented in the CDC bid.

Recommendation:

Guarantee that Medicaid programs have the right to purchase vaccines from all manufacturers who are awarded the CDC bids at the CDC price as long as the quantity of demand has been represented in the CDC bid.

Rationale:

To make sure all states have access to the most favorable prices for vaccines, an expanded CDC-administered bidding program makes sense. The Medicaid program could garner significant savings from CDC pricing for childhood vaccines. By combining the broadened eligibility with the most favorable vaccine pricing, we estimate that Medicaid potentially could save about 50 percent (or about \$50 mil.) of its total outlay on childhood vaccines (MMR, DPT, OPV, and HiB) while covering nearly double the number of children (see next page).

The concern over the affordably priced vaccines to Medicare programs has been one of the driving objectives for childhood vaccine reform. However, the affordability and the long term price stability of vaccines are likely to be tied to the medical-legal environment. The expiration of the Vaccine Injury Compensation Fund is anathema to long term cost containment of vaccines because manufacturers will need to provide for the uncertainty of enormous legal awards, and physicians need to provide for added malpractice. When the fund is restored, the newer vaccines (HiB for bacterial meningitis, and HBV for hepatitis B) should also be covered. Indeed, the long term price stability of vaccines lies not only in a mechanism to avail vaccines to the needy alone, but also in tort reform.

**SAVINGS TO MEDICAID IF FOUR VACCINES OFFERED AT FEDERAL
DISCOUNT PRICES WITH BROADER ELIGIBILITY**

Now		Proposed	
Children eligible at 159% of poverty line age <6 (1)(2)	8,902,000	Total # of children eligible at 185% of poverty line age <6 (1)	10,194,000
Age cohort (3)	1,570,313	# of children in the age cohort (2)	1,798,200
Assumed to be 60%	842,188	Vaccination rate assumed to be 90%	1,618,380
Assumed to be 90%	1,413,282		
		Cost of vaccines	
DPT (4)	\$9.97	DPT (5)	\$6.2
Hib (4)	\$14.55	Hib (5)	\$5.1
MMR (4)	\$25.29	MMR (5)	\$15.3
OPV (4)	\$9.46	OPV (5)	\$2.0
Vaccines	\$59.26	Total cost of vaccines	\$28.7
Medicaid:		Vaccine cost to Medicaid:	
0% coverage of 159% of poverty	\$55,834,042	- assuming 60% coverage of 159% of poverty	\$27,078,480
0% coverage of 159% of poverty	\$83,751,091	- assuming 90% coverage of 185% of poverty	\$46,512,800
0% coverage of 185% of poverty	\$95,806,324		
PROJECTED SAVINGS AT 90% COVERAGE AT 185% OF POVERTY		\$49,393,524	

(1) from "Poverty in the United States: 1991"

(2) rate of Medicaid poverty line from Table 3 "Annualized Medicaid Eligibility Thresholds" from National Governors' Association, January 1992
(3) age data from "Statistical Abstract of the U. S. A. 1991"

(4) Discount Price from Table 8 "Federal Vaccine Price Discount, 1991" from "Medicaid and Childhood Immunizations: A National Study"

(5) Discount Price from Table 8 "Federal Vaccine Price Discount, 1991" from "Medicaid and Childhood Immunizations: A National Study"

RECOMMENDATIONS

Issue 3: Guaranteed Participation in Public Market

It is critical that a federal immunization program ensure that multiple manufacturers participate in the public market so that supplies are adequate and incentives are strong for the development of new vaccines by existing players and new entrants.

Recommendation:

Replace the CDC winner-take-all system with an "apportioned" bidding system which would allocate a share of the bid to all bidders at the lowest bid price according to a formula. For example:

<u>NO. OF BIDDERS</u>	<u>LOWEST BID SHARE</u>	<u>OTHER BIDS' SHARES</u>
2	60%	40%
3	40%	30%-30%
4	32.5%	22.5%-22.5%-22.5%

If the lowest bidder could not satisfy the allotted share, then the other bidders would be awarded the excess share, at the next lowest bid price.

Rationale:

This expansion of the public market underscores the need to preserve a private market as well as guarantee the public market requires participation of multiple competitors. This is so for several reasons.

First, a sole-supplier situation has serious potential commercial and technical problems. The commercial problem is illustrated by the shortage of DTP vaccine experienced in the mid-80s. The technical problems, according to the 1985 Institute of Medicine report entitled Vaccine Supply and Innovation, includes potency variation, stability problems, quantitative imbalance of microbial components in polyvalent or combination vaccines, variations in the response to inactivation processes, excessive undesirable biological activity and inadvertent contamination.

Because vaccine manufacturing requires major investment in a sophisticated production plant and the establishment of teams with multidisciplinary expertise in the large-scale production of biological products, it is essential to preserve a market with multiple manufacturers. This public market

Moreover, without a private market and a guaranteed share of a large public market, manufacturers may either leave the vaccine development business or decide not to enter it at all. For a new entrant in the childhood vaccine market the potential disincentives are many—complexity of development, production and quality control; lengthy vaccine production processes which may adversely affect inventory and cash flow; cost of research and development; perception that vaccines historically have received less effective patent protection than drugs and apprehension over the liability situation.

Without healthy, competitive public and private markets, the incentives to enter the market will not be sufficient, especially for any company that possesses significant technological know-how, and is about to commit considerable resources in developing new pediatric vaccines.

RECOMMENDATIONS

Issue 4: Mechanism for Availing Vaccines to Medicaid Programs

How would the "apportioned" bid system actually work to make CDC vaccine prices available to state programs?

Recommendation:

A number of distribution approaches could be used and states should be given the option to select the approach that makes the most sense for them.

Here are at least two approaches:

1. **State replacement:** Where states currently buy vaccines directly from CDC and warehouse, and distribute directly or indirectly to Medicaid physicians, they would continue to do so, according to an apportionment scheme which may be administered by CDC.
2. **State-contracted distribution:** States would allow private wholesalers to bid for the right to distribute vaccines it purchases to Medicaid physicians within the state, according to an apportionment method.

Caution should be voiced towards the "free replacement" or consignment approach in the form proposed by some manufacturers because it is simply a consignment program targeted at high volume Medicaid physicians--not necessarily all physicians who could enhance the rate of vaccination--and is intended to create a de facto monopoly of the distribution channel within that state at the expense of retail pharmacies and physician supply houses. Moreover, this de facto monopoly can then be naturally broadened to include the vaccine supply to private patients as well as non-pediatric vaccines. Indeed, the long term consequence of this particular program is that the cost of vaccines will drift up by virtue of the distribution monopoly within the state.

RECOMMENDATIONS

Issue 5: Preservation of Healthy Private Market

Some private insurers do not cover immunizations. This forces physicians to pass on costs to parents or to refer them to already overloaded public clinics. A 1990 HIAA survey showed that only 62 percent of commercial insurers provided full immunization coverage.

Recommendation:

Require all private insurers to provide coverage of all AAP recommended childhood immunizations in their plans and make preventive care services, including immunizations, part of basic health care benefits in any plan that is adopted to provide universal health care coverage. Such coverage should be first dollar coverage and include all three components of the immunization: vaccine cost, administration cost and the office visit.

Rationale:

Requiring all private insurers to provide immunization coverage, like the Commonwealth of Pennsylvania, would eliminate any financial barriers to immunization for the privately insured and put a needed emphasis on preventive care as recommended by the Health Insurance Association of America's 1992 Good Health Prevention Initiative. Bolstering coverage in the private sector should relieve public clinics and alleviate the need for a universal vaccine purchase program. Long term savings on the health care system through such broadening coverage in the private sector is good public policy, as every \$1 spent on vaccination will save \$10 on future medical care.

The elimination of a private market is harmful to the public health interest. The elimination of the private market will raise the public price because the current level of private market vaccine prices are subsidizing the public vaccine market. If the price of the public market does not go up, then the number of manufacturers will go down while certain manufacturers on the cusp of entry will not enter as a result. There is no need to provide free vaccines to the insured or to those who can afford it.

RECOMMENDATIONS

Issue 6: Reducing the Hurdle for Rapid Availability of New Technology

The regulatory approval process is cumbersome and inefficient and slows the development of new vaccines.

Recommendation:

Speed up the regulatory approval process for vaccines, particularly the new combination products, with clearer guidelines and expedited approval. Articulate clearly the regulatory burden of proof for approving combination vaccines, with the advice of an advisory committee. The FDA should be encouraged to propose measures that will simplify the approval of vaccines.

Rationale:

Streamlining the regulatory approval process will help manufacturers get new products to market more quickly to the benefit of all. One of the more significant examples of such product technology advancements will be a combination pediatric vaccine that will contain several antigens. This combination will increase immunization rates by virtue of the reduction of number of injections. Furthermore, as the vaccination schedule of different antigens are unified, there is potential reduction in the number of physicians visits, thus saving significant public and private funds.

RECOMMENDATIONS

Issue 7: Improved Access and Outreach

Most public health officials agree that the cost of vaccine plays a minor role in the failure of large segments of the population to receive vaccinations. Important factors other than the ones mentioned above that have been recognized by the Public Health Service and the National Vaccine Advisory Committee include the following:

- lack of education about the benefits of childhood immunization
- missed opportunities for vaccine delivery due to the failure to sufficiently link immunization services with other private and public sector (e.g., private physicians, the WIC program, unemployment benefits) interactions with persons who are not immunized
- inadequate tracking of vaccine delivery and the failure to fully fund methods of providing immunization services to underserved populations (e.g., public health clinics, outreach programs)
- cultural misconceptions regarding vaccines, and hypersensitivity to perceived vaccine risks

Recommendation:

Require a multi-pronged approach to include:

- easier and increased access to public health clinics and outreach programs
- education programs to eliminate the misconceptions about immunization and ensure that information about the need for and methods of obtaining vaccines is widely disseminated
- coordination of Federal, state and local immunization programs to ensure that no opportunity to immunize a child is missed
- establish a national immunization tracking and surveillance registry at CDC to collect and analyze data on childhood immunizations

THE WHITE HOUSE
WASHINGTON

DATE: 3/8

NOTE FOR: *PAVETTA, PASTER, Rubin, Rasco*
VARNEY, LEA MAGGIER, HRC
The President has reviewed the attached, and it is forwarded to you
for your.

Information

Action

Thank you

JOHN D. PODESTA
Assistant to the President
and Staff Secretary
(x2702)

cc:

THE PRESIDENT HAS SEEN 3/8

THE WHITE HOUSE

WASHINGTON

March 4, 1993

MR. PRESIDENT:

Attached is a decision memo from Donna Shalala recommending that a childhood immunization bill, including universal purchase, be introduced within the next few weeks, but moved as part of reconciliation rather than as a free-standing bill.

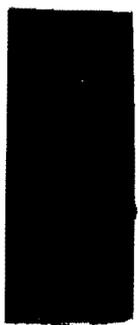
Howard Paster does not object to this approach, but wants you to be aware that currently there is not adequate money in the economic plan for a full-blown immunization initiative -- which means that if the bill is moved in reconciliation, money will have to be taken from someplace else in the economic plan to pay for it. If that cannot be done, then the bill would have to be moved separately.

OMB believes the bill could involve significant costs and would prefer to work out cost estimates with HHS before a final decision to go forward is made.

Approve Await Discuss
Shalala Cost
Proposal Estimates

JOP
John Podesta

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Do for in extramur
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New copies
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THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 3 1993 MAR 3 05:14

MEMORANDUM TO THE PRESIDENT

FROM: DONNA E. SHALALA 

SUBJECT: Childhood Immunization Initiative

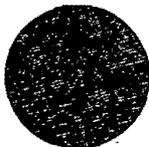
Based on recent conversations with Carol Rasco and Howard Paster, I believe there is now a consensus on drafting a comprehensive childhood immunization initiative for submission to the Congress, including a Federal universal vaccine purchase provision, to assure that all children in the United States are protected against vaccine preventable infectious diseases.

In addition to the universal purchase provision, the legislative initiative would create a national tracking system to provide accurate and timely information about the immunization status of children and monitor the efficacy of vaccines, reauthorize the Vaccine Injury Compensation Program, simplify the vaccine information materials that are provided to parents, enhance the capacity of the Center for Disease Control to ensure optimum safety and effectiveness of immunizations, clarify the authority of the Secretary to take appropriate action to protect the domestic supply of vaccines, require that all Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) programs under Medicaid provide vaccines as recommended by the Advisory Committee for Immunization Practices (ACIP) and approved by the Secretary, set a Medicaid fee schedule for vaccine administration costs at a level sufficient to enlist participation of private providers, and encourage additional appropriations as reflected in your stimulus package to rebuild our public health infrastructure and to expand educational programs.

We would like to proceed to draft this bill for introduction by key congressional supporters within the next few weeks. We would encourage the appropriate Committees to conduct hearings on the measure but refrain from moving the legislation as a free-standing bill. The entire package would be placed in reconciliation.

Needless to say, we would closely coordinate our activities with the White House.

THE WHITE HOUSE
WASHINGTON



DATE: 2/12/93



NOTE FOR:

MACK MCLARTY
HOWARD PASTER
CAROL RASCO

The President has reviewed the attached, and it is forwarded to you
for your:

Information

Action



Thank you.

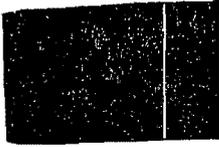
JOHN D. PODESTA
Assistant to the President
and Staff Secretary
(x2702)



cc:

THE WHITE HOUSE
WASHINGTON

February 11, 1993



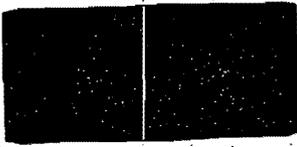
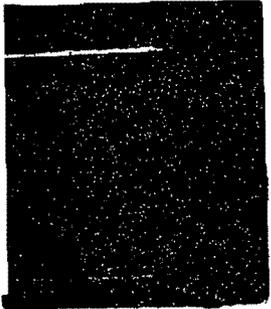
MR. PRESIDENT:

Mack, Mark and Carol have
seen and ok'd the Podesta/
Stern summary memo.



John Podesta

Handwritten notes:
Mack ok'd
C. J. Stern
High Strategy
W. J. Brown
Craw



THE WHITE HOUSE
WASHINGTON

THE PRESIDENT HAS SEEN
2/12/93

February 11, 1993

MEMORANDUM FOR THE PRESIDENT

FROM: JOHN PODESTA *JOP*
TODD STERN *TS*

SUBJECT: Childhood Vaccination Initiative

Attached is a February 7 decision memorandum from Donna Shalala (Tab B) together with a February 11 addendum (Tab A) recommending a major initiative to assure that American children are adequately immunized against infectious disease.

Sec. Shalala's initial memo recommended (1) inclusion of sufficient money in the economic stimulus package to begin funding measures to improve public immunization infrastructure and (2) introduction of comprehensive legislation -- including universal purchase of vaccines by the federal government -- as quickly as possible following your February 17 address to Congress.

OMB raised significant concerns regarding the "extraordinarily ambitious" scope of the proposed legislation -- citing such elements as universal purchase, a nationwide tracking system, and the creation of a new appropriated entitlement. OMB also raised concerns about new costs and whether the proposal would fit within the resources allocated during preliminary FY 94 budget decisions. Howard Paster raised concerns about the potential adverse impact a free-standing immunization bill could have on your larger health care initiative.

In the Addendum, Sec. Shalala proposes that you do the following:

(1) Announce at tomorrow's event your intention to submit, as part of your stimulus package, an immediate \$300 million infusion of funds to improve immunization services, education and outreach;

(2) Announce tomorrow that you have directed the Secretary of HHS to develop a comprehensive legislative package;

(3) Direct the Secretary of HHS to enter into immediate negotiations with drug manufacturers to provide lower cost vaccines to states for all programs administered by HHS;

(4) Introduce free-standing immunization bill, including universal purchase, within the next few weeks, with prompt committee hearings and movement toward a markup -- but hold the final bill for inclusion in the reconciliation package.

Howard Paster sharply disagrees with introduction of any free-standing immunization bill. See attached Paster memo. (Tab C)

Carol Rasco has reservations about the recommendation to introduce separate legislation in the next few weeks, describing this as a political call in terms of how we deal with Congress and the drug companies. Her comments are penned in on the February 11 Shalala memo.

Note that the first three recommendations could be decided without, at this time, resolving whether to introduce the free-standing bill recommended by Sec. Shalala. An early draft of your statement for tomorrow is also attached (Tab D), which does not reference the fourth recommendation.

Recommendation (1) -- Announce \$300 million infusion

Approve [] Disapprove [] Discuss []

Recommendation (2) -- Announce development of legislation

Approve [] Disapprove [] Discuss []

Recommendation (3) -- Announce negotiations with drug cos.

Approve [] Disapprove [] Discuss []

Recommendation (4) -- Introduce free-standing bill, including universal purchase, in next few weeks

Approve [] Disapprove [] Discuss []

Need to discuss



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D. C. 20201

February 11, 1993

MEMORANDUM FOR THE PRESIDENT

FROM:

DONNA E. SHALALA *DS*

SUBJECT:

Addendum to Decision Memorandum of February 7, 1993
Concerning Legislative Initiative to Comprehensively
Address the Nation's Childhood Immunization Crisis

We have received the budget passback from the Office of Management and Budget (OMB) which contains \$300 million in FY93 immunization funding to begin the process of rebuilding our infrastructure and financing necessary education and outreach activities. We believe that the \$300 million is a major investment in childhood immunization and should be heralded in this context in your announcement tomorrow. It will enable the Department to initiate vital activities to overcome the tragic neglect of the last twelve years.

We have also developed in consultation with key congressional staff the specifications for a Comprehensive Legislative Initiative that includes universal purchase of vaccines, the development of a national tracking system, and other long-range improvements in the current immunization program. Since this initiative funds the universal purchase program through new mandatory spending authority and suggests as an option a special research and development investment tax credit to encourage continued research in childhood immunizations, it has not cleared OMB and the Treasury Department at this time.

We would suggest that you announce tomorrow that you have directed the Secretary of Health and Human Services to develop a Comprehensive Legislative Package for early submission to the Congress without specifying the details. This would enable us to work through the specifics with OMB and the Treasury Department and to build additional support in Congress.

We believe that the legislative package should ultimately be considered as part of the reconciliation legislation and that a specific funding source for the universal program be identified in this context. This should remove congressional concerns about funding (an option to consider is identifying a funding source in the introduced bill). We would recommend that the legislation be introduced within the next few weeks and that the committees begin hearings and move toward a mark-up, but that the final package be held until reconciliation.

This will be a political call - both in terms of how we deal with Congress and the drug manufacturers.

In the discussions concerning the development of the comprehensive initiative between Department staff and staff from key Senate and House Members (Kennedy, Riegle, Bumpers, Waxman, Dingell, and Rostenkowski), it became clear that the congressional staff are concerned by the impact of a Universal Purchase Program on future research and development activities for new vaccinations. There is tremendous enthusiasm for the remainder of the Initiative (increased funding for infrastructure, education, and outreach activities, a universal tracking system, and reauthorization of the Vaccine Injury Compensation Program.)

Staff feel that the Members will support an Initiative with a universal purchase provision, despite their concerns, but they will not have much "fire in their bellies," particularly if vaccinations will be a mandated benefit under the National Health Insurance Reform.

Despite staff concerns, Marian Wright Edelman informed me this morning that in her conversations yesterday with Senator Kennedy and Congressman Waxman, that they did not share the reservations of their staff with regard to the universal purchase feature. Senator Riegle's staff informed Department staff this morning that he would enthusiastically support this initiative even with his reservations over the impact of a universal purchase program on future research and development activities.

In summary, let me emphasize my strong support for a universal purchase program. Therefore, I recommend that you announce tomorrow your intention to submit, as part of the stimulus package, a \$300 million immediate infusion of funds into immunization activities, and that you have directed the Secretary to develop a comprehensive package. (I assume that you will also direct the Secretary to immediately enter into negotiations with the drug manufacturers to provide reduced price vaccines to states for all programs administered by the Department.)

No final decision on this.



February 7, 1993

MEMORANDUM FOR THE PRESIDENT

FROM: DONNA SHALALA *DS*
SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Legislative Initiative to Comprehensively
Address the Nation's Childhood Immunization Crisis

I. ACTION-FORCING EVENT

We understand that you plan to include in your State of the Union Address a proposal for swift enactment of a comprehensive initiative to assure that all American children are adequately protected against preventable infectious disease. This initiative is a cornerstone of your prevention strategy. It is both a first phase of your overall plan to reform the American health care system and a free-standing effort aimed at addressing a fundamental matter of public health safety for all Americans. It reflects two promises made during the 1992 Presidential campaign: to assure all children access to preventive health services; and to control drug prices which now are escalating at three times the rate of inflation.

In order to have this initiative ready for introduction with key Congressional support immediately following your State of the Union Address, we need your approval to prepare legislation. The Department, in cooperation with the Domestic Policy Council, will develop legislation. In doing so, we plan to intensively consult key Members of Congress.

In readying the information and recommendations contained in this Memorandum, we have had wide-ranging discussions with experts both within and without the Department. We also have consulted with the First Lady in her capacity as head of the Interagency Health Reform Task Force.

II. BACKGROUND ANALYSIS

A. The Problem

Like clean water, immunization against preventable diseases constitutes not only medical care but a basic public health protection. A stable, reliable, easily accessible, and

affordable vaccination system is a tenet of all civilized nations. Indeed, so basic is the need for vaccination against disease that the United Nations has undertaken special childhood immunization efforts throughout the world as a fundamental public health measure.

In 1979, the Surgeon General of the United States established a series of public health goals for the nation, which were to be achieved by 1990. One of the most important goals was protecting all children against infectious, vaccine preventable disease. In order to achieve this goal, it was deemed essential that by 1990, at least 90 percent of all children under age two should be fully immunized.¹

The Surgeon General set clear outcome measures for determining whether the childhood immunization goal would be met. In the case of vaccine preventable disease, the outcome measure used was the number of preventable disease cases nationally in 1990. With respect to measles, for example, the Surgeon General estimated that successful immunization efforts would reduce the number of cases nationally to no more than 500 by 1990.

By 1990, however, only 60 to 70 percent of all infants and toddlers were fully immunized against preventable disease.² In some large cities, pre-school immunization levels as low as 10 percent have been reported by the Centers for Disease Control (CDC). Rather than improving immunization levels among America's youngest children they actually appear to have declined slightly.

Unacceptably low immunization levels pose a basic health threat to very young children. Moreover, very low immunization rates permit controllable diseases to spread throughout communities. A clear example of this phenomenon was the measles epidemic which swept the nation between 1989 and 1991. According to the CDC, the epidemic produced 55,467 cases of measles in three years. In 1990 alone, the year in which there were to be no more than 500 measles cases nationwide, there were more than 27,000 cases. One hundred and sixty people (by and large children) died. Most of these deaths were considered preventable.

¹ While 100 percent of all children should be vaccinated, a 90 percent immunization rate constitutes the minimum level required to assure community-wide protection against disease (often referred to as "herd immunity").

² Indeed, because the nation made no progress, the goal of protecting all children was postponed until the Year 2000.

The 1989-91 measles outbreak also produced significant and avoidable health care costs. Each dollar spent to immunize children has been estimated to save between ten and fourteen dollars. The recent measles epidemic illustrates these numbers. The outbreak produced 11,260 separate hospitalizations and 44,100 hospital days. Avoidable hospital costs alone amounted to more than \$20 million. These costs do not include either medical or the long term health, educational or social costs associated with measles and its complications. Experts believe that further outbreaks of measles and other preventable diseases will occur without significant improvement in childhood immunization levels.

B. Barriers

Health officials point to many factors underlying low immunization levels among American children. These are:

1. A significantly eroded public health care infrastructure which has further limited the availability of essential immunization services in inner city and low income communities. Publicly funded health programs, such as community and migrant health centers, rural health clinics, the National Health Service Corps, county and city health clinics, and public hospital clinics, are a principal source of care for low income patients. These clinics by definition are located in areas where poverty impedes access to health care and increases risks to health.

These programs are substantially under-funded. They do not have adequate staff. They cannot afford to remain open on nights and weekends. They do not have a sufficient supply of publicly purchased free vaccine. They do not have the community workers they need to find and assist particularly hard-to-reach families, whose children remain un-immunized.

As a result, the recent measles outbreak struck poor children with particular severity. Based on a 10-city study, the Public Health Service has estimated that between 40 and 91 percent of unvaccinated infants who developed measles were enrolled in public assistance programs.

2. High vaccine prices that make immunizations purchased outside the federal CDC procurement system all but unaffordable. Currently the CDC purchases half of all vaccines used in the U.S. These vaccines are sent to state health agencies which in turn distribute them to local clinics. In New England and Washington State, state health agencies purchase additional vaccines through CDC to

distribute directly to private physicians. In this way, physicians receive free vaccines purchased at a reduced price, participate in state immunization efforts, and charge families only a modest administration fee (if anything at all). In recent years, in response to high vaccine prices, several other states, including Texas, South Carolina and Hawaii, have sought to establish these programs but their efforts to buy additional vaccines through the CDC contract have been rejected by manufacturers as "against public policy".

* Childhood vaccine price increases over the past decade have been dramatic. For example, in 1981 a dose of DPT vaccine cost \$.33. By 1991, the cost of the same vaccine dose had risen to \$9.97 -- a 2,921% increase.

At the price private physicians now must pay, it costs \$ 245 for the vaccine alone for families with children cared for by private doctors to fully immunize each child against preventable disease. With the cost of injecting the vaccine included, each dose of vaccine costs a family about \$45.00.³ Children need 18 separate doses of vaccine to be fully immunized.⁴

Paying for vaccinations out-of-pocket poses a significant burden on lower income working and uninsured (or underinsured) families. This is particularly true for young families, who are most likely to have young children and who have seen their real earning levels decline substantially over the past 20 years. Reimbursement for vaccine at the full market rate also poses a major cost problem for private insurers and for both the Medicare and Medicaid programs.

The escalating cost of privately administered vaccines has led an increasing number of physicians to send families to public clinics, where vaccinations are cheaper. The same vaccination series that costs \$196.00 in a private physician's office costs only \$96.00 in a public clinic. It is no surprise, therefore, that families are routinely sent to public clinics. But many may fail to ultimately get the vaccine for their children because of the burdens imposed by multiple visits.

³ The CDC estimates that it costs about \$5.00 to administer an injection in a public clinic.

⁴ This includes 2 doses of oral polio vaccine, 2 measles/mumps/rubella vaccinations, 3 vaccinations against Hepatitis B, 4 vaccinations against hemophilus influenza, 3 vaccinations against diphtheria, pertussis and tetanus, and 2 vaccinations against acellular pertussis.

Experts agree that opportunities to immunize children cared for by private physicians thus are being lost. At least one-third of the children with measles during the 1989-1991 outbreak had at least one previous visit at which an opportunity for vaccination was lost. This shift of privately cared for children into the public system is also adding to the strain on the public system.

3. Poor provider understanding about appropriate immunization practices (such as the acceptable practice of giving multiple vaccines in a single visit) that leads them to under-immunize children.

4. The lack of a national tracking system (like the vital statistics system for recording births and deaths) which helps local, state and federal officials identify and vaccinate children who remain unvaccinated. A tracking system is deemed essential by public health officials. It permits them to measure the current immunization status of a community, not merely guess at it. Without a tracking system the nation has no accurate, "real time" information on immunization status and cannot respond to potential crises. Federal officials literally cannot measure with accuracy whether basic public health goals have been met.

5. The failure to develop safer, simpler vaccines through aggressive research. Although manufacturers claim they are spending billions of dollars on vaccine research, results have been inadequate. The NIH does not have sufficient research stimulus funds⁵ to generate an appropriate level of effort targeted on childhood immunization. Left to establish their own research priorities, manufacturers have not moved swiftly enough to bring safer and more efficient vaccines to market. Indeed, the sheer number of separate vaccinations children must now receive to be adequately immunized may be contributing to under-immunization. Parents simply do not understand that children need 18 separate vaccinations.

6. Insufficient funding for the FDA to assure that new vaccines are rapidly tested for safety and efficacy. This further slows innovation in research.

⁵ According to the Public Health Service, NIH research funds now represent 10 percent of all funds spent on immunization research.

7. A troubled, non-functioning vaccine compensation system which lacks sufficient funding to settle backlogged cases, is applying dated standards, and whose funding base for future cases is no longer authorized. In 1986 a federal vaccine compensation program was developed in order to address manufacturers' concerns over their liability for vaccine related injuries (they threatened to cease production of vaccines altogether). The system is now in need of repair in several respects. Four thousand cases arising prior to enactment await action and settlement and cannot be resolved without additional appropriations. Legislation authorizing a special vaccine excise tax to settle post-enactment vaccine injury claims has expired. Without a functioning compensation program, continued involvement by both manufacturers and physicians in vaccination activities is potentially in question.

8. A related problem is that federally developed informed consent materials (written information used to educate families about potential vaccine dangers to their children) are considered unnecessarily complex and difficult for families to understand. It may have a deterrent effect on both the families who read it and on physicians' willingness to provide immunization services.

C. An Action Plan

Experts both within and without the federal government have made numerous recommendations for effectively addressing all of these problems. Virtually all of these recommendations are contained in an Immunization Action Plan which was developed by the Public Health Service and which calls for improvements in both public and private immunization delivery systems. The plan is comprehensive. Yet it remains virtually non-implemented because of a lack of interest and commitment by the Reagan and Bush Administrations. The Action Plan's recommendations mirror approaches to vaccine purchase, distribution and administration used in virtually all industrialized nations with private health insurance systems.

The recommendations include the following elements:

1. An infusion of funds to improve and strengthen publicly funded primary health care programs. This means increased funding to local health departments, community and migrant health centers, rural health clinics, the National Health Service Corps, and other vital "safety-net" providers of

health care for low income and medically underserved patients. These clinics all need a stable supply of vaccine. They also need additional staff and operating resources to both furnish immunizations and to provide the primary health care for children that should accompany immunizations.

With funds included in the economic stimulus package, these improvements can begin as early as this summer.

2. A new system under which the federal government would purchase the vaccines needed by both public and private providers at a negotiated rate. Manufacturers would ship vaccines directly to physicians, clinics and other providers. These health providers would, in turn, charge families only a modest administration fee. Such a system also would permit the establishment of a national tracking system, since all providers participating in the vaccine distribution system would, like hospitals delivering babies, provide state and federal agencies with information about each child immunized. Insurers such as Medicare, Medicaid and private insurers potentially would realize significant savings, since vaccines would be bought and shipped in a coordinated fashion through negotiated rates.

Families and insurers (including Medicare and Medicaid) would therefore pay only a modest administration fee, regardless of whether patients receive care from public clinics or private doctors. The crisis of missed opportunities would be reduced dramatically, with potentially enormous financial savings to families, insurers and state health agencies.

3. Assurance of a stable funding source for vaccine infrastructure, purchasing and delivery activities that is based on mandated spending through a capped entitlement not subject to year-to-year variations (as is the case with discretionary appropriations). The number of needed doses is known and the prices can be negotiated. In this way, financing for vaccine activities would keep pace with the appropriate cost of a comprehensive vaccination effort. This type of budgeted and stabilized financing arrangement is consistent with your long-range thinking about how to purchase health care generally.

4. Funds to develop and maintain a vaccine tracking system, tied to the distribution of vaccines, that permits patient tracking and community surveillance.

5. Reforms in the vaccine compensation program so that it is once again operational, as well as simplification of the vaccine information materials in order to reduce the burden on families and providers. Funds will be needed in both Fiscal 1993 and Fiscal 1994. Additionally, the taxing authority for post-enactment claims will need to be extended.

6. A new approach to vaccine research that emphasizes funding through NIH (rather than less reliable, indirect funding through profits to manufacturers) for childhood vaccine research.

7. Increased funding to the FDA to improve and simplify approval systems and strengthen safety and oversight activities.

8. Funds for renewed international vaccine efforts in cooperation with the World Health Organization and UNICEF. According to the Public Health Service, the nation's experience with smallpox showed that the \$32 million spent by the U.S. to help eradicate smallpox worldwide through a combined international effort has led to savings of \$600 million annually.

9. Educational efforts aimed at patients and health providers to inform them about the importance of vaccinations (and in the case of providers, safe and effective immunization practices).

10. Involve the private sector in community vaccination efforts and make community vaccination outreach a key element of your National Service program.

D. Support for these recommendations

Support for improving immunization levels through these comprehensive reforms is widespread. Supporters include experts in public health, pediatricians, the Public Health Service, many Members of Congress, children's advocates and others. Key individual and organizational support comes from Mrs. Carter and Mrs. Bumpers and their childhood immunization effort (known as Every Child by Two), Marian Wright Edelman and the Children's Defense Fund, the American Academy of Pediatrics, (particularly its incoming President, Dr. Betty Lowe), the March of Dimes, and others.

E. Opposition to the reforms

Only two of the reforms described above have generated significant opposition. These are proposals to simplify vaccine information materials and to establish a universal vaccine purchasing program for all families.

Simplification of vaccine material: This is opposed by an organization known as Dissatisfied Parents Together, a group consisting of several thousand families with children who allege injury by vaccine.

Universal purchasing: This system is adamantly opposed by the manufacturers, as well as by Dissatisfied Parents (which opposes any effort to increase access to vaccines). In addition, a number of key industry critics are concerned by one issue as described in the first bulleted argument.

Manufacturers make several arguments. These are:

- o first, that by reducing current profit levels, a coordinated purchasing arrangement will cut into vaccine research (industry critics also are concerned about retaining sufficient funding levels for research efforts);

- o second, that such a system will provide free vaccines to rich children; and

- o third, that prudent purchasing lead them to give up the production of vaccine altogether.

The industry is extremely powerful. We believe that it will fight this effort because of its precedent-setting value.

F. Responding to opposing arguments

Public health experts, children's advocates, health care providers, and public officials respond strongly to these points. With respect to the parents group's concerns about the safety of vaccines, experts uniformly reply that the dangers associated with not vaccinating children vastly outweigh those associated with childhood immunization.⁶

⁶ Indeed, a new study from the National Academy of Sciences calls into question earlier conclusions about the injury potential of certain vaccines. At this time, there are widespread recommendations for tightening the Vaccine Injury Table contained in the Vaccine Compensation Act. Experts believe that many of these injuries are in fact not traceable to vaccines.

With respect to the manufacturers' arguments, public health officials respond as follows:

Research and marketing concerns: there is no evidence to suggest that negotiated rates will so reduce manufacturers' profits as to make research impossible. Indeed, many question whether funds paid to manufacturers for research have achieved adequate results. No one has suggested a negotiated rate so low that research can no longer be supported. Moreover, it may be preferable to directly fund added research through direct allocations out of a mandated spending fund (rather than by building it into the price) in order to increase childhood immunization research efforts.

Additionally, developing a strong and stable purchasing system for vaccines may have the opposite effect from that predicted by the manufacturers. Companies that left the business of vaccine production conceivably could be attracted back into the business through a more stable financing system with integrated purchasing and liability protection.

It is also important to note that manufacturers have produced no evidence showing that even the reduced price paid by CDC would harm them financially. Indeed, the CDC price may be equal to or greater than prices paid by other first world countries. Even the CDC price appears to be well above the CPI rate of growth.

* (It appears that manufacturers are realizing large profits without demonstrating sufficient reforms and improvements for children. Moreover, in no other Western industrialized country but South Africa is access to so basic a child health service as vaccine directly tied to family wealth.

Concerns about vaccines for well-to-do children: The most direct response to this concern is that unlike many other forms of medical care, vaccination is such a basic public good that, like clean water, it simply must be available to all. Moreover, families will continue to pay for the actual administration of vaccines if they are well off. The only issue is whether they should pay for vaccines themselves at the point of service. To make families do this is like forcing families to pay for a drink of clean water every time they turn on the tap. This is simply not the way to manage a basic public health need.

Paying for vaccines through a government purchasing system means that the vaccines have been paid for by families in advance of when they are actually needed by children. In this way, a child's access to vaccine is never dependent on his or her family's particular circumstances.

In short, the notion that it is against public policy to furnish free vaccines to children is incorrect in its basic assumption that the vaccines are "free". A coordinated purchasing system changes only when vaccines are paid for, not whether they are paid for. Moreover, the argument overlooks the unique nature of vaccines.

Threats of market pull-out: There is no evidence that this would happen if purchasing systems are mandated and stabilized. Indeed, as noted above, a more stable market might attract additional manufacturers. The only time that manufacturers withdrew from vaccine production was when their liability was at issue. This problem has now been addressed.

III. RECOMMENDATIONS

We recommend proceeding with the above-outlined reforms. Substantial consensus exists on all of the reforms discussed above except revising the informed consent materials and establishing universal purchasing. We believe industry critics who oppose universal purchasing will support it if, as recommended here, the system is financed through a stable, mandated funding source that includes sufficient funding for research. Repairing the vaccine compensation act and establishing universal purchasing will generate opposition. But experts agree that these reforms are essential to a successful effort to address the childhood immunization crisis in the U.S.

Opposition will be strong, particularly in the case of manufacturers. They understand the power of this issue and its precedent setting quality. They can influence many Members of Congress. This is also a particularly complex piece of legislation that requires many separate statutory reforms. Crafting the legislation will involve resolving a broad array of issues. Strong Presidential involvement will be needed to bring this initiative to fruition.

However, these reforms are essential to families who cannot meet the cost of health care for their children. They represent an extremely important step in containing the cost of vaccine and in promoting its availability. And this initiative allows you to take an early leadership role in national health reform on a "bellwether" issue of central concern to families and children.

For these reasons we recommend a two-step process:

- 1. Inclusion in the economic stimulus package of sufficient funds to permit initial implementation of the public investment reforms.
- 2. Introduction, and passage as quickly as possible, of comprehensive legislation that addresses all of the issues contained in this memorandum on a permanent basis.

IV. DECISION

<input checked="" type="checkbox"/>	Approve	<input type="checkbox"/>	Approve as Amended
<input type="checkbox"/>	Reject	<input type="checkbox"/>	No Action

cc: Hillary Rodham Clinton

*Need to discuss
legislation
[X] permanent
passage*

THE WHITE HOUSE

WASHINGTON

FEB 11 11:04

THURSDAY, FEBRUARY 11, 1993

MEMORANDUM FOR JOHN PODESTA

FROM: Howard Paster *HP*

SUBJECT: Immunization bill

I object strenuously to reopening the question of a free-standing bill on immunization. I assured Chairman Rostenkowski on Tuesday we would not create a problem for him, and he agreed to support the program. The last paragraph in the HHS memo of this date runs counter to the commitment I made subsequent to our meeting in the Oval Office on Tuesday.

The Director of OMB has had a similar conversation with Chairman Rostenkowski, because of a previous attempt to undo the commitment made to the Ways and Means Chairman. I urge that Mr. Panetta be consulted.

Statement of The President
Arlington County Department of Human Services
February 12, 1993

Good morning.

Today is a landmark day in the fight to protect the health of millions of American children. And I can think of no better place to announce a new immunization policy than right here on the front lines of the fight to provide accessible and affordable health care to every family.

I'm pleased to be joined here by a number of children's champions: Secretary of Health and Human Services Donna Shalala, Senator David Pryor -- with whom I've worked for years on children's issues -- and Representative Jim Moran. Our thanks to Sue Adams, the director of this clinic, and the rest of her staff, for opening up this facility to us this morning.

This week, I was startled to read of the case of Rodney Miller, a 20-month-old-child who lives in Miami. Rodney is currently being treated for meningitis in Jackson Memorial Hospital. He is there because his family could not afford the twenty-one dollars and forty-eight cents that a meningitis vaccine costs. The bill for his stay in the hospital has already topped forty-six thousand five-hundred dollars.

In the health care policy that our national task force, under the direction of the First Lady, is developing, nothing is more important than preventive care. Today American taxpayers are getting hit with ten dollars in avoidable health care costs for every one dollar we could spend on immunization. The recent resurgence of measles in this country afflicted over fifty-five

Arthur

thousand children and cost twenty-million dollars to treat. Prevention would have cost one million dollars. And those figures do not begin to take into account the terrible human cost -- to our families and our businesses -- that such inaction produces.

The price of vaccines, meanwhile, is rising at six times the rate of inflation. An immunization package that cost twenty-three dollars ten years ago runs more than two hundred dollars today. In a public clinic, the cost of full immunization has leapt from seven dollars to ninety.

Manufacturers cite the costs of research and development to defend the rising price of vaccines. Nobody wants research to slow down but let's be clear about what's really happening. The pharmaceutical industry is spending one billion dollars more each year on advertising and lobbying than it does on developing new or better drugs. Meanwhile, its profits are rising four times faster than the average Fortune 500 company. [insert foreign figures]

To make matters worse, the makers of vaccines have refused to make their products available to states at affordable costs -- or even, in some cases, to talk about it. The idea is simple: states order large quantities of vaccines and should receive lower prices. But while ten states have succeeded in negotiating agreements that allow them to immunize all their children, manufacturers are now balking at starting talks with other states. Just recently, Texas, South Carolina and Hawaii were turned away at the door.

Our message to the drug companies today is: "Change your priorities. You're not going to profit at the expense of our children. These practices must stop."

But dealing with the cost of vaccinations will not be enough. We must also improve the delivery of preventive health care.

Here at this clinic, and across the country, Hillary and I have seen the signs of an overburdened system. Our states and cities are struggling against increasing odds. Public facilities are overwhelmed by new patients as middle class families, who could once afford to use private providers, seek cheaper vaccines in clinics. Public health programs are understaffed, underfunded and underquipped. They have little or no ability to monitor who's protected and who isn't. And education efforts don't reach the families most in need.

The clinic we're standing in today is a perfect example of the struggles and success that parents and health care providers face. In the last two years Arlington County has made great progress; the number of immunized two-year-olds has jumped by almost 50 percent. But here, and across our nation, we must do so much more.

Today I am announcing a three-part policy that will protect our children's future while saving taxpayers millions of dollars.

First, I'm pleased to announce that the stimulus program which we'll outline on Wednesday will include two hundred million dollars (cq) to make vaccines more widely available. These funds will not only help public programs buy more vaccines, but also be

used to improve state outreach efforts. Those funds will mean extended clinic hours, more staff, increased education efforts and the resources to create a national tracking system.

Second, I am directing Secretary Shalala to negotiate with the drug manufacturers so that states can buy vaccines at affordable prices. There is no good reason why a child in Texas is unable to receive vaccination while a child in Massachusetts can. We are not going to stand by as this kind of inequality continues.

Finally, our health care task force is currently preparing legislation that will guarantee that every child has access and coverage to immunization. It is unacceptable that the United States is the only industrialized country which does not fully fund or fully reimburse the cost of immunization.

It's ironic, too, that the country which develops and produces the majority of the world's vaccines does not have an effective or affordable mechanism for distributing them. The steps I'm taking today will go a long way toward solving that dilemma -- and will make sure that excessive corporate profits do not stand in the way of protecting our children's health. We will not stop until preventible childhood diseases no longer threaten our families.

THE D.C. MEDICAID IMMUNIZATION INFORMATION & TRACKING SYSTEM

BACKGROUND

The District's Commission on Health Care Finance (CHCF) has utilized its Medicaid Management Information System (MMIS) to develop an immunization tracking system which will become operational on March 1, 1993.

The decision to do so was precipitated by an analysis of data from our MMIS which showed that approximately sixty percent of children covered by the District's Medicaid program were beginning their immunizations, but that there was a clear pattern of these children not being completely immunized. The data made it clear to us that there was a need to inform parents of the importance of immunizing their children. However, we also recognized that information would not be enough and that we needed to develop a tracking system that could be used for follow-up. Consequently, staff of the CHCF developed an immunization information and tracking system for Medicaid recipients.

Before the system was developed, discussions were held with staff of the Commission on Public Health (CPH) to explain the concept to them and to solicit their assistance in providing the necessary follow up.

THE SYSTEM

The tracking system is relatively simple. Claims data will be used to identify children whose delivery is paid for by Medicaid. Operating under the assumption that these children have retained their eligibility, six weeks after the birth of the child the MMIS will automatically generate a letter addressed to the parents of the child. The letter will include the following points:

- o Your child needs to be protected from dangerous childhood diseases including diphtheria, whooping cough, tetanus, hemophilus influenza type b, hepatitis B, polio, etc.
- o You can protect your child by having him/her immunized at no cost to you.
- o Your child should receive his/her first immunization when he/she is 2 months old and must receive all the vaccinations in a series to be fully protected.
- o Please make an appointment right away with your physician or public health clinic to have your child immunized against these dangerous diseases.

Immunization Tracking

Page Two

- o If you do not have a physician or do not know where the nearest public health clinic is located, call (202) 727-0725 to receive assistance in locating a provider who will immunize your child.

Assuming the child is immunized on time, additional letters will be generated automatically 2 weeks before the child's 4 month, 6 month and 25 month anniversary of life. These letters will contain the following points:

- o A reminder that to be fully protected, the child must receive all of the immunizations in the series.
- o A reminder that their child is due to receive the next immunizations in the series in 2 weeks.
- o A reminder that the immunizations will be provided at no cost to the parent.
- o A reminder that they need to make an appointment with their child's physician or with the CPH's clinic closest to their home.
- o A reminder that if they do not have a physician or do not know where CPH clinics are located, they can call (202) 727-0725 for assistance in locating a provider.

If the Commission on Health Care Finance does not receive a claim for reimbursement for immunizing a child within 45 days of the date the immunization should have been administered, the CHCF will assume the child was not immunized. If a child was not immunized, the MMIS system will automatically generate a follow-up letter which will be sent to the child's parents. The letter will contain the following points:

- o A notice that our records indicate that the child did not receive his/her immunization on time.
- o A reminder that children who are not fully immunized are not protected from potentially dangerous childhood diseases.
- o A reminder that these immunizations will be provided free of charge.
- o A request that they make an appointment with their physician or the nearest public health clinic.
- o An offer to provide assistance in locating a provider if they do not have one.

Immunization Tracking

Page Three

If a claim for reimbursement for administering the immunization is not received within 45 days of the date of the follow-up letter, the CHCF will assume the child was not immunized. The CHCF will generate a monthly report containing the names and addresses of the parents of these children who were not immunized and whose parents did not respond to the follow up letters. This report will be sent to the CPH, whose staff will follow up directly with a visit by a public health worker.

It is our expectation that the monitoring system and, if necessary, the CPH follow up, will lead to a direct increase in the number of District of Columbia Medicaid clients who are fully immunized by their second birthday.

EVALUATION

The project will be evaluated internally using a pre-test, post-test model with controls. Basically the evaluation will consist of a measurement of the difference in the percentage of children who are completely immunized before their second birthday after the introduction of the program against the percentage who were completely immunized before their second birthday before the program was introduced. Other factors that might have affected the outcome will be identified and controlled for.

In addition, we are also seeking to identify a university or some other party not related to District government who would be interested in conducting an independent evaluation of the effort at no cost to the District.

POTENTIAL PROBLEMS

We see potential for problems at two points in the system. The first is in the mailings. Medicaid recipients are a very mobile population. However, we expect that by sending the initial letter six weeks after the child is born, the parents will not have moved. In addition, we plan to contact the Commission on Social Services on all letters that are returned so determine whether we can obtain a more current address.

Another potential problem is the follow-up. Following up on the scale that we expect we will have to do requires resources that well may exceed those that the Commission on Public Health has available to it. The District's 1994 budget does not allow for additional staff, so our current plans are to seek funding for additional personnel to be devoted entirely to this task.

Immunization Tracking

Page Four

FUTURE EXPANSIONS

After the Commission has had an opportunity to operate the program and address any unforeseen problems in the system, there are plans to ask the D.C. Hospital Association to join us in the informational component of the program. We will ask that they use their computer systems to automatically generate the initial letter, reminding parents of children born in their hospitals who are not Medicaid eligible that they need to protect their newborn child against preventable childhood diseases by having them immunized, and urging them to make an appointment with their physician or with a CPH clinic.

In addition, if this effort is as successful as we expect it can be, we will examine the possibility of using the system for other applications.

THE WHITE HOUSE
WASHINGTON

DATE: 2/23

NOTE FOR:

Carol Rosco / Howard Pastor

The President has reviewed the attached, and it is forwarded to you for your:

Information

Action

Thank you.

Handwritten notes and signatures in the background

JOHN D. PODESTA
Assistant to the President
and Staff Secretary
(x2702)

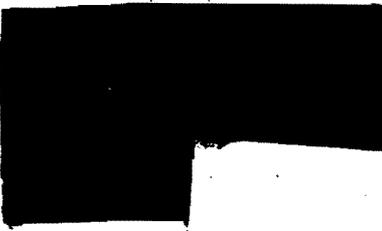
cc:

Howard -

Per our conversation
this a.m., I am assuming
the Pres. note to me is

handled - i.e. all parties
are OK? You don't need
to respond unless there
is something for

me to do.
Thank you.
CJP



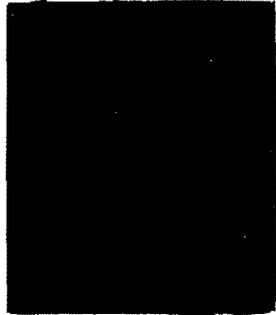
THE WHITE HOUSE
WASHINGTON

THE PRESIDENT HAS SEEN
2/23/93

February 19, 1993

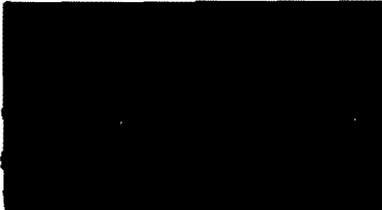
MR. PRESIDENT:

Howard has no problem with introduction of a separate bill in the manner described so long as Chairman Rostenkowski is briefed in advance.



John Podesta

Handwritten notes:
Podesta
Chairman
Howard
Rostenkowski
As a matter of
fact, Howard
Podesta



Podesta

cc: HRC

ASAP

done 2/18/93

MEMORANDUM

TO: The President and First Lady
FROM: Marian *Wright* Edelman
DATE: February 18, 1993

I have never been as proud of a President in my lifetime as I was of you last night. You were wonderful! (My favorite moment was your 'don't mess with me' response to Republican laughter.) Thank you for speaking the truth to all of us about the problems we face and for the balanced solutions you propose. We are ready to work really hard and to rally others to work hard to see that your policies succeed. We thank you for your investments in Head Start, WIC, and childhood vaccinations.

Your immunization speech was terrific. Hope we can keep the momentum going and give your supporters inside and outside of Congress an immediate universal bill to rally around. A lot of people, including freshmen in Congress, are eager to be identified with the immunization issue and to give you a clear victory. If you send the signal, Kennedy and Waxman will follow your lead. Introducing a separate bill immediately keeps pressure on the drug companies as you negotiate with them, allows hearings and support to build, and in no way limits your later options about when and how to bring the bill to the floor. Indeed, our desired strategy is to fold a comprehensive immunization package into an overall budget reconciliation or earlier revenue package so that it is not subject to undesirable amendments. Not to introduce a separate bill right away leaves a huge vacuum that will let countless people do their own version and undermine your friends who want a strong bill.

Yea on Janet Reno. She looks strong.

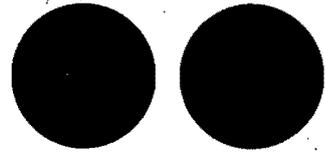
You and Hillary are in my prayers every day. Tell Chelsea she's making a great impression at school.

Please don't waste time responding to any notes I send.

MWE:bag

*Carol - FYI
this is for you. Roz*

WHITE HOUSE STAFFING MEMORANDUM



DATE: 3/3/93 ACTION/CONCURRENCE/COMMENT DUE BY: By 9:00 A.M.

SUBJECT: Childhood Immunization Bill

	ACTION	FYI		ACTION	FYI
VICE PRESIDENT	<input type="checkbox"/>	<input type="checkbox"/>	PASTER	<input checked="" type="checkbox"/>	<input type="checkbox"/>
McLARTY	<input type="checkbox"/>	<input type="checkbox"/>	RASCO	<input checked="" type="checkbox"/>	<input type="checkbox"/>
GEARAN	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RUBIN	<input type="checkbox"/>	<input type="checkbox"/>
PANETTA	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SEGAL	<input type="checkbox"/>	<input type="checkbox"/>
EMANUEL	<input type="checkbox"/>	<input type="checkbox"/>	STEPHANOPOULOS	<input type="checkbox"/>	<input type="checkbox"/>
GIBBONS	<input type="checkbox"/>	<input type="checkbox"/>	VARNEY	<input type="checkbox"/>	<input type="checkbox"/>
HALE	<input type="checkbox"/>	<input type="checkbox"/>	WATKINS	<input type="checkbox"/>	<input type="checkbox"/>
HERMAN	<input type="checkbox"/>	<input type="checkbox"/>	WILLIAMS	<input checked="" type="checkbox"/>	<input type="checkbox"/>
LAKE	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
LINDSEY	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
MONTOYA	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
NUSSBAUM	<input type="checkbox"/>	<input type="checkbox"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>

REMARKS:

RESPONSE:

JOHN D. PODESTA
Assistant to the President
and Staff Secretary
Ext. 2702



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 3 1993 MAR 3 P5:14

MEMORANDUM TO THE PRESIDENT

FROM: DONNA E. SHALALA 
SUBJECT: Childhood Immunization Initiative

Based on recent conversations with Carol Rasco and Howard Paster, I believe there is now a consensus on drafting a comprehensive childhood immunization initiative for submission to the Congress, including a Federal universal vaccine purchase provision, to assure that all children in the United States are protected against vaccine preventable infectious diseases.

In addition to the universal purchase provision, the legislative initiative would create a national tracking system to provide accurate and timely information about the immunization status of children and monitor the efficacy of vaccines, reauthorize the Vaccine Injury Compensation Program, simplify the vaccine information materials that are provided to parents, enhance the capacity of the Center for Disease Control to ensure optimum safety and effectiveness of immunizations, clarify the authority of the Secretary to take appropriate action to protect the domestic supply of vaccines, require that all Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) programs under Medicaid provide vaccines as recommended by the Advisory Committee for Immunization Practices (ACIP) and approved by the Secretary, set a Medicaid fee schedule for vaccine administration costs at a level sufficient to enlist participation of private providers, and encourage additional appropriations as reflected in your stimulus package to rebuild our public health infrastructure and to expand educational programs.

We would like to proceed to draft this bill for introduction by key congressional supporters within the next few weeks. We would encourage the appropriate Committees to conduct hearings on the measure but refrain from moving the legislation as a free-standing bill. The entire package would be placed in reconciliation.

Needless to say, we would closely coordinate our activities with the White House.

**THE WHITE HOUSE
WASHINGTON**

DATE: 2/10/93

NOTE FOR: CAROL RASCO

The President has reviewed the attached, and it is forwarded to you for your:

Information

Action

Thank you.

JOHN D. PODESTA
Assistant to the President
and Staff Secretary
(x2702)

cc:

THE PRESIDENT HAS SEEN

2/10/93

THE WHITE HOUSE

WASHINGTON

0183 06:15

February 9, 1993

MEMORANDUM FOR THE PRESIDENT

FROM: Howard Paster *HP*

SUBJECT: Follow-up conversation with Chairman Rostenkowski

Subsequent to our 1 p.m. meeting I called Chairman Rostenkowski's staff director to affirm the Administration's intention to pursue the policy of universal immunization, while assuring the Committee of our intention to work with them in framing legislation.

Chairman Rostenkowski later called back himself to assure you that he will support the policy, but to restate his concern that we proceed in a planned and thoughtful manner on the enabling legislation. I assured him we would work with him and his staff, and said we might consider incorporating the program in the overall economic package. He seemed calmed, and wanted you to know he will support your policies down the line. But he was sending over a memo recommending against an incremental ITC.

cc: Hillary Rodham Clinton

THE WHITE HOUSE

WASHINGTON

February 9, 1993

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cc: Hillary Rodham Clinton ✓

THE WHITE HOUSE
WASHINGTON

DATE: 2/10/93

TO: CAROL RASCO

FROM: JOHN D. PODESTA
Assistant to the President and
Staff Secretary

The attached has been forwarded
to the President.

THE WHITE HOUSE
WASHINGTON

February 10, 1993

MEMORANDUM FOR THE PRESIDENT

FROM: JOHN PODESTA *JJP*
SUBJECT: CHILDHOOD IMMUNIZATIONS

On Monday, Secretary Shalala forwarded to you a decision memorandum on childhood immunizations which calls for implementation of a comprehensive plan to address the childhood immunization crisis.

The plan includes elements which will improve health infrastructure investment (largely agreed to as part of the stimulus discussions), a new entitlement program implemented through a universal purchasing system, reform of the vaccine compensation program and other health care management reforms. OMB and Howard Paster have raised strong concerns about the details of this program. Alice Rivlin and Shalala have been in discussions to address the OMB concerns. Carol Rasco has been monitoring these discussions.

I have not forwarded the memo on to you until some of the problems can either be resolved or more clearly framed for your decision. I expect that a decision memo incorporating everyone's views will be available later today.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

F A X T R A N S M I S S I O N

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

Phone: 202/690-8204

Fax: 202/690-6154

TO:

Carole Raso

FAX NUMBER:

FROM:

Jerry Klepner

DATE:

TOTAL NUMBER OF PAGES BEING SENT:

13

COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

February 7, 1993

MEMORANDUM FOR THE PRESIDENT

FROM: DONNA SHALALA
SECRETARY OF HEALTH AND HUMAN SERVICES

SUBJECT: Legislative Initiative to Comprehensively
Address the Nation's Childhood Immunization Crisis

I. ACTION-FORCING EVENT

We understand that you plan to include in your State of the Union Address a proposal for swift enactment of a comprehensive initiative to assure that all American children are adequately protected against preventable infectious disease. This initiative is a cornerstone of your prevention strategy. It is both a first phase of your overall plan to reform the American health care system and a free-standing effort aimed at addressing a fundamental matter of public health safety for all Americans. It reflects two promises made during the 1992 Presidential campaign: to assure all children access to preventive health services; and to control drug prices which now are escalating at three times the rate of inflation.

In order to have this initiative ready for introduction with key Congressional support immediately following your State of the Union Address, we need your approval to prepare legislation. The Department, in cooperation with the Domestic Policy Council, will develop legislation. In doing so, we plan to intensively consult key Members of Congress.

In readying the information and recommendations contained in this Memorandum, we have had wide-ranging discussions with experts both within and without the Department. We also have consulted with the First Lady in her capacity as head of the Interagency Health Reform Task Force.

II. BACKGROUND ANALYSIS

A. The Problem

Like clean water, immunization against preventable diseases constitutes not only medical care but a basic public health protection. A stable, reliable, easily accessible, and

affordable vaccination system is a tenet of all civilized nations. Indeed, so basic is the need for vaccination against disease that the United Nations has undertaken special childhood immunization efforts throughout the world as a fundamental public health measure.

In 1979, the Surgeon General of the United States established a series of public health goals for the nation, which were to be achieved by 1990. One of the most important goals was protecting all children against infectious, vaccine preventable disease. In order to achieve this goal, it was deemed essential that by 1990, at least 90 percent of all children under age two should be fully immunized.¹

The Surgeon General set clear outcome measures for determining whether the childhood immunization goal would be met. In the case of vaccine preventable disease, the outcome measure used was the number of preventable disease cases nationally in 1990. With respect to measles, for example, the Surgeon General estimated that successful immunization efforts would reduce the number of cases nationally to no more than 500 by 1990.

By 1990, however, only 60 to 70 percent of all infants and toddlers were fully immunized against preventable disease.² In some large cities, pre-school immunization levels as low as 10 percent have been reported by the Centers for Disease Control (CDC). Rather than improving immunization levels among America's youngest children they actually appear to have declined slightly.

Unacceptably low immunization levels pose a basic health threat to very young children. Moreover, very low immunization rates permit controllable diseases to spread throughout communities. A clear example of this phenomenon was the measles epidemic which swept the nation between 1989 and 1991. According to the CDC, the epidemic produced 55,457 cases of measles in three years. In 1990 alone, the year in which there were to be no more than 500 measles cases nationwide, there were more than 27,000 cases. One hundred and sixty people (by and large children) died. Most of these deaths were considered preventable.

¹ While 100 percent of all children should be vaccinated, a 90 percent immunization rate constitutes the minimum level required to assure community-wide protection against disease (often referred to as "herd immunity").

² Indeed, because the nation made no progress, the goal of protecting all children was postponed until the Year 2000.

The 1989-91 measles outbreak also produced significant and avoidable health care costs. Each dollar spent to immunize children has been estimated to save between ten and fourteen dollars. The recent measles epidemic illustrates these numbers. The outbreak produced 11,260 separate hospitalizations and 44,100 hospital days. Avoidable hospital costs alone amounted to more than \$20 million. These costs do not include either medical or the long term health, educational or social costs associated with measles and its complications. Experts believe that further outbreaks of measles and other preventable diseases will occur without significant improvement in childhood immunization levels.

B. Barriers

Health officials point to many factors underlying low immunization levels among American children. These are:

1. A significantly eroded public health care infrastructure which has further limited the availability of essential immunization services in inner city and low income communities. Publicly funded health programs, such as community and migrant health centers, rural health clinics, the National Health Service Corps, county and city health clinics, and public hospital clinics, are a principal source of care for low income patients. These clinics by definition are located in areas where poverty impedes access to health care and increases risks to health.

These programs are substantially under-funded. They do not have adequate staff. They cannot afford to remain open on nights and weekends. They do not have a sufficient supply of publicly purchased free vaccine. They do not have the community workers they need to find and assist particularly hard-to-reach families, whose children remain un-immunized.

As a result, the recent measles outbreak struck poor children with particular severity. Based on a 10-city study, the Public Health Service has estimated that between 40 and 91 percent of unvaccinated infants who developed measles were enrolled in public assistance programs.

2. High vaccine prices that make immunizations purchased outside the federal CDC procurement system all but unaffordable. Currently the CDC purchases half of all vaccines used in the U.S. These vaccines are sent to state health agencies which in turn distribute them to local clinics. In New England and Washington State, state health agencies purchase additional vaccines through CDC to

distribute directly to private physicians. In this way, physicians receive free vaccines purchased at a reduced price, participate in state immunization efforts, and charge families only a modest administration fee (if anything at all). In recent years, in response to high vaccine prices, several other states, including Texas, South Carolina and Hawaii, have sought to establish these programs but their efforts to buy additional vaccines through the CDC contract have been rejected by manufacturers as "against public policy".

Childhood vaccine price increases over the past decade have been dramatic. For example, in 1981 a dose of DPT vaccine cost \$.33. By 1991, the cost of the same vaccine dose had risen to \$9.97 -- a 2,921% increase.

At the price private physicians now must pay, it costs \$ 245 for the vaccine alone for families with children cared for by private doctors to fully immunize each child against preventable disease. With the cost of injecting the vaccine included, each dose of vaccine costs a family about \$45.00.³ Children need 18 separate doses of vaccine to be fully immunized.⁴

Paying for vaccinations out-of-pocket poses a significant burden on lower income working and uninsured (or underinsured) families. This is particularly true for young families, who are most likely to have young children and who have seen their real earning levels decline substantially over the past 20 years. Reimbursement for vaccines at the full market rate also poses a major cost problem for private insurers and for both the Medicare and Medicaid programs.

The escalating cost of privately administered vaccines has led an increasing number of physicians to send families to public clinics, where vaccinations are cheaper. The same vaccination series that costs \$196.00 in a private physician's office costs only \$96.00 in a public clinic. It is no surprise, therefore, that families are routinely sent to public clinics. But many may fail to ultimately get the vaccine for their children because of the burdens imposed by multiple visits.

³ The CDC estimates that it costs about \$5.00 to administer an injection in a public clinic.

⁴ This includes 2 doses of oral polio vaccine, 2 measles/mumps/rubella vaccinations, 3 vaccinations against Hepatitis B, 4 vaccinations against hemophilus influenza, 3 vaccinations against diphtheria, pertussis and tetanus, and 2 vaccinations against acellular pertussis.

5

Experts agree that opportunities to immunize children cared for by private physicians thus are being lost. At least one-third of the children with measles during the 1989-1991 outbreak had at least one previous visit at which an opportunity for vaccination was lost. This shift of privately cared for children into the public system is also adding to the strain on the public system.

3. Peer provider understanding about appropriate immunization practices (such as the acceptable practice of giving multiple vaccines in a single visit) that leads them to under-immunize children.

4. The lack of a national tracking system (like the vital statistics system for recording births and deaths) which helps local, state and federal officials identify and vaccinate children who remain unvaccinated. A tracking system is deemed essential by public health officials. It permits them to measure the current immunization status of a community, not merely guess at it. Without a tracking system the nation has no accurate, "real time" information on immunization status and cannot respond to potential crises. Federal officials literally cannot measure with accuracy whether basic public health goals have been met.

5. The failure to develop safer, simpler vaccines through aggressive research. Although manufacturers claim they are spending billions of dollars on vaccine research, results have been inadequate. The NIH does not have sufficient research stimulus funds⁵ to generate an appropriate level of effort targeted on childhood immunization. Left to establish their own research priorities, manufacturers have not moved swiftly enough to bring safer and more efficient vaccines to market. Indeed, the sheer number of separate vaccinations children must now receive to be adequately immunized may be contributing to under-immunization. Parents simply do not understand that children need 18 separate vaccinations.

6. Insufficient funding for the FDA to assure that new vaccines are rapidly tested for safety and efficacy. This further slows innovation in research.

⁵ According to the Public Health Service, NIH research funds now represent 10 percent of all funds spent on immunization research.

6

7. A troubled, non-functioning vaccine compensation system which lacks sufficient funding to settle backlogged cases, is applying dated standards, and whose funding base for future cases is no longer authorized. In 1986 a federal vaccine compensation program was developed in order to address manufacturers' concerns over their liability for vaccine related injuries (they threatened to cease production of vaccines altogether). The system is now in need of repair in several respects. Four thousand cases arising prior to enactment await action and settlement and cannot be resolved without additional appropriations. Legislation authorizing a special vaccine excise tax to settle post-enactment vaccine injury claims has expired. Without a functioning compensation program, continued involvement by both manufacturers and physicians in vaccination activities is potentially in question.

8. A related problem is that federally developed informed consent materials (written information used to educate families about potential vaccine dangers to their children) are considered unnecessarily complex and difficult for families to understand. It may have a deterrent effect on both the families who read it and on physicians' willingness to provide immunization services.

C. An Action Plan

Experts both within and without the federal government have made numerous recommendations for effectively addressing all of these problems. Virtually all of these recommendations are contained in an Immunization Action Plan which was developed by the Public Health Service and which calls for improvements in both public and private immunization delivery systems. The plan is comprehensive. Yet it remains virtually non-implemented because of a lack of interest and commitment by the Reagan and Bush Administrations. The Action Plan's recommendations mirror approaches to vaccine purchase, distribution and administration used in virtually all industrialized nations with private health insurance systems.

The recommendations include the following elements:

1. An infusion of funds to improve and strengthen publicly funded primary health care programs. This means increased funding to local health departments, community and migrant health centers, rural health clinics, the National Health Service Corps, and other vital "safety-net" providers of

health care for low income and medically underserved patients. These clinics all need a stable supply of vaccine. They also need additional staff and operating resources to both furnish immunizations and to provide the primary health care for children that should accompany immunizations.

With funds included in the economic stimulus package, these improvements can begin as early as this summer.

2. A new system under which the federal government would purchase the vaccines needed by both public and private providers at a negotiated rate. Manufacturers would ship vaccines directly to physicians, clinics and other providers. These health providers would, in turn, charge families only a modest administration fee. Such a system also would permit the establishment of a national tracking system, since all providers participating in the vaccine distribution system would, like hospitals delivering babies, provide state and federal agencies with information about each child immunized. Insurers such as Medicare, Medicaid and private insurers potentially would realize significant savings, since vaccines would be bought and shipped in a coordinated fashion through negotiated rates.

Families and insurers (including Medicare and Medicaid) would therefore pay only a modest administration fee, regardless of whether patients receive care from public clinics or private doctors. The crisis of missed opportunities would be reduced dramatically, with potentially enormous financial savings to families, insurers and state health agencies.

3. Assurance of a stable funding source for vaccine infrastructure, purchasing and delivery activities that is based on mandated spending through a capped entitlement not subject to year-to-year variations (as is the case with discretionary appropriations). The number of needed doses is known and the prices can be negotiated. In this way, financing for vaccine activities would keep pace with the appropriate cost of a comprehensive vaccination effort. This type of budgeted and stabilized financing arrangement is consistent with your long-range thinking about how to purchase health care generally.

4. Funds to develop and maintain a vaccine tracking system, tied to the distribution of vaccines, that permits patient tracking and community surveillance.

5. Reforms in the vaccine compensation program so that it is once again operational, as well as simplification of the vaccine information materials in order to reduce the burden on families and providers. Funds will be needed in both Fiscal 1993 and Fiscal 1994. Additionally, the taxing authority for post-enactment claims will need to be extended.

6. A new approach to vaccine research that emphasizes funding through NIH (rather than less reliable, indirect funding through profits to manufacturers) for childhood vaccine research.

7. Increased funding to the FDA to improve and simplify approval systems and strengthen safety and oversight activities.

8. Funds for renewed international vaccine efforts in cooperation with the World Health Organization and UNICEF. According to the Public Health Service, the nation's experience with smallpox showed that the \$32 million spent by the U.S. to help eradicate smallpox worldwide through a combined international effort has led to savings of \$600 million annually.

9. Educational efforts aimed at patients and health providers to inform them about the importance of vaccinations (and in the case of providers, safe and effective immunization practices).

10. Involve the private sector in community vaccination efforts and make community vaccination outreach a key element of your National Service program.

D. Support for these recommendations

Support for improving immunization levels through these comprehensive reforms is widespread. Supporters include experts in public health, pediatricians, the Public Health Service, many Members of Congress, children's advocates and others. Key individual and organizational support comes from Mrs. Carter and Mrs. Bumpers and their childhood immunization effort (known as Every Child by Two), Marian Wright Edelman and the Children's Defense Fund, the American Academy of Pediatrics, (particularly its incoming President, Dr. Betty Lowe), the March of Dimes, and others.

E. Opposition to the reforms

Only two of the reforms described above have generated significant opposition. These are proposals to simplify vaccine information materials and to establish a universal vaccine purchasing program for all families.

Simplification of vaccine material: This is opposed by an organization known as Dissatisfied Parents Together, a group consisting of several thousand families with children who allege injury by vaccine.

Universal purchasing: This system is adamantly opposed by the manufacturers, as well as by Dissatisfied Parents (which opposes any effort to increase access to vaccines). In addition, a number of key industry critics are concerned by one issue as described in the first bulleted argument.

Manufacturers make several arguments. These are:

- o first, that by reducing current profit levels, a coordinated purchasing arrangement will cut into vaccine research (industry critics also are concerned about retaining sufficient funding levels for research efforts);

- o second, that such a system will provide free vaccines to rich children; and

- o third, that prudent purchasing lead them to give up the production of vaccine altogether.

The industry is extremely powerful. We believe that it will fight this effort because of its precedent-setting value.

F. Responding to opposing arguments

Public health experts, children's advocates, health care providers, and public officials respond strongly to these points. With respect to the parents group's concerns about the safety of vaccines, experts uniformly reply that the dangers associated with not vaccinating children vastly outweigh those associated with childhood immunization.⁶

⁶ Indeed, a new study from the National Academy of Sciences calls into question earlier conclusions about the injury potential of certain vaccines. At this time, there are widespread recommendations for tightening the Vaccine Injury Table contained in the Vaccine Compensation Act. Experts believe that many of these injuries are in fact not traceable to vaccines.

With respect to the manufacturers' arguments, public health officials respond as follows:

Research and marketing concerns: there is no evidence to suggest that negotiated rates will so reduce manufacturers' profits as to make research impossible. Indeed, many question whether funds paid to manufacturers for research have achieved adequate results. No one has suggested a negotiated rate so low that research can no longer be supported. Moreover, it may be preferable to directly fund added research through direct allocations out of a mandated spending fund (rather than by building it into the price) in order to increase childhood immunization research efforts.

Additionally, developing a strong and stable purchasing system for vaccines may have the opposite effect from that predicted by the manufacturers. Companies that left the business of vaccine production conceivably could be attracted back into the business through a more stable financing system with integrated purchasing and liability protection.

It is also important to note that manufacturers have produced no evidence showing that even the reduced price paid by CDC would harm them financially. Indeed, the CDC price may be equal to or greater than prices paid by other first world countries. Even the CDC price appears to be well above the CPI rate of growth.

It appears that manufacturers are realizing large profits without demonstrating sufficient reforms and improvements for children. Moreover, in no other Western industrialized country but South Africa is access to so basic a child health service as vaccine directly tied to family wealth.

Concerns about vaccines for well-to-do children: The most direct response to this concern is that unlike many other forms of medical care, vaccination is such a basic public good that, like clean water, it simply must be available to all. Moreover, families will continue to pay for the actual administration of vaccines if they are well off. The only issue is whether they should pay for vaccines themselves at the point of service. To make families do this is like forcing families to pay for a drink of clean water every time they turn on the tap. This is simply not the way to manage a basic public health need.

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Paying for vaccines through a government purchasing system means that the vaccines have been paid for by families in advance of when they are actually needed by children. In this way, a child's access to vaccine is never dependent on his or her family's particular circumstances.

In short, the notion that it is against public policy to furnish free vaccines to children is incorrect in its basic assumption that the vaccines are "free". A coordinated purchasing system changes only when vaccines are paid for, not whether they are paid for. Moreover, the argument overlooks the unique nature of vaccines.

Threats of market pull-out: There is no evidence that this would happen if purchasing systems are mandated and stabilized. Indeed, as noted above, a more stable market might attract additional manufacturers. The only time that manufacturers withdrew from vaccine production was when their liability was at issue. This problem has now been addressed.

III. RECOMMENDATIONS

We recommend proceeding with the above-outlined reforms. Substantial consensus exists on all of the reforms discussed above except revising the informed consent materials and establishing universal purchasing. We believe industry critics who oppose universal purchasing will support it if, as recommended here, the system is financed through a stable, mandated funding source that includes sufficient funding for research. Repairing the vaccine compensation act and establishing universal purchasing will generate opposition. But experts agree that these reforms are essential to a successful effort to address the childhood immunization crisis in the U.S.

Opposition will be strong, particularly in the case of manufacturers. They understand the power of this issue and its precedent setting quality. They can influence many Members of Congress. This is also a particularly complex piece of legislation that requires many separate statutory reforms. Crafting the legislation will involve resolving a broad array of issues. Strong Presidential involvement will be needed to bring this initiative to fruition.

However, these reforms are essential to families who cannot meet the cost of health care for their children. They represent an extremely important step in containing the cost of vaccine and in promoting its availability. And this initiative allows you to take an early leadership role in national health reform on a "bellwether" issue of central concern to families and children.

For these reasons we recommend a two-step process:

1. Inclusion in the economic stimulus package of sufficient funds to permit initial implementation of the public investment reforms.

2. Introduction, and passage as quickly as possible, of comprehensive legislation that addresses all of the issues contained in this memorandum on a permanent basis.

IV. DECISION

<input type="checkbox"/> Approve	<input type="checkbox"/> Approve as Amended
<input type="checkbox"/> Reject	<input type="checkbox"/> No Action

cc: Hillary Rodham Clinton

**Fox, Bennett & Turner
750 17th Street, N.W.
Suite 1100
Washington, DC 20006**

PLEASE DELIVER TO:

NAME: Ms. Carol Rasco
FIRM: The White House
CITY/STATE: Washington, DC
RECEIVING TELECOPIER: 456-2878
FROM: Ronald Saldarini
DATE OF TRANSMITTAL: February 15, 1993
TIME OF TRANSMITTAL: 4:59pm

TOTAL NUMBER OF PAGES
(including cover sheet): 6

TRANSMITTING TELECOPIER: (202) 778-2330

In case of problems: (202) 778-2300

**MESSAGE: I AM ALSO HAVING THIS HAND-DELIVERED WITH THE REDLENER
ATTACHMENT (WHICH CANNOT BE FAXED BECAUSE OF ITS SIZE).**

American Cyanamid Company
Lederle-Praxis Biologicals Division
One Cyanamid Plaza
Wayne, NJ 07470 USA
Telephone: (201) 831-4851
Telefax: (201) 831-5881

Ronald J. Saldarini, Ph.D.
President

February 15, 1993

Ms. Carol Rasco
Assistant to the President
for Domestic Policy
The White House
Washington, D.C. 20500

Dear Ms. Rasco:

On behalf of Lederle-Praxis Biologicals, I want to thank you for meeting with us today to discuss ways in which the childhood immunization program might be improved, with particular emphasis on increasing immunization rates among inner city and other underserved populations. It is our hope that this meeting was the first installment of an ongoing dialogue between vaccine manufacturers and the Clinton Administration regarding this matter of vital interest to our children and our public health.

Among the initiatives discussed at the meeting were the following:

- o Insurance Reform -- A majority of private insurance policies offer inadequate preventive health services. The Administration's proposal for health care reform should have as its centerpiece a requirement that all insurance policies provide first-dollar coverage for well-baby care, including age-appropriate immunizations.
- o Medicaid Reform -- Since most of the underserved, and currently underimmunized, population is Medicaid eligible, there must be an intensive review of the Medicaid program and the extent to which its reimbursement and other limitations discourage the participation of primary care physicians, particularly pediatricians. Every effort should be made to ensure that Medicaid children are assigned to a primary care physician, preferably a pediatrician, with the responsibility

Ms. Carol Rasco
February 15, 1993
Page 2

for tracking and followup for individual recipients. It is a striking statistic that 90% or more children under two receive at least one immunization, plainly indicating that the problem is with tracking and followup of individual children to complete their immunization series.

- o Mobile Outreach -- As several manufacturers mentioned, perhaps the most effective model of immunization and primary care outreach for children in underserved areas is the program operated by Dr. Irwin Redlener of the Children's Health Fund. Dr. Redlener operates a number of mobile vans, complete with computers for tracking immunization status and most of the medical apparatus that one would find in a pediatrician's office. Funded at least in part by Lederle-Praxis and other vaccine manufacturers, these vans have made an impressive inroad into immunization and other health problems of the inner city and other remote areas. (I am enclosing some background information concerning Dr. Redlener's programs as well as an article quoting him from yesterday's New York Times.)

* * *

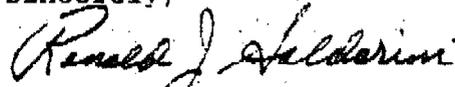
Finally, although it was not discussed at the meeting, I would like to make a specific suggestion concerning next steps which manufacturers and the Administration might take to continue our dialogue and to address jointly problems of low immunization rates. I encourage you to consider formation of a public-private task force consisting of the three or four major vaccine manufacturers and individuals from the Department of Health and Human Services who are most knowledgeable about the issues. These would include experts from Medicaid, the Centers for Disease Control, and other parts of the Public Health Service concerned with maternal and child health matters, minority outreach and community and migrant health centers. The task force should also include representatives from selected state governments since the states are key players on the front line in immunization efforts.

Ms. Carol Rasco
February 15, 1993
Page 3

If you believe that such a combined task force could develop useful new approaches concerning immunization, Lederle-Praxis would be delighted to initiate discussions with the other manufacturers and would be willing to devote all necessary resources to the undertaking. I will call your office in the next few days to ascertain your interest.

Regardless of the approach which the Administration decides to pursue in this matter, we appreciate your personal interest and your willingness to listen.

Sincerely,



Ronald J. Saldarini

Enclosure

Shots Are Often Free But Many Children Miss Immunizations

By PETER MARKS

Long after the hour of her scheduled appointment had passed, Michele Bryant sat with her 3-year-old son in the waiting room of the New York City Department of Health clinic in Fort Greene, Brooklyn. She had little choice but to wait it out in the dreary room on a snowy Saturday. As a single mother with a full-time job that offered no health benefits, she had neither the time nor the resources to go to a private pediatrician to get her son vaccinated.

"I got up this morning at 6:30 to bring him here," Ms. Bryant said, as her son, Taurean, scurried along the rows of plastic seats, restless after two and a half hours in the clinic. "This is what you have to do. If you love your child, you want them to have the best care you can get."

Vaccines are free and readily available in public health clinics in New York and many other states.

But for every parent like Ms. Bryant, who tries to have her child vaccinated, thousands of others do not try at all or give up after struggling with the public-health bureaucracy. Some, facing a mixture of economic and family pressures, do not think it is worth the trouble. Some are not aware of the in this country illegally, are simply afraid to bring their children for shots.

To encourage immunization by making it more affordable, President Clinton announced on Friday a plan to spend \$300 million next year to increase the number of American children who are vaccinated. White House officials said that as a result, a million more youngsters would be immunized starting this summer, most at public clinics.

The President strongly criticized drug manufacturers for failing to lower their prices on vaccines and for what he called spending on advertising and lobbying at the expense of developing new and better drugs.

Administration officials said they were still considering a plan for the Government to buy the entire supply of children's vaccines and distribute them free. Drug manufacturers dispute President Clinton's assertion that they are to blame for the rising costs of immunization, and argue that they offer substantial discounts on vaccines sold to government programs. The real problem, they say, lies in educating the public about how and where vaccines are available.

Many doctors and health-care experts say free vaccine will not solve the country's immunization problem. They say the lack of a centralized record-keeping system and a concerted educational campaign is partly to blame for the low immunization rates. Those functions are left up to a patchwork of clinics, doctors, hospital emergency rooms and charities. In some cases, record keeping is so abysmal that some children never get vaccinated and others receive the same vaccines over and over.

From Pioneer to Laggard

The failure to vaccinate is so widespread in this country that many health officials speak of an "immunization crisis" in a nation that pioneered the use of vaccines to fight childhood diseases. According to the Centers for Disease Control and Prevention, less than half of all children in the country between 2 months and 2 years old are properly vaccinated. In the inner cities and rural areas, proportions are even smaller. In New York City, the Department of Health reports that only 38 percent of schoolchildren have completed the full series of recommended vaccines by the time they are 2, the benchmark age for immunization because the natural immunity a baby receives from his or her mother has dissipated.

According to the American Academy of Pediatrics, the United States ranks 17th in the world in the percentage of infants vaccinated against polio. Health experts say immunization rates are higher in industrialized countries with a nationalized system for primary health care, like Britain.

"This is one of the true national disasters we're dealing with," said Dr. Irwin Redlener, president of the Children's Health Fund, a nonprofit group that offers health care to children at New York City homeless shelters. "Immunization is a fundamental marker of access to health care for children. The lack of it puts kids at a fantastic level of vulnerability."

'A Step Backward 50 Years'

Dr. Bruce Siegel, the New Jersey health commissioner-designate, said: "Immunization is one of the areas where we are seeing a step backward 50 years. Children should not be dying of measles in this day and age."

In responding to President Clinton's criticism of drug manufacturers, David J. Williams, president of Connaught Laboratories Inc. of Swiftwater, Pa., blamed lawsuits for driving up vaccine prices.

"The only profiteers in vaccine pricing have been the lawyers who launched hundreds of product liability lawsuits," Mr. Williams said. "If we were to distribute vaccines free to everyone, whether rich or poor, it would drive up the cost of immunization to the Federal Government. It doesn't make any sense to increase spending on buying a product that is in abundant supply when the money could be better used in eliminating the barriers that obstruct access."

The Connecticut Experience

Although Connecticut has a long-standing program to buy and distribute vaccine to doctors and clinics, Dr. James Hadler, the state epidemiologist, said that only 63 percent of Connecticut children receive the full complement of vaccines by age 2 — only marginally more than in New York and New Jersey, which do not provide all the vaccines doctors need.

"Universal distribution is just a component of what needs to be done," Dr. Hadler said.

Besides Connecticut, 12 states — Alabama, Colorado, Idaho, Maine, Massachusetts, New Hampshire, North Dakota, Rhode Island, South Dakota, Vermont, Washington and Wyoming — buy vaccine and distribute it free to doctors and clinics. The doctors are allowed to charge a nominal fee, usually \$5 to \$10, to administer the drugs. Since 1920, Massachusetts has manufactured its own diphtheria-tetanus-pertussis, or whooping cough, vaccine, but most other states buy their vaccines.

Thirty years ago, when the measles vaccine was licensed, health officials predicted that the childhood disease would be eradicated within a few years. But after years of decline, measles made a comeback from 1989 to 1991, with 4,000 cases and 23 deaths in New York State alone. State epidemiologists found that more than half the cases were among preschool children, most of whom had never received the measles-mumps-rubella vaccine, known as M.M.R.

At the height of the outbreak, health officials gave the M.M.R. vaccine to 6-month-old children, even though it is normally administered to 1-year-olds. When outbreaks subsided, administration at age 1 was resumed. Although few comprehensive statistics on underimmunization are kept, medical experts are convinced it remains so widespread among preschool children that there will be future outbreaks. "Where parents are not having their children immunized, diseases we thought we had under control are going to be popping up all over the country," said Dr. John Lee Clowe, president of the American Medical Association.

Health organizations say that to be properly immunized, all 2-year-olds should have had four shots of diphtheria-tetanus-pertussis, or whooping cough; three of polio and one of M.M.R. In recent years, two new vaccines, for hepatitis B and Haemophilus influenza type B, have been added to the recommended program.

Because most public and private schools require that children are completely immunized before they enter kindergarten, doctors say that many parents do not realize how critical it is for them to receive all the shots by the time they are 2 years old.

No National Registry

Conversely, doctors and health officials report, a much smaller proportion of children receive too many vaccines. Parents are issued immunization cards to keep track of their children's vaccination. But Dr. Redlener said that because there is no national registry to keep track of those records, children whose cards have been lost or misplaced get the same shots over and over as they move from doctor's office to clinic to emergency room.

For parents like Ms. Bryant, the problem is one of access as much as economics. Commuting two hours each way to a receptionist's job in White Plains from her home in East Flatbush, she has little time during the week to respond to a medical crisis, let alone to visit a doctor for preventive care. She is torn between her need to earn a living and her desire to care for Taurean. "My younger sister takes care of him while I'm at work," said the 20-year-old Ms. Bryant. "But I want to be the one to take him to the doctor. He's going to hurt and cry."

Several months ago, she had an appointment for her son at a city health clinic in Park Slope, Brooklyn, and took a day off from work to keep it. But when she showed up late, she was told she had to reschedule. It was not until she learned of the child health-care clinic in Fort Greene, which recently expanded its hours on Thursday nights and Saturdays, that Taurean was immunized. He was already six months behind. Before his visit, he had never been inoculated against polio and diphtheria.

New
York
Times
2/14/93

Vaccines Available but Many Children Go Without

Feeling of Failure

Health officials say that with costs rising and most insurers refusing to cover vaccinations, more and more middle-class families are going to public clinics for immunization — or are not having vaccinations at all. Still, the problem is most acute for lower-income and minority parents.

Dana Fort, a 25-year-old single mother, lives with her five young children in a homeless shelter in the Bronx. Some of them are fully immunized, she said, while others are missing several vaccines. Her youngest child, she said, did not get any vaccinations until he was 9 months old. She said that her frustration over what she believed was her inability to get

adequate treatment for herself and her children at local hospitals and clinics sometimes made her reluctant to take her children to doctors.

"It hurts me," she said. "I have cried lots of times because I feel like I've failed my children."

To reach people like Ms. Fort, hospitals and community organizations in inner cities have been trying new ways of coaxing people into clinics and mobile immunization units. Three months ago, Bellevue Hospital Center started a program in which two nurses screen children in the pediatrics emergency room to determine if any vaccinations are needed; of 450 children who have been screened, 72 were immunized.

But the obstacles to immunization remain daunting. At the Richard Allen Center on Life, a nonprofit child- and foster-care organization in Harlem, immunization outreach workers Danilda Abreu and Pamela Jones say that they would like to go door to door to find the underimmunized, but that they are afraid to enter many of the buildings. Instead, they go to trade schools and churches and community groups, handing out fliers and singing the praises of diphtheria shots.

"A lot of people say to me, it's the wait," Ms. Jones said. "A lot of people don't want to wait. I say, it's better to take one day out for your child than not to have that child at all."



"This is one of the true national disgraces we're dealing with," Dr. Irwin Redlener, president of a group that offers health care to children at New York City homeless shelters, said of the low rate of

vaccinations. He helped Dr. Karen Burke give Carlos Freneda a diphtheria inoculation. The boy's mother, Estrella Carbo, held her daughter, Tainary Freneda, at a mobile clinic in Harlem.

HEALTH

When Children Should Be Immunized

VACCINATION or TEST	COST*	AGE IN MONTHS				YEARS			
		2	4	6	12	12 to 15	15 to 18	18 to 21	21 to 25
Diphtheria-tetanus-pertussis	\$ 9.97	■	■	■	■				
Tetanus-diphtheria									■
Polio	9.91	■	■	■	■				
Measles					†				■
Mumps	25.29					■			
Rubella									■
Haemophilus influenzae type B		■							
Tuberculosis test						■			

*Average cost from a private doctor in 1992, where available.
 †The recommended age for the first measles shot is 12 months in New York City and other places where the disease is widespread.

SOURCE: Department of Health and Human Services, American Academy of Pediatrics

27255, February 15, 1993

IMMUNIZATION IN THE UNITED STATES

CURRENTLY RECOMMENDED VACCINES

- Children should be routinely vaccinated against nine diseases: measles, mumps, rubella, diphtheria, tetanus, pertussis (whooping cough), polio, Haemophilus influenzae type b (Hib) and hepatitis B.
- Children require 17-18 doses of vaccines up through age 12 for full immunization. Of these, 14-15 doses should be delivered prior to the second birthday in about 5 visits to a health care provider.
- The number of recommended vaccines and vaccine doses has risen dramatically in recent years. From the early 1970's through 1984, 10 doses of vaccines were recommended against 7 diseases. Between 1985 and 1989, one more dose was added. Since 1989, 6 to 7 more doses of vaccines have been added to the schedule.
- Approximately 1/2 of children are given vaccines in the public sector and 1/2 in the private sector.
- Recommendations are made by two major advisory bodies. The Advisory Committee on Immunization Practices (ACIP) advises the Centers for Disease Control and Prevention (CDC). The Committee on Infectious Diseases of the American Academy of Pediatrics (Red Book Committee) advises pediatricians. Because of extensive interactions between the two groups, the recommendations are almost identical.

CDC INVOLVEMENT IN IMMUNIZATION

- CDC began to supplement State and local immunization efforts in 1963 with implementation of the Vaccination Assistance Act of 1962.
- There are currently 63 Federal Immunization Grants administered by CDC including Grants to all 50 states, the District of Columbia, some large cities, and the territories. Each grantee runs its immunization program tailored to its own needs.
- CDC grants support vaccine purchase and program administration such as vaccine handling and shipment, immunization level assessment, disease surveillance, and outbreak control. Beginning in FY 92 funds could also be used to assist with the actual delivery of vaccines such as hiring nurses.

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THE CURRENT CDC CONTRACT

- Starting in the 1960's, CDC negotiated large Federal Contracts with vaccine manufacturers to purchase vaccines at reduced rates. Such contracts offered manufacturers advantages over their usual methods of doing business.
- CDC prices are lower than the private sector because of:
 - Large minimum guaranteed purchase
 - No return clause (private physicians can return unused or outdated vaccine for a full refund)
 - Limited number of delivery points (only to 63 immunization grantees)
 - The Federal government's assumption of the duty to warn parents of recipients of the benefits and risks of vaccines
 - The manufacturers' willingness to let the private sector supplement the cost of vaccine sold to the public sector
- The contracts require that the vaccine purchased must be used solely in federal, state, and local public health immunization programs. Sale of these vaccines to any person or entity is strictly prohibited. Vaccines can be provided to private physicians if the Grantee feels it is necessary to assure children are immunized.
- CDC grant guidelines allow a "reasonable administration fee" to be charged but require that a sign be posted in all places that receive vaccines purchased with Immunization Grant Funds stating that "No one may be denied vaccine for inability to pay".

THE "OPTIONAL USE CLAUSE IN CDC CONTRACTS

- All CDC contracts currently contain an "optional use clause" which permits purchase at the Federal Contract rate using state, local, and/or federal funds.
- Manufacturers have the option of accepting or denying applications for vaccines requested under the "optional use clause".
- Other public entities such Community Health Centers can purchase vaccines at the Federal Contract price by giving

public appropriated funds to grantees who in turn make the purchase. Some states such as California and Florida do not have mechanisms for receipt of such funds thereby precluding such purchases.

Recently, when additional states have indicated they want to purchase vaccines under the "optional use clause" and distribute them to all public and private providers, the vaccine manufacturers have responded that such distribution of vaccines to private sector providers represents an evasion of the intent of the Federal contract price system which manufacturers believe is intended to provide vaccines primarily for indigent children. Broader use of the optional use clause might involve a significant shift of vaccines to private sector providers at public sector prices. Manufacturers profits would thereby be reduced and it is likely the Federal contract price would rise to a level that would maintain the same overall revenues.

We are unaware of any order which has been placed under the optional use clause ever being denied; however, we know that both South Carolina and Hawaii were told by Lederle that they would not agree to furnish additional vaccines, at the CDC price, if they expanded their optional use purchases to include vaccine for all children in their states.

THE CURRENT VACCINE PURCHASE SYSTEM

In the public sector, CDC immunization grant funds support delivery of approximately 60-65% of the public sector need or about 30% of all vaccines purchased in the country.

The proportion of vaccines purchased by CDC varies widely by vaccine. For example, grant funds cover about 35% of public sector diphtheria, tetanus, pertussis (DTP) needs compared to virtually all of the needs for the first dose of Measles, Mumps, Rubella (MMR) vaccine.

All states receive vaccines purchased through the Federal contract.

Eleven states purchase all or some recommended vaccines for all children in the state, whether served by the public or private sectors, at the price negotiated in the Federal contract using state-appropriated and other Federal funds to supplement immunization grant funds. The former funds are used under the "optional use clause" for vaccines.

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- Two states, Michigan and Massachusetts manufacture their own DTP and distribute it free to both the public and private sectors for all children within their respective states.
- Immunization coverage is higher in states with universal purchase compared to other areas. However, the differences are not great. For example, median complete coverage (4DTP, 3 oral polio vaccines (OPV), and 1 MMR) by the second birthday for areas with universal purchase was 62% versus a median of 56% in other areas. Differences in median coverage rates for the individual vaccines vary from 9 to 12% with the universal purchase states always higher.
- Differences may not be solely a function of the purchase policy since the health care delivery systems in states with universal purchase, particularly the New England states, are very different from other states.
- Seven states purchase all Medicaid vaccines at the Federal contract price. States like Illinois and Ohio estimate they save more than \$1 million annually by purchasing at the low contract price. Other states allow private Medicaid providers to purchase vaccines at the catalog price and reimburse the private provider.

VACCINE PRICES

- In 1993, the full price of vaccines for immunizing a child was \$89.34 under the Federal contract and \$212.81 in the private sector. This excludes the Federal excise tax which was not reauthorized. With the excise tax, the overall prices would increase \$32.84 for each sector.
- This represents approximately a 10 fold increase from 1982 in both sectors.
- Variations in price over time are shown in the attached tables.
- Prices for DTP have paralleled increases in manufacturer liability. However, despite marked liability reductions due to the compensation system, prices have still not fallen to levels existing prior to the liability crisis.
- MMR prices did not change in the private sector even when demand was increased more than 150% in 1989 with recommendations for a two dose schedule. Only minor reductions occurred in the Federal contract price.

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IMMUNIZATION COVERAGE LEVELS

- All states have laws requiring immunization for entry to school.
- Immunization levels at the time of school entry are 96% or higher indicating virtually all children in the United States can be vaccinated under the present system.
- Immunization levels among preschoolers enrolled in licensed day care or Head Start are also 93% or higher indicating that with regulation high levels are possible.
- Immunization coverage levels among the overall preschool population, a group that should be receiving approximately 80% of the recommended vaccines, are much lower. National estimates for complete coverage by the second birthday in the United States range from 37-56% depending upon the survey and methodology used.
- National estimates can be quite misleading since there is substantial variation from area to area. For example, New Hampshire has the highest reported level, 79%, while Utah has the lowest, 36%.
- Urban areas tend to have levels 10-15% lower than state wide estimates. For example, Houston reports only 18% coverage.
- Immunization coverage among members of racial and ethnic minority groups are lower than in the general population.

REASONS FOR THE LOW PRESCHOOL COVERAGE

- Most studies have identified two major reasons for low coverage: 1) a health care system that is not "user friendly" which places obstacles in the way of parents seeking immunizations and that fails to take advantage of many opportunities it has to immunize and 2) lack of parental knowledge of the importance of preschool immunization.
- Barriers which serve as deterrents to immunization include long clinic waits, long waits for appointments, inconvenient clinic hours, difficult to reach clinic locations.
- Missed opportunities include making children come back for vaccines instead of giving all that are needed simultaneously, not vaccinating children with minor illnesses who could be vaccinated, and not taking advantage of the contacts many high risk children already have with

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public assistance programs such as the Supplemental Food and Nutrition program for Women, Infants, and Children (WIC) and Aid to Families with Dependent Children (AFDC).

- While most parents realize their children need "baby shots", many do not realize how many are needed. Often parents believe that the critical need for immunizations is at the time of school entry since that is the time at which they are required by law.
- The task of immunizing preschoolers is made more difficult because there is no tracking system to help providers identify children in need of immunization, remind parents when immunizations are due, recall parents who do not keep appointments, and monitor progress on an ongoing basis at the local level.

THE ROLE OF HIGH VACCINE PRICES IN LOW VACCINE COVERAGE

- High vaccine prices have played some role in low immunization coverage but the impact has been difficult to quantitate. Only about 1/2 of traditional employer-based indemnity health insurance plans cover childhood immunization.
- High prices cause fragmentation of care because parents may seek regular care with a private physician but go to a health department for immunizations where they are available free or at low cost. This creates burdens for an already overburdened public health sector. Many parents may defer immunization rather than make the extra visits.
- A 1992 survey of City Maternal and Child Health Programs (City MatCH) reported 88% of responding health departments had experienced a private to public sector shift of children. From 1989-1991, there was a median increase of 24% in children served and 31% in doses administered.

RESPONSES TO THE CRISIS OF LOW IMMUNIZATION COVERAGE

- \$45 million was made available in FY92 to 63 immunization grantees and 24 large urban areas chosen on the basis of size and proportion minority population to assist them in reaching the year 2000 goal of 90% full coverage by the second birthday.
- To receive the money each area was required to develop a comprehensive Immunization Action Plan (IAP) which addressed issues of improving immunization delivery, information and education, and assessment and evaluation.

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- Overall, the 87 areas requested \$250 million for the available \$45 million.
- The President has announced a \$300 million major initiative to make vaccination services more widely available to all Americans.

VACCINE PURCHASE OPTIONS INCLUDING MANUFACTURERS' CONCERNS

1. CONTINUE PRESENT SYSTEM

PRO

- Public Sector receives vaccines at favorable prices compared to the private sector prices
- Manufacturer R&D is maintained
- Limited competition in the market would continue to exist
- Neediest of children still receive vaccines free or at minimal cost with least cost under the Federal immunization grant
- Vaccine manufacturers are comfortable with this system
- The current vaccine purchasing system assures vaccine supplies are sufficient to vaccinate virtually all children by school entry. Vaccine supply is not the major reason for poor immunization coverage among preschoolers

CON

- Children normally served through the private sector will continue to be referred to an already overburdened public sector
- Referrals are likely to increase as more vaccines are added to the schedule and prices continue to rise
- There is no guaranteed purchase of vaccines at reduced rates for all medically indigent children served by programs such as Medicaid and community and migrant health centers
- It will be difficult to establish a national immunization tracking system because private providers have little incentive to undertake the administrative burden necessary to assure data on all vaccinated children are entered into

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the system. Such a system is essential if we are to assure all children are immunized as preschoolers

2. NEGOTIATE CONTRACTS TO ASSURE ALL GRANTEEES CAN PURCHASE AS MUCH VACCINE AS NEEDED TO ASSURE PUBLIC SECTOR PROGRAMS SUCH AS MEDICAID AND COMMUNITY HEALTH CENTERS RECEIVE REDUCED PRICE VACCINES

PRO

- Assures all needy children receive lower cost vaccines regardless of which public sector program serves them
- Permits some private sector market for manufacturers to obtain necessary revenues for R&D as well as enhancing competition
- Merck has already offered to provide vaccines to private Medicaid providers at the Federal contract rate with a surcharge for distribution

CON

- Many states do not have the funds to increase purchases thus maintaining the problems noted above such as private to public sector shift and difficulties in setting up a tracking system

3. MANDATE ALL FORMS OF PRIVATE INSURANCE COVER THE FULL COST OF IMMUNIZATION

PRO

- Would stem and potentially reverse flow of private sector patients to the public sector and avoid fragmentation of care
- Would end the financial barriers of both vaccine costs and costs of vaccine administration for insured persons
- Would accomplish vaccination of children served in the private sector without increasing Federal expenditures
- Would be strongly favored by the vaccine manufacturers. Maintains the current system with its incentives for vaccine R&D

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- Would put the onus of cost containment on the private sector instead of the government

CON

- Would probably be fought by the insurance industry because of rate increases they would have to pass on
 - May also be opposed by employers including those who self-insure because of increased costs
 - Would not cover the uninsured who fragment care between the private sector for acute illnesses and the public sector for immunizations or seek all care in the public sector
 - Would not give private physicians an incentive to participate in the national immunization tracking system because little would be gained for the administrative burden they would undertake
 - Private insurers have not been good at containing overall health care costs
 - May not impact on improving immunization levels in the public sector which serves the highest risk children
4. NEGOTIATE CONTRACTS TO ASSURE ALL GRANTEEES CAN PURCHASE AS MUCH VACCINE AS NEEDED TO SERVE ALL CHILDREN WITHIN THEIR RESPECTIVE STATES DEPENDING ON THEIR POLICIES AND AVAILABILITY OF FUNDS

PRO

- Permits additional states to universally purchase and distribute vaccines at lower cost to avoid fragmentation of care and reduce private to public sector shift in those states
- Will give incentives to private providers for them to participate in a national immunization tracking system in those states which provide vaccines to private providers

CON

- Federal contract price is likely to rise in order to maintain manufacturers current revenue requiring greater Federal immunization grant funds to purchase the same number of vaccine doses

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- Many states do not have the funds to increase purchases thus maintaining the problems noted above such as private to public sector shift and difficulties in setting up a tracking system

5. UNIVERSAL FEDERAL PURCHASE

PRO

- Would remove financial barriers regarding vaccine purchase for the parents of all children
- Would likely increase coverage among preschoolers although the magnitude is uncertain
- Would substantially reduce and potentially eliminate referral of children served by the private sector into the public sector
- Would greatly facilitate the establishment of a national immunization tracking system for all children by providing incentives for private providers to participate
- Would assist in monitoring safety of vaccines

CON

- Marked increase in vaccine prices and Federal outlay of funds to maintain current manufacturer revenues
- Potential decrease in already limited competition
- Potential decrease in manufacturer R&D

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Diphtheria and Tetanus Toxoids with Pertussis Vaccine (DTP)						
YEAR	FEDERAL CONTRACT			MARKET PRICE		
	Manufact. Price	Excise Tax ¹	Total Price	Manufact. Price	Excise Tax ¹	Total Price
1977	\$ 0.15	-	\$ 0.15 ²	\$ 0.19	-	\$ 0.19
1978	0.15	-	0.15	0.22	-	0.22
1979	0.15	-	0.15	0.25	-	0.25
1980	0.15	-	0.15	0.30	-	0.30
1981	0.15	-	0.15	0.33	-	0.33
1982	0.15	-	0.15	0.37	-	0.37
1983	0.42	-	0.42	0.45	-	0.45
1984	0.65	-	0.65	0.99	-	0.99
1985	2.21	-	2.21	2.80	-	2.80
1986	3.01	-	3.01	11.40	-	11.40
1987	7.693	-	7.693	8.92	-	8.92
1988	3.896	\$ 4.56	8.456	6.47	\$ 4.56	11.03
1989	3.401	4.56	7.961	6.09	4.56	10.65
1990	2.353	4.56	6.913	6.09	4.56	10.65
1991	1.685	4.56	6.245	5.41	4.56	9.97
1992	1.425	4.56	5.985	5.48	4.56	10.04
1993	1.425	-	1.425	5.377	-	5.377

¹ Excise tax was instituted January 1, 1988 as a result of the National Childhood Vaccine Injury Compensation Act of 1986; the tax was suspended December 31, 1992 by the Secretary of the Treasury.

² There was no Federal contract between 1977 and 1985; the figures provided represent average costs of state contracts

Diphtheria and Tetanus Toxoids with Acellular Pertussis Vaccine (DTaP)						
YEAR	FEDERAL CONTRACT			MARKET PRICE		
	Manufact. Price	Excise Tax ¹	Total Price	Manufact. Price	Excise Tax ¹	Total Price

1992	\$ 6.45	\$ 4.56	\$ 11.01	\$ 11.77	\$ 4.56	\$ 16.33
1993	6.45	-	6.45	11.77	-	11.77

1 Excise tax was instituted January 1, 1988 as a result of the National Childhood Vaccine Injury Compensation Act of 1986; the tax was suspended December 31, 1992 by the Secretary of the Treasury.

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Oral Polio Vaccine (OPV)						
YEAR	FEDERAL CONTRACT			MARKET PRICE		
	Manufact. Price	Excise Tax ¹	Total Price	Manufact. Price	Excise Tax ¹	Total Price
1977	\$ 0.295	-	\$ 0.295	\$ 1.00	-	\$ 1.00
1978	0.313	-	0.313	1.15	-	1.15
1979	0.332	-	0.332	1.27	-	1.27
1980	0.354	-	0.354	1.60	-	1.60
1981	0.396	-	0.396	2.10	-	2.10
1982	0.475	-	0.475	2.75	-	2.75
1983	0.582	-	0.582	3.56	-	3.56
1984	0.728	-	0.728	4.60	-	4.60
1985	0.804	-	0.804	6.15	-	6.15
1986	1.56	-	1.56	8.67	-	8.67
1987	1.363	-	1.363	8.07	-	8.07
1988	1.073	\$ 0.29	1.363	7.78	\$ 0.29	8.07
1989	1.63	0.29	1.92	9.16	0.29	9.45
1990	1.63	0.29	1.92	9.45	0.29	7.74
1991	1.7114	0.29	2.0014	9.16	0.29	9.45
1992	1.8038	0.29	2.0938	9.62	0.29	9.91
1993	1.8664	-	1.8664	10.137	-	10.137

¹ Excise tax was instituted January 1, 1988 as a result of the National Childhood Vaccine Injury Compensation Act of 1986; the tax was suspended December 31, 1992 by the Secretary of the Treasury.

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Measles-Mumps-Rubella Vaccine (MMR)						
YEAR	FEDERAL CONTRACT			MARKET PRICE		
	Manufact. Price	Excise Tax ¹	Total Price	Manufact. Price	Excise Tax ¹	Total Price
1977	\$ 2.42	-	\$ 2.42	\$ 6.01	-	\$ 6.01
1978	2.35	-	2.35	6.16	-	6.16
1979	2.62	-	2.62	6.81	-	6.81
1980	2.71	-	2.71	7.24	-	7.24
1981	3.12	-	3.12	9.32	-	9.32
1982	4.02	-	4.02	10.44	-	10.44
1983	4.70	-	4.70	11.30	-	11.30
1984	5.40	-	5.40	12.08	-	12.08
1985	6.85	-	6.85	13.50	-	13.50
1986	8.47	-	8.47	15.15	-	15.15
1987	10.67	-	10.67	17.88	-	17.88
1988	11.74	\$ 4.44	16.18	19.67	\$ 4.44	24.11
1989 ²	11.74	4.44	16.18	19.67	4.44	24.11
1990	10.273	4.44	14.713	19.63	4.44	24.07
1991	10.889	4.44	15.329	20.85	4.44	25.29
1992	10.889	4.44	15.329	20.85	4.44	25.29
1993	10.889	-	10.889	20.85	-	20.85

¹ Excise tax was instituted January 1, 1988 as a result of the National Childhood Vaccine Injury Compensation Act of 1986; the tax was suspended December 31, 1992 by the Secretary of the Treasury.

² On December 29, 1989, the Advisory Committee on Immunization Practices recommended a second dose of MMR be given to children entering school and to children entering college; this recommendation increased the demand for MMR vaccine as much as 150 percent, yet there was no corresponding decrease in price.

Haemophilus influenzae type b Conjugate Vaccine (HbcV)						
YEAR	FEDERAL CONTRACT			MARKET PRICE		
	Manufact. Price	Excise Tax ¹	Total Price	Manufact. Price	Excise Tax ¹	Total Price
1988	\$ 11.01	-	\$ 11.01	\$ 13.75	-	\$ 13.75
1989	6.00	-	6.00	13.75	-	13.75
1990	5.20	-	5.20	14.55	-	14.55
1991	5.16	-	5.16	14.55	-	14.55
1992	5.366	-	5.366	15.13	-	15.13
1993	5.366	-	5.366	15.13	-	15.13

¹ There is no excise tax for this vaccine

Hepatitis B Vaccine (HBV)						
YEAR	FEDERAL CONTRACT ¹			MARKET PRICE		
	Manufact. Price	Excise Tax ²	Total Price	Manufact. Price	Excise Tax ²	Total Price
1986	-	-	-	8.625	-	8.625
1987	-	-	-	10.325	-	10.325
1988	-	-	-	10.333	-	10.333
1989	-	-	-	10.333	-	10.333
1990	\$ 7.66	-	\$ 7.66	10.708	-	10.708
1991	7.43	-	7.43	10.708	-	10.708
1992	7.238	-	7.238	10.708	-	10.708
1993	6.85	-	6.85	10.708	-	10.708

¹ There was no Federal contract between 1986 and 1990

² There is no excise tax for this vaccine

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The Impact of Liability on Vaccine Prices

- Beginning in the early 1980's, increasing numbers of lawsuits were filed against vaccine manufacturers by persons claiming to have been injured by vaccines.
- The majority of claims were made against manufacturers of DTP vaccine. These lawsuits resulted in claims which reached a high of \$3.1 billion in 1985.
- As a result of this liability, several manufacturers left the DTP market, while others compensated by significantly raising the price of their DTP vaccine based on an internal liability surcharge.
- To prevent other vaccine manufacturers from leaving the market and to control increasing vaccine prices, the National Childhood Vaccine Injury Compensation Act of 1986 was passed.
- The Act established a no-fault compensation program and instituted excise taxes on DTP and its single antigen component vaccines, MMR and its single antigen component vaccines, and OPV to create a fund which would compensate persons claiming to have been injured by vaccines.
- As a result of the compensation program, the number of lawsuits filed against vaccine manufacturers has decreased dramatically (as shown in the table below), yet vaccine prices have not decreased to the levels that existed prior to the increase in lawsuits.

Diphtheria and Tetanus Toxoids with Pertussis Vaccine (DTP)			
YEAR	Federal Contract Price Without Excise Tax	Market Price Without Excise Tax	Number of Lawsuits Filed Against Manufacturers
1978	0.15	0.22	1
1979	0.15	0.25	1
1980	0.15	0.30	4
1981	0.15	0.33	3
1982	0.15	0.37	17
1983	0.42	0.45	41
1984	0.65	0.99	73
1985	2.21	2.80	219
1986	3.01	11.40	255
1987	7.693	8.92	178
1988	3.896	6.47	114
1989	3.401	6.09	47
1990	2.353	6.09	19
1991	1.685	5.41	18

VACCINE PRICES PER DOSE - FEDERAL CONTRACT VS. MARKET										
YEAR	DTP		OPV		MMR		HbCV ¹		HBV ²	
	Contract ³	Market	Contract	Market	Contract	Market	Contract	Market	Contract	Market
1977	\$ 0.15	\$ 0.19	\$ 0.295	\$ 1.00	\$ 2.42	\$ 6.01	N/A	N/A	N/A	N/A
1978	0.15	0.22	0.313	1.15	2.35	6.16	N/A	N/A	N/A	N/A
1979	0.15	0.25	0.332	1.27	2.62	6.81	N/A	N/A	N/A	N/A
1980	0.15	0.30	0.354	1.60	2.71	7.24	N/A	N/A	N/A	N/A
1981	0.15	0.33	0.396	2.10	3.12	9.32	N/A	N/A	N/A	N/A
1982	0.15	0.37	0.475	2.75	4.02	10.44	N/A	N/A	N/A	N/A
1983	0.42	0.45	0.582	3.56	4.70	11.30	N/A	N/A	N/A	N/A
1984	0.65	0.99	0.728	4.60	5.40	12.08	N/A	N/A	N/A	N/A
1985	2.21	2.80	0.804	6.15	6.85	13.50	N/A	N/A	N/A	N/A
1986	3.01	11.40	1.56	8.67	8.47	15.15	N/A	N/A	N/A	\$ 8.625
1987	7.693	8.92	1.363	8.07	10.67	17.88	N/A	N/A	N/A	10.325
1988	8.456	11.03	1.363	8.07	16.18	24.11	\$11.00	\$13.75	N/A	10.333
1989	7.961	10.65	1.92	9.45	16.18	24.11	6.00	13.75	N/A	10.333
1990	6.913	10.65	1.92	9.74	14.713	24.07	5.20	14.55	\$ 7.66	10.708
1991	6.245	9.97	2.0014	9.45	15.329	25.29	5.16	14.55	7.43	10.708
1992	5.985	10.04	2.0938	9.91	15.329	25.29	5.366	15.13	7.238	10.708

¹ Haemophilus influenzae type b conjugate vaccine (HbCV) was not licensed for use until 1988

² Recombinant Hepatitis B vaccine (HBV) was not licensed for use until 1986; there was no Federal Hepatitis B program until 1990, therefore there was no Federal contract before 1990

³ There was no Federal contract between 1977 and 1985; the figures provided represent average costs of state contracts

VACCINE PURCHASES UNDER OPTIONAL USE CLAUSE

The CDC's present vaccine purchase contracts with the manufacturers of childhood vaccines allow the public sector to obtain vaccines at the reduced Federal contract price, which is significantly lower than the catalog price. The funds for the Federal purchases are derived from appropriations under section 317 of the Public Health Service Act. The typical pattern of distribution is that CDC purchases the vaccines for its grantees (States, territories, and cities) and the grantees distribute the vaccines for use in public health departments and other public clinics. Approximately 50 percent of childhood vaccines administered in the United States are purchased through the Federal contracts.

The "optional use" clause allows the States that wish to do so to purchase additional vaccines with State or local funds at the Federal contract price, but only with the consent of the manufacturers. Eleven States have taken advantage of this clause to distribute the reduced-price vaccines to all providers, public and private. (The clause allows them to distribute the vaccines free of charge to private sector providers, but the providers cannot resell the vaccines.) The private provider may charge an administration fee, but cannot charge the parent or patient for the vaccine.

When additional States have indicated they would like to purchase and distribute vaccines to all providers through the optional use clause, the vaccine manufacturers have objected. They have complained that the distribution of vaccines to private sector providers through the optional use clause represents an evasion of the intent of the Federal contract price system, in that private sector providers now get the reduced "public" price, rather than the catalog price which they would otherwise have to pay. If the application of the optional use clause were to be extended to enable a significant shift of vaccines to private sector providers, it is clear that the manufacturers would raise the Federal contract price significantly, so as to maximize revenues, presumably at least at the level of their present revenues from both the contract sales and the catalog sales.

In future contract negotiations, it is expected that the manufacturers will seek to exclude or narrow the optional use clause, as well as renegotiate the prices.