

**IMPACT OF MEDICAID ON CHILD
IMMUNIZATION**

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
FOR FAMILIES AND THE UNINSURED
OF THE
COMMITTEE ON FINANCE
UNITED STATES SENATE
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IMPACT OF MEDICAID ON CHILD IMMUNIZATION

MONDAY, JUNE 1, 1992

U.S. SENATE,
SUBCOMMITTEE ON HEALTH FOR FAMILIES
AND THE UNINSURED,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 9:40 a.m., in room SD-215, Dirksen Senate Office Building, Hon. Donald W. Riegle, Jr. (chairman of the subcommittee) presiding.

Also present: Senator Durenberger.

[The press release announcing the hearing follows:]

[Press Release No. H-28, May 22, 1992]

RIEGLE HEARING TO EXAMINE MEDICAID'S IMPACT ON CHILD IMMUNIZATION; SENATOR SAYS SOME CHILDREN STILL NOT RECEIVING THEIR SHOTS

WASHINGTON, DC—Senator Donald W. Riegle Jr., Chairman of the Senate Finance Subcommittee on Health for Families and the Uninsured, Friday announced a hearing to look at the Medicaid and Maternal and Child Health Programs and its relationship to child immunization programs.

The hearing will be at 10 a.m. Monday, June 1, 1992 in SD-215 of the Dirksen Senate Office Building.

Riegle (D., Michigan) introduced the Comprehensive Child Health Immunization Act, S. 2116, last fall.

"It is unacceptable that in 1992, any child in Michigan or anywhere in our country could become ill from preventable diseases like measles, mumps, rubella, polio and a host of other dangerous illnesses. I am holding this hearing to examine ways we can work within the existing programs to increase access to immunizations," Riegle said.

"The bill presents a thorough strategy for making sure children, especially pre-school children, receive needed vaccinations by improving current public health and social service programs for children. I look forward to hearing from witnesses on this proposal and the issue of child immunizations."

OPENING STATEMENT OF HON. DONALD W. RIEGLE, JR., A U.S. SENATOR FROM MICHIGAN, CHAIRMAN OF THE SUB- COMMITTEE

Senator RIEGLE. The committee will come to order. Let me welcome all those in attendance this morning. In the last several years, we have seen a dramatic rise in the number of very young children becoming ill with vaccine-preventable diseases.

To increase immunizations among young children who need these very badly needed vaccines, I introduced S. 2116, the Comprehensive Child Health Immunization Act, last fall. And Senator Kit Bond of Missouri, who sits on the Appropriations Committee, is the primary co-sponsor of the bill.

And I want to say in Senator Bond's behalf—he had hoped to be here this morning; he necessarily must be in his home State of Missouri and cannot be here—that he is a very strong co-leader with me on this legislation. In addition, Senators Johnston, Cochran, and Bradley are also co-sponsors, and I envision adding several more.

The bill that I have just referenced was referred here to the Senate Finance Committee, but it also contains provisions which fall under the jurisdiction of the Senate Labor and Human Resources Committee.

Today, we are going to be hearing from expert witnesses from the public and private sector who will comment on specific Finance Committee provisions of this bill, and on other ways that we can increase the immunization of children in America.

Now, the U.S. has been very successful in reaching its goal of making sure that our children are fully immunized before they enter elementary school.

Over the last 3 years, however, we have seen a dramatic rise in the number of pre-schoolers who become sick, with some children even dying, from measles, for example.

In Michigan, total measles cases went from a low of 31 cases as recently as 1988, up to 359 cases just a year later in 1989. And, then, in 1990, Michigan had 478 cases and one death.

In addition, we have seen outbreaks of other diseases such as pertussis, or whooping cough, which doubled in Michigan between 1989 and 1990. Nationwide, about one-third of our 2-year-olds are not vaccinated against measles, mumps, rubella, polio, and a host of other harmful illnesses. That just cannot be tolerated when we have the vaccines in our country and we are in a position to protect these children. The measles outbreak and the declining immunization rates among young children highlight the serious systemic problems that we have regarding the ability for young children to receive these immunizations.

Now, this developing problem comes about because we have not been aggressive enough in finding young children who have not been immunized, and we have missed opportunities to actually immunize children when they do come into contact with certain public sector programs, such as the Women, Infants and Children's program, called WIC; Aid to Families with Dependent Children, known as AFDC; and Maternal and Child Health Programs.

We also must be far more diligent in informing parents about the need for immunizations, that these diseases have not gone away. In fact, vaccinations have to be undertaken in order to protect children, and, at the same time, make it easier for parents to get these vaccinations for their children.

There is an important economic saving over and above just the avoidance of a lot of human misery that can be accomplished here. Because vaccinating young children against preventable diseases is one of the most cost-effective health procedures we know.

It is estimated that we can save at least \$10 in later medical costs that can be avoided for every \$1 that we spend on the front end with immunizations.

Now, this legislation, S. 2116, puts in place a comprehensive strategy within existing health care and social service programs to

increase immunizations and to prevent widespread outbreaks of preventable childhood diseases, such as measles.

The bill would also help providers in the private sector by reducing current disincentives to participate in public programs and providing better information on the immunization status of our children.

The current public health system just misses too many opportunities to immunize America's children. Children and their parents regularly come into contact with a variety of public programs, whether they are the Maternal and Child Health Block Grant programs, Medicaid, AFDC, and other programs where individuals' benefit status is checked. We could easily, at the same time, be checking children's immunization status, and even administering vaccines.

These public programs should also be required to adhere to Federal immunization practice standards, such as setting age-appropriate vaccination schedules, eliminating mandatory pre-vaccination physicals, and specifying alternate locations for vaccinations, like, for example, welfare offices, and to remove barriers that make immunizing children more difficult.

We can also address poor outreach among Medicaid recipients through Medicaid's Early and Periodic Screening, Diagnosis and Treatment program called EPSDT. This program already requires that State Medicaid programs examine low-income children's health status.

We should explicitly require this program to monitor and track children's immunization status and conduct an aggressive outreach to ensure that these children are immunized. Because that protects not only those children, but other children out there who lack immunization.

Our bill would also provide funding for Medicaid demonstrations to examine ways to reduce the financial disincentive for private providers to immunize children in their offices.

The bill would also move in a direction of establishing a nationwide computerized information system to keep track of children's immunization status. In the kind of modern age that we have today with the technology available to us, that is clearly an achievable goal.

So, public health officials, physicians, and clinics could get the information they need on what individual children require in the way of vaccinations.

Most public health experts agree that a country's child immunization rate is a good measure of how successfully its health care system is addressing the needs of children. In this area, the United States lags behind other western countries in immunizing its young children.

I think until we as a country address larger issues of national health care reform and make basic health care coverage available to all Americans, clearly, an imperative in our society today, we have got to set our sights on the objective of giving America's children the best that our current system can offer.

Now, I will just make one other initial comment, and then I want to turn to Senator Durenberger.

I want to thank all of the witnesses for their willingness, not only to testify today, but to accommodate the adjustment that we have had to make in our schedule. We had to change the witness order today because we moved the hearing to an earlier time.

And Mr. Nadel, from the U.S. General Accounting Office, will be our first witness, instead of Christine Nye, from the Health Care Financing Administration.

There may be some other changes and adjustments this morning in the schedule, and I greatly appreciate the flexibility and patience of everyone who is going to be testifying this morning.

Senator Durenberger.

**OPENING STATEMENT OF HON. DAVE DURENBERGER, A U.S.
SENATOR FROM MINNESOTA**

Senator DURENBERGER. Mr. Chairman, thank you very much. I regret that with the change in the schedule, my morning has gotten a little complicated so I can't stay here with you, either.

But I did want to come at the beginning, first, to thank you for what you have been working so hard over the last couple of years to do for people who are the disadvantaged in our system, and particularly to use this relatively new subcommittee to deal with issues of family, and kids.

Even though it is necessary to do it a piece at a time, there is a consistency to this whole approach for which I want to compliment you and your staff.

Senator RIEGLE. Thank you.

Senator DURENBERGER. This morning we are talking about a relatively small piece of a larger problem. But if we were not here, we have been provided with copies of a story that one of our sort of assistant staffers, Spencer Rich, and one of these wonderful reporters who is always out there digging up stuff and helping us know what is going on, brought an article in the Post about a study that is going to appear in the Journal of the American Medical Association, about 20 percent of children lacking preventive care, and probably more than that if you get down into all of the specifics.

But, as I read through the article, I saw some of the same problems present there that exist with regard to immunization. I think perhaps some of the solutions that I am going to speak of in just a second here, and those recommended by the people who did the study, are similar.

First, I would like to begin by acknowledging the fact that for the 14 years the Senator from Michigan and I have been on this committee, we have tried to do our best within the parameters that we had to work with here in the Finance Committee to deal with this immunization issue.

We have done a lot in expanding the Medicaid program. Over on the Labor Committee, using the Public Health Service Act, a fair amount has been done, too. But the problem seems to be getting worse.

It is true, as you point out, Mr. Chairman, that by the time kids are enrolled in a mandatory public education system in America, most of them have received the required immunizations. But, as I think you pointed out in your opening statement, that is not good enough. I mean, I have been home in my own community dealing

with the measles epidemic, for example, among 2-year-olds and 1½-year-olds.

Senator RIEGLE. Right.

Senator DURENBERGER. Particularly refugee populations. In my case, the Mong population in St. Paul. So, it doesn't do any good to say by the time they get into the public school system a mandated immunization process captures 90 percent of the problem.

It would help us all, including the people from the administration, to read the statistics from the United Nations Development program on immunization rates for 1-year-old children, which is the process by which at least the members at this committee have immunized their child, I would imagine.

By the time our kids have reached 1 year of age, we have gone through a process of having them all immunized because we have access to a different kind of a system.

Senator RIEGLE. Right.

Senator DURENBERGER. The United States' rate for immunizations for 1-year-olds is 48 percent, which is literally the lowest percentage among the 45 countries the UNDP classes as highly developed.

The immunization rates for 1-year-olds in Germany is 68 percent; the United Kingdom, 82 percent; Japan, 84 percent; Canada, 85 percent; and Israel, 90 percent.

But it can get even worse than that if you look at the fact that we, the richest nation on earth and the one that devotes the highest percentage of our national income on health care, compares our 48 percent with Nigeria's 62 percent; Mexico's 74 percent; the Philippines, 82 percent; Tunisia, 88 percent. I mean, try that on for size. I guess that is the reason you are having this hearing.

I wanted to use my time just to mention several of the problems with which we are presented in this country. First, is the pluralistic health care system.

The chairman of this subcommittee and I have different ways to deal with that pluralistic system, but because it is so pluralistic and because it is a system in which square pegs are being driven into a variety of round holes all of the time, there is a lot of people falling through the space between the square and the round hole.

I have a member of my staff who has a 19-month-old daughter, and he was getting the child immunized against polio, diphtheria, pertussis, and tetanus. He sent the bill to Blue Cross, which is his carrier, and they wrote back saying, "The benefits are not available for these services."

Well, the whole notion that insurance is there only to protect us against adverse health conditions rather than helping us to prevent those more serious problems is an anachronism in today's world. It is one of the reasons why all of us feel so strongly about insurance reform.

One of the reasons why all of us believe that 95 percent of the people that are selling health insurance in America ought to go back to selling fire and casualty insurance and leave this business of maintaining the health status and improving the health status of Americans, is that those health plans that are really willing to engage themselves in health maintenance of the population of this country.

The second point I would like to make is that I would expect those of us that I spoke to earlier, if I still had a 1-year-old or somebody like that to go into the system, I would take them to the "doctor" for the immunization, and I would probably have a high-priced pediatrician giving them the shots and I would be paying the bill through my insurance company.

That is totally unnecessary. Totally unnecessary. You do not need a \$50 shot, or a \$75 shot, or a \$100 shot. It can be done a lot less expensively in this society.

But I suspect if you did not have your own doctor and your own insurance company and you relied on the public system, for example, in this community, I bet you the first thing you would do is look in the Yellow Pages or something like that for the source of your immunizations.

They give you a telephone number, you pick up the phone, you call there, and you would probably get a busy signal. If you did not get a busy signal, you get one of these things that tell you to wait until somebody can pick up the phone.

Finally, some bureaucrat someplace in the bowels of a big building would pick up the phone and they would say, well, the hours are such and such, and such and such, and this sort of thing. And you need to make an appointment, or you need to do this, that, or the other thing.

Then, once you made a commitment that you are actually going to do something about it, you would probably go down there and you would find that there is a line halfway around the block in order to get the service.

And, since the child is not sick, you are just trying to prevent the child from being sick—

Senator RIEGLE. Right.

Senator DURENBERGER. A whole series of those kinds of experiences in communities in America, I would guess, would discourage a whole lot of people from seeking health maintenance on their own, and probably, over time, has done a great deal to discredit the community-based health care delivery system.

It is true that parents are a problem. Parents are probably an increasing problem in our society. But, then, society has to find ways to deal with that problem, too. The educational role that communities must play with parenting is equally important.

I asked my staff person back here, Kevin Quinn, who is from Canada, what happens up there. And he said, well, we just happened to have a young child in that system, and he said what happens is that the public health nurse sort of follows you out of the hospital.

Within a few days of mom going home with the baby, the public health nurse is there to talk about this series of immunizations. Well, that is Canada, that is not the United States. But, that certainly is one of the parts of a Canadian system that people in the United States ought to say, well, gee whiz, does that not make sense?

The question always gets to be, for us, is whether or not the national government is ever going to—by your bill, Mr. Chairman, or any other—get communities in this country to respond the way they ought to.

We have had these urgent public health programs for 25 years, and the lines are still going around the block. The bureaucrats are still getting more of the money than the kids are getting. It is true of our public school systems; it is true of our public health systems in this country.

I have come to the conclusion that, until we make public health a community responsibility, we are not going to get the job done. And exactly how to get there, I am sure, is something that those of us on this committee ought to spend a little time dealing with.

Senator Moynihan and I have the Medicaid Managed Care Improvement Act, which is not a solution to a problem, it is just another way to try to take the child and the family and capture all of their needs in one program so that you have a care-giver walking with a person all through their life, particularly from conception through, let us say, age 12, 13, 14, or 15.

You have somebody walking with them, somebody that they can trust, somebody they are familiar with, their records are there; all of the things that are in your bill.

And I suggest that there may be other ways or additional ways here to deal with this problem, because it is certainly a very serious problem. But I am sort of gradually coming to the conclusion that we really need to federalize the national responsibility to medical access in this system.

In exchange for that, ask the communities of America to find out a better way to make the same commitment to public health that they make to public education, but find a better way to do it. I mean, I am impressed by the new mayor of Washington, DC. We still call her the new mayor, I guess, because the old one is still around.

But I am really impressed with the way in which she wants to ask the community to take responsibility for some of these problems, and wants to ask us to give this community and others the opportunity to do the job the way they would like to get it done, not the way we, in our sort of categorical way, would like to do it.

So, that is just a matter of sharing some sort of frustration with the way the current system works. Not to say that there is not an easy answer to it, but until communities begin to take more responsibility for this problem, it is going to be a frustration to you, Mr. Chairman, to sit here and try to approach this a bill at a time, an authorization at a time, an amendment at a time. Because that is probably not going to get the job done. These kids are in competition with a lot more powerful interests out there in those communities, too. So, I thank you for the opportunity to be here today.

Senator RIEGLE. Thank you, Senator Durenberger. And let me just acknowledge and express appreciation for your leadership on these health care issues over a great length of time. This is a matter of keen interest to you, as you have shown over and over again.

I might say with respect to this immunization effort, I feel strongly that we need to do this, beef it up on a bipartisan basis. And Senator Bond and Senator Cochran have joined on your side of the aisle.

And I am open to suggestions as to how we might take and make this legislative vehicle as strong as it can be. But I very much want

to go ahead with it. I think there is the basis of support out there. The cost involved is not overwhelming.

In fact, I think we can save probably \$10 for every \$1 we spend in terms of avoiding the heartache of diseases that are preventable and the cost of treating those diseases when otherwise they would not have occur.

So, in any event, I am going to try to press ahead with that. I will certainly welcome your suggestions and your help as we go. I think we ought to do this on a combined basis, and I would like to try to accomplish that.

Let me now call our first witness to the table, Ms. Christine Nye, who is the Director of the Medicaid Bureau for the Health Care Financing Administration.

We are delighted to have you here this morning, and welcome you. She is here to discuss the Department of Health and Human Services Immunization Action Plan, especially with regard to the Medicaid program.

And, in the interest of time this morning, I am going to make all of the witnesses' full statements a part of the record. I would like you to try to summarize in maybe 5 to 7 minutes, something like that, and then we can go back and forth with questions and answers.

But we welcome you, and we would like to hear from you now.

STATEMENT OF CHRISTINE NYE, DIRECTOR, MEDICAID BUREAU, HEALTH CARE FINANCING ADMINISTRATION, WASHINGTON, DC

Ms. NYE. Thank you. Mr. Chairman and members of the subcommittee, I am pleased to be here this morning to discuss the Medicaid program's role in providing immunization services to children.

As Secretary Sullivan recently pointed out, American's immunization program is one of the greatest success stories in medicine. Serious illness from diphtheria, mumps, pertussis, polio, rubella, and tetanus have been reduced by at least 90 percent.

Since 1982, 95 percent of children entering school have been immunized. However, the increased incidence of measles experienced a few years ago points out the need to fill gaps in our Nation's immunization program.

At the President's direction, the Department of Health and Human Services recently released a comprehensive action plan to improve access to immunization services.

Today I would like to discuss the Medicaid program's role in this extensive effort to immunize children vulnerable to preventable disease.

Medicaid finances immunizations primarily through the Early Periodic Screening, Diagnosis, and Treatment program, otherwise known as the EPSDT program.

EPSDT is a comprehensive program that considers the overall health status of children. Immunization is just one component of this broad health benefit. States have implemented outreach programs to enroll children in the EPSDT program.

HCFA is also developing and testing model outreach programs. Under these programs, States are targeting media campaigns to re-

cruit EPSDT providers. States are also working with community groups to establish one-to-one outreach among neighbors in targeted locations.

Under the EPSDT program, children are screened to evaluate their medical needs through a comprehensive physical examination, including laboratory testing, where needed.

Necessary immunizations, vision, dental, hearing, and other services are provided to treat identified conditions. Health care providers must also educate children and their parents on ways to correct unhealthy behavior.

I would emphasize that immunizations are required to be administered as part of the EPSDT screening evaluation. We have no indication that physicians and other EPSDT providers are failing to do this.

HCFA has several important projects under way to improve immunization services provided through Medicaid's EPSDT program. Since 1985, EPSDT providers have been able to use vaccines supplied through public health agencies.

The Public Health Service's Centers for Disease Control coordinate consolidated vaccine purchases for State and local agencies through national contracts with suppliers. These large-quantity purchases significantly lower prices from the high cost of vaccines purchased on the open market.

In several States, including Michigan, agreements between Medicaid and public health agencies enable a systematic replenishing of providers' vaccines supplied as they furnish EPSDT immunizations.

Easy access to vaccines removes a barrier that inhibits the appropriate immunization of children to EPSDT screenings. We are studying States that now take advantage of public health supplied vaccines.

The information that we glean from this will help us to assist other States to maximize the low-cost purchase and effective distribution of vaccines for the EPSDT program.

This April, we entered into an agreement with the Centers for Disease Control to develop a strategy to promote infant and childhood immunizations.

This agreement calls for three things: first of all, updating the guide for efficient vaccine acquisition through CDC purchasing contracts; we are exploring the development of an immunization data base; and, finally, we are disseminating technical assistance materials, including the standards for pediatric immunization practices to State Medicaid agencies and providers.

In fact, this week the State Medicaid directors are in town and we will be distributing that information to them. The activities I just described fit into the department's much broader action plan to improve access to immunization services.

The goals for the Health Care Financing Administration include: issuing updated guidelines for EPSDT immunizations; sponsoring immunization workshops; improving immunization services in cooperation with Maternal and Child Health programs; conducting EPSDT management reviews of all States; and tracking immunization status in the EPSDT program. The larger goals we are aiming

for is to have 80 percent of all Medicaid eligible children screened by 1995.

One way we hope to accomplish this goal is to enroll more Medicaid children in coordinated care plans, such as HMOs. Children with access to primary care are more likely to have immunizations than others receiving fee-for-service medicine. This Medicaid coordinated care approach is included in the President's Comprehensive Health Care Reform plan.

The Medicaid program is already involved in much of the activities of the bill, S. 2116. Accordingly, many of the activities are already under way and we do not support the enactment of S. 2116. In many ways, it duplicates Department and State efforts in the Medicaid program.

The Medicaid program is committed to improving immunization levels for all eligible children. Our efforts, combined with increased Federal funding for immunizations and action at local levels, form a national campaign to better our nation's immunization program. Thank you. I would be more than happy to answer any questions that you may have.

[The prepared statement of Ms. Nye appears in the appendix.]

Senator RIEGLE. Thank you very much. Let me begin by asking you a question that is very relevant and very important. And that is the reference to the United Nations data on the immunization of 1-year-olds. Now, this is U.N. data, and there is always a lag in this data.

But, for example, it indicates that the United States, in terms of its rate of immunizing children under the age of one—which is, of course, the most important time to do it to get that protection in there—that of a long list of industrial and modern nations—some not very industrialized, as a matter of fact—130 nations, and I am going to give you some of the references, we are very near the bottom of the list. It is really quite shocking.

For example, Lebanon. Here is Lebanon, torn by civil war, and such. Their rate of immunization of 1-year-olds is 88 percent. Our is 48 percent.

If you take other countries, Turkey, their level is 71 percent; Malaysia, 74 percent; Romania, 93 percent; Cuba, 93 percent; Korea, 89 percent; Poland—they obviously concentrate on it—97 percent. With all the other difficulties they have in Poland, they are getting their kids vaccinated. The United Kingdom is well above us; 82 percent; Canada, 85 percent.

But if you go down here, Bulgaria, hardly a modern nation, 99 percent. They concentrate on this. The U.S.S.R., the old Soviet Union, was summarized in that way under this data, 83 percent. Chile, 96 percent.

What I do not understand is all of these countries that I have named are poorer than we are. And yet they have got achievement rates that are so far beyond ours that it is an embarrassment, really, that we are not doing better than that.

We are going to spend the money one way or another, are we not? I mean, if we spend the money on the vaccination and we vaccinate the child and they do not get the disease, that is less expensive than to ignore it and to let them get the disease and have the

costs associated with treating the disease, is it not? Do we not spend more if we fail to vaccinate?

Ms. NYE. Study after study has found, as you indicate, that it is much more cost-effective and much better in human terms to provide preventive health care than to rely on acute episodic care.

Senator RIEGLE. So, we come out ahead. In other words, if we spend a small amount of money to vaccinate the child and then the child doesn't get sick, we save spending a much larger amount of money to treat the child. In some cases, the children die. I mean, we have had cases of that happening here in our own country; have we not?

Ms. NYE. That is correct.

Senator RIEGLE. What I am wondering is this. I feel, as Senator Durenberger said, not to try to turn his argument into my words, but somewhere in the system something is breaking down here that is preventing us from getting these immunizations into these children. We know how to do it. The science certainly exists. Other nations have made it a priority so they have gotten way out in front of us. They are looking after their children better than we are.

I know before you came into your current position you headed up the program, I think, in the State of Wisconsin under the Medicaid program. So, you were out on the firing line trying to implement these programs in terms of seeing to it that poorer families were getting the medical assistance that they need.

Can you tell us, what is it that is breaking down? I do not ask you to aim any huge criticism at anybody, but just from that experience, why are we not able to achieve the kinds of levels that we are seeing in other countries here?

Ms. NYE. Well, I think there are a number of factors, and there are persons who are more expert in this analysis than myself. But, based on my own experience, I think it has to do with a number of things.

It has to do with the availability and procurement of vaccines, lack of coordination, for example, through the public health system and private providers.

It has to do with failure of communities to recognize the need and the results from failure to immunize and the human and cost factors involved in that.

And, I think the study and others that you cite in terms of comparing this country to other countries in the world have resulted, since the first outbreak of measles in 1989, in a real stepped-up effort and commitment to improve and strengthen not only the service delivery systems, but to make vaccines available less expensively to the public and private providers caring for this population.

Senator RIEGLE. Now, I think I am correct in noting that in your testimony you are setting within this program that is now there, which carries the label EPSDT, that program, the goal is to achieve an 80 percent immunization, I gather, for children under that program. Am I correct in noting that?

Ms. NYE. That is partially correct. Our goal is that by 1995, 80 percent of children eligible for EPSDT services receive screening. That screening includes a developmental and health history, and

on-clothes physical exam, it includes the lab tests, for example, lead screening, et cetera. It also includes immunizations.

Senator RIEGLE. I see.

Ms. NYE. So, in order for somebody's screening to count, it has to include all of those things. So, we are taking that kind of comprehensive approach.

I am sure it is true that there are, in addition to those numbers, children who receive immunizations. But it might be that they did not meet all of the other tests.

Senator RIEGLE. Yes.

Ms. NYE. So, that is why I said it is partially correct.

Senator RIEGLE. Looking at that goal as being out in the future, that is 1995, why do we not set the goal at 100 percent?

Ms. NYE. I think that in 1995, or as we get closer to that year, it might be possible for us to revise our goal and have it to be a higher number. We found when we started this that 80 percent was a goal well worth achieving because of the levels that we were at, and States and local communities have really responded by trying to meet these targets.

For example, between last year and this year, the number of EPSDT children screened increased by almost 60 percent, or by 2.5 million. So, it might be possible to have a greater level of success, given the response we are getting. And you are right, we should achieve that goal.

Senator RIEGLE. Well, I am glad to hear you say that we should achieve it. And I think the only way we achieve it is to set it, frankly. I mean, I do not aim that to you as a criticism.

But I think that unless we decide we are going to go out and look after the health needs of all of our children in the country, particularly the ones that are in the worst circumstances because they are the ones that are likely to have the worst diet and the worst care conditions, and a lot of other things that would make it easier for illnesses to strike.

I think we have got to set as a goal for ourselves making sure that all of the children in the country get this basic health screening protection, and very particularly the vaccinations.

When I see these other countries—Argentina, Korea, Poland, and all these other nations—Bulgaria has a 99-percent vaccination rate for children under the age of 1. I think that is sensational.

I mean, how are they smarter than we are? I do not understand it. They are certainly not richer than we are, they are just putting a higher priority on it and they are getting it done.

One of the problems here is that doctors who might otherwise vaccinate children on Medicaid do not feel they are being reimbursed properly. Where are we today in terms of doctors who are reluctant to actually provide the vaccinations—private physicians?

Ms. NYE. It really varies by State. There are a couple of things I can say about that. One of the things your bill does, which is something we are really pushing eight or more States are doing this already, is to purchase vaccines more cheaply through the Centers for Disease Control and make them available through different mechanisms to physicians. So, that is one way it deals with the problem.

The other thing is that the EPSDT program, which was greatly expanded in 1989, has just completed monitoring all 50 State programs and is following up on the findings.

I point this out in terms of one of the things we look at for State compliance with these requirements. Whether, in fact, children are receiving appropriate immunization levels according to the right schedule.

So, I think both through oversight and monitoring of State activities and by piggy-backing on the Centers for Disease Control purchasing agreements, we are improving physician participation.

Senator RIEGLE. Is it fair to say, though, that the Medicaid reimbursement rates for private physicians for immunizations are too low in some States?

Ms. NYE. I think reimbursement rates really vary across the country. And I think that in some States, the rate may be a barrier to physician participation.

Senator RIEGLE. Give me an example, where might that be?

Ms. NYE. I cannot give you an example of that.

Senator RIEGLE. Well, then, let us try it this way. If there are some States—and you obviously feel there are—would the reimbursement rate be as much as 25 or 50 percent below the actual cost of providing the immunization?

Ms. NYE. It could be that. But, honestly, I do not know that figure. I could provide you that information for the record if you want that, but I do not know that off the top of my head.

Senator RIEGLE. Yes. I think we need to get that. And I say that because there is a problem out there, and you acknowledge that there is. It might be as much as 50 percent in some cases; you are not sure of the data.

But I think we need to be right on top of that, because that is a measure, I think, of why the immunizations are not happening, particularly with respect to poor children.

They are not getting immunized, in part, because the doctors who might provide those immunizations are not being reimbursed through Medicaid an amount equal to an appropriate cost for that service, so they are not doing it.

So, the kids are really the ones that are suffering. So, I think we need to know what it is in each State, and if we have States where that is a major problem, we need to target in on that.

Because a child should not be put at an extra disadvantage just because they happen to live in one State in America rather than another State in America. I mean, that is the kind of thing we can overcome.

Well, I would like you to produce that information for the record.

[The following information was subsequently received for the record:]

The attached table shows the Medicaid reimbursement rates for immunizations provided by physicians in the 50 States and the District of Columbia. Generally, the data came from State plan material submitted in connection with payment of pediatric services.

We do not have data that would allow us to compare private sector payments to State Medicaid payments. Such a comparison would require special community-based studies. These studies would involve comparisons with private sector experience, other insurance and payer plans, and would weigh the efficiency with which physicians acquired the vaccines (e.g., wholesale, discount from the manufacturer, or retail from the local druggist).

6/92.State Immunization Reimbursement Rates as reported in Medicaid State Plans

PROCEDURE CODES	90701	90702	90704	90705	90706	90707	90708	90709	90712	90737
	DTP	DT	MUMPS	MEASLES	RUBELLA	MMR	MR	RM	POLIO	HIB
REGION I										
Connecticut	unavailable	4.00	17.25	15.00	15.25	Rates are unavailable for these				
Delaware	13.24	4.16	20.38	17.36	18.53	33.61	24.05	26.72	15.28	18.00
Massachusetts	Immunizations are included in fees for office visits									
New Hampshire	Immunizations are included in fees for office visits									
Rhode Island	17.00	5.00	7.00	10.00	11.00	17.00	17.00	7.00	7.00	7.00
Vermont	17.00	5.00	12.45	11.05	11.35	14.00	16.00	7.15	9.55	21.00
REGION II										
New Jersey	16.34	1.79	23.60	18.39	22.04	19.87	N/A	N/A	14.44	25.79
New York	20.49	3.16	21.89	19.94	24.21	37.75	26.44	26.13	15.25	21.42
Puerto Rico										
Virgin Islands										
REGION III										
Delaware	10.25	2.60	N/A	N/A	N/A	27.25	16.50	N/A	10.80	15.25
Dist. of Col.	23.02	2.73	18.46	15.42	17.19	34.91	23.83	25.52	17.56	16.37
Maryland	15.76	1.72	18.34	14.73	15.22	34.00	21.06	22.54	12.85	19.00
Pennsylvania	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
Virginia	17.81	3.18	17.97	16.13	16.69	22.83	23.31	25.02	12.14	20.25
West Virginia	18.00	11.25	17.25	15.75	16.50	26.25	20.25	21.75	15.00	16.50
REGION IV										
Alabama	11.94	2.61	18.37	17.94	18.54	15.75	22.15	24.75	12.64	20.00
Florida	15.03	4.45	18.33	16.76	17.24	31.14	22.22	10.81	16.50	16.50
Georgia	10.83	4.85	14.10	11.95	12.72	24.10	21.22	25.01	10.83	14.10
Illinois	8.99	N/A	N/A	N/A	N/A	17.32	N/A	N/A	4.26	5.83
Mississippi	Top State Health Dept. pays for immunizations, provider charge to Medicaid									
North Carolina	13.14	9.41	18.68	15.77	17.35	34.74	24.41	23.41	14.21	27.09
South Carolina	The State Health Dept. provides vaccines to providers & bills Medicaid.									
Tennessee	16.45	2.00	18.00	16.15	16.70	17.00	23.15	11.00	12.60	20.00
REGION V										
Illinois	18.10	3.75	22.90	20.69	21.36	40.85	29.33	31.36	14.44	23.00
Indiana	16.10	5.40	20.55	17.71	18.80	33.03	24.01	28.56	14.93	17.87
Michigan	14.78	4.11	19.65	16.81	17.90	32.06	23.11	25.66	11.30	17.66
Minnesota	23.50	6.21	31.34	28.53	31.92	54.94	33.82	42.88	33.24	34.06
Ohio	ERFE	11.13	15.11	14.00	15.00	ERFE	20.00	21.00	ERFE	ERFE
Wisconsin	21.23	4.52	22.48	19.28	20.48	16.78	26.49	29.40	18.07	24.04
REGION VI										
Alabama	18.00	18.00	17.78	16.81	17.43	34.64	24.47	26.25	16.26	20.00
Arkansas	18.00	5.00	22.00	22.00	22.00	35.00	35.00	35.00	18.00	22.00
Delaware	20.00	15.00	N/A	19.00	20.00	16.00	27.00	28.00	15.00	47.98
New Mexico	16.00	5.00	16.90	16.30	16.90	12.00	21.40	26.30	13.00	17.90
Texas	6.24	1.14	N/A	N/A	N/A	15.33	N/A	N/A	4.00	3.16
REGION VII										
Arkansas	* Immunizations provided free to EPSDT providers in Texas.									
Illinois	19.42	4.26	10.85	15.70	15.56	14.74	20.72	9.07	11.34	19.59
Michigan	State of MS purchases vaccines through contract with Pfizer for his contract									
Mississippi	19.00	4.25	18.80	14.90	16.10	31.75	21.80	24.60	11.65	19.50
Nebraska	15.85	5.20	19.80	18.31	18.85	32.60	24.45	25.90	16.65	24.00
REGION VIII										
Colorado	20.19	5.88	15.23	13.13	13.89	33.35	20.66	22.26	17.89	20.10
Connecticut	17.74	11.07	17.49	17.74	17.84	29.60	19.30	17.75	14.31	18.40
North Dakota	24.24	5.24	22.91	17.74	17.84	26.97	24.40	18.12	9.96	20.93
South Dakota	Flat percentage of the submitted charge is paid for immunizations									
Utah	21.72	3.00	16.05	15.88	15.88	19.96	21.96	23.96	19.21	21.40
Wyoming	16.00	3.00	18.00	16.00	17.00	30.00	22.00	27.00	19.00	10.64
REGION IX										
American Samoa										
Arizona	11.54	11.64	16.93	16.93	16.93	11.74	25.39	25.39	11.64	10.00
California	16.20	5.87	18.64	16.21	17.16	19.23	21.58	23.74	12.61	19.94
Guam										
Hawaii	Providers are paid 52% for admin. and Blue Book price less 10.5%									
Nevada	Immunizations provided for in the EPSDT screen.									
Puerto Rico										
REGION X										
Alaska	10.00	12.00	as bill	19.00	as bill	34.00	as bill	as bill	as bill	25.00
Idaho	17.00	6.24	21.20	17.77	19.13	31.00	23.44	24.00	15.00	18.43
Oregon	22.65	7.28	18.88	17.44	17.66	32.92	23.80	25.48	18.72	23.48
Washington	15.19	4.31	20.51	18.89	19.16	13.84	25.10	26.79	14.26	12.08

1. DTP - Diphtheria and tetanus toxoids and pertussis
2. DT - Diphtheria and tetanus toxoids
3. MUMPS - Mumps virus vaccine, live
4. MEASLES - Measles virus vaccine, live, attenuated
5. RUBELLA - Rubella virus vaccine, live
6. MMR - Measles, mumps and rubella virus vaccine, live
7. MR - Measles and rubella virus vaccine, live
8. RM - Rubella and mumps virus vaccine, live
9. POLIO - Poliovirus vaccine, live, oral (any type)
10. HIS - Hemophilus influenza B

Senator RIEGLE. Let me just say, we feel, those of us that are sponsoring this legislation and I feel very strongly that we have to press ahead in this area.

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Tiny children are the most defenseless people in our society. They cannot protect themselves. And, in many cases, even their parents are not able to protect them if they do not have the information about how serious the threat is from these childhood illnesses.

And if they cannot get into the immunization system properly, cannot get in and get the vaccinations even though they are out there and exist, that is just not a condition that we can allow to stand in America.

And to just put it in the context of today's political discussion, everybody is following the Presidential race because we have this anomaly this time.

We may have a three-way race; it looks like we are going to. But, as a result, there is a lot of public commentary and a lot of discussion in the country by observers, columnists, and such as that.

And I was just out in Michigan for 4 days talking with people across the State. We had a health care forum in Battle Creek, for example, and some other things.

And when I talked to people about what is called the Ross Perot phenomenon, a third-party candidate coming on the scene and generating a lot of support across the country, I think it is because he gives the impression, the feeling that on problems like this where there should be answers, that he would undertake to see that there were answers, and not just reasons why we cannot get things done, but to figure out how we get things done.

And whether or not he would prove capable of doing that, I think the fact that he is sending that signal and the public is responding to it has a relevance to this hearing.

Because I think the American people do not want the United States near the bottom of a list of 130 countries. We do not want to become last on that list. We ought to be first on this list, and we certainly ought not to be last in immunizing our children up to 1 year in age.

So, I think it is clear that if we cannot make this system work better than that, there is going to be this continued build-up of a desire for change.

And the change is going to come, and it may come in terms of a kind of knocking the normal political calculus haywire because people are so frustrated by why it is we are last on the list and we do not seem to be able to take and move ourselves up to the top.

It is time we get to the top. We need to be to the top in immunizing our kids; and in terms of our productivity in our work force; our trade balance, which is a disaster, needs to be turned around. We ought to be having a major trade surplus.

So, I only cite this because I think it is indicative of a shortfall in national performance. In this case, it falls on all of these little tiny tots around the country who are in a situation where they are highly vulnerable. We are in a position to protect them.

If we do, we save money. I mean, we save their health, we save a lot of human grief, and we actually end up spending less money with preventive care than we are going to spend if we withhold the vaccinations and they end up getting sick and then we have to pro-

vide the care at that point and the cost is much higher, as you have testified.

So, let us keep working on this. We want to get this legislation enacted. My Republican colleagues who are co-sponsors with me feel strongly about it, as do I. And I would like to work with you.

I know there may be some reluctance in the Office of Management and Budget, or some other part of the government that says we cannot afford to protect and help our own people. That is nonsense.

People who believe that ought to be out of government and doing something else for a living. I think the best investment we could make is in our people, and this is a perfect example of that. So, we thank you for your testimony today.

Ms. NYE. Thank you.

Senator RIEGLE. Let me now call to the witness table Mr. Mark Nadel, who is the Associate Director for Health Financing and Policy Issues in the Human Resources Division at the General Accounting Office.

He is going to discuss the preliminary findings of a GAO study requested by Senator Bentsen, the Chairman of this committee, to examine ways to improve immunization rates. And I am very pleased that Mr. Nadel is here today to give us an advance look at this important study.

So, let me welcome you. Please introduce your colleagues. We will again ask you to summarize in about 5 to 7 minutes, and leave time for questions, if you will.

STATEMENT OF MARK V. NADEL, ASSOCIATE DIRECTOR, HEALTH FINANCING AND POLICY ISSUES, U.S. GENERAL ACCOUNTING OFFICE, WASHINGTON, DC, ACCOMPANIED BY TERUNI ROSENGREN, EVALUATOR-IN-CHARGE, HEALTH FINANCING & POLICY ISSUES, U.S. GENERAL ACCOUNTING OFFICE, AND ALBERT JOJOKIAN, ASSISTANT DIRECTOR, HEALTH FINANCING & POLICY ISSUES, U.S. GENERAL ACCOUNTING OFFICE

Mr. NADEL. Mr. Chairman, I am pleased to be here to discuss our work on childhood immunization, which will be issued as a report later this year. I am accompanied by Teruni Rosengren and Albert Jojokian.

This morning I will discuss our preliminary findings on ways to reduce Medicaid immunization costs and strategies to improve pre-school immunization rates.

In brief, we found that the States could save millions of dollars through a more efficient Medicaid vaccine purchase and reimbursement strategy. We found that 19 States save money by directly purchasing lower cost vaccines for Medicaid providers through CDC contracts rather than at the commercial price.

States would have saved over \$14 million in 1991 alone by purchasing all vaccines for Medicaid through CDC purchasing contracts. State health agencies get vaccines through CDC either free, through a CDC grant, or at reduced cost using their own funds. And, generally, these vaccines are supplied to public health providers, such as public clinics.

States can also purchase CDC vaccines for private providers to use for their Medicaid patients under a vaccine replacement program. As of May 1991, nine States had a vaccine replacement program.

In these States, Medicaid programs reimbursed the health departments for the lower cost vaccines and saved money by reimbursing for vaccines at the CDC contract price rather than at the regular commercial price.

Illinois, for example, saved over \$1.5 million in 1991 by reimbursing this way. In these States, health departments replaced the Medicaid provider supply of vaccines with vaccines purchased through CDC contracts.

Ten additional States purchase the low-cost vaccines from CDC and distribute them free to all providers, for both Medicaid and non-Medicaid use; a practice referred to as a universal vaccine distribution system.

In other States, Medicaid reimbursements for vaccines are based on private sector vaccine costs, which are considerably higher than costs under the CDC contracts. For example, the private sector price for oral polio vaccine is almost five times greater than the CDC contract price.

States told us that funding is a major barrier to establishing a vaccine replacement program. Medicaid will reimburse health departments for the cost of vaccines only after they have been administered to children, and so the States must first come up with enough money to purchase the initial supply of vaccines.

Nonetheless, this initial expenditure would be more than offset by recurring Medicaid savings while also benefitting children's health.

Senator RIEGLE. Let me just stop you right there. You are saying that the money spent on immunizations pays itself back more than dollar for dollar. In other words, we end up saving more by spending some money up front for preventive immunizations.

Mr. NADEL. Well, that is right in two ways. You could provide Medicaid coverage at a lower cost than we do now, so just those initial savings could be lower. And, as you pointed out earlier, the payoff for immunization, of course, is several fold.

Senator RIEGLE. Yes.

Mr. NADEL. Even when States have vaccine replacement programs, not all private providers participate in the replacement programs because there are also barriers to individual physician participation.

These include delays in vaccine replacement; administrative burdens of keeping records for both public and private immunization; and what some see as inadequate Medicaid reimbursement for the administration of vaccines.

We also found a second area where further savings of Medicaid funds could be achieved. That is, if States required the use of combined vaccines rather than reimbursing individual injections of single-antigen vaccines, combined vaccines provide protection against multiple diseases, such as measles, mumps, and rubella.

Except during a disease outbreak, the Public Health Services and the American Academy of Pediatrics' immunization guidelines recommend the use of a combined measles, mumps, and rubella vac-

cinations for routine immunizations of pre-school children. Most State Medicaid programs, however, routinely pay for single-antigen vaccinations.

A substantial number of single-antigen injections may have been given wastefully, as seen in a recent New York State Health Department analysis of Medicaid claims, which found that single-antigen vaccines were inappropriately administered in 45 percent of the immunizations given in physicians' office to pre-school children.

Because of this practice, opportunities were lost for achieving full immunization of these children, and immunization costs increased. Based on our survey results, the average Medicaid reimbursement for the three single-antigen vaccines is 60 percent higher than the reimbursement for the combined vaccine.

Although it is possible to reduce Medicaid expenditures for vaccinations, such savings alone will do little to improve pre-school immunization levels unless the funds are rechanneled to more proactive immunization programs.

Public health departments need to educate parents about the importance of completing the full immunization schedule, as well as to identify and reach out to children needing immunization.

Our analysis confirmed that States with State-wide integrated tracking outreach and education systems had higher immunization rates than those that did not; 66 percent compared to 58 percent. However, only 12 States have such systems.

In addition to having integrated systems, the two States with the highest rates, Vermont, at 84 percent, and Massachusetts, at 79 percent, supplied certain of the vaccines free to all health care providers, which may have contributed to the high rates.

In conclusion, although funding is a barrier to better vaccination programs, States could lower their Medicaid vaccination costs by adopting more cost-effective vaccine payment policies.

Savings on vaccine costs could allow the States to use their limited financial resources to improve the effectiveness of their immunization programs, including developing or enhancing a tracking outreach and education system.

This concludes my prepared statement. I would be happy to answer any questions.

[The prepared statement of Mr. Nadel appears in the appendix.]

Senator RIEGLE. Thank you very much. That is very helpful to us. According to your testimony, your report found that, although vaccine replacement programs—that is where States buy vaccines and give them directly to providers—may save money for State Medicaid programs, not all the doctors in those States participate.

And some of the doctors are still retaining Medicaid patients to public clinics, and, in effect, not wanting to do it themselves. Why is that? What is behind that, as nearly as you can tell?

Mr. NADEL. It is a combination of things. A large element of it is what a lot of doctors perceive as inadequate reimbursement by Medicaid. Since they believe that the child could be immunized anyway at a public health clinic, the easiest thing to do, rather than take a loss themselves, is simply to immunize only those children whose parents can pay or whose insurance will pay the full cost and ask the others to go to a clinic.

Some physicians even have signs posted in their office saying, the charge for immunization is X, or whatever it is. If you cannot afford it, there is a nearby clinic. That, of course, overloads the public clinics, whose primary purpose is to provide vaccinations to more low-income children.

Senator RIEGLE. Yes. That is troubling, is it not, that a child could be in a doctor's office and needing a vaccination and not get it simply because the reimbursement rate through the government system is so low that the doctor turns that child away. And maybe the child does not get to the public clinic. They may not go get the immunization there. Does that not happen?

Mr. NADEL. That is exactly right, Senator. Any time you lose an opportunity for immunization, that opportunity may be lost forever.

Senator RIEGLE. It seems to me that at a minimum we ought to have a reimbursement rate that is fair, that compensates the doctor appropriately for doing the immunization, and, also, as you pointed out in your study, we ought to use intelligent buying techniques to get the cost of these vaccinations down to the lowest level we can.

But should we not be trying to vaccinate those children at the point that they have that contact with the doctor and not just say, sorry, we are not going to vaccinate you, go somewhere else?

Mr. NADEL. Yes. Public health experts certainly believe that immunization opportunities should not be lost. And that when a child is brought in for a visit, that is the point at which you want to give the immunization, not refer them elsewhere.

Senator RIEGLE. Now, have some States been more successful than others in getting doctors to participate under the Medicaid program?

Mr. NADEL. The rate of participation does vary by State, just as the reimbursement rate does. I do not, at this time, have information as to which States are the most successful, except to say that we found you get a higher rate of immunization in States which provide the vaccine to all providers.

Senator RIEGLE. Yes. Was it difficult for you to get information on immunization rates among children that participate under Medicaid?

Mr. NADEL. Let me turn to Ms. Rosengren.

Ms. ROSENGREN. Yes. We did ask all the States for that information. Unfortunately, most States could not provide information on the immunization rates of their Medicaid recipients.

Senator RIEGLE. I see. That is one of the reasons why we think we need a national tracking system. It sort of goes to the whole concept of your study, too.

In our entire population we have all of these children out in our society and if we view them as important and we want to keep them well and healthy and help them come along and become good, strong, productive citizens, we do not want to lose track of them. We do not want them to miss their immunizations and then just disappear off the radar screen until something happens.

So, you did find difficulty in getting the data on these poorer children as you tried to do so. Is that right?

Ms. ROSENGREN. That is right. I think most State Medicaid programs do not have a data base which captures this kind of information.

Senator RIEGLE. What do you think of our idea? I mean, I do not know if you feel free to comment. Hopefully, you can, as a citizen. What do you think of our idea of, given the fact that we live in a modern age and we maintain all kinds of computer data, to try to register the information on these children and keep track of them so we make sure they get the preventive health care they need.

Ms. ROSENGREN. We think it is very important to have a birth registry system from all providers.

Senator RIEGLE. Mr. Nadel, do you?

Mr. NADEL. Yes. We certainly do support that. Although it was not mentioned in our testimony as part of this study, we also took a look at what some of the European countries are doing, and that is one noticeable difference.

They do, particularly in Great Britain and the Netherlands where we took a look, have a birth registry system, in addition, of course, to providing immunization services free to all children.

But the combination of those two things has greatly boosted their immunization rate. They are pretty much at the top of the heap at the 1 year and 2-year-old immunization levels.

Senator RIEGLE. You know, it is really astonishing. I was citing the data earlier, of the top 130 industrial nations in the country, we rank near the bottom in immunizing of our 1-year-olds. And if you take what are called truly under-developed countries, I mean, countries that most people would have difficulty finding on the map of the world, though they would recognize the names, of course, but in some of these areas, such as Tunisia, they have an 88 percent rate of achievement.

The Philippines have an 82-percent rate of achievement. China, which we think of as sort of backward by our standards, 96 percent. I mean, the Chinese pay attention to what is happening with their children. Pakistan, the same thing, 65 percent. Nigeria, 62 percent.

This is all with the United States down at 48 percent. It is really astonishing how much we lag the world. Especially when we spend so much on health care in this country and we have so much technology and modern science available to us.

I think what it represents is the fact that we just do not think it is important enough to channel the help and the resources to these young children, particularly the poor ones, because they are the ones that are most at risk.

It is almost as if we have decided, whether consciously or unconsciously, to sort of close our eyes to this problem and let this problem go on, where other nations are facing the problem and getting their kids squared away.

So, your results are very helpful to us, and I appreciate the work you have done. We are going to want to get back to you to make sure that any other questions we have that you can answer, that we get that information for the record. Thank you very much.

Mr. NADEL. Thank you, Mr. Chairman.

Senator RIEGLE. Let me now call our last group to the table. We are going to hear now from a panel representing State Medicaid

programs, pediatricians, and advocacy groups. And the four individuals who are going to be testifying—I am going to introduce them—but please all come up now, if you would.

Mr. Joseph Liu is a Senior Associate with the Children's Defense Fund. The Children's Defense Fund recently conducted a survey of childhood immunizations in the State Medicaid programs. And Mr. Liu will discuss their findings and the need for a comprehensive strategy to increase vaccinations in our country.

Mr. Ray Hanley is Director of the Medicaid Program in the State of Arkansas, and chairman of the State Medicaid Directors Association. And he will give us the State Medicaid perspective from across the country.

Then, Dr. Ed Cox, who is a pediatrician from Grand Rapids, MI. He is the President of the Michigan Chapter of the American Academy of Pediatrics, and is testifying on behalf of the academy.

Dr. Cox's testimony will focus on access to immunizations at the State and local level. And I especially appreciate your flying in from Grand Rapids for this hearing.

Then, Ms. Kay Johnson is testifying, both as director of policy and government affairs for the March of Dimes Birth Defects Foundation, and as a member of the National Vaccine Advisory Committee. Ms. Johnson will discuss the Vaccine Advisory Committee's proposal for increasing access to immunizations. So, let me welcome you all.

Mr. Hanley, I think we will start with you. And, may I say again, we will make your full statements a part of the record. If you can try to summarize in about 5 minutes and leave time for questions, that would be very helpful.

STATEMENT OF RAY HANLEY, DIRECTOR, OFFICE OF MEDICAL SERVICES, ARKANSAS DEPARTMENT OF HUMAN SERVICES, AND CHAIRMAN, STATE MEDICAID DIRECTORS' ASSOCIATION, AN AFFILIATE OF THE AMERICAN PUBLIC WELFARE ASSOCIATION, LITTLE ROCK, AR

Mr. HANLEY. Thank you, Mr. Chairman. I am Ray Hanley, Arkansas Medicaid director and chairman of the State National Medicaid Directors Association.

First, I want to tell you that the Medicaid Directors support the goals that we have talked about here. We are equally concerned about immunization rates and vaccine-preventable diseases.

We feel that our concern has been expressed in the efforts that we have made in the EPSDT area, which does encompass immunizations as a component, but is much broader than that in trying to do comprehensive child health screening.

I have to look on further than my own State of Arkansas where, 4 years ago, the comparative just-completed quarter, we only screened 800 children. This past quarter we screened 13,000 children. Our screening rates have grown by several hundred percent. You will find the same thing in a number of other States.

Senator RIEGLE. Could I just ask you there, Mr. Hanley. That is a big jump, 800 to 13,000. What do you consider to be the population? If you were screening every child in that category, what would that number look like?

Mr. HANLEY. We have approximately 80,000 children on Medicaid in Arkansas.

Senator RIEGLE. So, we have come up from 800 to 13,000, but the target, if we are going to get everybody, is 80,000.

Mr. HANLEY. Right. But, again, this is for a quarter. This is not a total year.

Senator RIEGLE. I see.

Mr. HANLEY. We are going to make the 80 percent. We are going to do it in advance of the 1995 date. It is my goal to go as far past that 80 percent as possible.

Senator RIEGLE. Good for you. I am glad to hear you say that. That would at least get us up there, in your State, somewhere near this list of other nations that I was citing earlier from this U.N. data.

Mr. HANLEY. As Medicaid programs, we have gone into school-based clinics. We have enrolled school districts as providers of health services to try to further expand EPSDT.

We have done extensive outreach for pre-natal, well-baby campaigns, again, without mandates. We have gone into extensive PSA—bus sign boards, brochures, radio announcements—to try to promote well-baby care and pre-natal care.

We are paying for case management services for high-risk pregnancies, mothers and infants. Again, not because it is mandated, but because it is an important health care area that we have emphasized.

Senator RIEGLE. Let me just ask you there. I mean, you are chairman of the State Medicaid Directors' Association. It sounds to me like Arkansas, where you are also in charge, has sort of really moved out strongly in this area. Are all of the other States doing that, too? I mean, would Arkansas be about par for the course, or are you ahead of the pack?

Mr. HANLEY. I hope we are toward the front. But there are not very many that are not making serious efforts. I cannot quantify it and tell you that we are number one, but I know we are trying hard and there are a number of other States that are also working hard in these areas. It is like somebody said earlier the Medicaid data does not lend itself to tracking at this point and telling what percentage of Medicaid children are properly immunized. That is one of the things that we are working on. I am sorry I cannot quantify that.

As far as the goals, we are supportive. We do have some concerns that there is an implied mandatory component here that could lead to some further fragmentation of the health care system than we have got now.

I am serving on the Robert Wood Johnson group to try to help give away some money to fund tracking systems for immunizations. We started with approximately 200 applications and are going to try to narrow it down to 40 shortly.

And I have reviewed applications from State health departments and local health departments over the last month and have had a real education personally on the range of some of these, how low some of the urban areas are, as you have talked about.

But I have also been really impressed by how States have recognized this concept of missed opportunities when immunizations are

not given and the need to deal with that, to educate the providers. There are several applications that deal with a birth certificate-based system of tracking that has been talked about.

In my own State, we are implementing something shortly that is known as the AECT system, which is going to be an automated eligibility claims transmission system where all of our recipients are going to have a plastic ID card, so that providers can verify eligibility at the point of sale.

Their eligibility will be verified, their claim edited, it will be electronically transmitted, which is going to do a lot for provider participation, particularly in the physician area.

But what we are also going to try to do is through a modem hook-up to this, capture immunization information and have it transmitted to the health department into a central tracking system.

We intend not only to try to use this for Medicaid, but for other immunizations that are paid for by other providers also, because the technology is there, as you implied earlier. We can do this.

That is what we intend to create in Arkansas, not because it is mandated, but because we are going to have the technology anyway in the claim system, and it can be done. And you are going to find other States that are looking at this same thing.

In my State, I talked to the pediatrician at the largest pediatric clinic last week about immunizations. He said, well, you know, you pay good rates. You kept up pretty well with the cost of vaccines. Medicaid children we immunize in the clinic here, most of the others we sent to the health department.

Well, it strikes me that what may be good economics in trying to send them to the health department to save money is not necessarily in the interest of continuity in health care.

We are interested in working with the drug companies on the replacement vaccine that might get the low-cost vaccine into all settings. We are meeting this week with Merck, Sharp and Dohme, who wants to pilot a vaccine replacement program in Arkansas. They are going to look at three or four other States.

So, in conclusion of my time here, we are quite supportive of the goals. We just have some concerns about a mandate that would depart from the EPSDT goals we have set and lead to some fragmentation we would like to avoid.

[The prepared statement of Mr. Hanley appears in the appendix.]

Senator RIEGLE. I am very sensitive to the issue of the Federal Government asking the States to do something that costs the States money that the Federal Government does not then provide.

In other words, I am very much of the view if the Federal Government is going to say to the States, do something, that the Federal Government then provide the resources to see that it gets done.

And I think we can do that in this area, and we undertake to do that in our bill, because we think that already there are some areas where the Federal Government is not doing enough to help.

I want to just say with respect to your State that both of your Senators have been real leaders on this issue. Senator Bumpers has been out front on the child immunization issue for years, and probably—

Mr. HANLEY. Yes. Even as Governor before he came to the Senate.

Senator RIEGLE [continuing]. Dating back literally over decades. So, he, I think, stands out perhaps as much as anyone in this country as having seen the importance of doing this and of spearheading it. So, we are adding to his work and his leadership in that area, and appreciate it very much, as well.

Senator Pryor, on this committee, is also very much in the forefront on the effort of seeing how we can not only get the people the medicines, the vaccines, and the other things they need, but to do it in a way where the costs are down at a reasonable a level as they can be. So, both of your Senators have been very much in the forefront of that effort.

I want to just say, if I got your numbers right—and I appreciate the major push that is being made in Arkansas, so do not misunderstand my point in saying this—you said there were roughly 80,000 children in that Medicaid population in Arkansas that you are trying to identify and help. And that on a quarterly basis you have jumped up from something like 800 to 13,000. Is that right?

Mr. HANLEY. That last quarter. Yes, sir. The most recently completed quarter.

Senator RIEGLE. Now, this may not be the fair way to do it, so you correct me if I am wrong. If I multiply four quarters times the 13,000, that brings me up to 52,000. And your population is 80,000 in that group, so that leaves you 28,000 short. Now, you may be on a rising—

Mr. HANLEY. We are.

Senator RIEGLE. So, what is the target, to get to 100 percent, 98 percent, 90 percent, 80 percent; what are you shooting for?

Mr. HANLEY. Well, the first target, obviously, is the 80 percent that we know we have to have, so we are emphasizing that. But with the technology we are implementing, we know we can accelerate that 80-percent goal and the technology that I talked about, and the fee structure which we have out there, which I did not mention, are two reasons that we know we are going to reach the 80 percent, and are confident we are going to exceed it.

Senator RIEGLE. Yes.

Mr. HANLEY. We elected last year to pay our physicians for Medicaid for the most common procedure codes a fee that is equivalent with the Blue Cross/Blue Shield rate; about 80 percent of the allowable. So, we are getting access that way.

Senator RIEGLE. So, you are jacking up the reimbursement rate to the physician.

Mr. HANLEY. Yes.

Senator RIEGLE. So the physician does not put a sign on the wall saying, go somewhere else to get the shots.

Mr. HANLEY. That is right. There are a lot of other barriers to access other than rates, and I have tried to help people understand that. Because the conclusion that too many people jump to is physicians would see all the Medicaid patients if we only paid a higher rate. And that simply is not true.

Even if paying at a Blue Cross/Blue Shield rate, we still probably have regular participation only about 40 percent or so of our physicians.

Senator RIEGLE. Well, I appreciate what you have said to us and the effort that you are making. I think, frankly, our goal ought to be 100 percent, and I will tell you why. I know there are people who say, well, that is hard to achieve.

As we get higher and higher levels, if we get up to 80 percent, it seems to me that the logic says that the 20 percent that is left is probably the 20 percent that, in many ways, is most at risk; that either the parents do not have the information they need about the importance of immunizations; they may think these diseases are defeated when they are not, or whatever; or they do not know where to go; or they do not understand the risk they are running by not getting their child immunized; they are afraid they cannot pay for it; whatever the reason is.

And, in a sense, the last 20 percent is probably the 20 percent that most needs to be found and helped here. And I realize that is the hardest part of the problem to solve, and I am not just putting it in an Arkansas context, I am concerned about it in Michigan, my home State, and all of the other States.

And that is why I think we should be setting for ourselves as a goal not only streamlining the system so that we get the help out there, we have adequate reimbursement rates, we get this bulk-buying in place so we can knock the costs down, and so forth.

But then start tracking these youngsters as they come along, get them in some kind of national system, a data bank, the technology, as you confirm, is now there. We do this with all kinds of other things. And there is another side to this.

And that is if, as a society, we start saying that every person is important, which I believe is a matter of just my own philosophy, not everybody believes that, quite frankly.

There are some people who would say, survival of the fittest, and if you cannot make it, if you are a 2-year-old that gets measles and you die, I mean, that is sort of a kind of harsh reality, but, nevertheless, that is the system at work.

I think to the extent that we can establish a national ethic of both responsibility on the one hand, and caring on the other hand, where we say everybody is important, and we start with things as fundamental as immunizations for children, and hopefully pre-school help and programs like Head Start, right on up the line for those who need it, we deliver a message that people do matter.

And, I think as a part of that, people tend to view themselves differently. I think they tend to view their importance, how they are seen by the society as a whole in a different way, in a more constructive way, in a more connected way, and people see themselves as being a part of the system and coming into the system because the system cares about them.

The system thinks they are important. Therefore, they are able to see themselves as being more important than just some anonymous, casual thing like a hamburger wrapper that we toss away at the end of the day because they happen to be in a low-income situation, or anonymous in our society.

So, I think the more we pay attention to our people and invest in our people, especially wise investments—I mean, good health care, we know, prevents bad health.

So, we can either pay a small amount of money for good health care on the front end, or we can pay a large amount of money for bad health on the other end.

Right now we are paying for a lot of bad health. I mean, people who get sicker than they need to, they get to the doctors later, whether it is kids or older people.

And if we can just back this thing up and concentrate on really investing in our people in a humane sense, and even in a more economically sensible way, we are going to have a stronger country and we are going to have a country that feels better about itself, feels more pulled together, where everybody feels like they are more a part of the whole.

So, I think there is something in this that goes just beyond the avoidance of disease. I think there is something in here about establishing the value of each person in our society.

And some kid who is out in a rural area of Arkansas or rural area of Michigan who, today, is on nobody's radar screen is important to our future, and ought to be on the radar screen.

It should not just be the children of the wealthy or the people who were in good circumstances that are cared about and get all the boost into life and forward that they do get.

So, I think that underneath this there is something quite fundamental about the future of the country, and it says something about how we feel about our people.

So, I am encouraged by what you are doing in Arkansas and I want to praise you for it. I appreciate the commitment that you are making in that area.

Mr. HANLEY. Thank you.

Senator RIEGLE. Let me move now to Mr. Liu. Mr. Liu, we are pleased to have you. We have introduced you, and we would like your statement at this time.

STATEMENT OF JOSEPH LIU, SENIOR ASSOCIATE, CHILDREN'S DEFENSE FUND, WASHINGTON, DC

Mr. LIU. Mr. Chairman, the Children's Defense Fund appreciates this opportunity to testify before you today. CDF is a national public charity that speaks to provide a strong and effective voice on behalf of the needs of low-income, minority, and disabled children.

CDF applauds you, Mr. Chairman, for calling this hearing, and for introducing S. 2116. S. 2116 would create a solid foundation on which to rebuild the nation's immunization system.

We stand at the end of a 3-year-long measles epidemic that struck tens of thousands of children, mostly pre-schoolers.

Yet, only a decade ago, we were on the verge of eradicating this disease. The reasons why we have lost so much ground so quickly must be examined if we are to avoid repeating this tragic lesson.

Key factors for the U.S. immunization decline have included skyrocketing vaccine costs; rising child and family poverty rates; inadequate access to health care; and under-funding of public health programs.

Medicaid, the nation's safety net health program which should be easing the immunization crisis, instead, is worsening the problems.

Despite the adequacy of pediatric payment requirements include in OBRA-90, States continue to reimburse Medicaid providers only a fraction of usual and reasonable fees.

Several States actually reimburse doctors for immunization services at a rate less than the cost of the vaccine itself.

Senator RIEGLE. So, let me get that down and emphasize it. You are saying that, in your analysis, in many States the reimbursement rates under Medicaid are so low that not only the doctor does not get paid anything for his services, but does not even get paid an amount equal to the cost of the vaccine that he has to buy to give the kid the shots. Is that right?

Mr. LIU. In a couple of States, for instance, a measles vaccine, a doctor has to pay \$25 just to buy the vaccine. And then another \$10 for his time. Well, the State Medicaid program pays maybe \$18 or \$19.

Senator RIEGLE. It does not even pay the cost of the vaccine itself.

Mr. LIU. Right. So, the doctor has to subsidize a program just to immunize a child.

Senator RIEGLE. I see.

Mr. LIU. The low Medicaid reimbursement rates lead to a series of problems combined with generally depressed rates for primary care services. Insufficient payment for immunizations can push a pediatric provider out of the program completely, or, more commonly, the low payment levels lead doctors to simply refer Medicaid children over to a public clinic.

In Milwaukee, 86 percent of the pre-school measles cases were among children entitled to Medicaid; in Los Angeles, the figure was 75 percent; and in Dallas, 22 percent.

Contrary to the administration's claims, managed care programs or coordinated care programs alone will not solve this problem in Medicaid. Among commercial managed care programs, the evidence suggests that immunization rates were not a whole lot better than in fee-for-service settings.

But in the case of Medicaid managed care programs, the potential for under-service may worsen the problems. In Milwaukee's measles outbreak, nearly all of the victims were young children enrolled in Medicaid managed care plans.

The plans were simply referring all of their enrolled children over to a public clinic. And this is a program that Tina Nye implemented herself when she was the Wisconsin Medicaid Director.

So, if there are problems in a plan that is put together by good leadership, we are very concerned about what may happen if managed care is loosened up nationally.

Senator RIEGLE. Tell me. Just take a minute. What was the breakdown there? Why, after the children were referred over there, did they not get the protection they needed?

Mr. LIU. Well, part of the problem is that the Milwaukee Health Department was not getting reimbursed for the service because the kids were in a managed care plan.

Senator RIEGLE. I see.

Mr. LIU. So, their resources were over-taxed, they were not getting Medicaid revenues for the immunizations they were providing

to Medicaid-covered children. So, kids had to wait, or were turned away. And all of the problems——

Senator RIEGLE. They just fell through the cracks.

Mr. LIU. Exactly.

Senator RIEGLE. They just did not get protected, and, therefore, they ended up with this measles epidemic.

Mr. LIU. Absolutely. And that is a problem we are concerned about in other managed care settings as well. And I think Senator Durenberger mentioned S. 2077, and we are looking for ways to strengthen the link between immunizations and managed care programs and making sure that there are protections for beneficiaries there.

Senator RIEGLE. Is that not another way of saying, though, that Medicaid's EPSDT screening program, by itself, is not sufficient to get the job done?

Mr. LIU. Absolutely. Every child enrolled in Medicaid is automatically entitled to EPSDT services. The problem is not whether they are "in EPSDT," the problem is whether the system is able to deliver the services that families need.

Senator RIEGLE. That is right.

Mr. LIU. I just wanted to add a little bit on S. 2116.

Senator RIEGLE. Please, go ahead.

Mr. LIU. The act is very important because one of the things it would do is re-orient Medicaid from just a payer of health services to ensuring a more active role in making sure that families get the care they need.

It would create a series of demonstration programs to lower the cost of vaccines and would also create a nationwide immunization survey to make sure that we will not get caught off-guard again by another preventable epidemic like we were last time.

Senator RIEGLE. Yes.

Mr. LIU. Each day we delay an overhaul of State and national vaccine programs and choose, instead, to blame and punish parents for events far beyond their control, brings us a step closer to the next epidemic.

This is a problem which both national, State, and local leaders can tackle and beat today, leaving both children and our health care budget better off.

Senator RIEGLE. Let me just ask you, before we move on. I am old enough, and others would be, to remember the terrible trauma of the polio outbreak we had in America, and the children that were killed and died, and those that were crippled and disabled from it.

Then, of course, we developed a vaccine, and we have the ability with the vaccine to protect people against that. Would it not be fair to assume, however, that if children are not getting the polio vaccine along with the other vaccines that at some point we could have another outbreak? I mean, we have seen measles now have a surge.

Is it not at least logical to assume that some other dread disease like polio could also suddenly appear in a large number of cases? Do we not run that risk if we do not have our children protected?

Mr. LIU. We have seen a high number of cases of disease like rubella, mumps, pertussis, of Haemophilus Influenza B meningitis among young children.

Polio is a very contagious disease, but we are less likely to have the kind of major outbreak as we had with measles because our water systems are good, we have clean water. It is a smaller problem. But, clearly, the potential exists.

Senator RIEGLE. What would be our major risk, as you would see it, as you look across the range of diseases? Which diseases are out there that might flare up that would create the greatest amount of harm or life-threatening or permanent damage problems for children?

Mr. LIU. Well, I think measles, though we have passed this epidemic, is simply going through a typical cycle where all of the at-risk kids have gotten sick for the last 3 years, and so they are not going to get sick again. They are immunized because they have been sick.

Senator RIEGLE. Right.

Mr. LIU. So, in another 2 or 3 years, the cycle is likely to begin all over again.

Senator RIEGLE. It will repeat itself. Right.

Mr. LIU. Just because the numbers have come down now does not mean the problem has gone away at all.

Senator RIEGLE. But beyond measles, what are the other ones that are out there that are latent now that would really pose, perhaps, the greatest risk if they went through one of these up cycles?

Mr. LIU. Well, one of the scariest is the Haemophilus Influenza B meningitis. That particularly strikes very young children and is easily spread in settings like day care programs.

The numbers of cases are very, very high. And the danger is that children suffer permanent brain damage from an episode of a disease that can be prevented by a simple immunization.

Senator RIEGLE. Let me just say, I very much appreciate the work of the Children's Defense Fund. I appreciate your work and that of your colleagues over a long stretch of time to frame these questions and to try to help bring to light the facts that we need to know.

It is an enormously important public service that is done there, and I just appreciate it. I wanted to say so, and would like you to carry that word back to your colleagues.

Mr. LIU. Thank you very much.

[The prepared statement of Mr. Liu appears in the appendix.]

Senator RIEGLE. Dr. Cox, let us go to you, next. Then we are going to have Ms. Johnson bat cleanup here today, if you will.

STATEMENT OF ED COX, M.D., PRESIDENT, MICHIGAN CHAPTER, AMERICAN ACADEMY OF PEDIATRICS, GRAND RAPIDS, MI

Dr. COX. Thank you. Mr. Chairman, I am Ed Cox, a pediatrician from Grand Rapids, and president of the Michigan Chapter of the American Academy of Pediatrics.

I am here today representing 43,000 members of the academy nationwide, as well as American children and families, all of whom

are grateful to you for your longstanding leadership in maternal and child health issues.

Mr. Chairman, your bill, the Comprehensive Child Health Immunization Act, is an important first step towards a much-needed national childhood immunization policy.

This committee is well aware of the effectiveness of preventive health care, particularly immunizations. Yet, despite having this knowledge and the means to prevent a growing number of serious childhood illnesses, preventable diseases are on the rise in virtually every State in this country.

In Michigan in 1990, as you mentioned, a 12-year-old girl died from measles; the first measles death we have had in more than a decade. Her death, and the more than 61 measles-related deaths, and tens of thousands of cases nationwide in 1991, are an unnecessary national tragedy.

In spite of our best intentions, our childhood immunization program is failing too many children whose access to vaccines has been compromised.

Particularly vulnerable children include those who are uninsured or underinsured, those who live in inner cities or rural areas, and many of those who live in middle-class families now in economic distress.

We see these children daily in the upper peninsula of Michigan where, by all socioeconomic standards, many families live in conditions worse than Appalachia.

The system failed that Michigan child who died, and continues to fail all children who are denied immunizations. S. 2116 offers promising solutions to some of the most pressing immunization problems.

However, the academy would urge that the committee go even further. While we appreciate the budgetary constraints that tend to stymie bold initiatives, the efforts you describe do not necessarily need further study through limited demonstration projects.

Rather, these project ideas should formulate the basis of a national childhood immunization program which we sorely lack. In my remarks today I would like to concentrate on three areas we feel are essential to implementing a successful nationwide immunization policy.

First, the need for improved enrollment and referral procedures. Second, the development of a nationwide registry and tracking system. And, third, the need to remove existing financial and system barriers which keep too many kids from being immunized.

Organized, consistent outreach and referral to, and among, appropriate public and private programs and services is essential to assuring a fully immunized population.

Most States' mandatory requirement that children be immunized before school entry has been quite effective, but rates among pre-school children, the time when immunization is, perhaps, most crucial, reveal that U.S. lags behind European rates by as much as 50 percent.

Low immunization rates suggest that our children are not only vulnerable to preventable infections, but that many are not receiving other forms of preventive health care.

S. 2116 provides for central linkages among various programs for the pre-school population, including AFDC, Maternal and Child Health programs, WIC, and Child Care.

At relatively low cost, a child's immunization status can be determined, information provided to parents, and referrals made to facilitate immunizations.

However, even if we significantly strengthen our outreach capabilities, we will not be successful in immunizing all pre-school children if we do not have in place an effective nationwide registry and tracking system. A common record-keeping system is a must, given the mobility of our population.

We would urge that you go beyond the provisions of S. 2116 for limited demonstration grants to States and go immediately to the institution of a national system.

Most European countries have tracking systems that begin at birth and are designed to assure continuing participation of the infant in one or more systems of health care.

Nearly all U.S. children are born in hospitals or birthing centers and all are registered with official State agencies when birth certificates are filed. If all newborns could be issued a Social Security number at birth, immunizations could be tracked through that number.

Providers would need to enter appropriate information into a State data bank on immunizations administered; likewise, at virtually any clinic or office site a provider could access this number to determine a child's immunization status to assure age-appropriate immunizations.

The cost of vaccines remains a formidable barrier for many families, whether they receive their immunizations in a private physician office or public clinic.

Purchase costs for vaccines in the private sector are approximately double the costs for the same vaccine doses in the public sector. Oral polio vaccine costs three times more in the private sector.

For example, in Michigan a single dose of the MMR vaccine costs \$15.33 in the public sector. The same vaccine would cost me anywhere from \$26 to \$29 in the private sector.

For the Hib vaccine, the Michigan public sector price is \$14, and the private sector price is more than \$28. Ironically, this high cost of vaccines in the private sector is having a direct impact on the already scarce public resources.

Because immunizations are generally not covered by health insurance, they must be paid "out-of-pocket" by parents. Financially strapped young families are increasingly turning to public clinics for immunizations, clinics that are not adequately funded nor staffed to meet this increased demand.

Vaccine costs are also having a negative impact on this committee's tireless efforts to improve Medicaid coverage and eligibility. While many Medicaid-eligible children now have what we call a "medical home" in the private sector, that is, an ongoing, comprehensive source of medical care, the high cost of immunizations forces referral of children to public clinics for their immunizations, thus fragmenting care and frustrating recordkeeping. Sometimes

there are delays in their receiving necessary immunizations, and sometimes they do not make it to the clinic at all.

In a recent survey of all 2-year-olds in our clinic, the number one reason for incomplete immunization was the simple fact that the parent had not brought the child back since the 2-month preventive health visit.

Even though Medicaid is one of the few health insurance programs that covers immunizations, in many States the program's payment for immunizations often falls short of provider costs, erecting another immunization barrier.

The Michigan Medicaid program referred to earlier, for example, will reimburse private physicians for the purchase cost of vaccines for children on Medicaid.

However, to be reimbursed, a physician must fill out paper work with data, including the name of the patient, the date, the type of the vaccine being administered, the manufacturer, the lot number, and the dose given.

This information is then submitted to Medicaid, which may send it back for clarification or revision before final payment is received. Requiring this extensive documentation increases the expense to the private sector beyond its ability to be efficient. Thus, referrals to overburdened public clinics continue.

Although we now have public policies in place that recommend new vaccines and vaccine schedules, children dependent on public clinics are often denied a second MMR, or protection from meningitis or Hepatitis B because they simply are not available in public clinics due to funding constraints.

Senator RIEGLE. Now, wait. Let me just stop you there. This is very important testimony. You are saying some of these vaccines against some of the worst diseases, because they are expensive, are not even available through the public health clinics.

Dr. COX. In certain States, that is true.

Senator RIEGLE. Do you know which ones that might be?

Dr. COX. I do not have that information, but I am sure we can get that for you.

Senator RIEGLE. Would you, please? I mean, that is another shocking fact. It is tough enough to try to get through all of these other problems.

[The information was not received at press time.]

Senator RIEGLE. But if, in fact, somebody shows up at a public health location to get a vaccine against Hepatitis or the other ones you mentioned and there is not a vaccine there in some States, you know, that is the final breakdown of the system, if you will. And I find that very troubling. I would like to know where the evidence would suggest that that is occurring.

Dr. COX. Well, for instance, in Grand Rapids, we recently had a meeting of the health department and the pediatricians in all three hospitals that care for children to try to find out how we are going to efficiently immunize children against Hepatitis B.

And although the science is there to do this, to make sure that children are protected against Hepatitis B, the number one concern was money, and who was going to pay for the vaccine. This is a reasonably expensive vaccine compared to some of the others, and it was the major barrier.

Senator RIEGLE. What does that shot cost? I mean, what does just the vaccine cost?

Dr. COX. Well, one shot of the vaccine—the cost to the provider is \$10.42. But to be immunized, the child needs to have three separate shots. So, that would be approximately \$32.50.

Senator RIEGLE. And they have got to come back then. They have got to come three different times in order to do this.

Dr. COX. Right. And, of course, that is the other problem, because some of these kids are lost to follow-up and never do receive the second or third dose.

Senator RIEGLE. Well, I want to work with you on that, and the others in Grand Rapids and throughout Michigan that are trying to solve this problem on Hepatitis B. Because, one way or another, we have got to find an answer to that problem.

So, I would like to work with you to see if we can do that. I am going to have Debbie Chang, on my staff, follow up to see how we go about getting a system in place. Now, I am interested in a national system, but I do not want to see a shortfall occurring in Michigan.

Dr. COX. Well, we congratulate you on the provisions within S. 2116 which provide for innovative vaccine purchasing plans. State-purchased vaccines would be provided to private physicians who would give the vaccines at a minimal administration charge.

The academy developed model State legislation similar to this section of S. 2116, which now has been adopted in 10 States, with action pending in several other States, including New York.

I would conclude by reiterating our support for S. 2116 as a first step toward a much-needed national childhood immunization policy that could certainly be implemented by taking into consideration the academy recommendations I have just outlined.

Ideally, all children, regardless of family income or geographic location, should have access to basic preventive health care. As this country debates national health care reform, we can do no less than insist that these services be assured for all American children. Thank you.

Senator RIEGLE. Thank you very much. I think that is very important testimony. We are going to follow up with you on both the Federal and the State level with respect to that.

[The prepared statement of Dr. Cox appears in the appendix.]

Senator RIEGLE. Ms. Johnson, we are very pleased to have you. And, also, your leadership with the March of Dimes Birth Defects Foundation, and also your membership on the National Vaccine Advisory Committee, I think, equip you to really help us to understand what we ought to be doing here. We would be very pleased to hear from you now.

STATEMENT OF KAY JOHNSON, M.P.H., DIRECTOR, POLICY AND GOVERNMENT AFFAIRS, MARCH OF DIMES BIRTH DEFECTS FOUNDATION, AND MEMBER, NATIONAL VACCINE ADVISORY COMMITTEE, WASHINGTON, DC

Ms. JOHNSON. Mr. Chairman, on behalf of the March of Dimes, I want to thank you for the opportunity to testify today regarding immunizations and their impact on the health of children.

Of course, the history of the March of Dimes, particularly our involvement with polio and rubella vaccines, does not allow us to forget how important vaccines are as a tool in improving child health.

Our current mission is to improve the health and survival of babies, and that brings us right back into looking at the crux of the problem in immunization today—that is our failure to immunize infants on schedule.

As a member of the National Vaccine Advisory Committee, I want to commend you for holding this hearing today to focus attention on childhood immunization and its relationship to Medicaid.

I also want to commend you on introducing S. 2116 to look comprehensively at this issue. Through my work at the Children's Defense Fund, at the March of Dimes, and in other locations I have had an opportunity to work with this committee, and with your office and your staff in particular. We welcome the opportunity to have your vision and your leadership on the issue of immunization.

I have submitted my full statement for the record, but I want to summarize my testimony which emphasizes three points. First, that immunizations should be a priority on the Federal agenda.

Second, that there is a need to strengthen and improve the nation's immunization system and to protect all of our children against vaccine-preventable diseases.

Third, that Congress should give attention to this issue and to some of the recently released plans and recommendations for action in particular, the Finance Committee needs to tune in on those recommendations related to Medicaid and to other programs in its jurisdiction.

Why should immunizations be a Federal priority? Because vaccines are the most important prevention tool we have in our health armamentarium. If we do not use them well, we miss the opportunity to save \$10 for every one that we invest. We know that vaccines have saved billions of dollars and millions of children's lives in this country alone, and we cannot afford to miss any more of those opportunities.

We also know that failure to vaccinate children leads to disease outbreaks. The National Vaccine Advisory Committee reported on the measles epidemic which led to over 27,000 cases of measles, and over 70 deaths. The committee concluded that the principle cause for the epidemic is failure to deliver vaccine on schedule to pre-school aged children.

Our evidence indicates that many of those children who do not receive vaccines on schedule are eligible or enrolled in Medicaid or they are seen in Title V funded clinics, and that there are missed opportunities when those children who do not have health insurance to pay for the care are referred out of their private physician's office for immunizations.

The financing of immunization services has become very important as access to health care overall has become a more important issue to children. This is true because health care is now more expensive, and vaccines are more expensive. Therefore, what we used to think of as something that parents could afford to pay for out-of-pocket we no longer can take for granted in that way. And we have this growing debate over how we are going to finance—

Senator RIEGLE. Let me just stop you there, because I think this is another point that has not really been made yet this morning forcefully.

And that is, that as the cost of these vaccinations are going up for families, and as more and more families are sliding backward in terms of their disposable income, and the national income data show that, it is partly unemployment, it is partly that higher-income jobs are disappearing and lower-income jobs are taking their place.

But as families go through this backward slide in income, coming up with the money to pay for a more expensive vaccination is becoming a major economic problem for many, many families. I just know too many cases of people that are trading off health care with some other urgent bill in the family budget.

So, immunizations, I think, if they are going to cost \$20, \$25, or \$30 to go and get them for families, it may well be postponed simply as a matter of economic pressure.

Ms. JOHNSON. Clearly, they will. I happen to know that is true in some of our larger cities. Here in Washington, DC, I know is a specific example where we have people working in clerical and support positions in offices all over this city. Many of them do not have health insurance for their children, or, if they do, we know that 50 percent of employer-based private plans do not cover immunization.

For those families, taking a toddler to the doctor to get that immunization is not a \$25 proposition, it is a proposition of between \$75 and \$100 for the visit. We know that people do not have that kind of money out-of-pocket.

So, it is a symptom of what has gone wrong overall in the health care financing system, how we have not invested in prevention and how we have not provided families with the kind of coverage that they need for their children.

So, as the Finance Committee looks overall at the issue of how are we going to recreate the health care system, we need to think about some of the special issues that relate to mothers and children.

Thinking for a moment about Medicaid and childhood immunization reforms, the members of the Finance Committee, and of this subcommittee in particular, know well that since 1984 Medicaid and its child health component, EPSDT, have been restructured. This occurred as a result of congressional action and leadership of many of the members of this committee.

As a result, we now have one-third of all pre-school children eligible for Medicaid. That is one-third of the population we are trying to reach whose health care should be financed through the Medicaid program, whose immunizations should be financed through the Medicaid program. That means that how Medicaid responds to this problem is absolutely critical.

I have had an opportunity to work with Ray Hanley and with Governor Clinton in Arkansas. They are doing remarkable things with their Medicaid program. They have really exercised leadership. That does not mean that that is going on in every State in the country.

Senator RIEGLE. Right.

Ms. JOHNSON. And Joe Liu's work testifies to that. You have heard about other studies, today, including the work of the GAO, trying to determine precisely what is going on with State Medicaid programs.

We know that we have basically three problems. One is failure to reimburse for recommended vaccines. The second is failure to pay adequately for immunizations as a service, both the vaccine and the overhead costs. The third is having mechanisms to get the lowest-price vaccine to that private provider who wants to see a Medicaid child, or is willing to, if they are treated fairly.

I have five recommendations for action in Medicaid. First, that Federal law should require establishment of Medicaid provider vaccine distributions. It is very clear they are going to save money by doing it; you have heard the GAO figures here today.

Second, in order for Medicaid immunization policy to be well-implemented in every State, we need leadership from the Congress and the Health Care Financing Administration to communicate to every State what its roles and responsibilities are, and particularly to underscore that they need to cover all of the recommended vaccines—many States are not covering the meningitis or the Hepatitis B vaccine—and that they need to reimburse for both the cost and the overhead cost for delivering that vaccine.

The third area is to ensure the capacity of provider reimbursements and the adequacy thereof. The Secretary already has responsibility for looking at the adequacy of pediatric payment rates. We recommend that they look at the subset of immunization rates as a part of that review.

Outreach and enrollment initiatives are essential and having a major nationwide campaign that is the responsibility of the Secretary would get us a long way toward getting eligible children, that one-third of the pre-school population, into Medicaid for not only immunization, but all of the other services that they need.

And, finally, we need more data. You asked some very pertinent questions of the GAO staff who were here today about how easy it was to figure out what was going on. We could have some demonstration projects looking just at Medicaid, but we also know that there is a bigger picture.

There are six other areas that I think are of interest to the Finance Committee. Several of these have really been addressed well in S. 2116, which aims very broadly and takes a comprehensive view.

One, we need to have any health care reform plan ensure an adequate supply of vaccines and a way to pay for the service.

Two, we need to be sure that Federal support is there for programs that make clinic services available where there are no doctors, and that can be done primarily through the Title V Maternal and Child Health Block Grant program, under the jurisdiction of this committee.

Three, we need coordination among public assistance programs that is encouraged, but no child should be denied nutrition, health, or other basic supports because of their immunization status. AFDC and WIC are not the same as universal schools. We all know families already have a hard time getting into public assistance programs.

Four, we need planning for a national immunization registry system. This is an area where I have been working intensively, and I really am pleased to see your leadership on this.

Five, we need to ensure the safety, efficacy, and of availability vaccines so that we protect the public trust in our vaccine system, and that is ensured through the coordination of the National Vaccine Program.

Six, and, finally, we need to protect the integrity of our National vaccine injury compensation program. We have an excise tax being collected for this compensation fund so that we protect providers, families, and manufacturers so as not drive them out of the system and allow the vaccine system to collapse under fear of liability.

I thank you for the opportunity to address you today.

[The prepared statement of Ms. Johnson appears in the appendix.]

Senator RIEGLE. Thank you. Those are really very important recommendations, and I so applaud the work that you and your colleagues are doing and the recommendations you have made. We are determined to press forward here.

Do you know offhand, if we were producing more vaccine—in other words, if one assumes that we have got all these children out there not getting the vaccines, we are probably producing an amount that is something close to what we are actually giving in the way of inoculations.

So, in effect, if we were to expand this supply in order to make sure that we had enough to treat all of the rest of the children we are now missing, does the cost of the vaccine drop?

Or if the vaccine makers were going to produce 50 percent more vaccine than they are now making, does that bring down their unit cost, or does it stay relatively flat.

Ms. JOHNSON. This is a very interesting question, and it is one that the National Vaccine Advisory Committee took a long, hard look at. Essentially, we have an adequate supply of vaccine being produced, and the number of doses would not necessarily change in a year.

What we have is a situation where we are taking a child that should have been immunized at one and a half, and we are running an August kindergarten round-up and running them through right before they go into kindergarten at 4½. So, the vaccine is being given 3 years later than it should have been given.

Senator RIEGLE. So, we use up the vaccine.

Ms. JOHNSON. Right.

Senator RIEGLE. But we are just not getting it in them at the point of time when they really need to get it.

Ms. JOHNSON. Exactly. So, we sort of have a stable market for our vaccines. It really is an important issue when we look at how they are priced. We have a stable market, and we have a limited market. We have roughly four million births.

Senator RIEGLE. Right.

Ms. JOHNSON. That is about how many vaccines there are, multiplied by three, if it is a three-dose series the first year, and so on.

Senator RIEGLE. Right. Right.

Ms. JOHNSON. But we also have the situation where, when we look at that market, we have to remember that we guarantee a market for that product for the vaccine manufacturers.

Senator RIEGLE. Right.

Ms. JOHNSON. And that right now the States and the Federal Government pay for half of all of the doses that are purchased. Therefore, when we look at pricing we have to say not only what is the size of the market and what is the stability of the market, but who is paying, and how much income is guaranteed on that share of the product market.

Senator RIEGLE. It seems to me that in something as fundamental as this where the science now exists—I mean, the scientific breakthroughs are sort of behind us. We know how to make the vaccines, it is pretty simple to put the vaccine in the child in terms of once we have got the right child, the right time, and the right dose, boom.

It seems to me that what we ought to do now is take and get to a uniform buying and pricing system. We ought to get these costs down to absolute rock bottom, and they ought to be spread across society in such a way that a private physician in Grand Rapids or somewhere else, that that provider is getting the rock bottom price just as the government entities that are buying larger quantities and shipping it out.

I mean, we should not have these variations. I mean, that does not really make sense, I do not think, in a situation like this, which is so fundamental to the well-being of the country.

I mean, this has to do with whether kids live, whether they are well and healthy, and whether we avoid a lot of expense and a lot of heartache. I mean, this is about as basic as you get in our society.

It is like food, only it is, in some respects, more important, because if you get a terrible illness that is a life-threatening illness or a disabling illness, you know, you cannot go back and undo the damage and it is an horrendous consequence.

So, it seems to me, I want to take all of the recommendations you have developed on both lists that you cited and work them through and see what we can use here.

I want to again say, Senator Bond, who is my lead co-sponsor on the Republican side, was unable to be here today because he had to be in his home State of Missouri. But he has been a real leader in this area; feels very strongly about it. And I appreciate his leadership.

So, I think this is one issue where we need to work together and are working together to get a much stronger plan in place and strategy in place. I am confident that we can pay for it. We are paying for it now, anyway. We are more than paying for it by not doing it.

We end up paying this much money in extra costs and unnecessary costs and heartache and suffering when, if we back up and get these immunizations out there to these little tots when they need it, we spend far less money and we come out better off as a country.

So, this is a way to save money. Because we are going to spend it one way or another. We can either wait and spend this much, or we can move in early and only spend this much.

Ms. JOHNSON. Senator, what is particularly exciting about this hearing today is that we need this committee to come together with the Labor Committee to come up with a strategy if we are going to get to a system that looks like universal purchase and if we are going to include the appropriate recommendations in health care reform.

Senator RIEGLE. Right.

Ms. JOHNSON. And as well we are spending money that we do not need to spend on vaccines, we are spending money that we do not need to spend on inefficient surveillance systems when we could have a national registry, and we clearly are spending money through fragmented health care systems and paying this and that for Medicaid when we could be much more efficiently spending money all the way across the board.

Senator RIEGLE. Well, I am going to talk to Senator Hatch, who is the Ranking Minority Member on the Labor and Human Resources Committee who now serves on this committee. So, that provides a cross-connect here.

Also, Senator Kennedy, I know, has a keen interest in this area and I am going to talk with him about it. But there is every reason to work this out between the two committees.

But this has been very helpful today. I want to thank you all very much for your testimony and urge you to continue to press ahead. I mean, we are going to mount this effort here.

As long as I think we continue to work closely together, I think we are going to be able to get this done. Thank you very much. The committee stands in recess.

[Whereupon, the hearing was concluded at 11:30 a.m.]



APPENDIX

ADDITIONAL MATERIAL SUBMITTED

PREPARED STATEMENT OF EDWARD O. COX

Mr. Chairman, members of the committee, I am Ed Cox, M.D., a pediatrician from Grand Rapids and President of the Michigan Chapter of the American Academy of Pediatrics. I am here today representing 43,000 members of the Academy as well as American children and families, all of whom are grateful to you for your long-standing leadership in maternal and child health issues.

Mr. Chairman, your bill, the "Comprehensive Child Health Immunization Act," is right on target. This Committee is well aware of the effectiveness of preventive health care, particularly immunizations. Yet, despite having this knowledge and the means to prevent a growing number of serious childhood illnesses, preventable diseases are on the rise in virtually every state in this country. In Michigan in 1990 a 12-year-old girl died from measles—the first measles death we have had in more than a decade. Her death and the hundreds of other measles cases in Michigan are unnecessary tragedies.

The United States today finds itself tangled in a web of improved technology which has produced new vaccines, of inadequate public and private resources, and of outbreaks of preventable diseases. In spite of our collective best intentions, our childhood immunization program is failing children whose access to vaccines has been compromised.

Particularly vulnerable children include those who are uninsured or underinsured, those who live in inner cities or rural areas and many of those who live in middle class families now in economic distress. We see these children daily in the upper peninsula of Michigan where, by all socioeconomic standards, many families live in conditions worse than Appalachia. The system failed that Michigan child who died and continues to fail all children who are denied immunizations.

S. 2116 effectively says "no" to more compromises where our children are concerned and offers promising solutions to some of our most pressing problems. The Academy would urge that the Committee go even further. While we appreciate the budgetary constraints that tend to cloud bold initiatives, the initiatives you describe don't necessarily need further study through limited demonstration projects. Rather, these project ideas should formulate the basis of a national childhood immunization program which we sorely lack. We know what to do. It's a national shame in which we all share the responsibility if we don't act now.

In my remarks today, I would like to address the following areas: (1) the need for improved enrollment and referral procedures; (2) the development of a nationwide registry and tracking system; and, (3) the barriers to the implementation of infant immunization plans. All of these areas are critical to the success of a comprehensive program that will necessitate the commitment and involvement of both the public and private sectors.

ENROLLMENT/REFERRAL

Most states' mandatory requirement that children be immunized before school entry has been quite effective, yielding about a 98 percent compliance rate. But data on immunization rates among preschool children—the time when immunization is perhaps most crucial—reveal that U.S. rates lag behind European rates by as much as 50 percent. Failed immunization rates suggest that our children are not only vulnerable to preventable infections, but that many are not receiving other forms of well-child care such as developmental assessment and anticipatory guidance.

Our lack of an overall child health policy has yielded a patchwork of programs for our preschoolers that fails to reinforce, or even emphasize, the importance of age-appropriate immunizations.

We are paying a high price for declining and/or incomplete immunization rates. In 1989 there were more than 16,000 cases of measles in the United States with 41 deaths. Measles case numbers rose in 1990 to more than 25,000. Forty-six percent of the cases were in unimmunized preschool children. In 1991, there were more than 60 measles deaths nationwide. In Michigan alone, measles cases rose from 359 in 1989 to 478 in 1990. Fortunately in Michigan, we were able to reduce measles cases to less than 60 in 1991, due to an aggressive immunization push and the second measles dose initiative.

The Centers for Disease Control (CDC) has also reported more than a three-fold increase in the number of cases of rubella in 1990 as compared with 1989. In Michigan, rubella cases jumped from a single case in 1989 to 25 cases in 1991—the largest number of rubella cases since 1982.

Pertussis cases have increased 17 percent nationwide, with rates highest in children under one year of age.

S. 2116 provides for important linkages among various programs for the preschool population, including AFDC, maternal and child health programs, WIC and child care. At relatively low cost, a child's immunization status can be determined, information provided to parents and referrals made to facilitate immunizations. On-site providers of well-child care and immunizations should also be considered a viable option.

REGISTRY AND TRACKING

Even if we significantly strengthen our outreach capabilities, we will not be successful in immunizing all preschool children if we do not have in place an effective nationwide registry and tracking system. We would urge that you go beyond the provisions of S. 2116 for limited demonstration grants to states and go immediately to the institution of a national system. A common record-keeping system is a must, given the mobility of our population. It is here that we need to utilize the record-keeping experience of public programs, such as Medicaid and Maternal and Child Health, to record and track the immunization status of all children.

Most European countries have tracking systems that begin at birth and are designed to assure continuing participation of the infant in one or more systems of health care. We now have the motivation and opportunity to do so in the United States.

Nearly all U.S. children are born in hospitals or birthing centers and all are registered with official state agencies when birth certificates are filed. We also now have in place a new CDC policy recommending immunization of all newborns with the Hepatitis B vaccine in the first few days of life. If all newborns could be issued a social security number at birth, immunizations could be tracked through that number. Providers would need to enter appropriate information into a state data bank on immunizations administered; likewise, at virtually any clinic or office site, a provider could access this number to determine a child's immunization status to assure age-appropriate immunizations.

BARRIERS

While our childhood immunization program is the most cost-effective health program we have, cost remains a formidable barrier for many families, either directly or indirectly. Ironically, the cost of vaccines in the private sector is having an enormous impact on already scarce public resources.

Purchase costs for vaccines in the private sector are approximately double the costs for the same vaccine doses in the public sector. Oral polio vaccine costs three times more in the private sector.

For example, in Michigan a single dose of the MMR vaccine costs \$15.33 in the public sector and anywhere from \$26 to \$29 dollars to the private sector. For the Hib vaccine, the Michigan public sector price is \$12.50-\$14 and the private sector price is more than \$28. In the private sector a \$6-\$10 administration fee is usually added to cover office overhead.

Since immunizations are generally not covered by health insurance, they must be paid out-of-pocket, causing financial hardship to many working and middle class families. For immunizations, these families are increasingly turning to public clinics, which are not adequately funded or staffed to meet this increased demand.

Vaccine costs are also having a negative impact on this Committee's tireless efforts to improve Medicaid coverage and eligibility. While many Medicaid-eligible children now have what we call a medical home in the private sector—an ongoing,

comprehensive source of medical care—the high cost of immunizations often forces referrals of these children to public clinics for their immunizations. This has only served to fragment care for these families and frustrate record keeping and timely immunizations.

Medicaid is one of the few health insurance programs that covers immunizations, yet Medicaid does not cover all eligible children. Even for those it does cover, the program's payment for immunizations often falls short of provider costs.

The Michigan Medicaid program, for example, will reimburse private physicians for the purchase cost of vaccines for children on Medicaid. However, to be reimbursed a physician must fill out paperwork—in triplicate—with data including the name of the patient, the date, the type of vaccine being administered, the manufacturer, the lot number, the dose and the unit. Then this paperwork must be submitted in the hope that it just might be processed in a timely manner.

Requiring this extensive documentation increases the expense to the private sector beyond its ability to be efficient. And thus referrals to overburdened public clinics continue.

We now have public policies in place that recommend new vaccines and vaccine schedules, yet public clinics do not have the funds to comply, largely due to the lack of adequate funding to meet the demand. Across this country this means that many children are denied a second MMR or protection from meningitis and Hepatitis B . . . vaccines that are simply not available for children dependent on public programs.

Clinics, particularly in inner cities and rural communities, raise additional access barriers to families seeking immunizations for their children. These include: limited hours (no evening/weekend appointment hours) due largely to staffing constraints, long waiting times both on site and for appointments, and additional leave time from employment for the parent(s). The irony is that the private sector has removed many of these barriers through extended office hours and more efficient scheduling of appointments. However, there remains the much higher cost for the vaccine to families due to pricing policies.

S. 2116 provides for innovative vaccine purchasing plans to meet the needs of the childhood population. State-purchased vaccines would be provided to private physicians who would give the vaccines at a minimal administration charge. No child, therefore, would be denied immunizations due to the family's inability to pay. The Academy developed model state legislation similar to this section of S. 2116 which has now been adopted in ten states, with action pending in several other states, including New York.

CONCLUSION

S. 2116 provides some of the solutions to the immunization crisis currently facing the United States. However, the ultimate solution would be a national childhood immunization program incorporating these additional initiatives recommended by the American Academy of Pediatrics. Ideally, all children, regardless of family income or geographic location, should have access to basic preventive health care. As this country debates national health care system reform, we can do no less than insist that these services be assured for all American children.

Thank you.

PREPARED STATEMENT OF RAY HANLEY

INTRODUCTION

Mr. Chairman, members of the Subcommittee, I am Ray Hanley, the Arkansas Medicaid Director and Chairman of the State Medicaid Directors' Association (SMDA), an affiliate of the American Public Welfare Association. I appreciate the opportunity to speak with you today about the Comprehensive Child Health Immunization Act, (S. 2116) introduced by Senator Riegle. I would like to address some of the specifics of the legislation from the state Medicaid perspective, and will therefore limit my comments to the Medicaid provisions. Further, I would like to take this opportunity to talk about state efforts in the area of universal distribution and vaccine replacement because there is a growing congressional interest in these programs. Maternal and child health has become a top priority of states and Congress in recent years and immunizations are vital to promoting the health of low income children served by the Medicaid program. My comments are in this contest.

Enrollment—In general, the legislation does not seem to specify whether outreach activities, conducted at the point of Medicaid and AFDC eligibility determinations and redetermination, are to focus on the all applicants including the elderly, or whether the focus is only on children. This could be an important distinction to be made since the elderly are indeed vaccinated against the flu and other illnesses. The focus of the enrollment outreach program—whether it is broad or narrow—has significant implications for state administration. Lengthening the time it takes to make a determination of individual or family eligibility, and possibly modifying all the various Medicaid application forms to accommodate the requirements of the legislation, will have staffing and resource implications for states. We all know that both funds and personnel are in short supply.

I also believe that the legislation's requirement for aggressive immunization outreach should be considered in the context of the need to enroll a child in the Early, Periodic, Screening, Diagnosis and Treatment (EPSDT) program at the point the eligibility application is taken. States have focused on EPSDT enrollment as a high priority. Because timely immunization is an important part of the preventive part of EPSDT, along with periodic screenings, it is possible to view enrollment and care in EPSDT as a higher priority than the immunization history alone. It may be better for children's health in the long run to allow states to continue to place the highest priority on EPSDT enrollment and let immunizations be subsumed under this program as is now the case.

There is also the issue of how the immunization-related questions required by this legislation would affect state efforts to streamline eligibility determinations. In recent years states have sought to shorten the application form because lengthy forms, regardless of the content, are often barriers to enrollment. Adding more questions, however well intended, is at odds with current state and federal policy direction. It is also important to know whether full and accurate responses to questions about a child's immunization status are to be a condition of eligibility and what effect such requirements will have on enrollment and staff time.

It is important to be clear about what is to be done with this information after it is collected by the eligibility worker. If the state operates a Medicaid coordinated care program where the client must choose from a specific group of providers and make that choice known to the state, then providing this information to the client's physician makes sense and the information can be useful. In a normal fee-for-service program, however, no specific physician or clinic is designated to receive this information. If this information is not provided to the client's physician, then using this information becomes more problematic, unless there is a registry outside the Medicaid Management Information System. It is very difficult for state administrators when various provisions of Medicaid statute and policy require actions that are seemingly at odds.

EPSDT Outreach and Reporting—State Medicaid agencies are concerned about the legislation's requirement that states aggressively pursue parents regarding the immunization status of their children. State agencies are currently working hard to implement the 1989 EPSDT mandates, which obviously include outreach, so that states can meet the new EPSDT participation goals for child screening and preventive care. Because EPSDT is such a high priority, we believe that outreach concerning immunizations should be integrated into the overall EPSDT outreach/participation functions, rather than structuring legislation to create a new, separate, and narrowly focused outreach effort. If an EPSDT program is working properly, and state agencies and providers are coordinated, appropriate immunization will result. The problem, of course, is that no system is perfect. There are many problems in the general coordination of public and public/private systems of health care for low-income children, many of which the Medicaid program alone cannot surmount. Despite the question of how well current systems work, the point is that states are trying to make them work better. We hope that federal legislation will support the overall trend toward integrated outreach and service delivery to facilitate greater use of the health care system by poor children.

With regard to tracking Medicaid child immunizations, the SMDA has requested that the Health Care Financing Administration (HCFA) redesign the EPSDT enrollment and service delivery report so that immunizations can be tracked and reported separately from screening services. Given that states have already made this request, we support the provision in the bill for improved reporting and tracking. Despite the desire to separately track immunizations, state experience has shown that this is difficult for a variety of reasons. Because of the peculiarities of the Medicaid program and the interaction between Medicaid and other health programs, Medicaid-covered childhood immunizations are undercounted in some states, leading to in-

correct information on the number of vaccines administered through the Medicaid program.

States have problems tracking information from hospitals, public health providers and mobile units, especially when vaccines are provided free of charge and Medicaid is not billed. Given the high cost of vaccines, many private providers refer clients (both private pay, and Medicaid) to the public system for vaccinations. Further, most states have not yet developed a common computer system to link health screenings and vaccine referrals to the actual administration of immunizations. Finally, the majority of states do not require specific procedure code information from public providers when those providers are paid an overall encounter rate for a visit (a common reimbursement methodology for a variety of clinic settings). States are working on solutions to these problems. States, with Medicaid's assistance, are working to establish immunization tracking systems. On behalf of the SMDA, I am working with the Robert Wood Johnson Foundation to provide grants that will assist states in development of tracking systems. The response from states for the grants has been tremendous—over 200 applications from state and local health organizations.

Greater involvement of private providers, as envisioned in the Riegle bill, would also help in tracking immunizations. Nevertheless, some state experience indicates that supplying physicians with low cost vaccines is not the complete solution to the problem. In Arkansas, we are currently installing a state of the art, point of sale, electronic billing system that will verify eligibility, edit and submit claims, all within 20 seconds or less. We believe this type of system will encourage greater private physician participation in the program. We are also exploring a modem hook-up to transmit immunization information for both Medicaid and non-Medicaid children to the health department for tracking and outreach purposes. In general, states are looking to develop solutions to improve the rates of childhood immunization and to improve our ability to track what children have or have not received.

Demonstration Programs—State administrators would support legislation that permits greater state experimentation with vaccine distribution strategies. State agencies have already learned a great deal about how to run these programs although there are some drawbacks that must be considered. Further experimentation would allow states more flexibility to address the problems that have surfaced in existing programs. We believe that the approach taken by the Riegle bill is far preferable to mandating specific system since no one approach has proven applicable to all states.

I would like to take a moment to discuss some information states shared with APWA about how their programs work and the problems they have confronted; some problems have been resolved and others are still outstanding. A better understanding of these programs and the interlocking issues may help the Subcommittee as it considers this legislation.

CURRENT ALTERNATIVE MEDICAID VACCINE PROGRAMS

States have been successful in reducing Medicaid expenditures for childhood immunizations by maximizing their ability to purchase vaccines at discount rates through the Centers for Disease Control (CDC). States purchase vaccines for their public health programs through the CDC contract at rates greatly reduced from those available to an individual provider. At least a dozen states are taking advantage of the lower prices by offering Medicaid providers the opportunity to use CDC-purchased vaccines for Medicaid clients. A few states are exploring other ways to minimize vaccine costs, such as bulk purchasing from the manufacturer or seeking a rebate on vaccine purchases.

There are three basic methods used by Medicaid agencies to pay for immunizations provided to eligible children: (1) fee-for-service (FFS), the traditional method whereby a provider bills Medicaid for the cost of the vaccine plus an inoculation fee, (2) vaccine replacement, in which the provider obtains a dose of vaccine at no charge from the health department for each dose provided to a Medicaid recipient, and (3) universal distribution, in which the health department distributes vaccine at no charge to all health care practitioners for inoculation of all children. This bill appears to provide funds for demonstrations of the vaccine replacement models although SMDA believes both replacement and universal distribution models merit further exploration.

Under the replacement and distribution systems, the dispensing practitioner bills Medicaid and is reimbursed a small fee for inoculating the recipient, then the Medicaid agency may reimburse the health department for the price of the vaccine.

Vaccine replacement and universal distribution are potentially more cost-effective than IFS because the state purchases the vaccine at the CDC discount rates. According to a recent Children's Defense Fund (CDF) report, twenty states use re-

placement or universal distribution to serve Medicaid clients, thereby achieving savings in the Medicaid program. The CDF report contends that all states could implement replacement systems with relative ease and should do so in order to reduce Medicaid expenditures for immunizations. APWA has worked with states to ascertain what it takes to implement a replacement or universal distribution system and there are in fact many barriers to doing so. In addition, states all employ modifications to the two basic models to accommodate state-specific situations and conditions.

The attached chart summarizes information about some state replacement/distribution programs. Several aspects of current state programs are important to consider in developing federal policy to encourage cost-saving programs: (1) provider participation in most state replacement/distribution programs voluntary; (2) several states with replacement programs continue to allow FFS billing for vaccines in order to accommodate changing situations and provider concerns; (3) replacement and universal distribution programs are typically limited to the most commonly used childhood immunizations; and (4) replacement/distribution programs appear to generate significant savings. These issues are addressed individually below.

Provider Participation: Several states with replacement/distribution programs (Conn., Kan., Nev., Ohio, S.C., Texas and Vt.) do not allow providers to bill FFS for vaccines included in the system. These states see use of a vaccine replacement or distribution program as a important tool to increase provider participation in the Medicaid immunization program because many providers prefer receiving free vaccine and a nominal administration fee to traditional FFS reimbursement for vaccinations. This is particularly likely if the provider sees a high volume of Medicaid patients and the state FFS reimbursement for vaccinations is relatively low.

Other states with replacement/distribution programs (Ky. Maine, Mich., Minn., and Wash.) allow FFS billing for those vaccines included in the system. These states are concerned that the requirements of a replacement/distribution program (additional provider agreements with the health department, more stringent informed consent and reporting requirements, and additional paperwork) could overburden private physicians who see relatively few Medicaid patients. In Minnesota, for example, two-thirds of immunizations are given by private doctors for whom Medicaid patients typically comprise only 10 or 15 percent of their practice. The state gives providers the option of billing FFS out of concern that providers would refuse to immunize Medicaid children if forced to participate in the vaccine replacement program. States make accommodations to private providers because while public providers (community health centers, maternal and child health clinics, and others) are crucial in delivering services to Medicaid recipients, they may not be able to handle the increased volume that would result if private providers cut back on immunization administrations. The Riegle bill would accommodate the various approaches taken by states on this important issue.

Maintaining Fee For Service Billing: In addition to concerns about provider relations, there are other reasons why states continue to allow FFS billing even when a replacement or distribution program is in place. FFS billing allows a fallback mechanism when there are gaps or limitations in a replacement/distribution program. For example, FFS billing can provide more timely vaccine administration when demand rises suddenly during a disease outbreak and there is a shortfall in publicly available vaccine, or when a new vaccine enters the market. Because such events are unpredictable, states need flexibility in program administration to quickly respond to changing service needs and changing supply.

Vaccines Included In Replacement/Distribution Programs: The comprehensiveness of state replacement or distribution programs does vary. All states surveyed cover measles-mumps-rubella (MMR), diphtheria-pertussis-tetanus (DPT), and polio. Other vaccines that may be included in the program are hemophilus influenza B, hepatitis B, influenza pneumococcal, and separate doses of measles, mumps, rubella, pertussis, diphtheria, or tetanus. A state may want to limit the scope of the replacement/distribution program during the start-up phase, then bring additional vaccines on line when the program operates smoothly. A state also may find that single disease vaccines, such as mumps or pertussis, are administered infrequently so that including them in the replacement/distribution system is not cost-effective or efficient. Therefore, states must maintain enough flexibility to determine when it is most efficient and cost-effective to add vaccines to, or remove vaccines from, their replacement or distribution program. Again, by its flexible approach through demonstration programs, this legislation would allow states to consider how best to address these types of issues.

Potential for Cost Savings: State data indicate that cost-avoidance or savings may result from implementation of a replacement or distribution system. The savings are significant, even when providers are given the option to choose between the CDC

system and FFS billing. For example, Michigan estimates that it avoided \$1 million in state costs in one year. Kentucky estimates savings of more than \$400,000 in state dollars in calendar year 1991 and Maine saved about \$92,000 state dollars during state fiscal year 1991. These savings compare favorably to estimates provided by Ohio and South Carolina, which do not allow FFS billing for vaccines in the program. Ohio estimates state savings of \$1.3 million in state fiscal year 1991 and South Carolina estimates state savings of more than \$165,000 during the same period.

Barriers to Implementation

Medicaid agencies are interested in administering their programs as cost-effectively as possible and are certainly open to the prospect of saving money in the purchase of vaccine. The fact that thirty states continue to use FFS reimbursement for vaccine, and some states with "universal" replacement or distribution systems allow private practitioners to bill FFS, indicates that implementing a statewide system to purchase, distribute, and deliver immunizations is not as simple and easy as it may appear. The issues of administration, accountability, coordination, and cost increases are outlined below.

Administration: Assuming the state can purchase all the vaccine it needs through the CDC contract, the state must determine where to store the vaccine, how to ensure that the supply stays fresh during storage and delivery, and how to get the vaccine to public and private practitioners. State start-up costs, associated with system design and infrastructure creation, has also been a barrier to state implementation. A state must also anticipate the ongoing administrative costs and staffing needed to maintain the system and implement changes as new vaccines are developed or immunization guidelines change. The state will also incur costs and devote staff time to provider education concerning the distribution/replacement procedures, accounting procedures for inoculations to Medicaid children, and billing practice changes. Two states supplied estimates of the operating costs to APVA—\$175,000 in Ohio and \$28,500 in Kentucky.

Many state governments are operating under tight fiscal constraints that affect staffing as well as program service dollars. Given this, implementing a new vaccine program can mean that states would have to reallocate staff from other projects and move funding out of current programs to this new effort. Depending on state priorities and programs, this shift could be significant. The approach taken in the bill, providing specific demonstration authority, could eliminate this barrier by providing specific funding for a replacement program that would accommodate staffing/resource concerns.

Accountability: This is a critical issue, especially from the viewpoint of the Medicaid agency. By law, state Medicaid agencies can only receive federal matching funds for services delivered to Medicaid recipients. In order to reimburse the health department for the cost of the vaccine, the Medicaid agency must receive documentation—usually a bill for the inoculation—from the practitioner who vaccinated the child. Some providers may decide that billing for the small inoculation fee is not cost-effective when the vaccine itself is free. If a provider does not bill Medicaid for vaccine administration, the health department may not be reimbursed for the vaccine provided to a Medicaid-eligible child because the Medicaid agency has no record that a vaccine was actually administered. The demonstration authority provided in the Riegle bill would help state agencies determine how reimbursement levels affect provider billing. Such demonstrations would help us gain an understanding of whether there is a reasonable reimbursement level that will encourage providers to bill for administration fees.

If a state purchases vaccine for all children (regardless of income or insurance status) through the CDC contract, the state may be subsidizing costs otherwise paid by private insurers or families with the ability to pay. Existing law does not allow state agencies to reimburse for services that are provided free of charge to the general public, without regard to the individual's ability to pay (the so-called "free care" issue). States wishing to implement a universal program must either bill insurance companies and individuals (based on ability to pay) for immunizations or forgo using Medicaid funds to pay for vaccines delivered to Medicaid children. In Massachusetts, and Connecticut, which operate universal distribution systems, the Medicaid agency does not reimburse the health department for vaccines delivered to Medicaid children because the health department and the private physicians which receive the vaccine through the health department, do not charge anyone for the cost of vaccines. Admittedly, there is confusion over this free care issue in HCFA regions and the states. APWA strongly supports a provision in Senator Moynihan's Medicaid Managed Care Improvement Act (S. 2077) that would clarify the law and eliminate the "free care" issue.

This issue is likely to become more problematic as states move to extend health services to individuals not covered by Medicaid. Current interpretations of Medicaid law do run counter to state policy objectives of trying to immunize all children in the state. The Riegle bill does not address this complicated issue, but I mention it here because current federal interpretations of statute may complicate state ability to immunize children.

In addition to the implications of "free care" for universal distribution systems, a prohibition on Medicaid payment for services provided free of charge to non-Medicaid clients will impact state Medicaid agencies' ability to track the number and type of immunizations provided to Medicaid children through the public health system. If public health and private providers participating in the universal distribution system cannot bill Medicaid, Medicaid cannot track what is provided. This is clearly a dilemma for states with universal programs.

Replacement systems, which can require more provider administrative time, can in fact encourage providers to send their clients (Medicaid and private pay) to public health facilities for inoculations, especially if the cost of the vaccine is low or is free. This can lead to fragmentation in a system in terms of tracking immunizations but states are working on computer and other systems to overcome this. Universal distribution can lead to fragmentation, or at least the appearance of such, if there is no comprehensive tracking system outside the Medicaid program. The Riegle legislation would most certainly help states with universal distribution programs by providing funds for statewide registries compatible with the needs of a universal system.

Coordination: There is a strong need for interagency coordination to make a replacement or distribution system work. In addition to the logistical questions discussed above, states must consider how to coordinate the immunization standards used by Medicaid and the public health program. For example, during the recent measles outbreak, one state Medicaid program offered a second dose of measles vaccine to all clients statewide. The health department, however, did not have funding to offer two doses in all areas of the state and confined its efforts to outbreak areas. Providers need to be kept apprised of differences in coverage between the programs, which can be complicated when the two programs are so closely linked for distribution and billing. Even though the Riegle bill would establish national immunization standards, we hope such standards would be flexible enough to permit the type of state initiatives just mentioned. National standards cannot always address the complications arising from differences in funding and administration between various health programs that will likely exist.

Administration can be further complicated when a state has a strong county government system. Not only must the state Medicaid and health agencies coordinate their efforts, but local offices have a critical role to play. In the majority of states, local health departments are largely autonomous and in several states, local Medicaid agencies have a great deal of responsibility for program administration. Rather than implementing one system statewide, these states must coordinate numerous local programs.

Cost Increases: Several states have considered asking vaccine manufacturers to provide rebates to the Medicaid program. There is considerable concern, however, that this would backfire and lead to general vaccine cost increases. Evolving experience in pharmacy reform, and earlier experience with WIC infant formula purchasing, demonstrate that voluntary price reductions from manufacturers tend to evaporate when mandatory reductions are imposed. Costs seem to be shifted to other payers or increased for all payers. If a state purchased all vaccines through the CDC contract, the possibility exists that the manufacturer would lose revenue and may have the incentive to increase the cost of vaccine to the CDC and/or to other public or private payers. This issue is not addressed by the Riegle bill, but it is worth mentioning in the context of overall Medicaid immunization policy since it is a strategy some states have considered.

Along these lines, Merck Sharp and Dohme manufacturers have approached Arkansas and three other states with a proposal to institute a low-cost vaccine replacement program outside of the CDC contract for private providers. We are still exploring the specifics of the proposal but it is a sign of growing concern for better immunization of children.

PROMOTING COST-EFFECTIVE PURCHASE OF VACCINES

Federal policymakers can promote the implementation of vaccine systems. States should be able to explore several types of programs, including replacement, distribution, bulk purchasing and rebates. One option is to provide demonstration or start-up grants to states interested in doing so, as does this legislation. This can serve

two purposes: implement programs in more states and to collect, analyze and disseminate information on the cost-benefit of vaccine replacement and distribution programs. Cost-benefit research should explore the impact of these programs on administrative costs, provider participation (both public and private) and immunization rates among children in Medicaid. Concrete information on the costs and benefits are critical to spurring interest among policymakers in other states. Senator Riegle's legislation would do a great deal toward promoting better vaccination rates among children.

A second alternative would be to increase the federal match for administrative costs associated with starting and operating some form of vaccine program. This would reduce the amount of up-front state funding required, and reduce long term state and federal program costs for vaccinations. If the programs are cost-saving, increased federal administrative outlays should be more than offset by reduced program costs. There is precedent in family planning, management information systems, and other areas of Medicaid for enhancing administrative match to achieve federal goals.

SUMMARY

State Medicaid agencies will continue to search for the best way to promote proper childhood immunizations as part of a multi-faceted strategy to improve the health of the children served by the program. States will develop programs that best serve multiple policy goals including access, improved outcomes, improved provider participation, and program cost-effectiveness. Some provisions of this legislation would help states move forward in promoting appropriate access to vaccination. We do urge Congress to seriously consider the impact of seemingly "simple" mandates on an administratively complex system such as Medicaid and to recognize some of the barriers and complications that exist in coordinating various public programs and public programs and the private sector.

I hope this information has been helpful to your continued deliberations. State administrators remain ready and willing to assist you in your efforts as you proceed with policy development in this area.

Thank you.

SELECTED STATE VACCINE PURCHASING/DISTRIBUTION PROGRAMS

State	Program Description	Participating Providers	Vaccines Included	Comments
Connecticut	Providers receive vaccine through DOH. Bill admin fee only. Bill vaccine cost plus admin for vaccine not in program.	a,b,c,d,e	MMR, DPT, polio HIB, rubella, hepatitis B	Non-Medicaid providers may participate. HIB given to public providers only.
Kansas	Providers may receive vaccine through DOH. Bill admin fee only.	a,b,c,d,e,f	MMR, DPT, polio HIB, Hepatitis B DT, TD	
Kentucky	Providers may receive vaccine through DOH. May bill admin fee or vaccine cost plus admin.	a,b,c,d,e,f	MMR, DPT, polio HIB	Est. state savings of \$416,145 calendar 1991. Est. cost \$26,500
Maine	Providers may receive vaccine through DOH. Bill admin fee or vaccine cost plus admin.	a,b,c,e,f,g	MMR, DPT, polio HIB	State saved \$92,000 in SFY91.
Michigan	Providers may receive vaccine through DOH. May bill admin fee or vaccine cost plus admin.	a,b,c,d,e,f,g	MMR, DPT, polio	Est. for 10/1/90-9/30/91 Cost: \$2.57 million FFB est. cost: \$4.75 million Cost avoided: \$2.2 million State saved \$1 million.
Minnesota	Providers may receive vaccine through DOH. Bill admin fee or vaccine cost plus admin.	a,b,c,d,e,f	MMR, DPT, polio	Two-thirds of providers obtain vaccine through private means.
Nevada	Provider may receive vaccine through DOH. Bill admin fee only. Bill vaccine cost plus admin for vaccines not in program.	a,b,c,d,e,f,g	MMR, DPT, polio, HIB	Program begins 5/1/92.
Ohio	Providers receive vaccine through DOH. Bill admin fee only.	a,b,c,d,e,f,g	MMR, DPT, polio, HIB	State saved about \$1.3 million in SFY 91. Cost est. \$175,000 admin; est. \$1.8 million for vaccines. Hospital clinic participation is optional.
South Carolina	Providers receive vaccine through DOH. Bill admin fee only.	a,b,c,e,f,h	MMR, DPT, polio, HIB, DT, TD, mumps, measles, rubella.	EPBDT enrolled screeners may participate. Will add Hepatitis B vaccine. Est. state saved \$166,366 in SFY 91.
Texas	Providers receive vaccine through DOH. Admin fee included in EPBDT rate. Admin fee \$6 for vaccine at follow-up visit. May bill vaccine cost plus admin for vaccines not in program.	a,b,c,d,e,f	MMR, DPT, polio, HIB influenza pneumococcal.	Child must be enrolled in EPBDT.
Vermont	All providers receive vaccine through DOH. for all children. Bill admin fee. Bill vaccine cost plus admin for vaccine not in program. No Medicaid reimbursement to DOH.	all providers licensed to administer immunizations.	MMR, DPT, OPV, IPV, Td, DT, HIB	Non-Medicaid providers participate.
Washington	Providers may receive vaccine through DOH. Bill admin fee or vaccine cost plus admin.	a,b,c,d,e,f,g	MMR, DPT, OPV, HIB, DT, Td, eIPV	Non-Medicaid providers may participate.

American Public Welfare Association, April 1992

PREPARED STATEMENT OF KAY A. JOHNSON

Mr. Chairman and Members of the Committee: On behalf of the March of Dimes, I want to thank you for this opportunity to testify today regarding immunizations and their impact on the health of children. Our mission to improve the health and survival of infants includes preventive health services in the first year of life. As a member of the National Vaccine Advisory Committee, I commend you for holding this hearing today to focus attention on childhood immunization.

BEST AVAILABLE COPY

I have submitted a fuller written statement for the record. However, in the interest of time, I will briefly summarize my testimony today. My testimony emphasizes three points:

1. Immunizations should be a priority on the federal agenda.
2. There is a need to strengthen and improve the nation's immunization system and to protect all of our children from preventable disease.

Congress should give attention to recently released plans and recommendations for action.

Specifically, the Senate Finance Committee should give attention to recommendations related to immunization services financed through the Medicaid program.

1. IMMUNIZATIONS SHOULD BE A PRIORITY ON THE FEDERAL AGENDA

Vaccines are the most basic tool in preventive health care. Immunizations are one of the nation's most cost-effective health services—saving on average \$10 for every \$1 invested. The effectiveness of reducing death and disability with vaccines is a great achievement. Vaccines have saved billions of health care dollars and have saved the lives of millions of children. In the future, new vaccine technology has the potential to prevent other diseases and save millions more children in the United States and worldwide.

However, to protect public health and prevent disease, high levels of immunization be achieved and maintained. Failure to vaccinate inevitably leads to disease outbreaks. An outbreak of contagious disease among children anywhere in this country is a threat to all. In 1990, the National Vaccine Advisory Committee reported on a measles epidemic in which more than 27,000 cases of measles and over 70 deaths were reported for 1990—a figure higher than any year in the 1980s. The Committee concluded that: "The principal cause for the epidemic is failure to deliver vaccine to vulnerable preschool children on schedule."

Each year, the nation's immunization system misses the opportunity to fully protect hundreds of thousands of children from eight vaccine preventable diseases (measles, mumps, polio, rubella, diphtheria, pertussis, tetanus, and meningitis). While about 95 percent of children catch up on their vaccinations by the time they enter school, preschoolers often are behind schedule and unprotected. Our national goal is to have 90 percent of two-year-olds complete the basic series. Yet, only 50 to 80 percent of two-year-olds are adequately immunized. Less than half of poor and minority preschoolers in our nation's cities are fully protected, with some cities rates measured as low as 14 percent immunized by the second birthday.

Our failure to vaccinate children on time has led to outbreaks of preventable disease. The measles epidemic of 1989 and 1990 is the most dramatic evidence of what happens when immunization rates are low and a disease sweeps through a community. Pertussis (whooping cough), rubella, and mumps also have been on the rise in recent years. In order to protect all Americans, particularly the most vulnerable very young and very old, immunization rates must be high enough to prevent disease outbreaks and epidemics.

Key barriers to immunization have been identified and the nation should move quickly to remedy these problems. The National Vaccine Advisory Committee report on The Measles Epidemic identified the following barriers: inadequate access to health care; shortfalls in the health care delivery system; missed opportunities to vaccinate children; and provider policies and practices that reduce access to immunization.

2. THERE IS NEED TO STRENGTHEN AND IMPROVE THE NATION'S HEALTH CARE FINANCING SYSTEM IN ORDER TO PROTECT ALL OF OUR CHILDREN FROM PREVENTABLE DISEASE

Evidence indicates that many of the children who do not receive vaccines on schedule: are eligible for Medicaid; use a Title V funded clinic as their regular source of preventive care; and have missed opportunities to be vaccinated when they do not have health insurance to pay for services through a private physician.

The financing of immunization services has become particularly important to access as the cost of health care and the cost of vaccines has risen. A more efficient child health financing system can improve access to immunization services. It is clear that the nation needs: more efficient structures for distribution of vaccine; support for private and public providers who give vaccination (including adequate and timely payment); activities to increase demand; and adequate funds to purchase vaccines.

A growing debate over the financing and access questions in the U.S. health care system, makes decisions on how to finance the nation's immunization system timely

and important. For regardless of whether health insurance is public or private, ensuring that vaccines to prevent communicable disease are available must continue to be a national-priority.

3. CONGRESS SHOULD GIVE ATTENTION TO RECENTLY RELEASED PLANS AND RECOMMENDATIONS FOR ACTION. SPECIFICALLY, THE SENATE FINANCE COMMITTEE SHOULD GIVE ATTENTION TO RECOMMENDATIONS RELATED TO IMMUNIZATION SERVICES FINANCED THROUGH THE MEDICAID PROGRAM

A. Medicaid and Childhood Immunization Reforms

As Members of the Finance Committee know well, since 1984, both Medicaid and its child health component, the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program have been substantially restructured through Congressional action. As a result, at least one-third of preschool age children now are entitled to Medicaid, and national statistics indicate that about one-quarter of all preschool age children are enrolled in Medicaid in a year. This makes Medicaid agencies' vaccine policies, reimbursement practices for childhood immunizations, and interactions with state health agencies of critical importance.

You have heard today about several recent studies¹ undertaken to determine more precisely how states' Medicaid programs currently reimburse providers for vaccine acquisition and administration costs. Certain conclusions can be drawn from the available evidence. There are three basic problems: (1) failure to reimburse for recommended vaccines; (2) failure to pay adequately for immunizations as a service; and (3) inadequate mechanisms for providing lowest priced vaccines to Medicaid providers.

To improve the delivery of immunization services through Medicaid and EPSDT, action should be taken in five areas.

1. Federal law should require establishment of Medicaid provider vaccine distribution programs. It is clear that Medicaid dollars are being wasted whenever Medicaid providers purchase vaccine at the private sector price and states are pressured to reimburse these higher vaccine costs. Medicaid providers, particularly private providers, in every state should be able to purchase vaccine at the public sector price. This can be done through the state health department or through direct arrangements with vaccine companies. We know these programs can work—the Centers for Disease Control and National Vaccine Program have studied state models with an eye toward replication.

2. In order for Medicaid immunization policy to be well implemented in every state, federal law and regulation will need to be clarified. To eliminate confusion regarding the extent of states' obligations to cover childhood vaccines as a Medicaid service, EPSDT program guidance on immunization should be strengthened. Sound guidance would:

- Underscore states' obligations to cover all medically necessary vaccines as a mandatory service for children under age 21 as part of the EPSDT program;
- Emphasize the standard immunization schedule in setting periodic visit schedules—states are obligated to provide coverage of vaccines and their administration both under the EPSDT periodic exam schedule² and as an "interperiodic" service (i.e. in the event that children not appropriately vaccinated are identified at times outside of the periodic visit schedule, they are nonetheless entitled to coverage for needed immunizations);
- Clarify that state EPSDT vaccine programs will not be considered in compliance with federal requirements regarding the amount, duration, and scope of mandatory Medicaid services unless state vaccine coverage policies include all officially recommended vaccines;
- Clarify states' obligations to reimburse Medicaid and EPSDT providers for both the cost of purchasing vaccine and the cost of administration; and
- Clarify the obligation of state agencies to assure that all managed care and continuing care providers are vaccinating enrolled children as necessary and appropriate.

¹For example: *Medicaid and Childhood Immunizations: A National Study*, Children's Defense Fund; *Access to Childhood Immunizations: Recommendations and Strategies for Action*, National Vaccine Advisory Committee; and the Medicaid and immunizations report being prepared by the General Accounting Office.

²Federal law (Pub.L. 101-329) specifies that EPSDT schedule standards be based on the American Academy of Pediatrics "Guidelines for Health Supervision." In the case of immunization services, states may also wish to consult the recommendations of the U.S. Public Health Service Immunization Practices Advisory Committee (ACIP).

3. To ensure the adequacy of provider reimbursements for immunization services, a regular, comprehensive review of state Medicaid programs' vaccine coverage and reimbursement policies should be conducted. In particular, the Secretary of the Department of Health and Human Services (DHHS) should be required to:

- Examine reimbursement levels for immunization as a part of the review of pediatric payment rates submitted annually in state plan amendments; and
- Study the immunization patterns of managed care and/or prepaid health plans (Section 1915 and 1903(m)).

4. Outreach and enrollment initiatives are essential if Medicaid is intended to reach that one-third of all preschool children entitled to preventive and therapeutic health services under the program. These actions are particularly important to DHHS Secretary's Program Directive No. 8 (see Appendix B). The Secretary should be authorized to:

- Conduct a major nationwide campaign to encourage poor families to apply for Medicaid coverage for their children. Such a campaign would increase public perception of Medicaid as a program now intended to reach working poor families and should aim to increase awareness of the value of preventive health services such as immunizations;
- Provide incentives states to aggressively enroll infants in the EPSDT program and to keep infants enrolled throughout the first year without interruption.³ Incentives could be in the form of enhanced federal matching for immunization services (at 75 or 90 percent).

5. More data should be made available regarding: the immunization status of Medicaid recipient children; the vaccines covered by each state's Medicaid program; and the amount of Medicaid expenditures being used by pay for vaccine acquisition and administration. Currently, these data are not routinely available at the state or federal level. To improve program monitoring authorization should be given to:

- Conduct demonstration projects designed to test techniques for using Medicaid Management Information Systems (MMIS) to provide immunization status data on individual children.

B. Other Reforms of Interest to the Finance Committee

1. Any health care reform plan should include mechanisms to finance sufficient quantities for all recommended vaccines to ensure immunization of all children. This is a recommendation of the National Vaccine Advisory Committee's report on Access to Childhood Immunizations, which also recommends including immunization services as a basic benefit in any health care reform plan and exploring federal purchase of all childhood vaccine.

2. Increase federal support for programs that ensure the availability of pediatric providers in medically underserved communities. In particular, the Title V Maternal and Child Health Block Grant program forms the basic infrastructure for ensuring that immunization services are readily available to low income families. Without adequate funding for the program clinics and health personnel will not be available in areas where private providers are in short supply.

3. Coordination among public assistance programs should be encouraged, but no child should be denied nutrition, health, or other supports based on immunization status. Congress should reject any proposal which would link AFDC or Medicaid eligibility to immunization status. At a time when Medicaid is seeking to reduce barriers to enrollment, such a proposal moves in exactly the opposite direction. The interagency Committee on Childhood Immunizations has developed a plan which identifies ways by which immunization can be promoted or delivered through AFDC, Medicaid, and other public programs—without penalizing poor families.

Special attention should be given to the use of federal funds supporting child care through the Title IV (A) AFDC/Family Support and similar programs. Federal funds should not be used to finance child care in settings that do not require children to be adequately immunized at the time of enrollment.

4. Planning for a more efficient system to track immunization status should begin in FY 1992. Several other nations now have a central, national registration system for immunizations. The technology to create such a system now is available, but a plan to apply our tools is needed (see Appendix D).

³OBRA 1989 strengthened Medicaid's automatic and continuous enrollment provisions for infants up to one year of age.

5. Ensuring the safety, efficacy, and availability of vaccines is essential, and the nation must lead with a vision of the future potential of vaccines. This is the mission of the National Vaccine Program. Without a coordinating agency, the nation's immunization system has stalled. The National Vaccine Program has been the source of funding for special vaccine research at the time of outbreaks or to improve vaccine safety, as well as the leadership for the Interagency Committee on Childhood immunization and its recently released plan (see Appendix E).

6. The integrity of the National Vaccine Injury Compensation Program should be protected. Similar to the workers compensation program, the National Vaccine injury Compensation Program is a no-fault approach to compensation for adverse events occurring as a result of immunization with recommended vaccines. It is funded through an excise tax that is pooled in a trust fund. This taxing mechanism and fund should be protected to ensure that vaccine manufacturers and providers are free of excessive fear of liability for vaccines and that families have just compensation for vaccine-related injuries.

APPENDIX A

National Vaccine Advisory Committee Report Access to Childhood Immunizations: Recommendations and Strategies for Action

"Recommendation: Medicaid programs should be improved through: adequate provider reimbursement; inclusion of all recommended vaccines in the benefit package; and distribution of public sector vaccine to providers serving children on Medicaid"
"Strategies:

- Encourage states and vaccine companies to create vaccine purchase and distribution systems that serve private providers who administer vaccines to Medicaid recipient children.
- Encourage state Medicaid programs to set adequate reimbursement rates for vaccine purchase and administration costs.
- Examine provider reimbursement levels set for immunization as a part of the HCFA review of pediatric payment rates submitted annually in state Medicaid plans.
- Provide an enhance federal matching rate for immunization services. A matching rate of 75 or 90 percent would provide an incentive for states to enhance immunization reimbursement.
- Issue HCFA/Medicaid guidance that would clarify the current immunization schedule, American Academy of Pediatrics (AAP) Guidelines,⁴ and Standards for Immunization Practice to be used by states in structuring EPSDT programs. In the future, new recommendations of the AAP and the U.S. Public Health Services Immunization Practice Advisory Committee (ACIP) should be routinely incorporated into guidance with immediate notification of state Medicaid agencies.
- Provide technical assistance to HCFA regarding immunization issues through placement of a National Vaccine Program Coordinator or public health advisor."

National Vaccine Advisory Committee Report The Measles Epidemic: The Problems, Barriers, and Recommendations

"Medicaid, and its child health component, the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program, should be integrally involved in tracking children in need of immunizations and providing adequate reimbursement for the service. Thus, Medicaid should assess immunization levels of clients served by individual providers as a measure of quality and to assure compliance with Federal EPSDT requirements. Medicaid providers should either be given vaccine through the public sector or should be adequately reimbursed for the cost of purchasing vaccine and its administration. To reduce these costs, vaccine used by Medicaid providers should be purchased at low Federal contract prices.

State EPSDT programs should better comply with federal guidance to make aggressive efforts to enroll families; recruit and retain health care providers; provide appointment scheduling and transportation assistance; and establish a recommended well-child visit schedule that follows the guidelines of the American Academy of Pediatrics."

⁴Federal law (Pub. L. 101-29) specifies that EPSDT schedule standards be based on the American Academy of Pediatrics "Guidelines for Health Supervision." In the case of immunization services, states may also wish to consult the recommendations of the U.S. Public Health Service Immunization Practices Advisory Committee (ACIP).

APPENDIX B

Department of Health and Human Services Secretary's Program Directions

The Secretary of DHHS has issued a Program Directions Plan which calls for improved coordination of Medicaid activities directed through the Health Care Financing Administration (HCFA) and immunization activities supported through the CDC and the Health Services and Resources Administration (HRS). This focus is stated in:

Direction No. 4: to improve the health and well being of individuals through improved preventive health care and promotion of personal responsibility;

Objective 3: Examine cost-effectiveness of Medicaid and Medicare reimbursement for preventive services.

Direction No. 8: to improve access of young children and their families living in poverty to a wide array of developmental, support services, and income assistance, including nutrition, foster care, health, mental health, and social and child protective services.

Objective 1: increase access of children in families living in poverty to health services; includes efforts to increase access to immunization services for children.

APPENDIX C

1. Coverage of Immunization Services under EPSDT

The federal Medicaid statute requires that states provide EPSDT services to all categorically needy individuals under age 21.42 USC Section 1396a(x)(10) (C) and (E). Categorically needy individuals include persons under age 21 whose Medicaid eligibility is a function of either their receipt cash assistance under the Aid to Families with Dependent Children (AFDC) or Supplemental Security Income (SSI) programs or their poverty status (i.e., all children ages one to six with family incomes under 133% of the federal poverty level; infants under age one with family incomes below 185% of poverty in states that extend such coverage; and financially needy children ages six to 21).

Immunizations constitute a required EPSDT services, since the statute defines the screening component of EPSDT to include "appropriate immunizations according to age and health history." 42 USC Section 1396d(r)(1)(B)(iii).

Moreover immunization services can be provided during either a periodic EPSDT exam (i.e., a full health 'screen' provided in accordance with the state's EPSDT periodic visit schedule) or on an "interperiodic" basis (i.e., in between regularly scheduled health exams). The 1989 amendments to the EPSDT program clarify that states may not restrict EPSDT services to the routine periodic visit schedule but must allow children access to such services any time that a health problem (e.g. lack of appropriate immunizations) is suspected. 42 USC Section 1396d(r)(1)(A)(i) and (ii). Thus, for children who are otherwise up-to-date on routine health exams but who need an additional "medically necessary" vaccination, immunizations can be provided and billed as an interperiodic EPSDT service.

2. Coverage of All Medically Appropriate Immunization Services

The standard for coverage of immunization is appropriateness. States must cover immunizations which are "appropriate (for) . . . age and health history." 42 USC Section 1396d(r)(1)(B)(iii). HCFA guidelines for immunizations under EPSDT are as follows: "C. Appropriate immunizations—assess whether the child has been immunized against diphtheria, pertussis, tetanus, polio, measles, rubella and mumps, and whether booster shots are needed . . . Provide immunizations as recommended by the American Academy of Pediatrics or the local health departments." State Medicaid Manual Part 5—Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Transmittal Number 3 (April 1990) at p.6-14.

Therefore, AAP and/or ACIP recommendations should be followed, and immunizations provided according to the standard schedules. Note: no Hib vaccine appears in guidance.

APPENDIX D

Proposal for a National Immunization Registry

Computerized systems of tracking immunization status from birth now have been operationalized in several countries, including Great Britain and the Netherlands. In Taiwan, a national registry enables public health officials to identify unvaccinated children. Such systems aid in providing reminders to parents when

vaccines are due, measuring immunization status, tracking adverse events, and monitoring vaccine distribution.

The Division of Immunization of Centers for Disease Control (CDC) has primary responsibility for measuring the immunization status of the nation's children. Throughout the history of the program, several approaches have been used to fulfill this responsibility. However, today's methods fall short of our need for information and tracking capacity. Beginning with 1991, the National Health Interview Survey (NHIS) is the tool for collecting national data on the immunization levels, but the NHIS is limited in application (e.g. no state estimates). Several methods to collect state data have been developed and refined over the past twenty-five years. By 1989 several methods had been combined, and the CDC guidelines recommend that states conduct a "retrospective" survey using health records at school entry to measure immunization status of two-year-olds.

Experts believe a national immunization record system is possible in the United States. The advantages of the system would far outweigh any disadvantages. Implementation would require new resources; however, the resources needed would likely not far exceed the combined total now spent on data collection at the federal, state and local level. The advantages of a national registry system primarily relate to its 'universality.' Such a system could:

- Eliminate the need for several current national, state, and local level surveys and improve data quality;
- Allow more efficient follow-up of children by tracking each preschool age child through each immunization visit;
- Become the basis of a national early childhood data system through which birth certificate, infant death certificate, birth defect, and other information could be reported;
- Provide a central, standard immunization record to be used by families, providers, and public health agencies;
- Better coordinate public and private provider systems; and
- Increase the capacity to monitor safety and effectiveness by linking specific doses of vaccine to individual children.

APPENDIX E

Selected National Vaccine Program Activities

- Leadership of the Interagency Committee on Childhood Vaccines and development of Interagency plan.
- Econometric study of alternative approaches to vaccine financing, both purchase and distribution mechanisms.
- Study of federal statutes and regulations that impede childhood immunization efforts.
- Staff vaccine coordinators at NIH, FDA, CDC, and (in 1992) HCFA.
- Pertussis vaccine research, including clinical trials to develop a new and improved pertussis vaccine (NIH and FDA).
- Support for an initiative to develop vaccines for sexually transmitted diseases (NIH).
- Research on the measles virus to determine possible causes of the measles epidemic (CDC and FDA).
- Support for a large, linked database system to study and monitor vaccine injuries and adverse events (CDC).

PREPARED STATEMENT OF JOSEPH LIU

Mr. Chairman and members of the Subcommittee: The children's Defense Fund appreciates this opportunity to testify before you regarding the impact of Medicaid on childhood immunizations. CDF is a national public charity which exists to provide a strong and effective voice on behalf of the needs of low income, minority, and disabled children. For nearly 20 years, CDF has engaged in extensive efforts to improve poor children's access to decent health care. Because Medicaid is the largest publicly funded health program for children, its scope and quality at both national and state levels have been of the utmost concern to us.

THE IMMUNIZATION CRISIS

One appalling manifestation of the broader crisis in the nation's health care system has been the falling number of children immunized against wholly preventable diseases like polio, measles, mumps, rubella, diphtheria, tetanus, pertussis, and

meningitis. Falling immunization rates have inevitably led to more cases of disease and death and disability. The most glaring result has been a three-year long measles epidemic that has claimed over 5,000 Americans, including 89 who died in 1990 alone. Twice as many children contracted pertussis last year than in 1981, and rubella cases stood five times higher than in 1988.

While the rest of the world, including developing nations, has rapidly increased immunization rates, the U.S. has fallen behind. During the 1980s, the proportion of American preschoolers immunized against routine childhood diseases fell to fewer than one-half.

The United States ranks behind 16 other nations in the proportion of infants immunized against polio. When the proportion of U.S. nonwhite infants adequately immunized is compared to other nations' overall rates, the United States ranks 70th in the world, behind Burundi, Indonesia, Cuba, Jamaica, and Trinidad and Tobago.

Key reasons for the U.S. immunization decline have included skyrocketing vaccine costs, rising child and family poverty rates, inadequate access to health care, and underfunding of public health programs.

- Since 1981, the price of a single dose of diphtheria, tetanus, pertussis (DTP) vaccine rose from 33 cents to nearly \$10. The price for a dose of polio vaccine quadrupled from \$2.10 to \$9.45. Measles, mumps, rubella (MMR) vaccine nearly tripled, rising from \$9.32 to \$25.29.
- In one recent study, 84 percent of pediatricians and 66 percent of family practitioners reported referring at least some of their patients to public clinics for immunizations. The overwhelming majority of these doctors cited the affordability of immunizations both to themselves and their patients as the underlying cause.
- After adjusting for inflation, funding for community health centers fell by 38 percent between 1981 and 1991. With shrinking resources and rising demand for immunization services, 70 percent of all health centers have reported vaccine shortages in their clinics.

MEDICAID AND CHILDHOOD IMMUNIZATIONS

Last fall, the Children's Defense Fund undertook a survey of 49 states and the District of Columbia to determine how well Medicaid programs are providing immunizations. It showed that Medicaid, the nation's safety net health program which should be easing the immunization crisis, instead is worsening the problems. In 1990, nearly one-quarter of all young children, 5.3 million youngsters under age 6, relied on the Medicaid program for health care.

There are two basic price levels for vaccines in this country. The "catalog" price that physicians or other providers pay for vaccines (and then in turn charge to insurance companies or patients) is far higher than the "contract" prices that the federal Centers for Disease Control (CDC) pay for bulk purchase of vaccines they distribute to public clinics. Oral polio vaccine, for example, is \$9.45 for private purchase and \$2.00 when bulk purchased by CDC.

CDC's contract with vaccine manufacturers allows states to bulk purchase as much vaccine as they want. In theory every state could—and should—buy and distribute enough vaccine at least for its Medicaid eligible children, rather than reimbursing physicians to buy vaccine at far higher prices.

But only a minority of states bulk purchase some or all types of vaccine, either for Medicaid recipients or for all children in the state. Thirty states instead continue a fee-for-service reimbursement system in Medicaid. But most of these states, while paying far more than the CDC price for vaccine alone, pay providers an unreasonably low combined amount for vaccines and administration. This led many physicians to discontinue delivering immunizations to Medicaid children.

- States reimburse Medicaid providers only a fraction of the fee typically charged by office-based physicians for immunization services. On average, Medicaid programs pay just 53 percent of usual fees for the diphtheria, tetanus, and pertussis (DTP) vaccine and only 67 percent of usual fees for oral polio vaccine (OPV). Average state Medicaid reimbursements for measles, mumps, and rubella (MMR) and meningitis (HiB) vaccines were 72 and 84 percent of usual fees, respectively.
- In a single office visit for immunizations for a 15-month-old child, the typical Medicaid program underpays doctors by nearly \$40. In some states, Medicaid underpays physicians more than \$60 compared to usual fee for vaccinations.
- Only one state out of the 30 states that use a fee-for-service vaccine system in Medicaid pays over 85 percent of the usual fee charged by private doctors to immunize children for all four routine vaccines.—diphtheria, tetanus, and per-

tussis (DTP); oral polio vaccine (OPV), measles, mumps and rubella (MMR); and haemophilus influenza B (HiB).

- Several states actually reimburse physicians for immunizations services at a rate less than the cost of the vaccine alone. Kentucky's reimbursements for all four routine vaccines fell below the catalog price available to private doctors. Nevada and West Virginia set reimbursements for measles, mumps, and rubella (MMR) and meningitis (HiB) vaccines below cost. And Georgia, Hawaii, Nebraska, Oklahoma, and South Dakota have Medicaid vaccination fees set below the cost of vaccines for at least one antigen.
- When a child needs a followup visit to complete an immunization series, 17 states refuse to pay physicians for the second office visit and only allow billing for the vaccine and administration. The result is that many children never get the additional immunizations they need.

Low Medicaid reimbursement rates for immunization services and the absence of followup visit fees lead to serious problems. Combined with generally depressed reimbursements for other primary care services, insufficient payment for immunization services may push a pediatric provider out of Medicaid completely. More commonly, the low payment levels can lead providers to cease offering immunization services to Medicaid-enrolled children and to routinely refer their patients to public immunization clinics. The result is that Medicaid-covered children get pushed into an already overwhelmed public health system that cannot meet all their needs and safety net health services deteriorate even further for both Medicaid-eligible and other children. As a consequence fewer and fewer children receive protection against preventable disease.

In Milwaukee, 86 percent of the preschool measles cases reviewed by the CDC were among children entitled to Medicaid, similarly, 60 percent of the cases in Los Angeles, 75 percent of the cases in New York, and 22 percent of the cases in Dallas occurred among children entitled to Medicaid benefits.

CONCLUSIONS AND RECOMMENDATIONS

Skyrocketing vaccine costs have made the cost of basic immunizations almost prohibitive to middle class families and very expensive to public and private insurers. Yet instead of instituting aggressive, readily available steps to control the price of vaccines, get vaccines to all health providers through a bulk purchase system, and pay reasonable administration fees, most states have elected to simply allow their Medicaid reimbursement rates to fall far behind the cost of immunizing children on a fee-for-service basis. The result is widespread non-participation in Medicaid programs by private physicians, and another flood of children to under-funded public providers, already faced with the diversion of uninsured or privately insured children. The public programs do not have enough free vaccine and when they depend on Medicaid to repay their costs for Medicaid recipients, they too are under-reimbursed. In the end, parents are blamed by leaders who do not understand the problem, because casting blame on poor families almost always is so much easier than fixing systems.

But this system is unusually easy to fix. The ready answer to the problem lies in establishing universal vaccine programs at the state level. Funded through general funds and other special taxes (for example, small taxes levied on all hospitals, physicians, and payments by Medicaid agencies and insurers who otherwise would have to pay higher catalog rates for vaccines), a universal bulk purchase program administered by a state health department could secure all the vaccines a state needs at the CDC contract price, leaving parents, Medicaid agencies and insurers responsible for a reasonable administration fee only. In many states, the savings from Medicaid alone could account for much of the funding needed to operate a universal vaccine distribution system.

Medicaid savings could also be invested in more reasonable reimbursement rates and increased support to private and public providers for administration of vaccines and, ideally, other primary care services. Insufficient reimbursement levels discourage participation in the Medicaid program, and without a sufficient number of providers willing to serve Medicaid-enrolled children, a Medicaid card becomes practically useless for millions of children.

Because of the enormous cost-effectiveness of immunization services, Congress should encourage states to improve their immunization systems. Medicaid programs should be required to implement vaccine replacement systems, at a minimum. Federal grants for states to start-up vaccine distribution systems could pay for themselves through reduced Medicaid costs. Incentives could include enhancing federal financial participation for Medicaid immunization services to 90 percent to encourage better payments to providers. Another companion approach to assist states and

localities would be to expand the CDC's childhood immunization program to provide resources for administering immunizations to children. The current program provides help for vaccine costs and only limited assistance for the doctors and nurses needed to administer the vaccines. Expanded funding would allow state and local public health programs to develop innovative outreach strategies and more accessible clinic hours and locations.

While a universal vaccine distribution system can be established by any state alone, it is one that should be established for every state and for every family. All the necessary vaccines for American children could be purchased by the Centers for Disease Control and distributed free of charge to all health care providers in the country. Considering that over a quarter of all vaccines are paid for by the federal government and another quarter is purchased by states, creating a universal vaccine program is a logical next step towards eliminating preventable childhood diseases in the nation.

Physicians and clinics could continue to be reimbursed for administration activities by parents and public and private insurance plans (or alternatively, through an additional per-child administration payment made directly by CDC or a state health agency). A universal vaccine initiative should be coupled with resources for doctors and nurses to administer immunizations and other primary health care services and to provide outreach and parent education, especially in medically underserved areas. Such reforms could be instituted, for approximately \$500 million more in funding in the first year, with ongoing support coming from the health insurers and providers that will realize major short term and long term savings from this type of system. In the end the new system would more than pay for itself.

The advantages of a universal vaccine program include better controlled costs and the guarantee that no American child will be denied immunizations because of cost. Coordinated vaccine purchasing and distribution systems are used even in many countries that otherwise maintain an insurance approach to payment for services. These nations recognize that immunizations are such a crucial public health activity and the purchase of the vaccine such a large portion of the cost of the service that the financing and distribution of childhood vaccines cannot be left to normal market forces.

This nation is in the midst of a terrible immunization crisis that cannot and need not wait for a full-blown national health plan before being resolved. Vaccines are incredibly cost-effective, saving between \$10 and \$14 for every dollar spent. Each day we delay an overhaul of state and national vaccine programs and choose instead to blame and punish parents for events far beyond their control brings us a step closer to the next epidemic, which experts say surely will come. This is a problem that national and state leaders can tackle and beat today, leaving both children, and the national health budget, far better off for their efforts.

PREPARED STATEMENT OF MARK V. NADEL

Mr. Chairman and Members of the Committee: I am pleased to be here today to discuss our work on childhood immunization. At the request of the Senate Committee on Finance, GAO studied how the states and the federal government can improve the immunization rate in the United States through more efficient and effective programs. Specifically, we examined (1) ways to reduce Medicaid costs for immunizing children and (2) strategies to improve preschool immunization rates to ensure all preschool children receive vaccinations. Our complete report will be issued later this year. This morning I will discuss our preliminary findings.

In brief, we found that the states could save millions of dollars, in the aggregate, through a more efficient Medicaid vaccine purchase and reimbursement strategy. States can also improve their immunization rates by establishing or improving tracking, outreach, and education systems.

BACKGROUND

Although the Public Health Service had a goal of immunizing 90 percent of preschool children by 1990, the United States has one of the lowest rates in the Western Hemisphere for preschool immunizations against such diseases as measles, mumps, and polio. In 1990—less than one decade after the United States had nearly eliminated measles from within its borders—this nation reported over 27,000 measles cases and 89 resulting deaths. Unvaccinated preschool children accounted for nearly half of these measles cases and 55 percent of the deaths. Failure to vaccinate preschool children has been largely attributed to inadequate access to preventive health care services and the increased cost of vaccines.

Childhood immunization is one of the most effective means of health promotion and disease prevention. Immunization against childhood diseases averts the costs of treatment for preventable diseases and saves as much as \$14 for every \$1 invested. Nevertheless, based on information that the states provided to us, the average preschool full immunization rate among the states is 59 percent. The Centers for Disease Control (CDC), which studied immunization rates in selected states and cities, believes the overall national immunization rate is actually lower and points out that only about one-third of all urban preschool children are fully immunized. The Public Health Service and the American Academy of Pediatrics recommend that all children be vaccinated against measles, mumps, and rubella; oral polio; diphtheria, pertussis, and tetanus; hemophilus influenza type b; and perinatal hepatitis by 2 years of age.

About half of American children are vaccinated by private physicians and half by public providers such as community health centers. In either case, Medicaid may reimburse for eligible children. As a result of recent program expansions, preschool children with family incomes up to 133 percent of the federal poverty level are potentially eligible for Medicaid—this group now accounts for about one-third of all preschool children.

Financial support for state immunization programs also comes through CDC activities. CDC is responsible for providing leadership and direction in the prevention and control of preventable childhood diseases. To help meet this responsibility, it provides technical assistance and grants to state and local health agencies for planning, developing, and conducting childhood immunization programs. CDC grants in fiscal year 1991 totalled \$182 million. To achieve cost savings in immunization programs, CDC has contracted for the bulk purchase of vaccines for state and local health agencies. CDC's contract price is substantially lower than private-sector prices for vaccines because manufacturers have agreed to lower prices in order to make the vaccines available to poor children.

Health agencies have used CDC grants to acquire vaccines at reduced cost for about half of the public-sector needs. State and local health agencies may also buy vaccines through the CDC contract with their own funds. Health agencies that purchase such vaccines and distribute them to Medicaid health care providers may be reimbursed for the vaccines' cost by state Medicaid programs.

To meet our review objectives, we administered questionnaires on immunization practices and vaccine reimbursement costs to all state health and Medicaid officials. Only one state did not respond to our survey. We also examined innovative childhood immunization programs in Massachusetts, Illinois, and Arkansas. Finally, we met with CDC and Health Care Financing Administration officials to obtain programmatic information.

STATE MEDICAID PROGRAMS COULD SAVE ON VACCINATION COSTS

Most state Medicaid programs could save money if low-cost vaccines acquired through CDC contracts were made available to health care providers who administer vaccinations to poor children. Currently, state and local health departments can purchase low-cost vaccines through CDC's bulk-purchase contracts with manufacturers. Generally, these health departments distribute these vaccines to public health providers, such as public health clinics. In about half the states, these clinics are the major source of Medicaid immunization services.

Vaccine Replacement Programs Can Yield Substantial Savings

States can also purchase vaccines acquired through CDC contracts for running vaccine replacement programs for all providers to use for their Medicaid patients. As of May 1991, public health agencies in nine states purchased vaccines through CDC contracts and supplied them free to those Medicaid providers who wanted to obtain their vaccines in this manner.¹ In these states, Medicaid programs reimburse the health departments for the lower cost vaccines and save money by reimbursing for vaccines at the CDC contract price rather than the regular commercial price. Illinois, for example, saved over \$1.5 million in 1991 by reimbursing this way. Even in these nine states, however, not all Medicaid providers take advantage of this opportunity. For those who do, health departments replace the Medicaid providers' supply of vaccines with vaccines purchased through CDC contracts.

Ten additional states purchase the low-cost vaccines from CDC and distribute them free to all providers, for both Medicaid and non-Medicaid use, a practice referred to as a universal vaccine distribution system.

¹A month later, one of these states discontinued its vaccine replacement program because of funding constraints.

In the other 30 states that responded to our survey, low-cost vaccines are not supplied to all private Medicaid providers. In most of these states, Medicaid reimbursements for vaccines are based on private-sector vaccine costs, which are considerably higher than costs under the CDC contracts. For example, the private-sector price for oral polio vaccine is almost five times greater than the CDC contract price. The private-sector price for hemophilus influenza type b vaccine is almost three times more expensive than the CDC contract price.

Thirty-two state Medicaid programs provided GAO with information on the number of vaccines for which they reimbursed providers in 1990. Had these vaccines been acquired at the CDC contract price rather than the private-sector price, Medicaid programs in those states would have saved \$14.2 million.

States Face Barriers to Wider Use of Bulk-Purchase Vaccines

States told us that funding for purchasing and distributing CDC contract vaccines to Medicaid providers is a major barrier to establishing a vaccine replacement program. First of all, Medicaid will reimburse health departments for the costs of vaccines only after they have been administered to children. Therefore, the states must first come up with enough money to purchase the initial supply of vaccines. Even though making the initial purchase of vaccines would be a one-time cost (since subsequent vaccine purchases would be reimbursed), most states told us that funding the initial outlay is a significant hurdle. Nonetheless, this initial expenditure would be more than offset by recurring Medicaid savings while benefitting children's health.

Secondly, establishing and maintaining a system to handle, store, and distribute vaccines to private Medicaid providers entails additional expenditures. Creating such a system also expands the traditional public health role, and some state health departments are reluctant to get involved in what they perceive as a wholesale distribution system.

Even when states have vaccine replacement programs, not all private providers participate in the replacement programs because there are also barriers to individual physician participation. These include delays for vaccine replacement, the administrative burden of keeping separate records for public and private vaccines, and what some see as inadequate Medicaid reimbursement for vaccine administration.

Use of Individual Rather Than Multiple Vaccines Results in Higher Medicaid Costs

Further savings of Medicaid funds could be achieved if states required the use of combined vaccines rather than reimbursing individual injections of single-antigen vaccines. Combined vaccines provide protection against multiple diseases, such as measles, mumps, and rubella, whereas single-antigen vaccines protect against only one disease. Except during a disease outbreak, the Public Health Service's and the American Academy of Pediatrics' immunization guidelines recommend the use of a combined measles, mumps, and rubella vaccination for routine immunizations of preschool children. At least 36 state Medicaid programs, however, routinely paid for single-antigen vaccinations.

According to CDC officials, medical justification for using a single- rather than combined-antigen vaccine for preschool children should be rare. A substantial number of single-antigen injections may have been given wastefully as seen in a New York State Health Department analysis of 1989 Medicaid claims. In that study, the health department concluded that single-antigen vaccines were inappropriately administered in 45 percent of the 23,885 immunizations given in private physicians' offices to children between the ages of 1 and 4. Because of this practice, opportunities were lost for achieving full immunization of these preschool children, and immunization costs increased. Based on our survey results, the average Medicaid reimbursement for the three single-antigen vaccines is 60 percent higher than the reimbursement for the combined vaccine.

BETTER TRACKING, OUTREACH, AND EDUCATION CAN IMPROVE IMMUNIZATION LEVELS

Although it is possible to reduce Medicaid expenditures for vaccinations, such savings alone will do little to improve preschool immunization levels unless the funds are rechanneled to more proactive immunization programs. Public health departments need to educate parents about the importance of completing the full immunization schedule, as well as to identify and reach preschool children in need of immunizations. According to CDC these activities are key elements of an effective immunization program.

Our analysis of immunization data that states provided indicates that states with statewide integrated tracking, outreach, and education systems are twice as likely to have greater success in immunizing children. However, only 12 states have integrated statewide tracking, outreach, and education systems. Immunization rates in

these states are generally higher than rates in states that do not have such integrated systems; their median immunization rate for preschool children was 66 percent compared with 58 percent in the other states.² Five of these states had rates that ranged from 72 percent to 84 percent. In addition to having integrated systems, the two states with the highest rates—Vermont (84 percent) and Massachusetts (79 percent)—supplied certain of the vaccines free to all health care providers, which also may have contributed to the high rates.

While states that have statewide integrated tracking, outreach, and education systems do better than states that do not have such systems, immunization rates for preschool children in almost all states are still well below the Public Health Service's 1990 goal of 90 percent. In most states, tracking, outreach, and education activities have serious limitations. Tracking systems often do not maintain a complete record of newborns, outreach is generally limited to mail notices with no personal contacts, and educational materials on childhood immunizations frequently are not disseminated and explained to new mothers at the time they leave the hospital as suggested by CDC.

State health department officials told GAO that a number of challenges exist to establishing an effective tracking and outreach system. These include:

- limited state, local, and federal funding for computer equipment and staff;
- difficulties in obtaining birth records in a timely manner; and
- privacy issues inherent in maintaining and using centralized files containing confidential health information.

CONCLUSION

There is wide agreement that immunization rates should be dramatically increased. Although funding is a barrier to better vaccination programs, states could lower their Medicaid vaccination costs by adopting more cost-effective vaccine payment policies. Savings on vaccine costs could allow states to use their limited financial resources to improve the effectiveness of their immunization programs, including developing or enhancing a tracking, outreach, and education system.

PREPARED STATEMENT OF CHRISTINE NYE

Mr. Chairman and members of the subcommittee: I am pleased to be here this morning to discuss the Medicaid program's role in providing immunization services to children.

As Secretary Sullivan recently pointed out, "America's immunization program is one of the greatest success stories in medicine." Serious illness from diphtheria, mumps, pertussis, polio, rubella and tetanus have been reduced by at least 90 percent. Since 1982, 95 percent of children entering school have been immunized. Immunizations are critical to ensuring that our nation's most valuable asset—our children—are protected from serious and potentially fatal illnesses.

The increasing incidence of measles, experienced a few years ago, points out the need to fill gaps in our nation's immunization program. At the President's direction, the Department of Health and Human Services recently released an "Action Plan to Improve Access to Immunization Services" that describes a comprehensive approach involving four cabinet departments of the federal government. Under the plan, efforts will be carried out in all 50 states, 13 territories and 24 large cities to develop community-based immunization action plans. Today, I would like to discuss the Medicaid program's role in this extensive effort to immunize children vulnerable to preventable diseases.

BACKGROUND

Medicaid finances immunizations primarily through the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) program. EPSDT is a comprehensive program that considers the overall health status of children. The administration of immunizations is just one component of this broad health benefit.

In 1991, the EPSDT program served almost 7 million Medicaid children under age 21 and cost Federal and State governments a total of \$285 million. These are dollars well spent considering the EPSDT program is the most effective tool we employ to combat childhood illness in our Nation's vulnerable children.

Each State is required to inform eligible families about the EPSDT program. In fact, most States have implemented outreach programs to enroll children in the

²This percentage is based on 11 of the 12 states that provided us with immunization rates.

EPSDT program. HCFA is also developing prototype outreach programs and is now testing them in five States. Under these programs States are targeting media campaigns to recruit providers to furnish prenatal and EPSDT services to Medicaid children. States are also working with community groups to establish one-to-one outreach among neighbors in targeted locations.

Under the EPSDT program, children are screened to evaluate their health status and medical needs through a comprehensive physical examination, including laboratory testing where appropriate. As a result, necessary immunizations, vision, dental, hearing and other services are provided to treat identified medical conditions, regardless of whether these services are covered under the Medicaid State plan. Health care providers must also educate children and their parents on ways to correct unhealthy behavior.

I would emphasize that immunizations are required to be administered as part of the EPSDT screening evaluation. We have no indication that physicians and other EPSDT providers are failing to do so.

IMMUNIZATIONS

The Health Care Financing Administration provides national direction and guidance to State-administered Medicaid programs. There are several important projects underway to improve immunization services provided through Medicaid's EPSDT program. Many of these activities are part of the Department's Action Plan to Improve Immunization Services. Others are strategies undertaken independent of the Plan that have been in place for years. All of these efforts will have an interactive effect to improve immunization practices nationwide.

Vaccine Acquisition

Since 1985, EPSDT providers have been able to use vaccines supplied through public health agencies. This resulted from a joint effort of the Health Care Financing Administration and the Public Health Service to develop a guide for State Medicaid and public health agencies to implement efficiencies in immunization programs.

The PHS' Centers for Disease Control coordinates consolidated vaccine purchases for State and local agencies through national contracts with suppliers. The CDC contracts also allow States to use federal funds other than CDC grants to purchase additional amounts of vaccines. These large-quantity purchases significantly lower prices from the high cost of vaccines purchased in the open market. These vaccines are paid for by Medicaid or under grants from the Public Health Service. In several States, including Michigan, agreements between Medicaid and public health agencies enable a systematic replenishing of providers' vaccine supplies as they furnish EPSDT immunizations.

Easy access to vaccines could remove a barrier that may inhibit the appropriate immunization of children at EPSDT screenings. All States now take advantage of public health-supplied vaccines. The Department and the General Accounting Office are studying the degree to which States use these vaccines. This information will help us assist States in maximizing the low-cost purchase and effective distribution of vaccines for the EPSDT program.

Another way to improve immunizations would be for Congress to streamline the requirement that physicians' offices provide lengthy vaccination information. The complex nature of this information could act as a disincentive for parents to get their children vaccinated.

Inter-Agency Agreement

This April, we entered into an inter-agency agreement with the CDC to develop a strategy to promote infant and childhood immunizations. The agreement calls for collaboration on several important action steps, including:

- updating the 1985 guide for efficient vaccine acquisition through CDC purchasing contracts and effective distribution to Medicaid providers;
- exploring the development of a data base for analysis of immunization issues; and
- planning for the dissemination of technical assistance, including the *Standards for Pediatric Immunization Practices* to State Medicaid agencies and providers;

In fact, we plan to release the immunization standards this week, when they are distributed at the annual State Medicaid Directors meeting.

The 18 Standards for Pediatric Immunization Practices were developed by a working group composed of representatives from professional organizations; public health organizations; and federal, state, and local health departments. Though simply stated; the standards succinctly structure key practices that must occur if we are to

strengthen our national immunization program. The standards address the issues of eliminating barriers or prerequisites, minimal or no fees, tracking and record-keeping, vaccine management, medical protocols, and patient oriented, community approaches.

Action Plan

The activities I just described are interrelated and fit into the Department's much larger and broader Action Plan to Improve Access to Immunization Services published in April. The Plan was developed as part of the Report of the Interagency Committee on Immunization and spells out specific goals and objectives for several government Departments and agencies.

The goals for the Health Care Financing Administration include:

- Issuing guidelines for immunizations provided by the EPSDT program. In July 1990, we distributed manual instructions advising States to:
 - assess whether children screened by EPSDT have been immunized against diphtheria, pertussis, tetanus, polio, measles, rubella, and mumps;
 - make immunization records available to providers;
 - provide appropriate immunizations; and,
 - inform the supervising providers of children's immunization status.

This week, we will distribute updated guidelines at the State Medicaid Directors meeting that include immunizations for haemophilus B and hepatitis B. Manual instructions will follow within the next few weeks.

- Sponsoring immunization workshops to encourage cooperation between Medicaid and local health departments;
- Improving immunization services in cooperation with the Maternal and Child Health Technical Advisory Group;
- Conducting an EPSDT management review in every State to determine immunization patterns, the extent Medicaid acquires vaccines through the CDC contracts, and reimbursement for immunization services; and
- Tracking immunization status in EPSDT programs.

The larger goal we are aiming for is to have 80 percent of all eligible children served by the EPSDT program by 1995.

One way to help accomplish this goal is by enrolling more Medicaid children in coordinated care plans, such as HMOs. Children with access to primary care through coordinated care plans are more likely to have immunizations than those children receiving only episodic care.

The concept inherent in coordinated care is the efficient use of health care resources, with an emphasis on preventing disease. Virtually all coordinated care plans provide immunizations. And, under our new model quality assurance plan, which will be ready for State use in the next 6 months, Medicaid coordinated care plans could track all immunizations for their enrolled children, regardless of where the vaccine was administered. Significantly, the tracking would begin at age 2, unlike current practice which begins when the child enters school at age 5.

Greater use of coordinated care in the Medicaid program is a key part of the President's Comprehensive Health Care Reform Plan. The President proposes to eliminate obstacles to the use of coordinated care plans and encourages States to adopt innovative approaches to serve needy populations.

S. 2116

We believe the coordinated efforts of the Department will be effective in strengthening our nation's immunization practices. The Medicaid program is already involved in many activities that accomplish the objectives of the Chairman's bill, S. 2116.

For example, many of the access and referral problems the bill addresses would be mitigated by greater use of coordinated care. The demonstration on vaccine purchasing would duplicate our ongoing activities with CDC and State public health departments. Data and tracking issues addressed by the bill are being reviewed at many levels within the Department.

We do not support a demonstration on enhanced reimbursement for immunization services without evidence that payment levels are, in fact, inhibiting access to immunizations. We recognize the value of an aggressive outreach program and are already working with States to implement outreach to bring children into their EPSDT programs. However, we stand by our pledge to the Governors to refrain from additional Medicaid mandates during this period of fiscal crisis in both the State and federal budgets. Accordingly, in view of activities already underway, we do not favor enactment of S. 2116.

CONCLUSION

The Medicaid program is committed to improving the immunization levels for eligible children. Our collaborative activities will streamline access to immunization programs by coordinating federal efforts. These efforts, combined with increased federal funding for immunizations requested in the President's FY 1993 budget and action taken at local levels, form a national campaign to better our nation's immunization program.

COMMUNICATIONS

STATEMENT OF THE AMERICAN CYANAMID CO.

Chairman Riegle and members of the Subcommittee, Lederle-Praxis Biologicals is pleased to have this opportunity to submit a written statement for the hearing record on "Medicaid Impact on Child Immunizations." Your focus on this issue is very appropriate because we believe that continuation of the successful partnership between industry and government, at the local, state and federal levels, is essential for the achievement of our shared goal of improving immunization levels in this country. We commend the Chairman for holding these hearings and for sponsoring S. 2116, the "Comprehensive Child Health Immunization Act." We support the objectives of this legislation, although we have some concerns about specific provisions that may duplicate existing efforts.

The vaccine business of Lederle's Laboratories has a long and proud history. Beginning at the turn of this century with Dr. Lederle, we have long worked closely with public health officials to immunize children against vaccine preventable diseases. Since the introduction of oral polio vaccine thirty years ago, we have consistently supplied that vaccine and combined diphtheria, tetanus and pertussis vaccines to the American public. We stayed in the vaccine business even when confronted in the mid-1980's with the threat of crippling liability, with no insurance, after irresponsible media reports of alleged risks associated with DTP stimulated hundreds of lawsuits. When other companies ceased distributing DTP vaccine or dropped out of the business entirely, Lederle took extraordinary measures to continue providing DTP to the American public. At that time we faced over 340 lawsuits claiming damages in excess of \$3.5 billion—an amount greater than the entire net worth of our company.

The fact that we stayed the course during those troubled times is just one example of our commitment to our nation's children. Another example is our long-lasting commitment to vaccine innovation, as evidenced by our \$238 million purchase of Praxis Biologicals that greatly enhanced our biotechnology capacity. This substantial research investment has recently begun to show dramatic results.

Two years ago, our *Haemophilus influenzae* type b vaccine, HibTITER, was the first new vaccine to be approved for infant use since the introduction of OPV. The *Haemophilus* bacterium and associated meningitis caused hundreds of deaths and neurologically damaged children each year—with more than \$2.5 billion in annual costs, according to CDC estimates. Within one year of full use of HibTITER, the disease incidence has declined dramatically.

Last year, we became the first U.S. company to obtain approval for an acellular pertussis vaccine, the long-awaited less reactive alternative to whole cell pertussis vaccine. The public clamor for this vaccine illustrates an important point about childhood vaccines. Despite solid scientific evidence that whole cell DTP was not associated with serious or permanent damage, the public perception was to the contrary, with perhaps thousands of children going unimmunized or delaying immunization. We committed substantial expenditures and resources on research to develop and obtain FDA approval for an acellular pertussis vaccine. To lower its cost, we are currently lobbying Congress for a substantial reduction in the federal excise tax, which is imposed on the acellular vaccine under the Vaccine Injury Compensation Program. We propose that the tax on this vaccine be lowered from the current \$4.86 per dose to \$1.00 per dose or less based upon its lower reactivity.

At present we are concentrating our research efforts not only on new antigens for sexually transmitted diseases and respiratory and gastrointestinal illnesses, but also on new combinations of existing products. Currently pending at FDA is our application for a combination DTP/Hib vaccine which will be an important step toward consolidating the increasing number of inoculations. In addition, we are moving toward the goal of a multi-valent children's vaccine—one step at a time as we must

to ensure that the successes of the past will not be jeopardized by short cuts that might imperil our children.

As indicated by the General Accounting Office, increased use of combination products will reduce the number of separate shots necessary for full immunization, which in turn could produce significant cost savings, in general, and Medicaid savings, in particular. Moreover, from a public health perspective, combination products should improve immunization rates by lessening the number of health care visits required for full inoculation.

The cost of all this effort and achievement should not be overlooked or unappreciated. We have recently committed in excess of \$70 million for new research and manufacturing facilities. Our expectation is that the development of each new or improved vaccine will require considerable additional investment well in excess of what has already been committed.

In the current environment, manufacturers, confronted with an endless demand for new vaccines and combination products, have less time to recoup their investment as the pediatric market is a fixed-volume market. Technology is changing rapidly which increases the potential for new approaches while it simultaneously increases the risk of obtaining a return on investment. This leads us to a discussion of the single greatest threat to the industry/government partnership and to the long-term success of the childhood immunization program: the well-intentioned but misguided effort to have government purchase all childhood vaccines.

The impetus for universal vaccine purchase is traceable to the variance between prices charged to private physicians and those given the public sector under contract with the CDC. Simply stated, the underlying reason for the difference in price lies in the fact that private sector purchases subsidize vaccine sales to the public sector. This has been a conscious policy of Lederle-Praxis, one which we regarded as a public service to ensure that those children in need would have access to subsidized vaccines.

Now, however, some are urging that the public sector buy all or most vaccine. They presume that this purchase will be done at the current, heavily subsidized CDC price level. That presumption, which may be consistent with a government-owned and operated vaccine industry, completely ignores the realities of production and distribution of our existing system, that relies on the private sector. The chairman of the State Medicaid Director's Association, whose members are responsible for leading state efforts to ensure that vaccines are delivered to children in need, has cautioned the Committee that based on past experience such a dramatic shift could well "backfire" and result in general vaccine cost increases.

For many reasons, universal purchase is a seriously flawed approach to childhood immunization. First, because of the prohibitive cost of universal purchase, limited public resources which are subject to annual budget review, will not be adequate to meet immunization needs. Second, universal purchase does not address the underlying reasons for low immunization rates. Third, the plan will seriously undermine private incentives for vaccine research and development.

To compensate for the price difference as well as for the introduction of new products, universal purchase of vaccines would require multifold increases in public sector expenditures. We would be happy to share with the Committee the potential cost impact for each state under various universal purchase scenarios. In addition to increased state and federal vaccine expenditures, monies would be required to cover the cost of distribution of the vaccines. Current state and federal resources are stretched thin to keep up with demand, let alone meet new vaccine requirements and Medicaid mandates. Even with the recent renewed commitment to immunization, securing the high level of state and federal expenditures needed to inaugurate and maintain universal purchase is highly unlikely given annual Federal budget cost-saving pressures. More importantly, universal purchase proposals do not address the central problem of childhood immunization—how to improve low immunization rates for pre-school children. Public health experts appear in agreement that low immunization rates are due in large part to inadequate delivery systems which fail to track immunizations and provide outreach to those who remain unimmunized. The fact that some 90% of children under age two receive at least one immunization strongly suggests the need for enhanced tracking and outreach to identify and immunize those who at some point have entered the system but have subsequently been lost.

While some may argue that immunization is discouraged by supposed high cost, that argument is belied by the fact that vaccines are currently available *free of charge* to anyone who enters a public health clinic, yet low rates of immunization persist in areas served by these clinics.

A recent study by the Children's Defense Fund divided states into three vaccine purchase system categories: universal purchase (13 states); vaccine replacement (7

states); and fee for service (30 states). If universal purchase is the key to improving low immunization rates, then those states currently purchasing all or most of their vaccines through the public sector should have the lowest incidence of childhood disease. But, the pertussis incidence data from the Morbidity and Mortality Summary of Notifiable Diseases suggests that the rate of pertussis per 100,000 people is significantly higher in universal purchase states than in replacement or fee for service states.

Another chart from the National Vaccine Program Office shows coverage of measles vaccine and incidence of measles in eight cities. If public purchase is the key to widespread immunization, then Seattle and Boston, both located in universal purchase states should have the highest coverage and the lowest incidence. In fact, the chart shows little discernible impact of the purchase system on coverage and incidence. Moreover, Pittsburgh, the city with the highest coverage and the lowest incidence, is in a fee for service state.

We realize that data from widely varying state passive surveillance systems has limited value as an accurate measure of success. But neither does it indicate that universal purchase is the silver bullet for all the problems we face.

In addition, we should all appreciate that vaccine cost is only a fraction of the total cost of immunization in the private sector. If, despite strong evidence to the contrary, one persists in the belief that cost is a major factor in the rate of immunization, then one has to also consider the significant cost of administration.

Because of the preceding concerns and for other reasons, we suggest modification of section 7 of S. 2116, which would establish vaccine purchase and distribution demonstration programs. Since a number of these proposed programs already exist in the states, we recommend instead that section 7 of the bill direct the Secretary of Health & Human Services to conduct a comprehensive assessment of currently established universal purchase and Medicaid replacement states with regard to immunization rates, disease incidence levels and efficiency of vaccine delivery and report to Congress on his findings.

Mr. Chairman, Lederle has come to the conclusion that the underlying causes of low immunization rates among indigent populations have little to do with cost and much to do with education and accessibility. In line with this understanding, we have invested significant resources in programs that provide solutions to these problems, including education and outreach efforts at the national and local levels. For example, Lederle has contributed in excess of \$2 million to one project begun in New York City which provides immunization and primary health care to homeless children. This program, operated by Dr. Irvin Redlener, uses mobile medical vans to bring immunization opportunities to homeless and other indigent children and utilizes computers to provide recordkeeping and tracking. Dr. Redlener's approach is a useful model for addressing the needs of both urban and rural localities. In fact, Lederle's contributions have helped to expand his program to remote, rural areas like the Mississippi River Delta and West Virginia as well as other urban areas like Newark and Dallas.

From the standpoint of a U.S. vaccine company, the most problematic feature of universal purchase is its impact on research and development. If the government were the sole purchaser of childhood vaccines, it is difficult to see how more than one company could remain in the market. Losing the procurement for a vaccine would effectively terminate a company's involvement in providing a particular vaccine because continuous production is necessary for obvious reasons, not the least of which is job loss, elimination of inventory, manufacturing lead-time and quality control.

The U.S. has been the source of most major advances in vaccine technology, ranging from polio vaccine to haemophilus b and hepatitis b. Our own significant research and development investment in vaccines could not continue if we faced exclusive government purchase, price controls and exclusion from the market for even short periods of time.

The childhood immunization program can be improved, but that will not happen by effectively destroying the current industry/government partnership. The very real problem of low immunization rates in certain populations must be addressed and must be consistent with limited public resources and with maintenance of an appropriate balance between public and private initiative. We believe there should be four elements to achieve this result:

First, and most importantly, available resources must be targeted to those most in need. We must not continue to permit the affluent to take advantage of government-sponsored programs while the poor are underserved.

The first priority should be the Medicaid population. We believe that "replacement" programs like that in Ohio are a good model for ensuring that Medicaid beneficiaries can receive federally purchased vaccine. Merck has announced a distribu-

tion initiative to test ways to improve immunization for Medicaid recipients. While Lederle will be interested in reviewing the results of these pilot programs, we have some concerns about the extent which private practitioners will agree to serve the burgeoning Medicaid population given limited reimbursement rates in some states. We believe that the public sector of necessity must take the lead role in coordinating and targeting vaccine distribution to Medicaid recipients.

The uninsured represent a second deserving target population, and public health clinics can help us identify them. Accordingly, community and migrant health centers and similar public health clinics should have access to publicly purchased vaccines.

But simply providing subsidized vaccine supplies to public health clinics will not be enough if those subsidized vaccines are then distributed in an untargeted fashion. Mr. Chairman, you were disturbed, and rightly so, to learn that there were shortfalls of certain vaccines at public health clinics in Michigan. The particular vaccine discussed, hepatitis B, likely was not available at the public health clinic because it is a product that only last year began to be recommended for use in children. The fact that it is a newly recommended pediatric vaccine, means that, as yet, adequate funds have not been appropriated to purchase large supplies under the CDC contract. With regard to this particular vaccine, therefore, the problem should be remedied relatively soon as the appropriations cycle adjusts to the new recommendations.

The hepatitis B example, however, should not be surprisingly given our current lack of effective targeting. Neither federal nor state authorities impose significant guidelines on the distribution of federally-purchased vaccines except to require that they be given "free of charge." While states are placed upon those who can receive free vaccines, shortages at public health clinics are in fact likely to occur.

Just as affluent individuals should not be the beneficiaries of free vaccine programs, states should not be allowed to take lower cost vaccine from the federal contract disproportionately to their needs. It is a matter of simple fairness. If a state or locality is to receive more than 50% of its vaccine from the federal contract, it should be because it is heavily impacted by need for its inner cities or rural areas of poverty.

In order to target vaccines more equitably among the states, there must be some flexibility in the system. Currently there are so-called "maintenance of effort" provisions in some bills moving through Congress that would severely limit CDC's ability to re-allocate vaccine supplies to states in need. If those provisions are enacted, it will be very difficult to adjust the system to benefit most states.

Second, the program must improve the efficiency of its delivery of vaccines to the public sector. Special emphasis should be given to improved tracking and outreach programs, such as those proposed in S. 2116. We should work together to ensure that appropriated public funds are directed to assist in developing a tracking system flexible enough to meet both local and national needs.

Third, private insurance plans should be encouraged to cover the cost of immunization. The private pediatrician may truly become an endangered species if health insurance reform, at the federal or state level, does not include provisions for well-baby and well-child care, including routine vaccination. To accomplish this, Lederle proposes that Congress include in any health insurance reform or tax incentive package proposals to require insurance companies to make health insurance plans with both well-baby and well-child coverage available to self-employed and small businesses at group rate discounts. Reimbursement for such coverage should be without a coinsurance or annual deductible payment requirement. It would include all recommended immunizations and would add less than 2% to the cost of a basic employee health insurance plan.

In 1991, Lederle's parent company, American Cyanamid, expended only \$16.50 per employee for well-baby, well-child care, pediatric preventative screening, immunizations and vision care for children age 0 to 12. This is a bargain compared to the \$4,000 per employee the company paid for other health care expenses. That is only four tenths of one percent of the total cost! In addition, studies of the Health Insurance Association of America indicate that the average cost nationally of this coverage under private health insurance plans is only \$35 in additional premiums per year.

To encourage employers to offer, and employees to elect health insurance coverage for pediatric preventative services and help them pay for it, we recommend that insurance reform proposals pending in Congress be amended to allow employers a special 125% or other appropriate increased federal tax deduction rather than the 100% deduction allowed if they select minimum coverage plans. Under the President's plan, eligible employees would receive a proportionately larger tax credit voucher for purchasing their insurance if they elect pediatric preventative coverage. This ap-

proach would eliminate the bias against prevention in employee health insurance. It is good public policy for the tax code to favor cost-effective, preventative insurance coverage over high-cost hospitalization/treatment coverage.

Fourth, there is a need for more effective public education regarding the benefits of childhood immunization. Regrettably, private insurance companies and employers remain to be educated concerning the cost-effectiveness of immunizations and other well-baby care. Parents, too, need to be constantly reminded of the importance of careful attention to immunization schedules, particularly in the early childhood years. Toward this end, Lederle has initiated and supported a wide variety of immunization awareness and educational programs.

Achievement of these four broad results would ensure that the 90% of children now receiving at least one shot would receive all the shots necessary for full immunization. Ultimately, these initiatives implemented through the existing partnership between the federal government, the state and local governments and the private sector would help us reach our shared goals of 100% immunization. Equally important, vaccine manufacturing would have the continued ability to support important research so that new and improved vaccines with fewer inoculations will be developed to protect our children from devastating infectious diseases.

Thank you.

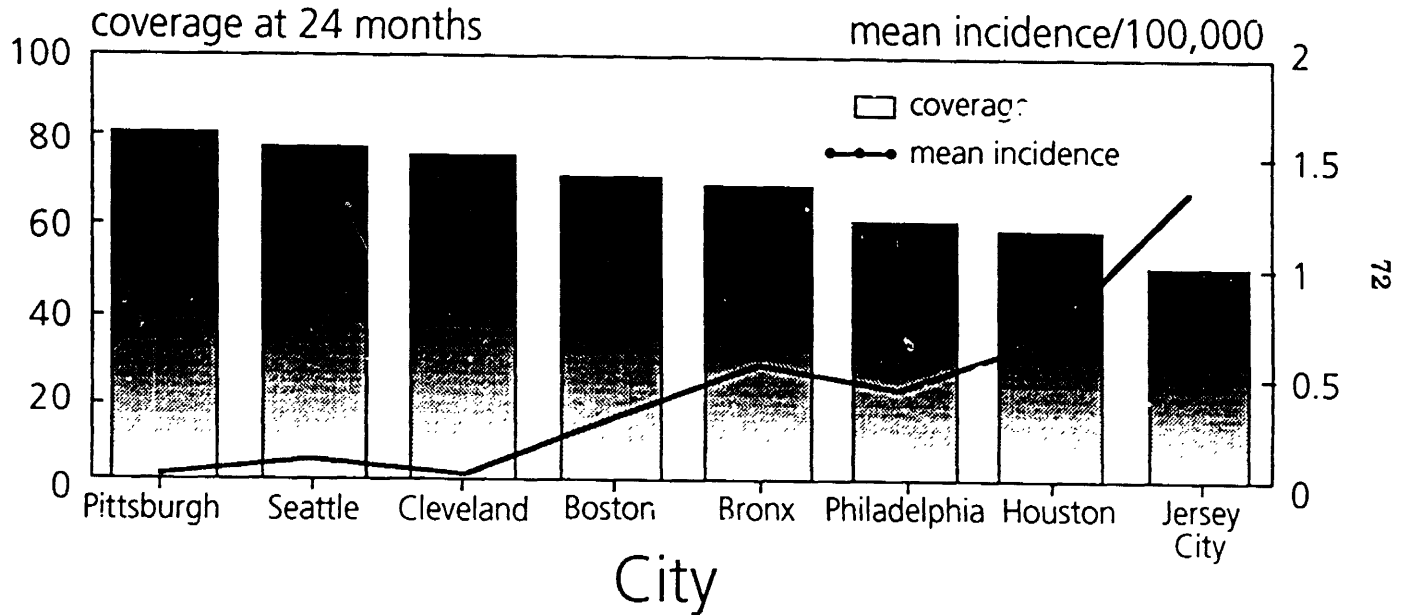
Pertussis Incidence per 100,000 People

Year 1990

<u>State Vaccine Payment System</u>	<u>Population</u>	<u>Pertussis Cases</u>	<u>Rate per 100,000</u>
All "Universal Distribution" States	37,541,187	1,040	2.77
All "Fee-for-service" States	158,508,905	2,643	1.67
All "Replacement Vaccine" States	49,003,663	810	1.65
National Total	245,053,645	4,493	1.85

Source: *MMWR*

Measles Vaccine Coverage at 24 Months* and Mean Measles Incidence 1980-89



*based on retrospective survey of first grade students immunization records in inner-city public schools, sample chosen by Immunization Projects, not randomly selected.

STATEMENT OF THE CONNAUGHT LABORATORIES, INC.

Connaught Laboratories, Inc. appreciates the opportunity to offer its comments to the Subcommittee on Health for Families and the Uninsured of the Senate Committee on Finance regarding S. 2116, the Comprehensive Child Health Immunization Act.

Connaught's principal focus is pediatric vaccines. In December 1989, Connaught Laboratories became part of the family of Institut Merieux of Lyon, France. This acquisition, coupled with Merieux's merger with Pasteur Vaccins, established Connaught as a member of the world's largest company dedicated to the development of vaccines and biologicals. Pasteur Merieux Connaught represents the largest private effort in basic vaccine research and development in the world, and Connaught provides the broadest range of vaccines and biologicals commercially available in the United States from a single company. We have a significant research program for new and improved vaccines, which will be discussed further, and we develop and distribute vaccines against childhood diseases such as diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b, among others. We are a major provider to both the public and private sectors and, in fact, are one of only two U.S. companies that continued to distribute DTP in the 1980's during the liability crisis.

Connaught's focus in the pediatric vaccines arena provides us with a unique vantage point on the immunization program in the U.S. While significant strides have been made in pediatric immunization, we all agree that the program in this country has some problems. These include limited access to and low utilization of vaccination services, which have led to depressed immunization levels and to outbreaks of preventable diseases in this country.

Pediatric immunization is one of the most important and valuable elements of our nation's public and private health care systems. Every study on the subject has shown that the costs associated with treating preventable childhood diseases are far greater than the costs associated with immunizing against them. For example, a CDC study showed that \$180 million spent on measles vaccinations reduced the incidence of acquired hearing impairment and mental retardation, thereby saving \$1.3 billion in acute and long-term medical care—more than sevenfold the cost of prevention.

The great strides that have been made in providing immunization are the successful result of a longstanding partnership between the public and private sectors. The goals of that partnership have been, and continue to be, to protect against as many illnesses as possible in the greatest number of children possible. We can achieve that goal only if we continue to aggressively research and develop new and improved vaccines, maintain a reliable source of supply and effectively distribute these vaccines to a growing and increasingly vulnerable population.

Perhaps the most significant area to which we have committed resources is in the development of combination vaccines, which would protect against a number of diseases in a single immunization. These vaccines may become the most significant weapon in the arsenal to achieve full immunization. Such vaccines have been a long-time goal of the public health community. They will involve fewer injections and fewer visits to health care offices, and should lessen demand on immunization providers, as well as encourage increased compliance. We are also working on improved delivery systems, such as vaccines taken orally, which are preferable to injections. They will preclude the need for syringes, for example, and will be easier on both parent and child. This, too, is expected to ease the burden of service suppliers and increase compliance. In addition, research is currently underway on time-release vaccines.

While we currently have most of the antigens in single administration vaccines, combining them into one is not a simple matter. The development of combination vaccines is a demanding process because of the need to ensure that no adverse reactions occur as a consequence of combining, that the vaccines are at least equally effective as when administered separately and that the vaccines are compatible and stable in the mixture. Arriving at the ideal combination of preservatives and adjuvants also presents a difficult problem, as the preservative can destroy the vaccine and each protein reacts differently to each adjuvant. The end result must be a safe, effective, non-reactive, stable, compatible mixture of antigen, preservative and adjuvant.

The public and private sectors each play important roles in vaccine research and development. There are three sources of basic research—industry, academia and the government—and interplay among the three is critical for optimal innovation. There are many examples of how collaboration among these groups has resulted in new vaccines and we would like to mention just a few. The first example is the develop-

ment of the vaccine for *Haemophilus influenzae* type b. Carrier-hapten technology was first discovered by an academician, but for years no one understood how to use it. It took the work of industry to develop the first application, which resulted in the first conjugate vaccine and protected against *Haemophilus* disease, which was developed by Connaught. The role of government in this enterprise was significant, as well, for it was the NIH that sponsored one of the clinical trials. The vaccine for hepatitis B began with basic research from university scientists, after which industry developed an applied form, which was later improved—again by industry—through recombinant technology. Acellular vaccines come out of the collaboration of academia and industry particular to Japan, and have been further adapted by industry here for the U.S. population. Thus, we see that cooperation among the three sectors benefits the overall enterprise—from basic research, to vaccine development and, ultimately, in bringing products to market. While the NIH serves the important functions of basic research and administration of clinical trials, it is not the role of that body to bring vaccines to market. Traditionally, the vaccine industry has been the source of commercialization of basic research, whether discovery occurs in academia, at the NIH or from industry research. These efforts in research and development, represent a continuous, complex process with a goal of broadening the reach of immunization, refining existing vaccines to improve efficacy and simplifying their administration. The promise that these developments hold, however, may take longer to become a reality—if they are to become a reality at all—if research and development efforts are threatened.

One approach that has been proposed to address the issue of low immunization rates is universal purchase. Although well-intended, universal purchase is a dangerously short-sighted proposal. Furthermore it is not necessary. In fact, in those states that have tried universal purchase, immunization rates appear to be no better than in states that have not. It also diverts attention from more critical barriers to immunization.

I urge you to consider three important objectives—(1) guaranteed supply, (2) at a reasonable price, (3) in an atmosphere that fosters innovation. The delicate balance of maintaining these objectives will be critically affected by universal purchase, which could ultimately jeopardize any real possibility of achieving universal immunization. The goal of guaranteeing a stable source of supply was achieved after much effort, thanks to a public/private partnership that supported the Vaccine Injury Compensation Act of 1986. Universal purchase, would undermine the stability that we've worked 10 years to achieve.

Data compiled by the Centers for Disease Control show that the primary barrier to expanded immunization is access, not cost. Each year an adequate supply of vaccine is purchased to fully immunize all children. Where the system fails is in getting vaccines to children and children to vaccines. The provision of the same number or even more doses of vaccine at a lower cost will not solve the problem of delivery, particularly in light of the fact that the cost of the vaccine itself is a relatively small part of the overall cost of immunization programs.

It is very clear, however, that a dramatic reduction in the revenues realized by the companies developing and manufacturing vaccines (by selling all vaccines at CDC contract prices) would essentially eliminate the required resources—and the incentives—for private-sector vaccine research and development. Continued stability of the industry will be jeopardized if the distribution of CDC-purchased vaccines is expanded to cover other than those in need. Our company currently has several contracts with the CDC in which we discount our prices heavily. We are not unwilling to help further in expanding the public sector to ensure that all those in need receive vaccines. Our ability to do that is, however, supported by revenues we receive from the private sector. With universal purchase, the support for the public sector that is provided by the private sector would be eliminated. Thus, universal purchase would ultimately result in higher pricing of vaccines.

Competition among manufacturers would be reduced as well, as individual producers would be unable to maintain personnel and the capacity to produce specific vaccines in those years in which they do not win government contracts. The manufacturer who failed to win government contracts would be under great pressure to curtail operations or, at worst, be forced out of business. This would directly impact our stable vaccine supply. Price increases would be inevitable—a further drain on government funds.

Using CDC-purchased vaccines to immunize the needy is a concept that vaccine developers have long supported. However, we believe it would be imprudent to devote scarce federal and state government resources to pay for vaccines for those who can afford them.

The nation's childhood immunization system can be improved, but not at the expense of destroying a key partner—industry. The principal problem is low immuni-

zation rates. This must be met through a workable balance of public and private initiatives.

There are a number of solutions proposed within the Comprehensive Child Health Immunization Act, that we believe would move the nation toward ensuring that all children are adequately immunized.

We support the objective of linking the various programs for child and maternal health to maximize opportunities to identify children who need immunizations, and to provide them. We are particularly interested in utilizing WIC sites as points of screening.

We fully support the development of a nationwide computerized tracking system and registry to assess children's immunization status. The development and implementation of such a system on a national basis would be a significant step toward achieving immunization goals.

We believe that general media efforts as well as outreach programs are potentially valuable. We believe that providers should inform parents about the benefits and risks of immunization with a variety of materials. We feel that some of the currently mandated federal material will prove cumbersome and difficult for the target population to read and understand. In that regard, it is conceivable that some of this educational material may prove to be a deterrent rather than an enhancement to immunization efforts. There are many organizations, as well as vaccine developers, that have produced, or are in the process of producing, educational materials. Therefore, it is probable that a great deal of duplication of effort is taking place.

We support the goal to create incentives that enable all children to receive ongoing, comprehensive health care, including routine vaccination, from private providers. We are supportive of the concept that all public and private third-party payers should reimburse immunization providers adequately for the cost of immunization. Currently, many private physicians refer Medicaid-eligible children to the public system for immunization and other health care in part due to Medicaid's low reimbursement rates. A key to solving this problem is to provide adequate reimbursement for the costs of both the vaccine and administrative fees. We should encourage private insurance companies to join this subcommittee's efforts to expand access by providing reimbursement for preventive measures, particularly for immunizing children. Insurance coverage should recognize the very favorable cost benefits of vaccines.

As we discussed previously in our critique of the concept of universal purchase, using CDC-purchased or priced vaccines to immunize the needy is a concept that vaccine developers have long supported. If the distribution of CDC-purchased or priced vaccines were to expand to cover other than those in need, reduced competition, higher prices and no new vaccine development of improvements would result. In turn, efforts to immunize all children will suffer. Therefore, we would want any vaccine replacement systems to be capable of verifying and accounting for the Medicaid eligibility of their beneficiaries.

We think these solutions will go a long way toward solving systematic barriers of access to immunization.

We agree with the intent of S. 2116 the Comprehensive Child Health Immunization Act—to improve the health of children by increasing access to childhood immunizations, and we appreciate this opportunity to provide our thoughts on the very important matter of assuring that our nation's children are protected against vaccine-preventable diseases.

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