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S. Hrg. 103–169

COMPREHENSIVE CHILD IMMUNIZATION ACT OF 1993

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Comprehensive Child Immunization Ac...

' HEARING

BEFORE THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

AND THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

TO PROVIDE FOR THE IMMUNIZATION OF ALL CHILDREN IN THE UNITED STATES AGAINST VACCINE-PREVENTABLE DISEASES, AND FOR OTHER PURPOSES

APRIL 21, 1993

Serial No. 103–23
Committee on Energy and Commerce

Printed for the use of the Committee on Labor and Human Resources and the House Committee on Energy and Commerce

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COMPREHENSIVE CHILD IMMUNIZATION ACT OF 1993

WEDNESDAY, APRIL 21, 1993

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
AND
U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
OF THE COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The joint committees met, pursuant to notice, at 10:08 a.m., in room SDG–50, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the committee) and Hon. Henry A. Waxman (chairman of the subcommittee) presiding.

Present: Senators Kennedy, Pell, Metzenbaum, Dodd, Mikulski, Wellstone, Wofford, Kassebaum, Jeffords, Gregg, and Durenberger; Representatives Waxman, Synar, Wyden, Bryant, Rowland, Towns, Slattery, Brown, Kreidler, Bliley, Upton, Klug, Franks, and Greenwood.

Also Present: Senator Riegle and Representative Louise Slaughter.

OPENING STATEMENT OF REPRESENTATIVE WAXMAN

Mr. WAXMAN. The meeting will come to order. I have a few organizational comments before we begin.

We all know that this is the first joint hearing between the Labor Committee and the Health Subcommittee in a long time, and I am sure there are going to be some confusing moments of procedure.

First, in the interest of time, I would ask all members to keep their opening statements brief. I would also ask that all members limit their first round of questions to five minutes and seek a second round only if there are pressing issues that have not been explored.

We will try to alternate questions between majority and minority and between House and Senate, and I apologize in advance if this gets to be awkward, and it certainly will be awkward.

Second, I would ask witnesses to keep their oral remarks to five minutes. Your written statements will be included in the record in full.

I'd like to start off with an opening statement.

Today's hearing is on childhood immunization and the President's proposals for improving immunization rates. This is the right place to start. In this area, as in all parts of the health re-

form debate, an ounce of prevention is worth more than a pound of cure.

For years, the Federal Government has short-changed this program. Clinics are inaccessible and have hours that are difficult for working parents. There are fewer school nurses and public health workers. Public information efforts have been trimmed simply to leave funds for buying vaccine. The result has been immunization rates as low as 37 percent in preschoolers.

At the same time, the American family has had to pay more and more to vaccinate their children against disease. While much of the price increase in recent years has been from new vaccines and for the compensation program, the end result for the family is the same. They have to dig deeper to pay for basic protection.

With this proposal, President Clinton has also set the tone for health reform, emphasizing preventing illness before it occurs and emphasizing access for all Americans. This is good for each child, and it is good for the Nation. It has been too long that the Federal Government has been penny-wise and dollar-foolish in dealing with health care. We cannot allow children to die from diseases that should never occur, and we cannot afford to treat children for crippling conditions that we can prevent. This proposal starts to rebuild American health care from prevention up, and I look forward to working together to begin.

Senator Kennedy.

Opening Statement of Senator Kennedy

The Chairman. Thank you very much, Congressman Waxman.

I just want to express on behalf of our colleagues here in the Senate how much we appreciate the opportunity to work with an administration as concerned about the issues of immunization as this administration is, and to work closely with the House of Representatives.

Today, we will hear from the Secretary and many other witnesses. This legislation requires the cooperation of a variety of different committees. What we are trying to do in public policy is to bring everyone involved together to really benefit the children in this country.

So I would express all of our appreciation to our colleagues, and as Henry Waxman has pointed out, we are going to try to accommodate each of their interests, but do it in a way that will permit even our last witnesses the opportunity for a full and fair hearing.

I think all of us want to ensure that every child in this country receives their immunizations. I applaud President Clinton for outlining this as one of his top priorities in achieving a national health insurance program. Rather than waiting for the actions here in the Senate and the Congress that many of us hope will come later this year, he has put the issue of childhood immunization first, out front. Let's get all Americans and all parties behind this program to ensure that vital vaccines, which can make such a difference in terms of a healthy child, are purchased at the lowest possible price while recognizing that drug companies need incentives to be able to go forward in terms of additional research for new types of vaccines. Getting vaccine at the lowest possible price and removing financial barriers is only part of the puzzle. What we need is a pub-

lic health system that reaches out to children and ensures that they are going to actually be immunized, and then second, that the appropriate kinds of follow-up is available for parents to make sure that their children are going to have follow-up shots in a timely manner. We have follow-up information, as all of us know, in a variety of different other areas of public policy; why not for children?

I believe we have in this particular proposal a comprehensive immunization program that can really meet the needs of millions of families. I think most parents understand the importance of immunizations. Some have difficulty with language barriers, many have difficulty with transportation, and many others do not understand that if a child is sick or maybe has a sniffle that this need not delay receiving immunizations. We need to address all these considerations through a sound, comprehensive public policy approach. This legislation does it, and I am very hopeful that we'll have early consideration of it this year. We will certainly do so in the Senate Labor Committee and hopefully in the other committees as well.

[The prepared statement of Senator Kennedy follows:]

Prepared Statement of Senator Kennedy

Today we open hearings on Président Clinton's bold and far-reaching initiative on health care for children—universal childhood immunization.

I am pleased that the Senate Labor Committee's first joint hearing with the House Subcommittee has childhood immunization as the topic. Senator Riegle and Senator Bumpers join us from the Finance Committee and the Appropriations Committee in the Senate, and they deserve great credit for their leadership on this issue.

For many years, we have paid lip service to the goal of immunization but failed to achieve it. To a large extent that failure is the failure of governments at every level to fulfill their public health responsibility.

Now, faced with the festering problem of unacceptably low preschool immunization rates, the time has come to develop a new approach to protect children from preventable diseases.

With the leadership of the Clinton Administration, a comprehensive approach is within reach, and can become a reality for all children in every community in America.

We know the many barriers to immunization. We know that overcoming them presents a complex challenge. There is no simple answer or magic bullet. What is needed is a sustained national commitment to removing these barriers as effectively and as rapidly as we can.

Health insurance coverage of vaccinations is one important step. Yet insurance alone is not sufficient. Even among major HMOs where vaccination is fully covered, immunization rates have fallen below 60 percent. In some States, the key to greater margins has been a vaccine distribution program for all providers. Those States have a higher rate of immunization, but they too fall short of the national goal of a 90 percent rate for all 2-year olds.

We have seen other successes in communities with public health education and free vaccination programs. But these successes are hard to maintain without adequate resources.

The role of public health workers has steadily eroded, as more and more children come to understaffed clinics. Working parents and parents without transportation find it difficult to obtain these services, even though their children are at growing risk for unnecessary illness.

We know from the experiences of recent years that a half-hearted approach will not work. President Clinton's proposal gives us a real chance to break through barriers that exist, and I look forward to today's hearings and early action by Congress on this worthwhile and long overdue initiative.

The CHAIRMAN. I recognize Senator Kassebaum.

OPENING STATEMENT OF SENATOR KASSEBAUM

Senator KASSEBAUM. Chairmen, it is a pleasure to have this joint committee hearing, because I think it indicates the importance of the problem that we face with the low rate of early childhood immunization. I, too, commend President Clinton for the national attention that he has focused on this compelling problem and for sending us a strategy with which to deal with it.

However, I am concerned that the centerpiece of the President's plan, an over $1 billion yearly program for the Federal purchase and free distribution of all vaccines, misdiagnosis the causes of the problems and prescribes a remedy that is likely to be ineffective and perhaps wasteful. And I think that the importance of these hearings is to try to analyze that and to try to put together some constructive alternatives. I think that the President's plan, based on the premise of the rising cost of vaccines as the major reason for low immunization rates, is misdirected. While cost is a factor, there are other factors, and Senator Kennedy addressed some of those as he spoke.

Mr. Chairman, there are many comments to be made and important witnesses to hear from, so I would like to ask unanimous consent that my full statement be made a part of the record.

The CHAIRMAN. Without objection, so ordered.

[The prepared statement of Senator Kassebaum follows:]

PREPARED STATEMENT OF SENATOR KASSEBAUM

Messrs. Chairmen, today's hearing on strategies to improve our Nation's low rates of early childhood immunization may be one of the most important we hold in this Congress.

The measles epidemic that swept across our Nation in 1989 and 1990 and outbreaks of other preventable diseases reveal that our Nation's children are again at risk for devastating childhood diseases which we thought we were conquering. Fewer than 60 percent of 2-year olds in most States—and in some inner-city areas as few as 10 percent of 2-year olds—are fully immunized against childhood diseases.

President Clinton is to be commended for the national attention he has focused on this compelling problem and for sending us a strategy for solving it.

Messrs. Chairmen, I am deeply concerned about our Nation's low immunization rates. I share the President's and your own strong commitment to ensuring that every child is fully immunized on

schedule. As you may know, I have been working with several of my colleagues on a strategy for achieving this goal, and we hope to introduce our plan in the near future. In developing this strategy, my staff and I have studied reports on the causes of the problem and recommendations for addressing it and have conferred with public health officials in my own State of Kansas and in other States.

Frankly, I am concerned that the centerpiece of the President's plan—an over $1 billion a year program for the Federal purchase and free distribution of vaccines—misdiagnoses the causes of the problem and prescribes a remedy likely to be ineffective and wasteful of scarce taxpayer dollars.

The President's plan is based on the premise that the rising cost of vaccines is the major cause of our low immunization rates. But that is not the case. I agree that the cost of vaccines may be one facet of the problem for some parents. But the National Vaccine Advisory Committee, former Surgeon General Koop, and most public health officials across the Nation find that the major causes of low immunization rates are the lack of parental education about the continued importance of immunizing their children, the failure of health professionals to use every opportunity to vaccinate children, our overburdened public health clinics where immunization services are not readily accessible, and the lack of private physician participation in Medicaid due to unreasonably low Medicaid reimbursement rates.

If we are to achieve the goal of appropriately immunizing every child, these are the problems on which we should be focusing.

With the proposed $1 billion the President would allocate to the Federal purchase and distribution of free vaccines, we could triple the number of community health clinics operating in the United States. We could substantially increase the number of children eligible for immunizations under Medicaid and improve payment rates to encourage private physicians to participate in that program. With this same $1 billion, we could launch intensive outreach programs and put immunization clinics at our WIC sites.

My own State of Kansas, for example, is launching "Operation Immunize" this weekend, a massive immunization education and outreach program. The Department of Health, working closely with health care providers, businesses, the National Guard, and thousands of volunteers, will offer immunization services at over 200 sites across the State. Services will be provided in malls, in trailer parks, and from mobile vans in rural communities. Voluntary advertising campaigns by Kansas businesses are blitzing Kansans with information on the importance of immunizations and where to go for services.

Messrs. Chairmen, in addition the serious reservations I have about the public health effectiveness of the President's universal vaccine purchase and free distribution plan, I am also concerned about the impact of this program on incentives and resources for the development of new and improved vaccines.

I recognize that the administration plan proposes to take research and development costs into account in determining the Federal purchase price for vaccines. However, our experience with other Federal entitlement programs calls into question the reliabil-

ity of that commitment. The Medicaid program provides a pointed example. The Medicaid statute requires States to establish reasonable reimbursement rates to ensure provider participation. The Secretary of HHS can enforce this requirement by failing to approve proposed State Medicaid plans until they are modified to include reasonable rates. But this requirement is not enforced, and unreasonably low Medicaid reimbursement rates are one of the root causes of low childhood immunization rates.

The second major component of the President's plan—in addition to universal purchase—is a national vaccine tracking and surveillance system. This is intriguing in its potential to help the States identify and reach out to unvaccinated children and to improve the data base we use to measure our progress toward the goal of universal immunization. I will be interested today in learning more about how such a system would be structured and would work.

I do want to note that several public health officials have raised questions about the plan's cost-effectiveness in States that already have relatively high rates of immunization. They have also raised concerns about how the privacy of sensitive medical records can be maintained. I hope that we can also focus on these issues today.

Again, Mr. Chairmen, I share the President's and your own commitment to ensuring that every child is appropriately immunized. I want to work closely with you and with the President to ensure that the strategy we adopt to achieve that goal is grounded in sound public health policy and the wise and efficient use of our scarce Federal resources.

The CHAIRMAN. Senator Riegle, on the Finance Committee, has been a real leader in this area in the Senate along with Senator Bumpers, but Don has been instrumental in the fashioning of the legislation.

Senator Riegle.

STATEMENT OF THE HONORABLE DONALD W. RIEGLE, JR., A U.S. SENATOR FROM THE STATE OF MICHIGAN

Senator RIEGLE. Thank you, Senator Kennedy and Chairman Waxman as well.

Let me just say at the outset how much I appreciate the leadership of Secretary of Health and Human Services, Donna Shalala, for stepping forward on this issue and also the President and the First Lady.

Children in our country have really not had strong advocates in their behalf at the highest levels of our government for some time, and that has changed. We are talking about children in the country who are going today without vaccinations. Our country ranks among the lowest of countries around the world in the failure to get our children vaccinated by the age of 2, and many, of course, end up being vaccinated by the time they go to school, but there is a gap in time where they are susceptible to diseases, and they are hit by diseases, and that is really not acceptable in our country, and it is very expensive as well.

So the legislation that we have here really falls between two committees—the Senate Labor Committee under Senator Kennedy, and part of it under the Finance Committee and the Subcommittee on Health for Families and the Uninsured, which I chair. We will

be having hearings in the Senate Finance Committee in May on this issue.

But with respect to the universal purchase and distribution, we now have 11 States that have some kind of a universal purchase program. This is not a new idea. This is an idea that several States have decided makes sense, including even in my home State of Michigan, where we produce and distribute the DTP vaccine free to all providers, and as a result, there has been a sharp increase in the number of doctors who in fact provide these shots to children who come in and need them.

One of the problems we face—and I talked with one family in this situation in Grand Rapids, MI, where they have four younger children, they do not have health insurance that provides vaccinations, and they go to a private physician—the cost of the vaccines has become very expensive, and they can't afford them any longer through that channel, so they must go to a public health clinic. It is impossible to make a scheduled appointment there. It takes a great deal of time, and for working families that is often not a practical route. And many of our children are not getting vaccinated, and they are out there, susceptible to these diseases, not only to catching them themselves, but passing them on to others.

So I want to insert for the record a list of 70 national organizations, Chairman Kennedy, that have come forward to endorse this plan and to say that in the end, what we are trying to do here is to get the cost down to the lowest possible level and to do so consistent with providing a fair return, a fair profit for research and development and for earning a return on the investment to the vaccine manufacturers. That is built in here.

But having said that, the job now is to see to it that we are providing the basic medical protection to our children that they must have; that is really the purpose of having a civilized Nation and a Federal Government, in conjunction with the State and local units of government, to see that this is done.

The children have been waiting for this for a long time, and they shouldn't have to wait any longer, so I am very anxious to see this enacted.

Thank you, Mr. Chairman.

[The prepared statement and information of Senator Riegle follows:]

PREPARED STATEMENT OF SENATOR RIEGLE

This hearing is in the true spirit of cooperation and I am very pleased to co-chair it with Senator Kennedy and Congressman Waxman. S. 732 and S. 733, bills Senator Kennedy and I introduced, together represent President Clinton's immunization initiative. S. 733, which has been referred to the Finance Committee, establishes a central bulk purchasing program for all vaccines, restores the excise tax for the injury compensation trust fund which expired in October 1992 and makes improvements to the Medicaid program. The Finance Subcommittee on Health for Families and the Uninsured that I chair will hold a hearing in early May to further explore these areas.

The bills that we introduced, together with the $300 million in the economic stimulus package, are a comprehensive plan to make sure every child is immunized by age 2.

The United States ranks 103rd among 130 nations of all levels of development in immunizing its 1-year-olds. We only immunize 48 percent of our 1-year-olds. Countries such as Cuba (93 percent), Bulgaria (99 percent), and Honduras (76 percent) all have better immunization rates of their young children than the United

States has. In 1992, over one-third of Michigan's children (or 160,000 children) did not receive their full set of vaccinations by their second birthday.

I have been working on this issue for many years. Senator Kennedy and I had been working on a bill since December last year based on a bill I first introduced in November 1991.

Many children who go to private physicians are being referred to public clinics for immunizations because of the high cost of vaccines, creating missed opportunities. Public clinics generally receive vaccines for free and charge a nominal amount, if any at all, for administering vaccines. The Academy of Pediatrics found that over 50 percent of pediatricians refer patients for immunizations. Many of our public clinics are extremely overburdened and we will hear about one of these clinics today, from Dr. Dean Sienko of the Ingham County Health Department in Michigan.

Let me give an example that illustrates why this is a problem:

A middle-income couple in Grand Rapids, MI, have 4 young children under 7 years old. The family has private insurance through the husband's employer but it does not cover immunizations. The mother used to take her 4 children to their private doctor for immunizations, but it took the family 3 to 4 months to pay off the costs of these visits and it became too much of a financial burden.

About a year ago, the mother began taking her children to the local health department for their immunizations since the health department did not charge for most vaccinations. The health department, however, does not make appointments and works on a first come, first serve basis. The youngest child in the family is 9 months old and requires several vaccinations a year. This means several times a year the family must wait up to 2½ hours in the health department for the immunizations. This major inconvenience acts as a significant barrier to immunizing children.

A universal purchase program decreases missed opportunities to reach more children by making vaccines available and free to providers for any child who needs care for any reason. It will encourage private doctors to immunize children in their offices, rather than refer them to already burdened public clinics.

A universal purchase program eliminates a major cost barrier—cost now varies from $114 for a full set of vaccinations in the public sector to over $230 in the private sector. Eleven States have some type of universal purchase programs and these programs have made vaccines more affordable and increased the rate of private doctors who deliver vaccinations. Michigan produces and distributes the DTP vaccine free to all providers—there has been an increase in private doctors providing DTP due to this.

I understand the concern that setting too low a price could discourage vaccine research and development. That's why we specify that the negotiated price would include costs for research and development as well as a fair rate.

Children can't look out for themselves, we have to look out for them. By getting vaccinations to kids by the time they are two, we meet an important public need. And we save $10 in future health care costs for every $1 we spend now on immunizations. This program will improve the health of our people while bringing health care costs under control.

National immunization week begins on April 24 and runs through April 30 and I urge everyone to join me in bringing attention to the need for vaccinations. I will continue to travel throughout Michigan seeking the views of advocates, parents, and providers. I commend the Clinton administration for their efforts on this issue. I ask unanimous consent that a statement of 70 groups who support the plan be included in today's record.

STATEMENT OF SUPPORT FOR THE COMPREHENSIVE CHILD IMMUNIZATION ACT OF 1993

We, the undersigned organizations, applaud President Clinton's initiative to protect all of America's children against preventable diseases. It is unacceptable that almost half of our Nation's preschoolers are not fully immunized. The Nation's shameful immunization record is a testament to the need for comprehensive health care reform to guarantee comprehensive health care coverage for all Americans. This legislation is an important step toward that goal.

The President's initiative will guarantee that no child will go unimmunized because his or her family cannot afford the shot. It is unacceptable that 40 percent of American preschoolers are not fully immunized when each dollar invested in immunizations saves our society more than $10 in health care costs by preventing disease and disability. This legislation will also create a national immunization registry to follow the vaccination status of individual children. The registry will provide reminder notices to families for their children's shots and identify communities with low coverage rates for outreach and public education. The Act will also improve

Medicaid coverage of immunizations for low-income children, and reauthorize the National Vaccine Injury Compensation Program.

The organizations are:

Action for Families and Children of Delaware; Advocates for Children and Youth; American Academy of Family Physicians; American Association of University Affiliated Programs for Persons with Developmental Disabilities; American College of Nurse-Midwives; American Dental Association; American Federation of State, County, and Municipal Employees; American Federation of Teachers; American Hospital Association; American Indian Health Care Association; American Public Health Association; American School Health Association; American Speech-Language-Hearing Association; The ARC (formerly the Association of Retarded Citizens); Association for Supervision and Curriculum Development (ASCD); Association for the Care of Children's Health; Association of Junior Leagues International; Association of Maternal and Child Health Programs; Association of Schools of Public Health (ASPH); Association of State and Territorial Health Officers; Bridgeport Child Advocacy Coalition; Catholic Charities, USA; Child Welfare League of America; Children Now; Children's Advocacy Institute (California); The Children's Alliance, Seattle, WA; The Children's Council of San Francisco; Children's Defense Fund; The Children's Foundation; Children's Health Fund; Children's Policy Institute of West Virginia; Citizens for Missouri's Children; Colorado Children's Campaign; Community Services, Inc. (Head Start); Consumers Union; Florida Children's Forum; Friends Committee on National Legislation; Georgia Alliance for Children; Hadassah, the Women's Zionist Organization of America; Hawaii Advocates for Children and Youth; Human Development Center of Mississippi; Interfaith Impact for Justice and Peace; Jesuit Social Ministries, National Office; Lutheran Office of Governmental Affairs (ELCA); March of Dimes Birth Defects Foundation; Maryland Committee for Children; Massachusetts Committee for Children and Youth; Michigan Head Start Child Development Association; Michigan League for Human Services; Mid-Michigan District Health Department; Mississippi Human Services Agenda; Missouri Valley Human Resource Head Start; National Association for the Education of Young Children; National Association of Children's Hospitals and Related Institutions; National Association of Community Action Agencies; National Association of Community Health Centers; National Association of Developmental Disabilities Councils; National Association of Partners in Education, Inc. (NAPE); National Association of WIC Directors; National Black Child Development Institute, Inc.; National Black Nurses Association; National Community Education Association (NCEA); National Easter Seal Society; National Indian Education Association; National PTA; National Parent Network on Disabilities; New Hampshire Alliance for Children and Youth; North Carolina Child Advocacy Institute; Office of Domestic Social Development, U.S. Catholic Conference; Pennsylvania Head Start Staff Association; Pennsylvania Partnerships for Children; Philadelphia Citizens for Children and Youth; Planned Parenthood Federation of America; Results, Inc.; San Francisco Child Abuse Council; Service Employees International Union; Statewide Youth Advocacy, Inc.; Sudden Infant Death Syndrome Alliance (SIDS Alliance); Unitarian Universalist Association of Congregations; United Auto Workers of America; United Cerebral Palsy Associations; United Educators of San Francisco; The Children's Council of San Francisco; the Vaccine Project; Vermont Children's Forum; Virginia Perinatal Association; Wisconsin Council on Children and Families, Inc.; Women's Legal Defense Fund; and Zero to Three/National Center for Clinical Infant Programs.

Mr. WAXMAN. Thank you, Senator Riegle.

I want to recognize Mr. Greenwood to make an opening statement.

OPENING STATEMENT OF REPRESENTATIVE GREENWOOD

Mr. GREENWOOD. Thank you, Chairman Waxman and Chairman Kennedy.

I am pleased to be here today to hear the testimony of our distinguished witnesses on the issue of childhood immunization. I am the father of four children, so I am well aware that immunizations are among the most vital and cost-effective medical interventions available.

I am also a former Pennsylvania legislator, so I know that we really do have to do a better job of immunizing our children.

It is interesting to note that over 95 percent of children are immunized before entering school, so it appears that requiring immunizations is effective and that if parents are required to do this, they will.

Unfortunately, we know that fewer than 50 percent of children are completely immunized by their second birthday, and that this rate is unacceptable.

This hearing gives us the opportunity to discuss some important policy questions. What is the most effective way to make sure that the children are vaccinated and to ensure their health? Is it cost-effective to give free immunizations to individuals who can afford to purchase vaccines for their children, or does doing that add unnecessarily to the cost of the program? Does this target our limited resources wisely? What responsibilities do parents have in ensuring that their children receive proper vaccinations, and what is the role of our health care providers?

Eleven States currently provide free vaccines to all children. What has their experience shown? Have the intended beneficiaries been reached in this manner? Can some type of public-private partnership be developed to reach this goal? Is the rate of childhood immunization in fact directly related to the cost of the vaccine? How will universal purchase by the Federal Government impact vaccine development and innovation?

I appreciate the opportunity to participate in this important hearing and look forward to participating in a constructive dialogue with all of our witnesses.

Thank you, Mr. Chairman.

Mr. WAXMAN. Senator Kennedy and members of our committees, I want to recognize a House member next who is not even a member of either or any of the committees of jurisdiction on this question, but she has been invited to sit with us this morning because this legislation is very much modelled on the legislation that she introduced to deal with this immunization program.

I am delighted to have her with us and to work with her on this important program—the gentlelady from the State of New York, Ms. Slaughter.

OPENING STATEMENT OF REPRESENTATIVE SLAUGHTER

Ms. SLAUGHTER. I thank you very much, Chairman Waxman and Chairman Kennedy and appreciate very much your letting me be here this morning.

As you just mentioned, for 2 years, I have worked on this legislation, and I want to say it was a very proud moment for me when, earlier this month, I could stand next to Secretary Shalala, Senator Kennedy, Chairman Waxman and other leaders and talk about the President's initiative to vaccinate America's children.

At hearings like this one, we can easily become mired in hypotheticals and hyperbole, muddying the facts and losing sight of our objective. So I would like to begin with simple facts.

The first one is that fewer than half of America's preschoolers are immunized against routine childhood diseases—that is less than one-half—a vaccination rate that is only marginally better than that achieved in Bolivia and Haiti.

The cost to a single parent now to get the necessary vaccines for a child can range from $250 a year to $500 a year. A single parent, often struggling to put food on the table and a roof over their heads, finds it difficult to pay up to $1,500 a year to vaccinate one's children before they must be vaccinated at school age; so we have the spectacle of some mothers or fathers having to decide which of their children are probably the strongest and can make it through the next year without vaccines.

The fact is that 70 percent of the Nation's community health centers where vaccines are offered free-of-charge have reported vaccine shortages in their clinics. It is a fact that in 1981, when the government opted out of vaccinating our children, we had the highest rate in the world of compliance, and when we decided to opt out of it, we also gave up the education process that is so necessary to make sure that children are protected.

Between 1981 and 1991, the price of a single dose of DTP rose from 33 cents to $10, an almost 3,000 percent increase. Between 1981 and 1991, profits in the pharmaceutical industry have increased by 400 percent, while in comparison, the manufacturing sector had a 33 percent decrease.

But the tragic bottom line is this. Measles, pertussis and rubella cases are on the rise, leaving young, unvaccinated children sick, disabled or dead, and devastating thousands of American families.

That is what we have to remember during this morning's hearing—we are here today for the children. Their health and their welfare is our only objective. Politics and profit margins aside, the young children of America must be our only concern.

The bill that was introduced on April 1st by the Clinton Administration will make sure that every, single child in the country under age 2 will be protected from preventable disease. Expecting government to assume the responsibility for public health is not a new idea. When I was growing up in the coal fields of Harlan County, KY, the last thing we did on the last day of school was to line up before the school nurse to get our typhoid shots so we could survive the summer. When I left the University of Kentucky with a bachelor's and master's in microbiology and public health, we were in the golden age of public health, when the government was heavily involved in not only vaccine but education programs.

But somewhere along that line, the focus was lost. We lost sight of the economic common sense that paying for a vaccine is cheaper than paying for a hospital stay, and we lost sight of the simple humanity of trying to prevent suffering and sickness and death among our smallest citizens.

Especially as we have made dramatic breakthroughs in medical research and the development of medical technology, it is unethical that we have been unable to make sure that the American public has access to the fruits of our research, often funded by the public's own tax dollars. It is not too late to reclaim the luster of the golden age of decades past.

Today, we want to make sure that at least in the case of vaccines, our children are guaranteed protection.

I appreciate the active role that Secretary Shalala has played in developing and advancing this legislation, and I am very grateful for the participation of all the witnesses here this morning, espe-

cially public health experts from States where universal programs of purchase have been tested and been successful.

I look forward to the testimony and working to make sure that never again will we see the spectacle of the rise of measles, the onset again of polio and other diseases that we thought had been eradicated but knew that we could control.

Thank you very much.

The CHAIRMAN. Thank you.

Senator Pell.

Senator PELL. I want to get on with hearing the witnesses, so I will desist with no comments, but just congratulate you on holding this hearing.

The CHAIRMAN. Did everyone hear that? Claiborne Pell wants to get on with hearing all of the witnesses.

Senator Metzenbaum.

OPENING STATEMENT OF SENATOR METZENBAUM

Senator METZENBAUM. Mr. Chairman, I am very pleased to participate in this meeting this morning of these two joint committees. I think it is an historic occasion.

But I had to make a decision whether I would come to this hearing this morning or go to an important hearing of the Judiciary Committee on the subject of terrorism. I concluded in my own mind that there is a kind of terrorism that is much more serious than that which we normally talk about, when fewer than 60 percent of the 2-year-olds in this country are vaccinated, when the urban and rural poor are being left by the wayside, forgotten, and not being vaccinated, when Hispanic and black children are being shortchanged of the opportunity to be vaccinated.

And then, I am aware of the fact of the unbelievable increase in costs, which rose more than 1,000 percent, for vaccinations over the past 15 years. The drug companies claim that they have to continue recouping their capital costs. That's just an unbelievable and an incredible statement to make.

I think that the administration's leadership in this effort is one of the most major undertakings the administration is involved in, and I hope to be able to work with Donna Shalala and President and Mrs. Clinton in moving this program forward rapidly, and I certainly will be working with the chairman of this committee and the chairman of the health subcommittee. I think terrorism does exist in America for the children of America, and I am pleased to be here and work with you.

Mr. WAXMAN. Thank you, Senator Metzenbaum.

Mr. Kreidler.

OPENING STATEMENT OF REPRESENTATIVE KREIDLER

Mr. KREIDLER. Thank you, Mr. Chairman and Senator Kennedy, for allowing us to come here and participate in this hearing today on such a notable and commendable program that is being proposed here, dealing with immunization.

Nothing really demonstrates more clearly the failure of public health policy than the return of childhood diseases that many of us thought many years ago had been left behind, as measles, mumps,

whooping cough and rubella epidemics have started to raise their heads over the last decade.

Over half the population of America's infants fail to receive the full series of immunizations that they should be receiving, measles and rubella have seen a 500 percent increase, and whooping cough has more than doubled.

Many of us thought that, by virtue of current and existing immunization programs, the phenomenon of herd immunity would take hold, and these epidemics would never raise their heads again in this country.

There is enough blame to go around in the whole system for what has happened, in our policies, whether it be the prices of vaccine, the inadequate funding of public health clinics, doctors and nurses who don't carry through with vaccination programs, or parents, who perhaps don't care enough to take care of their kids' needs.

We must improve awareness of the need for immunization, and we must make it easier for children to be vaccinated. This speaks strongly to the need for comprehensive reform of our health care system in this country so that we do have the kind of adequate follow-up and recordkeeping that is so necessary.

Last week, I had the opportunity to visit a community care clinic, where one of the nurses told me that as she was immunizing a woman's children, the woman said, "Don't give me any shot record; I'm only going to lose it anyway." Perhaps one of the major shortfalls that we have right now is that we don't have the ability to do the kind of follow-up that is so necessary and that will be a fundamental part, I presume, of what we do in health care reform.

I also want to mention that the universal purchase program in the State of Washington is an example of what should be happening in the entire country. When I served in the State legislature, we enacted laws requiring that children entering the school system had to have their full shots. But that has not worked for infants, because we are still only operating at about 50 percent in the State of Washington.

I am pleased that the committee is going to be able to hear from Dr. Marcuse, who played an active role in our universal purchase program in the State of Washington. He is from Seattle's Children's Hospital.

This is not a perfect bill, and I am certainly willing and eager to hear what people have to say about how we could make it even better and more workable, so that we can achieve the goal of universal access.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Gregg.

OPENING STATEMENT OF SENATOR GREGG

Senator GREGG. Thank you, Senator and Chairman Waxman. I appreciate your having this hearing.

I come at this, I guess, with a little bit of a different perspective. I was president of a polio clinic for many years, and as Governor of the State of New Hampshire, we helped introduce universal distribution of drugs for immunization without any cost. As a State,

we have the highest percentage of 2-year-olds who are vaccinated in the country.

I helped initiate the universal distribution of drugs for immunization without doing it through the public policy of having the government take over the program. In fact, we presently have the non-Federal sector pay for 60 percent of the drugs that are distributed under this program, free, to all the kids in the State of New Hampshire.

Thus, I have great concern about a program which would basically lead to the nationalization of the immunization drug programs in this country, because my concern is that the problem is not going to be resolved by the nationalization of the industry, and I think it will aggravate the problem considerably by taking this course of action.

It will aggravate it because it will significantly reduce the incentive for research, which is absolutely critical to the production of more and even better drugs for immunization. But it will also aggravate it because people will think the problem has been resolved when it hasn't been resolved by creating, with the magic wand approach of government, a program which buys up all the drugs and says now they are free, and they are available. Because the issue isn't the availability of drugs—as much as you'd like to think it is, that is not the issue.

When drugs are available, immunization occurs. That's at the age when kids get into school, when we have 95 percent of the kids being immunized. They are immunized because the drugs are there, they are available, and they are delivered—in order to go to school, you've got to be immunized, so it occurs. So it is not an issue of lack of availability of the drugs or the price of the drugs that is driving the problem.

The problem is driven by the fact that 2- and 3-year-olds are not immunized because parents don't take responsibility to have their kids immunized. And if you aren't willing to accept that premise, then you must reject the numbers that show that when kids hit the school systems when they are required to be immunized, 95 percent of them are immunized.

So the issue is how do we get 2-year-olds immunized, in order to address the question? It is not buying up all the drugs and then claiming that you've resolved the problem in some populist explosion of rhetoric.

I think if you want to address the issue of 2-year-olds and immunizing 2-year-olds, you've got to address parent responsibility, and you've got to address how you integrate those parents who are responsible for their children into a system that requires them to be immunized. And there are a number of instances where parents come into activities which the government has the legitimate right to require of them to take certain actions in order to participate in those activities.

I would take, for example, parents participating in the WIC program, parents participating in AFDC, parents participating in Medicaid, parents who receive tax refunds or receive earned income tax credits. In all these instances, a parent is engaging in benefit from the Federal Government, and in all these instances, if a parent has a 2-year-old, possibly a precondition of obtaining that bene-

fit should be some sort of recognition that the parent has immunized their 2-year-old or participated in obtaining immunization for their 2-year-old and their 3-year-old. And certainly, the cost that would be incurred to do that could be borne by parents of moderate incomes. In fact, I think it is a legitimate request to ask the parents of moderate income to pay $400 to $500 over a 2-year period for immunization—probably significantly less than they pay in car payments or maybe even for their cable television costs. The moderate-income individuals should invest in their children's health care, and the government has no obligation to pick up that cost. If the parents are going to pay for their cable TV, they can pay for their children's immunizations.

And for the low-income parent, yes, the government can pick up that cost, and pick it up without any great burden being put on the government and without any great need to wipe out the incentive of the drug industries to produce new and more vibrant types of drugs for immunization through a nationalized program.

So I think the goals are obviously the same. How do you get everybody immunized? That was my goal as Governor, and that's the goal of this committee. But I do have to say that, having been through the program both on a hands-on basis as head of a polio clinic and as a Governor who has helped institute universal immunization and had some results from it, I don't see that nationalization of the industry is the way that is going to get us there. I see, rather, developing a program that draws the parents into an active responsibility pattern as the way you are going to get there. To the extent that government interfaces with parents, we should be able to accomplish that.

Thank you, Mr. Chairman.

Mr. WAXMAN. I want to recognize at this time the ranking Republican member of our subcommittee, Tom Bliley from Virginia.

OPENING STATEMENT OF REPRESENTATIVE BLILEY

Mr. BLILEY. Thank you, Mr. Chairman.

I am pleased to participate in this hearing on a subject very important to all of us—the health and well-being of our children and grandchildren. Immunization probably represents the most cost-effective means our society has for preventing suffering and death.

I remember the polio epidemic quite well. We are very fortunate to have eradicated that disease as well as many others. Centers for Disease Control estimates that in the past three decades, more than 77 million cases of measles and 25,000 cases of mental retardation have been avoided, and over 7,000 lives saved, thanks to the development of just the MMR vaccine.

Reviewing the barriers to immunization that have been identified in our vaccine delivery system reinforces the view that I have held for some time—our public assistance system is highly fragmented and imposes unnecessary bureaucratic roadblocks to providing the services it was created to provide. Our current system simply misses too many opportunities to immunize the children most at risk.

Children and their parents frequently come in contact with a variety of programs, such as the maternal and child health block grant program, Medicaid, AFDC, and the WIC program, where in-

dividuals receive benefits. We could easily also check children's immunization status and administer vaccines if necessary.

I have long advocated legislation that would permit one-stop shopping, whereby families could meet all their related needs in the same program and at the same time, instead of being shuffled from one bureaucracy to the next.

While I commend the administration's emphasis on childhood immunization, I do have concerns about the logic of some elements of their proposal. For example, does it really make sense to establish a new entitlement program for well-off Americans, the majority of whose children are vaccinated by their pediatricians without any difficulty? While the goal of a national tracking system for every child in America is certainly Utopian, does it really make sense? Do we really need to spend scarce Federal tax revenues for such a system when millions of pediatricians and families already keep these records? Shouldn't we begin to target such a system to populations of greatest need first?

I look forward to working with my colleagues and the administration to resolve these concerns and to ensure that all children are immunized in the most cost-effective fashion.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Chairman, under previous agreement, the Senators will have to vote soon. Since we've got four or five Members here, if you are agreeable, we could let each of them take perhaps a minute or a minute and a half, then hear from Senator Danforth, and Members could go and vote at that time.

So I would suggest this, and call on our colleagues who wish to speak—I'd recognize Senator Dodd first, then Senator Mikulski, Senator Durenberger, Senator Wellstone and Senator Wofford—if that is agreeable, hopefully, and then have Senator Danforth proceed.

Mr. WAXMAN. Well, we're going to have give the opportunity for the House Members to make their statements. If we're going for a minute and a half, let's hear from four Senators and then—well, you've only got a short time before 10:45 when you'll have to leave—then the House Members will have our chance to take over with opening statements.

The CHAIRMAN. Senator Dodd.

OPENING STATEMENT OF SENATOR DODD

Senator DODD. I'll save some time for you. First of all, let me commend both of our chairs here for conducting this hearing. Obviously, it is a critically important issue to all of us, and there is obviously a tremendous need that I think everyone understands.

Mr. Chairman, I have a short opening statement and an article from the Bridgeport Post that I'd like to have included in the record.

Connecticut is one of the few New England States that have a full program. We spend $4 million a year, and Governor Weicker is now going to include hepatitis B as one of the diseases to be covered by the universal program. We have about 50 to 60 percent coverage; New Haven, CT, about 50 percent. Obviously, making immunizations available is a major part of the issue, but also the infrastructure issues—how you get people to show up. So even with

a full program, we have a critical problem, and this Bridgeport Post article cites the example of a woman who spends the good part of half a day in New Haven, just with various bus transfers and waiting and so forth, to get there, with great determination. So that is the other side of the equation.

But you also can't talk just about infrastructure problems. You've got to have the resources as well to deliver the vaccinations as necessary.

I commend you for the hearings and look forward to working with you.

[The prepared statement and article of Senator Dodd follow:]

PREPARED STATEMENT OF SENATOR DODD

Mr. Chairman, I am pleased to be here today. I am excited that President Clinton has placed the health of our children high on his list of priorities. He is committed to ensuring proper immunizations for all children. Three hundred million dollars was included in the economic stimulus package for immunizations and he has now sent the "Comprehensive Child Immunization Act of 1993" to Congress.

We all recognize that immunization rates in this country are much too low. We have fallen behind the rest of the developed world in immunizing preschool children—fewer than 63 percent of American 2-year-olds have received the complete immunizations series.

A recent article in the Connecticut Post points out that measles kill one out of every 1,000 people who get it, and leave one out of every 1,000 brain damaged. A few dollars worth of vaccines could prevent this terrible tragedy.

We must take action, and I believe Members on both sides of the aisle are anxious to address this issue. Immunization rates are low for a variety of reasons, and unfortunately, a simple solution does not exist.

We do know that any solution must include improvements in the delivery system. For many working parents, limited clinic and physician office hours and transportation problems are real obstacles. We must remove these obstacles.

We also must conduct greater outreach, and do a better job of educating parents about the importance of vaccinating their children. And, in instances where the price of vaccines is an obstacle, we must address that.

I want to thank all of the witnesses for coming here today. I look forward to their testimony.

Plenty to Plague Efforts to Immunize All State's Cities Lagging in Vaccination of 2-year-olds

By JOHN G. CARLTON
Staff writer

Maribel Carrasquillo left her New Haven home at about 9:30 Friday morning with a 4-month-old nephew in tow.

Thirty minutes and two bus transfers later, she arrived at a clinic in the city's tough Hill neighborhood. Ninety minutes after that, she was ushered into a small examining room in the Hill Health Center where Pedro Fuentes, her nephew, was jabbed in the thigh with a short needle and given a shot to prevent a trio of diseases she's never heard of.

"I know it's important," Carrasquillo said as Pedro screamed in the background. "It's important that he get the shot so that he doesn't get sick."

It is a message not every Connecticut parent has absorbed, but one attracting increased attention in recent weeks on a state and national level.

With the two jabs of the needle and a swallow of oral vaccine, Pedro was on his way to joining the 65 percent of Connecticut children who have received recommended immunizations by the time they are 2 years old.

The good news, public health officials report, is a Department of Health Services program provides vaccines at nominal cost, making Connecticut a national leader in the percentage of children fully immunized by age two.

And virtually every child in Connecticut has received the shots, as required by state law, by the time they begin school.

The bad news is 35 percent of the state's 2-year-olds have not received the immunizations, which protect against a host of diseases that can kill or cause brain damage. And in large cities, the rate is even higher.

"These diseases can occur so relatively early in life that we have to offer children protection," explained Dennis Dix, director of the state health department's immunization program.

Two weeks ago, President Clinton chided drug companies for the high price of vaccines — their

cost has soared from $23 for a full course in 1982 to $244 for the same dosages last year. He announced a major initiative aimed at getting every American child fully immunized by age two.

And in Connecticut, one of a handful of states to make the drugs available to every child, Gov. Lowell P. Weicker Jr. has proposed additional funding to add hepatitis B to the list of vaccines provided.

But even with roughly $4 million spent by state officials each year for the immunization program — even with 600,000 doses of vaccine distributed annually — many Connecticut children do not get protected.

Money, public health officials said, is not the only obstacle.

In New Haven, where Carrasquillo spent the better part of her morning Friday getting little Pedro his shots, only 53 percent of the children have been immunized by age two.

Some American cities have an even lower rate — in Houston for example, only 10 percent of children have received shots. Nationally, the rate is about 50 percent.

Carrasquillo said she understands the importance of the vaccination, even if she's never heard of pertussis (whooping cough) or diphtheria. She would gladly take Pedro back for his next round of shots if her sister asked. After all, Carrasquillo has done the same for her own 10-month-old child.

Still, her bus odyssey may help to explain why so few of the city's children have been vaccinated.

"There are problems about transportation, problems about getting the free time," explained Dr. Stephen Updegrove, medical director of the Hill Health Center. "If you're talking about a working mother, she's got to give up the time from work to bring her children in."

But, increasingly, youngsters in affluent areas of the state are missing out on vaccines as well.

Dr. Robert D. Chessin, a Bridgeport Hospital pediatrician whose practice includes many families from the suburbs, said over the last year or so, "the recession has really hit."

"We've seen more and more parents putting off their kids' checkups," which are often when the vaccinations are administered, he said. "Some of it is financial. If their insurance has been cut off, they may not realize they can get the vaccinations for free from their local health department."

Outmoded thinking also plays a role, public health experts said.

Many parents, and even some doctors, may believe they cannot vaccinate children who have a slight fever or are complaining of feeling ill. But recent studies have shown that's not necessarily the case.

Ironically, the very success of vaccinations in eradicating disease has also worked against doctors.

But other immunizations protect children from diseases just as harmful — and far more common.

"Measles, which many of us had as children, kills one of every thousand people who get it and leaves another one of every thousand brain damaged," Chessin said.

"All of this," Dix observed, "all of it could be prevented for a few dollars worth of vaccines."

Pediatricians and the state Department of Health Services recommend children receive the following vaccinations at the following ages:

Birth ■ Hepatitis B

2 months ■ DTP (diphtheria, tetanus and pertussis or whooping cough); hepatitis B (second dosage); HIB (hemophilus and influenza type B); and oral polio

4 months ■ DTP (second dose); polio (second dose); and HIB (second dose)

6 months ■ DTP (third dose); HIB (third dose); and hepatitis B (third dose)

15 months ■ MMR (measles, mumps and rubella)

15 to 18 months ■ Polio (third dose); and DTP (fourth dose)

4 to 6 years ■ DTP and polio boosters

11 years ■ MMR (second dose)

VACCINATIONS

Source: Connecticut Department of Health

Post/Bob Rich

The CHAIRMAN. Senator Mikulski.

OPENING STATEMENT OF SENATOR MIKULSKI

Senator MIKULSKI. Thank you, Mr. Chairman.

I am delighted to be once again at a hearing with my colleagues from the House Committee on Energy and Commerce, Subcommittee on Health, a committee and subcommittee that I served on that has been the incubator of Senators.

I remember in the first days of the Reagan administration when Henry Waxman and I were in hand-to-hand combat with then our former colleague, Mr. Stockman, trying to get $6 million—Henry, do you remember that—for the immunization of children. And now, here we are, 11 years later, still in hand-to-hand combat, trying to get immunization and the stimulus package, and yet the needs continue at an even more increasing and more alarming rate.

I would hope that we would pass the stimulus package, and I would hope that we would support this immunization effort. When one looks at the obstacles to children being immunized, we know that one thing that has been lacking has been national leadership. We now have that in our President and in our Secretary.

We know that another obstacle is cost, and we now know that aggressive intervention has dealt with that. But also, we need to be able to put our children through a system that not only immunizes them, but gets them into a primary care network.

Therefore, I hope that whatever we do in immunization, we don't see it only as another government program to be delivered, but as a national effort to focus on the needs of children, to immunize them and get them into primary care, and that we mobilize the public and private resources of the United States of America to accomplish this goal, so that when President Clinton and Mrs. Clinton walk Chelsea to school next year, every child will be immunized, with special focus particularly on children under the age of 2.

I would hope we would use the resources of the National Guard and of other nonprofit organizations as well as traditional mechanisms for delivering this service, because what we need is not more government—yes, we need more personal responsibility, but we need to mobilize our people so that they can see that, working together, we can do this. And I would hope that immunization does not become a further problem in the gridlock and deadlock that is focusing on the U.S. Senate.

Six million dollars in 1982; now it is up to $120 million in 1993. It is time to end the decade of neglect.

[The prepared statement of Senator Mikulski follows:]

PREPARED STATEMENT OF SENATOR MIKULSKI

Nothing should shock us more than the fact that nearly one-half of all children have not been fully immunized by the time they have their second birthday.

The Comprehensive Child Immunization Act, of which I am a cosponsor, seeks to close the health care gap for children. It closes the gap between what we promise and what we deliver. Between

what we know how to do and what isn't being done. Between gridlock and a government that works.

We know that immunization works. We don't need any more studies. We don't need any more reports. We don't need any more convincing.

Vaccines save lives. They are effective in preventing nine major childhood diseases.

What we need is resources and a program that works. Because for all that we know and for all that we have studied the problem, the reality is that too many children are not being vaccinated on time or at all. They are unprotected. Vulnerable to diseases that were once virtually eliminated. And dying needlessly.

Measles is a case in point. In 1963, when the measles vaccine was licensed there were an average of 500,000 to 1 million cases every year. By the early 1980s we had all but eliminated measles. But in the last 3 years, we have seen over 54,000 cases of measles and over 160 deaths. Almost one-half of these occurred in unvaccinated preschool children.

There is no excuse for this. Not in a country like ours with the resources, the medical expertise and the ingenuity to get this job done. Some today may argue that the Government can't afford to spend more money. And some would say that we shouldn't control the cost of vaccines. Well, I say we can't afford not to.

We have to turn our thinking around. Immunization not only save lives, it saves dollars. For every dollar invested in immunizations, $10 is saved in later medical costs. For every dollar invested in a measles shot, we can expect to save $14.

We need to stop spending needless dollars at the back end of the health care system. We need to spend them right up front—to prevent illness and disease.

We are fortunate to have a President and Secretary of Health and Human Services who believe in prevention. And who know a good deal when they see one.

The President's bill, is investment in a healthy future that fills the heart and the pocketbook.

If we can show the American people that every child has been fully immunized than we can show them that Government can work. That it can make lives better. That it can change good intentions into reality.

For too long Americans have seen a lot of talk about caring for children. No Action. This immunization program is real. It is concrete. And it will make a difference.

A poet once said, "it is a wise man who plants seeds for trees under whose shade he will never rest." The time for planting the seeds for our future—our children—is now.

The CHAIRMAN. Senator Durenberger.

Senator DURENBERGER. Mr. Chairman, I ask unanimous consent that my statement be entered into the record, along with questions for Mike Moen, Ed Thompson, Secretary Shalala, and Marian Edelman. And I would strongly associate myself with the remarks of my colleague from Kansas, Senator Kassebaum, and my colleague from New Hampshire, Senator Gregg, and what I hope will be the comments of my colleague from Missouri, Senator Jack Danforth.

[The prepared statement and questions of Senator Durenberger follow:]

Prepared Statement of Senator Durenberger

Along with all the Senators here today, I am fully committed to a healthier America and to prevention and well-baby care. It is indisputable that early childhood immunization is essential to a successful strategy for improving the health of our children.

I applaud the commitment of others here today, from the new administration, from the Democrats in the House and in the Senate, and from all our witnesses who have come to testify. I do not deny that low immunization rates are a real problem in this country.

Indeed, we are long on commitment today. Commitment often leads to answers, and this bill is full of answers. But I would like to introduce a caution at this point. There is a health policy expert at the University of Minnesota named Bryan Dowd, who says the problem with health policy today is—and I quote—"we have 1,000 answers and no questions."

And I am afraid that, despite the commitment of its authors, this bill has not asked the right questions.

The centerpiece of this bill is so-called "universal purchase" where the Federal Government will buy all vaccines needed each year and distribute it to States. But, the question is: Is the cost of vaccines the real barrier to immunizations? Is there evidence that this "answer" will solve the problem?

Will the investment of a billion dollars in the purchase of vaccines really work? I have my doubts.

There are so many other factors that affect the immunization levels. Many of those barriers are cultural, some are lack of education, and some due to infrastructure problems (limited clinic hours, long waits, no transportation, etc.). The fact is that every community is different, and that strategies to overcome these barriers depend on understanding the people in those communities. We need to allow State flexibility to address these issues, community by community. Federal dollars simply won't solve these problems.

Last session, I supported efforts by the Appropriations Committee to expand funding for immunization grants to States. We raised appropriations for immunizations under this program to $341.78 million, an increase of $45.08 million over fiscal year 1992.

These grants allow States to determine what barriers really exist to access in their communities. In other words, States have the flexibility to ask the right questions, and then come up with appropriate solutions. Under this program, the CDC awards grants to States and local governments to develop and implement immunization action plans (IAP's).

I am pleased that Dr. Michael Moen, who is the director of Disease Prevention and Control in the Minnesota Department of Health, is one of our witnesses here today. He is among the truly committed individuals who have worked tirelessly to improve immunization rates in Minnesota.

Minnesota has received a grant of $900,000 to develop an action plan and implement an improved vaccine delivery system. What Mike will show us is that, even in Minnesota which is a relatively

homogenous State, there are tremendous variations among communities in immunization rates, and the causes are as variable as the solutions.

Wise policy dictates, and experience supports, a program that allows States to use all the necessary tools to raise immunization rates without throwing resources into communities that do not need these funds. We must concentrate our efforts where they can do the most good. We simply do not have money to waste.

I am concerned that the bill's free vaccines for all will spend scarce dollars where they are not always needed and deplete resources to solve the hard problems.

There is really only one basic question, and it is this: What is the real goal here? The answer is: healthy children. What I am concerned about is that we will fixate on immunizations rather than on the whole child. Will we spend vast resources to raise immunization rates from 55 to 75 percent, for example, but overlook the child's well-being? A child's health needs and a child's human needs are much greater. And, we are going to need an intelligent commitment to public health and healthy communities if we want to reach our goal.

I look forward to hearing the testimony that will be presented today. I also look forward to asking the questions that will produce the best answers. We don't need and can't afford wrong answers. Our children are too important for that.

RESPONSES OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO QUESTIONS ASKED BY SENATOR DURENBERGER

Question 1. One statistic has been bothering me, and I want to ask you about it. Five year olds have very high immunization rates, don't they? About 95 percent. BUT, for some reason, 2-year-olds have only 53 percent compliance.

Can you explain why 5-year-olds have such a high rate? Because it is required for school is my guess. Somehow parents are finding their way to vaccinations when there is a powerful stimulus. It seems to me it is less a problem of economics and more one of infrastructure, given these facts.

Answer. mmunization rates for children entering school have reached unprecedented levels of 96 percent or greater, largely as a result of a national campaign started in the late 1970s that encouraged States to enact and enforce mandatory vaccination laws.

Immunization rates of 2-year-olds are much worse, ranging from 37 to 56 percent depending on the method of data analysis. Data from the 1991 Health Interview Survey indicate that only 41 to 60 percent of whites were fully vaccinated (4 DTP, 3 OPV, 1 MMR) at 2 years of age, and only 20 to 33 percent of blacks were fully vaccinated.

A mere 42 to 61 percent of the respondents to that survey above the poverty level were fully vaccinated and an appallingly low 25 to 38 percent of those below the poverty level were fully vaccinated.

The barriers contributing to the low immunization rates among 2-year-olds are complex and require a comprehensive solution. The barriers include the lack of education of parents and providers about the importance of immunization, the lack of outreach programs and the lack of access to vaccines and immunization services. In addition structural barriers exist that require parents who are seeking immunization services to have advance appointments, physician referrals, or to be enrolled in comprehensive well-baby clinics when such services take weeks to months to obtain. Public health clinics are underfunded, lack sufficient staff, are unable to be open at hours convenient to parents. Finally, we know that the cost of vaccines and vaccine administration fees are having a substantial negative impact, especially among those without insurance benefits that cover immunization services.

Data also indicate that traditional private-sector patients are being shifted to the already overburdened public clinics where free vaccine is available.

A 1992 survey of City Maternal and Child Health Programs (CityMatCH) reported 88 percent of responding health departments had experienced a private-to-public

sector shift of children. From 1989 to 1991, there was a median increase of 24 percent in children served and 31 percent in doses administered.

A survey from Dallas County, TX, reported that between 1979 and 1988, private practitioners increased referrals 281 percent. The percentage of children referred during the same time period increased by 693 percent.

The American Academy of Pediatrics (AAP) surveyed 1,600 private pediatricians in 1992 regarding their immunization practices. Approximately 45 percent of those who responded reported referring patients to the public sector for immunizations; 2.5 percent reported referring all patients to the public sector for immunizations.

This survey also noted that 40 percent of the pediatricians that refer patients to the public sector indicated they had increased referrals during the previous 10 years, whereas only 7.3 percent reported they made fewer referrals. Most referrals were made to health department clinics and cost was listed most frequently as the reason for referring children to other sources for routine immunization.

In a Northern California study of barriers to immunization among children attending public immunization clinics, 63 percent of parents whose children had a source of well child care indicated they would have preferred to have their child vaccinated at the source of care; 53 percent indicated cost was the main barrier.

Question 2. I'm very concerned about the impact of this universal purchase program on innovation. In fact, it seems to me that innovation in the vaccine industry may hold the key to our problem.

In yesterday's Washington Post, it said that the FDA approved a new vaccine that mixes the standard DPT shot with an influenza vaccine. Instead of needing eight shots, only four would be necessary. Wouldn't it be ironic if we damage this fast-moving research through nationalization of vaccines through universal purchase?

Answer. We agree that vaccine research and development is critical to improving our prevention of infectious diseases and simplifying our immunization schedule.

As you may know, the universal access compromise proposal, requires that the Secretary of the Department of Health and Human Services enter into negotiations with vaccine manufacturers for a Federal purchase price for each vaccine recommended for routine use in children. A key element of the proposal is the requirement that the cost of research and development for vaccines be considered in determining a reasonable profit.

Neither universal purchase, nor the universal access proposal, should be viewed as the "nationalization" of the vaccine industry. On the contrary, the initiative merely seeks to obtain the best price for a public good that is manufactured and marketed, in part, by the private sector.

Question 3. The price tag for this bill is very high. Most of it is spent on the universal purchase portion of this effort. Don't you think we should give the infrastructure reforms a chance, working in the communities, before we spend ALL this money and threaten the innovation of the industry?

Answer. The projected costs of the compromise proposal to ensure that all children are appropriately immunized by age 2 are high. However, immunization is one of the most cost-effective prevention measures we have. For example, past analyses of the measles, mumps and rubella vaccine have estimated that society saves more than $14 for every $1 spent of the vaccine program.

The Congressional Budget Office estimates that the vaccine purchase provision of the universal access proposal would cost about $300 million per year. In addition, funds for the State-based immunization registries would include costs of $50 million in 1994 for planning and initial purchase of equipment, further development costs of $152 million in fiscal year 1995 and $125 million for fiscal year 1996, and $35 million maintenance costs in fiscal years 1997 through 1999. Finally, the bill would reauthorize the Centers for Disease Control and Prevention Immunization Program at a total of about $640 million, about $200 million of which would be available for strengthening the vaccine delivery infrastructure by funding of the State Immunization Action Plans.

RESPONSES OF MICHAEL E. MOEN TO QUESTIONS ASKED BY SENATOR DURENBERGER

Question 1. Minnesota has received a grant under the current CDC Immunization Action Plan that allowed it to do a local population-based assessment of community needs. What would happen to that community-based assessment and program development capacity under legislation that ties those funds to a federally mandated registry program?

Answer. Population-based assessment of immunization levels in Minnesota has enabled us to identify geographic areas and populations which are underimmunized, and to develop interventions targeted to these specific areas. Mandating a federally operated registry program would have the effect of diverting resources from areas

of greatest need as evidenced by the lowest immunization levels to areas that have adequate or satisfactory immunization levels. This would occur because a registry program, as currently being discussed, would incorporate children throughout the State including those children from areas where immunization levels are satisfactory. Developing this registry with the short timelines currently proposed would divert our efforts from "pockets" of unimmunized children to developing a statewide registry to keep track of all children, many of whom are already adequately immunized.

Question 2. In your testimony, you State that in order to attack the problem of low immunization rates, we must focus our limited resources to where the problem is, and not to where the problem is not. From your experience as the Director of the Division of Disease Prevention and Control at the Minnesota Department of Health, wouldn't universal purchase of vaccines and requiring the establishment of registries direct limited resources to places that don't have low immunization rates?

Answer. Universal purchase of vaccine and the establishment of registries would have the effect of directing limited resources to all areas of the State, including those areas that do not currently have low immunization rates.

Question 3. Are there more cost effective ways to conduct effective surveillance than registries?

Answer. Effective surveillance can be conducted in more cost-effective ways than operation of population-based registries. Population-based registries and provider-based registries have an important service role in assisting parents and providers to identify children who are falling behind in their immunizations and notifying those parents in order that they may acquire the needed immunizations. Determining immunization levels on a population basis, i.e., surveillance of immunization rates, can be conducted in other more inexpensive, cost-effective ways. For example, retrospective surveys have been utilized in Minnesota to ascertain immunization rates for all children born in the state in 1987. This methodology utilizes records kept on all kindergarten children which contain the child's date of birth and the dates the child was immunized. Utilizing these records, public health officials can "reconstruct" the immunization history of a child who is currently 5 years old and in kindergarten. A sample of these records have been validated with the child's medical record. This survey methodology provides information to the zip code level about immunization rates on a population basis in Minnesota. This allows public health officials to identify "pockets" of unimmunized children and target resources to those "pockets." While retrospective surveys provide information which is several years old, other survey methodologies using birth certificates and follow-up can provide more recent information. Together, these survey methods provide important, relevant data about immunization rates on a population basis for a fraction of the cost and time that would be required to operate a statewide registry for this purpose.

RESPONSES OF F.E. THOMPSON TO QUESTIONS ASKED BY SENATOR DURENBERGER

Question 1. What are your concerns about the requirements for States under the Federal Tracking Model and system specifications of registry design?

Answer. The most important concern is that any requirements placed upon the system will be for data elements to be included and for output that the system can provide, rather than for specific software compatibility or particular data processing requirements. It is appropriate to mandate what basic information will be contained in the registries in each state and also what basic information can be provided to other states from these registries. It would be extraordinarily expensive and burdensome to states to require that it be done through a particular program or using a particular set of software. Many States, Mississippi included, are well on the way to having developed a State immunization registry already and may have something in place and working well that can deliver the necessary output to any national tracking system but may not do it through the same software that the national system uses. Provided we can print out and deliver hard copy of the necessary material, the real need for tracking systems will have been met.

Another concern is that the data elements to be included under "the Federal tracking model" be only those required to track a child's immunization status. Additional information, such as history of adverse reactions, any vaccine contraindications present for this child, and any religious or legal exemptions that may pertain for an individual child are not appropriate for inclusion in a national system. The child's medical record should contain this information.

Question 2. You have stated in your testimony that the universal purchase of vaccine will not contribute significantly to raising childhood levels. What would be the best strategy for overall well-baby care in your State?

Answer. I cannot answer the question as to the best strategy for overall well-baby care because that is not at issue. The issue is raising childhood immunization levels, and that is what I addressed. In terms of raising childhood immunization levels, the best strategy would be to take the resources that would be used to purchase vaccine for distribution to private providers and use those funds to hire additional staff to give immunizations, to do outreach work and to operate and maintain tracking systems. The funds could also be used to purchase the necessary hardware and software to develop tracking systems, and to provide for outreach and education efforts to promote immunization awareness among parents. Above all, the additional staff necessary to immunize the children, the people required to give the vaccines are the heart of any effective strategy to raise and maintain immunization levels in our preschoolers.

RESPONSES OF MARIAN WRIGHT EDELMAN TO QUESTIONS ASKED BY SENATOR DURENBERGER

It is true that the immunization rate for 5-year-olds is greater than 95 percent and that this rate is the result of school entry requirements. However, immunizing a child to enter school is both easier and cheaper than fully immunizing a child from birth. It takes 18 doses of vaccines given at seven doctor visits to fully immunize a child through the preschool years. The cost is more than $230 plus administration fees and office visit charges. If a child has never been immunized, most school systems require Just three doses of vaccines which can be administered at one visit at a cost of less than $50. A child who receives three shots is not protected from diseases. Therefore, economics is a significant factor in the problem of low preschool immunization rates.

We wholeheartedly support the development of vaccines which are safer, necessitate fewer shots and prevent additional diseases. Such advances would increase our ability to protect our children from illness and death. This legislation specifically requires that the negotiated price for vaccines include production costs, research and development expenses and sufficient profits to encourage further vaccine research and development. The legislation assumes that the negotiated price will be the average of the current public and private market prices. Therefore, the manufacturers should see no loss of revenue and there should be no financial disincentive for research and development. In fact, a universal system might contribute to the development of new vaccines because the manufacturers will see increased demand (and increased profits) as financial barriers for families and providers are eliminated. However, the vaccine manufacturers will not be able to unilaterally increase prices at rates far higher than inflation. In 1977 polio vaccine (OPV) cost $1.00 per dose. If the price had increased at the general rate of inflation for medical care, it would cost $3.64 per dose today. Instead, the price increased at a rate of 59 percent per year to reach $10.43. The $6.79 excess (above inflation with the excise tax) costs American families an extra $80 million per year for this one vaccine.

Infrastructure reforms are a vital part of the solution to the immunization crisis, but an immunization strategy that only addresses the public sector will exacerbate the current problems. A central problem is the referral of many children to public clinics by their private doctors because of the high cost of vaccines. As a result, children miss opportunities to be vaccinated and increase the demand at already overburdened clinics. Focusing on the public sector alone could result in a cycle where the cost of vaccines for the private sector is increased, even more children are forced into public clinics and more barriers to immunizations and well-baby care are created.

The Government tried in the mid and late 1980's to invest more in immunizations without negotiating a universal price but manufacturers' large vaccine price increases offset federal funding increases and families still found themselves priced out of the market. If families can't afford vaccine, they can't afford vaccine, no matter how much outreach there is. The participation of private physicians must be enlisted as part of a comprehensive solution which keeps immunization services delivered in private offices, where most children get their regular health care.

We oppose any alternative to the President's immunization act which calls for an expansion of Medicaid eligibility to cover immunizations. This would be bad for children, parents, States and the Federal Government. The Medicaid application would be one more barrier for families trying to get their children immunized in a system which already has too many barriers. The majority of children who might gain eligibility would be patients of physicians who do not accept Medicaid. In these cases the doctor would still send the family to a public health clinic for immunization. Parents would have to take additional time off work either to go to the public clinic or to visit a Medicaid office and then return to their doctor for the shots. The num-

ber of missed opportunities for immunization would escalate. The frequent eligibility redeterminations required by Medicaid would necessitate the filing of a Medicaid application each time a child needed a vaccination. This would be yet another obstacle to getting children immunized on time and a bureaucratic and financial burden for States. Such a system would burden middle class families and State Medicaid programs, raise Federal and State costs, and benefit only the pharmaceutical companies.

An effective plan for immunizing all children on schedule has four components: education and outreach; improved public health infrastructure; a registry and tracking system; and universal assurance of affordable vaccines. Each of the components is crucial. Education and outreach will not succeed if parents are frustrated by systemic barriers to providing for their children's needs. Public health service delivery changes will not help those children who have a private physician. Our failure to appropriately immunize all of our children has multiple causes and the response must include multiple remedies. This bill encompasses the essential components of a lasting solution and has our full support.

The CHAIRMAN. I'll place in the record the statement of Senator Thurmond, who very much wanted to be here.

[The prepared statement of Senator Thurmond follows:]

PREPARED STATEMENT OF SENATOR THURMOND

Mr. Chairman, it is a pleasure to be here this morning to receive testimony on the "Comprehensive Child Immunization Act of 1993". I want to join the Chairman and my colleagues in extending a warm welcome to our witnesses. I would also like to welcome my colleagues on the House Subcommittee on Health and the Environment.

Mr. Chairman, the focus of the "Comprehensive Child Immunization Act of 1993" is universal federal purchase and distribution of vaccines. The premise underlying this plan is that low immunization rates result from the high cost and unavailability of vaccines. President Clinton has proposed to authorize $1 billion a year to purchase all vaccines.

While I agree that immunizations are among the most cost-effective means of preventing disease, I am concerned that this plan fails to recognize that there are a number of factors contributing to the low incidence of vaccination. Some of these factors include: inadequate public education, inadequate outreach to poor and minority populations, and lack of accessible systems for delivery.

This plan would also establish a national system to track the immunization status of children. It would condition the receipt of free vaccines upon the states implementing a registry and tracking system which would link up with a national registry system. In other words, no registry and tracking system—no free vaccine.

Mr. Chairman, I have a number of concerns surrounding this plan. One, as I mentioned already, whether universal purchase is the best solution to the problem. Two, whether registry systems work. Three, whether there is potential for waste from spoilage and overpurchase. Four, what the impact will be on the manufacturers of the vaccine.

Mr. Chairman, I wish to join you in thanking the witnesses for being here and I look forward to reviewing their testimony.

The CHAIRMAN. Senator Wellstone.

Senator WELLSTONE. Thank you very much, Mr. Chairman.

I just have a one-hour statement that I was hoping to be able to make right now.

The CHAIRMAN. What about tonight at midnight? [Laughter.]

Senator WELLSTONE. I would just ask the chair to include my statement in the record.

The CHAIRMAN. Fine.

[The prepared statement of Senator Wellstone follows:]

PREPARED STATEMENT OF SENATOR WELLSTONE

I am very happy to speak in support of the revised version of S. 732, the Comprehensive Child Immunization Act of 1993. This bill has taken the concepts laid out in the original version and improved upon them to produce a piece of legislation that will really help get preventive vaccinations to our children. I feel fortunate that I have had an opportunity to work and plan for this program which promises to help strive toward the immunization goals set for the year 2000.

Four key points have been added to this bill which will improve its effectiveness as a national immunization program, while allowing significant flexibility for State implementation. First, the bill provides grants to States to improve the public health infrastructure. This includes public education, development of alternative methods of delivering vaccines, and increasing clinic hours.

Second, the bill provides for the refusal of vaccines based upon philosophical or religious objections. The Federal regulations may in no way override those designed by a State.

Third, the bill provides for the continued success of the Vaccine Injury Compensation Program. This program, aside from lack of funds, has been successful in resolving claims resulting from adverse reactions to included vaccines. I am happy to see this program continued and improved in the current bill.

Fourth, the revised bill fosters the States' role in the surveillance and registries of children. The States will be receive grants to produce accurate surveillance data regarding immunization data, assist in identification of localities with inadequate immunization rates, monitor safety and effectiveness of vaccines, and improve the management of immunization programs at the State and local level.

The national registry, on the other hand, will provide technical assistance to the States as well as collect aggregate epidemiologic data from them. This relationship between State and National registry, should on the whole, provide for an efficient and useful system.

Minnesota has developed a system for surveillance of immunizations, and for targeting communities that have low immunization rates for outreach activities. This model, discussed in the hearings on April 20th by Dr. Michael Moen, provides an excellent model worth examining. Allowing States the flexibility to design immunization surveillance programs that best suit their population while requiring aggregate data on a national level is a key element in the solution to the problem of improving our low immunization rate for children under 2 years old.

Once again, I express my support for this necessary and timely piece of legislation.

The CHAIRMAN. I thank the House Members for their courtesy.

Mr. WAXMAN. Mr. Wyden.

Opening Statement of Representative Wyden

Mr. Wyden. Thank you, Mr. Chairman. I want to commend you and Chairman Kennedy, and just make three very quick points.

First, this is really the President's and Secretary Shalala's first major initiative in the health and human services area. I think it is illustrative that it is a commitment to kids and indicative of how strongly they feel about it, and I want to commend both of them for it.

It seems to me that the big challenge that we face is coming up with fresh, creative ways to reach the millions of kids who are going without immunizations. I want to associate myself with the comments of Senator Mikulski, because I am convinced that what works in my home town of Portland may not necessarily work in the Bronx or in southern Illinois; we are going to have to have a grassroots mobilization, in effect, as our colleague said, and I think she is right on target.

The last point that I would make is that—and maybe some of the other members experienced this yesterday—but as we see so often, when important issues heat up, there are groups that go out and try to distort the debate, try to frighten people and scare people into thinking that legislation is something that it isn't.

For example, our telephones rang off the hook yesterday with people calling, saying that they were concerned that the bill mandates immunization for all children without exception. I think the concern here was on the part of some groups that somehow this legislation would strike the religious and medical exemptions that are by and large protected in State law.

The fact of the matter is this bill doesn't mandate immunization for all children without exception. This legislation is about payment; it essentially protects the religious and medical exemptions that are for the most part provided by the States. And I think what we heard this morning is that members on both sides of the aisle want to fashion strong legislation, and to do that, we've got to make sure that people get the facts about this legislation. And I look forward to working with my colleagues to make sure that gets done, and yield back.

Mr. Waxman. Thank you, Mr. Wyden.

Mr. Upton.

Opening Statement of Representative Upton

Mr. Upton. Thank you, Mr. Chairman.

First of all, the issue is really about the future of America and certainly, the health of our kids. My State of Michigan is a good example of a State that has made an aggressive commitment to the immunization of our kids.

As one of only two States in the Nation that has a State-owned lab that produces vaccines, Michigan produces these vaccines for the benefit of its citizens and distributes them throughout the State free-of-charge. However, even though immunization is available for free, we still have unacceptably low rates of immunization for children between birth and 2 years old. This indicates to me that we must allocate funds not only for providing the vaccines, but for infrastructure support in local immunization programs, includ-

ing monitoring and tracking, expanded clinic hours, more staff to eliminate long lines, and educational programs to educate parents on the availability and importance of childhood immunization.

Some States—not Michigan—have taken steps requiring that those receiving State assistance must verify their kids' immunization before receiving such assistance. I commend those States, and I believe we should look to these States to see if, while searching for a national solution, we might learn from them.

I yield back the balance of my time.

Mr. WAXMAN. Mr. Bryant.

Mr. BRYANT. Mr. Chairman, not wishing to be subjected to interminable opening statements by members of the House and the Senate that precede every committee hearing, I am not going to subject my colleagues to one, either. I look forward to hearing from the witnesses.

Mr. WAXMAN. Thank you, Mr. Bryant.

Dr. Rowland.

OPENING STATEMENT OF REPRESENTATIVE ROWLAND

Mr. ROWLAND. Thank you, Mr. Chairman.

I do have a statement that I wish to submit to the record; I do want to make a couple of points, though.

I am a cosponsor of this legislation. I do have mixed feelings about it, but I think the positives outweigh the negatives. I am very concerned about the number of reported cases that are increasing in childhood diseases. I think one of the very important things that we need to do in this legislation is to educate the public in general about the necessity of these childhood immunizations.

I do not believe that the public in general realizes how important it is that that be done.

With that, I yield back the balance of my time.

Mr. WAXMAN. Thank you, Dr. Rowland.

[The prepared statement of Mr. Rowland follows:]

PREPARED STATEMENT OF REPRESENTATIVE ROWLAND

Mr. Chairman, congratulations are in order for everyone responsible for this hearing. I understand it's been more than a decade since House and Senate committees have held a joint hearing on a health issue of this magnitude. This sets a good example of cooperation for other to follow.

As a physician who practiced family medicine in middle Georgia for 28 years, I've been concerned for a long time about the low number of preschool children receiving immunizations against infectious diseases like measles, whooping cough, diphtheria, and even polio.

These diseases are costly. Every $1 spent on immunizations saves an estimated $10 in health care costs. They can be fatal. Although it may be rare, a disease like measles takes a few lives every year. The real tragedy is that these diseases are often preventable. Out of 13,000 preschoolers who contracted measles in 1990, as many as 10,000 would have escaped the disease with immunizations.

Unfortunately, three out of every 10 2-year-olds fail to get proper immunizations. Cuba and Syria and Mongolia have better immunization records than this. The United States ranking in preschool immunizations is 70th in the world. Even though the polio vaccine was developed in our country, the United States ranks behind 16 other countries in the percentage of young children immunized against polio.

This is a comprehensive, cost-effective program. With parents and health care providers and Government at all levels working together, we can provide greater protection for children and make a real contribution toward getting health care costs down.

Thank you.

Mr. WAXMAN. Mr. Klug.

OPENING STATEMENT OF REPRESENTATIVE KLUG

Mr. KLUG. Thank you, Mr. Chairman. I too want to make a couple of quick points.

Like many Americans, I am troubled by the problems with immunization rates in the United States, and like a number of members of Congress, I also think we need to spend more money on children's programs.

But I also think we have to spend that money more intelligently, and in my opinion, nationalizing this country's vaccine business is not part of the intelligent solution. There are pockets in this country, primarily in large cities, but not exclusively, where it is clear that vaccination rates lag. In Wisconsin, the State immunization rate for 2-year-olds is 53 percent; outside the city of Milwaukee, the rate is 61 percent; in the city itself, the rate is below 40 percent.

We have pockets of hunger in this country, but we don't nationalize the bread industry, and we have a shortage of apartments in some cities, but we don't nationalize the housing industry. If nationalization were the key to success, it would be the Russian Parliament working on a foreign aid package to the United States.

There are three things I think we need to do. We obviously have to spend more money on community education and outreach programs. The Federal Government should also perhaps make available to States on a matching grant basis funds to help track kids. One round of shots is clearly not enough, and recently in Ohio, doctors are now able to use a statewide computer system to keep track of their young patients and, rather than forcing rural doctors to buy their own computers, doctors can access their young patients through their touchtone telephones.

It also seems clear to me that we need to encourage parental responsibility, and I would recommend that Secretary Shalala carefully evaluate a series of programs now implemented by a number of States to force parental responsibility. For example, as of yesterday in South Carolina, a new State law says no shots, no daycare. All private and public daycare providers must demand verification of immunizations before a child can be enrolled, and a number of States, including my home State of Wisconsin, obviously, have the same kind of laws on the books now for kindergarten.

In Georgia, in a program instituted in January, parents who receive AFDC payments must provide proof of vaccinations or else AFDC payments are reduced. And Maryland has both a carrot and

a stick approach, which reduces AFDC payments by $25 if a child is not immunized, but if parents get annual checkups including immunization, recipients get an annual bonus of $20 for each child and each adult.

We have the ability to leverage AFDC, WIC, or food stamp payments, and food stamps may be the best vehicle, because it is the largest universe of any Federal program.

It is clear that those of us in the Federal Government have a responsibility to make sure kids are vaccinated and to make vaccinations available to parents who cannot afford it, but we also have a responsibility to say to those parents: You have a responsibility to make sure your own kids are vaccinated, or else suffer penalties if you do not.

Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Synar.

Mr. SYNAR. Pass.

Mr. WAXMAN. Mr. Towns.

OPENING STATEMENT OF REPRESENTATIVE TOWNS

Mr. TOWNS. Thank you, Mr. Chairman. Mr. Chairman, I'd like to ask permission to include my entire statement in the record.

Mr. WAXMAN. Without objection, so ordered.

Mr. TOWNS. And I will just make a couple comments. Inasmuch as I support the legislation, I have some real problems with it. First of all, the fact that only 10 percent is being used for outreach. I think that we should make that flexible. I come from a State where many doctors will not take Medicaid, and if a doctor does not take Medicaid, then you need to make certain that you have a strong outreach program to get them into a facility to be able to get the immunization. So I think that outreach in those areas is very, very important.

The other thing that I must submit that I am very concerned about is the fact that private physicians will be able to charge at the same time with the free medication. I am concerned about the profit made in that regard as well.

So I think that the spirit of the legislation is great, but I do see a lot of pitfalls as we move forward. So inasmuch as I want to support it, I do have these concerns.

Mr. WAXMAN. Thank you, Mr. Towns.

[The prepared statement of Mr. Towns follows:]

PREPARED STATEMENT OF REPRESENTATIVE TOWNS

Mr. Chairman, I want to thank you for this opportunity to make an opening statement.

I applaud the spirit and feeling of the proposal before us "today. To assure that" every child in America is protected against often deadly and completely preventable childhood disease is noble and necessary.

However, I am not sure that the approach of universal purchase of vaccine will actually accomplish the goal of universal immunization of children. There is a great need in this country for widespread immunization. The General Accounting Office (GAO) reports that childhood immunization is one of the most effective

means of health promotion and disease prevention. Yet, fewer than 63 percent of 2-year-olds in the United States have received all of the immunizations recommended. In some inner city areas, the vaccination rate is as low as 10 percent. When we have numbers as stark as this, we must ask why?

Providing free vaccine implies that the problem is supply. But that is not completely the case. In public health clinics, vaccines are offered free of charge to every child who walks through the door. We have not heard report of clinics running out of vaccine. So if the problem is not supply, it may be demand.

In a recent Washington Post story, it was reported that an immunization project run by former President Jimmy Carter not only had to canvass from door-to-door but also had to offer an incentive—families who come in for free shots will get a free ticket to see Michael Jackson. If you have to hand out free tickets to give away free shots, then the problem is not the availability of shots. The problem is demand for shots and the lack of understanding that the shots are necessary.

This kind of demand can only be increased by comprehensive outreach and education programs. If you have a young mother who does not understand that from birth to age 6, a child requires a series of 18 shots and that those shots must be properly spaced to be effective—you will have a young parent who does not see the necessity and will not be willing to traverse a sometimes hostile, confusing and extremely bureaucratic public health care system. This is a system that often requires parents to make appointments, wait for hours despite an appointment, and may refuse to vaccinate a child visiting the doctor for different reasons. And let us bear in mind that children and their parents are required to go through this bureaucratic ritual 18 times in 5 or 6 years. It is my understanding that Federal and State Governments could streamline the existing system to improve the delivery of services.

For the poor and working class, improving public health clinics would go a long way toward increasing demand for any and every kind of service offered there. But the proposal we have before us today does not do that.

Out of all the money we are looking at to supply vaccine ($1.5 billion)—we are only asking for 10 percent of that for education and outreach. In a GAO report on childhood immunizations, the Centers for Disease Control recommended that the three most important factors to improve immunization levels would be (1) educating parents on the importance of immunizations for children; (2) tracking of each child's immunization status; and (3) follow-up with children needing immunization. So I am not alone in my belief that supply of vaccine is the only part of this problem. Yet the bill devotes only 10 percent of the resources to getting the word out to parents that vaccines are necessary and that free vaccines are available.

But turning to another aspect of free supply, I am also deeply concerned about whether this bill will provide a major financial windfall for private physicians. You see, nowhere does the bill require that doctors who receive free vaccine either administer it without charge or accept patients who may not be able to pay. Lets be honest about this. In the district I represent and throughout

New York, many physicians will not take medicaid or medicaid eligible patients. This means that the poor must resort to the public health clinic system. But with this system, the wealthy will be able to take their children to their private pediatrician and receive free government-supplied vaccine. The physician will be able to receive his standard fee even though the government has supplemented some of his overhead costs. I have a serious problem with this. If we are going to provide this kind of benefit, then we must require that the doctor provide services to everyone. I deeply concerned about the linkage of free vaccine and services for private physicians.

In conclusion, Mr. Chairman, while I support the spirit and driving idea behind this bill, I am troubled by several of its aspects. I do not think that the increase in supply alone will create more demand. I do not think that the provision of free vaccine will help to streamline an overburdened system of public health clinics—often the only access to health care available to the poor and working class. Thank you.

Mr. WAXMAN. Mr. Franks.

OPENING STATEMENT OF REPRESENTATIVE FRANKS

Mr. FRANKS. Thank you, Mr. Chairman.

Mr. Chairman, the issue we address today is vital to the health of our country. We are fortunate that modern technology and research has allowed us to develop the vaccines that will prevent deadly diseases in our children, diseases that at one time we were powerless against.

The issue at hand is how to best deliver these vaccines to the children and how to properly educate parents about the importance and availability of the vaccines.

It is somewhat unbelievable that our immunization rates are so low among preschool children. My daughter Jessica will turn 2 in June, and I am happy and relieved to be able to protect her against measles, mumps, polio and other diseases, and I wish the same for all parents.

The question we must examine today is what are the barriers to immunization, and how do we break them down; and then second, how do we pay for it.

Thank you very much, and I yield back the balance of my time.

Mr. WAXMAN. Thank you, Mr. Franks.

Senator Danforth is our first witness, and I understand he'll be walking in the door any minute. [Pause.] Meanwhile, we are pleased that Senator Jeffords is with us, and we're looking forward to his opening statement.

OPENING STATEMENT OF SENATOR JEFFORDS

Senator JEFFORDS. Thank you, Mr. Chairman. It is a pleasure to see all of you here.

I have a brief statement. Unfortunately, like everyone else, I have to be elsewhere for most of the time this morning, but I certainly wanted to come and lend my support to your endeavors.

I believe the hearing this morning is more than timely; it is very, very long overdue. We all know this country has a problem when

it comes to children's immunizations. The problem is costing us billions of dollars in health care costs because every dollar spent on immunization saves at least $10 in treatment costs.

But tragically, it is costing us untold numbers of deaths and illnesses. How can we begin to measure that pain?

Fewer than 60 percent of the 2-year-olds in most of our States are fully immunized. Clearly, the question is not whether something should be done, but what; at what monetary and other costs, and how do we pay for it?

The Comprehensive Child Immunization Act of 1993 is one approach. Is it the best? That is what we need to discuss at these hearings.

My State of Vermont, like other New England States, already has the universal distribution system called for in President Clinton's proposal essentially in place, and it is working, at least in Vermont, which has been recognized nationally for its high immunization levels of preschoolers. However, even the Vermont Department of Health acknowledges that significant numbers of preschoolers still are not vaccinated appropriately, particularly with respect to follow-up vaccinations, and the department stresses the need to motivate parents to utilize the increased vaccination opportunities.

So I will be looking for some basic clarification of concerns brought to my attention, specifically, how much of a contributing factor to the disappointing vaccination rate in this country is cost? What are the other major factors? How will the Vermont program, for example, be wrapped into the national program without damaging a program which already is doing pretty well? How will the national program affect U.S. industries' leadership in world vaccine development? Will artificial price and market constraints endanger R and D efforts? How will the $1 billion that the program is estimated to cost be raised? Thus far, we have been told only that the revenue will be identified in the overall health care reform legislation, and that doesn't do it. We need to have specifics on how this is going to occur. I know, because I have wrestled with this issue in preparing my own comprehensive health care reform proposal, called Medicore.

We have to know exactly where the dollars are coming from, both for overall immunization and reform. I for one want to work to identify these issues and find the answers to those hard questions.

This hearing should be very helpful, and I commend everyone who is involved and here today, as I think, hopefully, after this hearing and with some further investigation, we will be able to answer these questions and move forward.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Senator Jeffords.

We are pleased at this time to recognize Senator Danforth, who is a member of the Senate Finance Committee and has a strong interest in the area of childhood immunizations.

Welcome, Senator.

STATEMENT OF THE HONORABLE JOHN C. DANFORTH, A U.S. SENATOR FROM THE STATE OF MISSOURI

Senator DANFORTH. Mr. Chairman, thank you very much. This is a terrific hearing. I have never seen so many people in Congress at one hearing before. I feel like Oliver North. [Laughter.]

Mr. Chairman, I along with Senator Kassebaum, Senator Durenberger and others have been working on proposed legislation dealing with immunization, and we had hoped to have something to present to the committee before this hearing. We do not have it as yet. We look forward to introducing a bill perhaps later this week or maybe next week—in any event, in the very near future—for dealing with exactly the issue that is before this committee, although in a somewhat different form.

Let me say first of all that the problem that has been identified is an obvious problem. I first recognized it, I guess, about 3 years ago, when I was visiting the director of St. Louis Children's Hospital, an absolutely first-rate hospital, and I asked the director during that visit what is the main reason for admissions right now at Children's Hospital, and the director's answer was measles. To me, that was an astounding answer—measles. There shouldn't be any admissions for measles. And yet at that particular point of time, it was the leading reason for admissions in St. Louis Children's Hospital.

Then we started getting into the facts, and some of them have been mentioned already this morning, but one thing that struck me was that with respect to polio immunization for children under the age of one, the United States ranks behind Albania and behind Pakistan. So clearly, something is terribly wrong, and something has to be fixed.

And as I say, Senator Kassebaum and Senator Durenberger and I have been looking into ways to fix this serious problem. We believe that there is the basis for agreement, that there is the basis for bipartisan cooperation. Some are doubting whether that's possible. Of course, it is. And it is possible with respect to this all-important issue.

So we think that there is a basis for agreement and for reaching across the aisle and working together in legislation, and that some of the things that have been focused upon by the administration's bill really have to be done, and we have approaches which are pretty close, maybe a little bit different in some of the details, to some of these key issues that have been identified by the administration.

In looking into the whole question of lack of immunization and the reasons for it, we have come to the very strong conclusion that the reason for the problem is not cost, by and large, the reason is not cost. The reason, instead, is access, knowledge, various issues relating to the actual delivery, the availability of vaccinations to children.

When you talk to people about these reasons—and I had two meetings during this past recess in Missouri, one in Kansas City and one in St. Louis, with experts in the area—the reasons are complex. There are a number of them. They deal with such matters as the complexity of the informed consent form; transportation problems; parents' lack of knowledge about the importance and the various facts relating to immunization; doctors' lack of knowledge

about the circumstances under which vaccines can and cannot be administered; the hours public health clinics are open, whether they are open for after-work hours for parents who work to take their children by, whether they are open on weekends, and whether they are really accessible.

And then, one thing that we ran into in a number of States in the present system is the way that physicians are reimbursed if parents bring kids to private physicians. This varies. There are several different ways of doing it according to the States, but in a number of States the physicians are reimbursed in cash at a rate lower than the actual cost of buying the vaccine. So late last year, some of us introduced legislation which provided that physicians should be reimbursed in kind, that they should receive a dose for dose and that the dose would be bought under a mass purchasing arrangement, negotiated by the Federal Government, but the purchase is made by the States.

So what I am saying is that there are a number of problems relating to the actual delivery, the knowledge, the information, the outreach, the tracking, that are complex and that are related to the overall problem.

The legislation that Senator Kassebaum and Senator Durenberger and I are working on is legislation that deals, as the administration's bill does, with outreach; it deals with tracking, it deals with delivery, it deals with information. But the principal difference is that we do not have the universal purchase provision that is in the administration's bill. We don't have it because according to the Center for Disease Control, universal purchase, where it has occurred in some 11 States, has not in fact led to substantial changes in the actual rate of immunization—some five percentage points. Apparently, those five points are accounted for perhaps by other reasons other than universal purchase. But we feel that this is not the time in our country to provide another entitlement program that is not means-tested, another entitlement program for high-income people.

We feel that it is necessary for the general health of the country to try to get some grip on the rapid growth of entitlement programs. We are also concerned that to have a universal purchase program to totally disrupt the market system is one which attacks a very basic economic premise in this country which has worked very well with respect to developing and bringing into the marketplace new products.

So for those reasons, we do not agree with the universal purchase proposal. We are working on a proposal which would increase the number of people for whom no-cost vaccine would be available. Of course, it is generally available in public health clinics; it would continue to be for whomever shows up. But we would increase and expand access for Medicaid at least for the purpose of vaccination and maybe beyond that to 185 percent of poverty, which I am told would raise from about 30 percent to about 50 percent the number of kids who would be covered by the free vaccine program. To us, that would be a much more targeted approach, and it would avoid the pitfalls in the universal purchase program.

But I want to close simply by emphasizing the positive. While there is a point of disagreement, and while that point of disagree-

ment has become, I guess, the most famous part of this whole enterprise, the one that has attracted a lot of attention, we think that this is an important issue; we think that this is an issue on which there really should not be partisan or even philosophical differences. We believe that a bill could be passed which really does deal with the problem, that it could be passed very quickly, that it could be passed with very strong support from Republicans and Democrats, conservatives and liberals, and everybody else, and we would urge that on the people who are attending this hearing.

Thank you.

Mr. WAXMAN. Senator, I want to commend you on that statement. I think it is a very constructive approach to a problem that is not partisan, and I look forward to working with you and all of our colleagues on both sides of the aisle to try to meet the needs of the American people for immunization and do it in a most effective way.

Thank you very much. I don't know if any members want to ask any questions; if not, thank you for being here, and we'll work together.

Senator DANFORTH. Thank you, Mr. Chairman.

Senator KASSEBAUM. I would only comment, Mr. Chairman, that I appreciate Senator Danforth's patience and the patience of those who have been waiting to testify.

Mr. WAXMAN. Another person who has been very patient and is now going to make a presentation to us needs little introduction to those of us here. Secretary Shalala, we are honored that you have joined us today to address the issue of childhood immunizations.

Many of us have been working on this problem for years now, but within a few months of taking office, you have coordinated the administration's legislative proposal for comprehensive childhood immunizations. We are working hard to keep up with you. We welcome you to this joint hearing and look forward to your continued leadership on this issue.

STATEMENT OF HON. DONNA E. SHALALA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC.

Secretary SHALALA. Thank you, Congressman Waxman.

I am honored to appear at this special joint hearing before two of the key Senate and House committees that have taken the lead on ensuring the health of the American people.

Joint congressional hearings have been traditionally reserved for issues of the highest importance, and I can think of no issue that is more deserving of our time and interest than the immunization of our children against preventable infectious diseases such as mumps, measles, polio and whooping cough.

We should all be appalled that our Nation's childhood immunization system has become so ineffective that it is necessary for Congress to hold this hearing, and that our youngest Americans face barriers to immunization precisely when they are most vulnerable—before the age of 2.

But I am also pleased that we are here to discuss the solution, not just the problem. We are here to begin the process of removing barriers to immunization and ensuring that all children in the

United States of America are protected at the appropriate age against crippling childhood diseases.

The problem is enormous. Although 95 percent of school-age children are properly immunized, our preschool vaccination rates are dismal. According to the Centers for Disease Control and Prevention, some 40 to 60 percent of American toddlers have not received the proper vaccination series by their second birthday. In some inner-city areas, the rate is as low as 10 percent.

A brief look at this chart shows that to be fully immunized, a child must be protected against nine diseases. Administering the entire sequence of shots is no easy matter. Full immunization requires that a child be inoculated 18 times with five vaccines, and all but three of the 18 doses should be received by the age of 2. This regime would require five additional visits to the doctor's office after birth—at 2 months, at 4 months, at 6 months, 12 months, and 15 months.

America's immunization delivery system is deteriorating rapidly. Reductions in resources, increases in disease incidence, and patient-shifting from private providers to public sector clinics have outstretched our abilities to identify children who need vaccinations and to provide them.

There are not enough clinics, and where they do exist, they are often understaffed, overworked, and closed during critical hours. Unfortunately, too often, children who need shots are required to make advance appointments or to have a physician referral.

Sometimes children are denied shots because they have a runny nose or haven't had a physical exam. Each of these obstacles makes it more difficult for parents to have their children immunized.

American families are getting squeezed by the skyrocketing prices of vaccines. As this accompanying graph illustrates, the vaccine cost to fully immunize a child has increased significantly from 1982 to 1992. In 1982, the cost of vaccine to fully immunize a child in the public and private sectors was approximately $7 and $23, respectively. By 1992, those costs had risen to $122 in the public sector and $244 in the private sector. In part, these cost increases can be attributed to recommendations for new vaccines, to additional doses of existing vaccines, and to an excise tax used to fund the vaccine compensation program.

But these factors do not account for the net increase in the cost of existing vaccines. For example, another graph I'd like to share with you shows that in 1982, the measles, mumps and rubella, or MMR vaccine, cost $10.44 per dose in the private sector, but in 1992, the same dose cost $25.29. Even if you subtract the $4.44 per dose excise tax instituted in 1988, the price of the MMR vaccine still doubled. The diphtheria, tetanus, and pertussis vaccine, or DTP, increased even more sharply—from 37 cents in 1982 to a whopping $10.04 in 1992. With the $4.56 excise tax excluded, that's a net price increase of $5.11, or almost a 14-fold hike per dose.

But what is the societal cost? According to our most recent estimates from the CDC, the failure to immunize our children on time led to the measles resurgence between 1989 and 1991. This epidemic resulted in over 55,000 cases of measles, 130 deaths, 11,000 hospitalizations, and 44,000 hospital days, with an estimated $150 million in direct medical costs—and that doesn't include the mas-

sive indirect costs stemming from the lost time on the job, lost productivity, and lost wages—costs that could have been avoided by merely providing families with a vaccine that cost about $24 a dose in 1988.

I'd like you to look at another chart I've brought here today. It graphically illustrates that the United States has one of the lowest immunization rates for preschool children when compared to European countries. And note that for the United States, the percentages are for children aged one to 4, while the European figures are for children under 3 for DTP and polio, and under 2 for measles. Parenthetically, I would also note that the data from the World Health Organization places our immunization rate for one dose of measles by 24 months of age behind countries such as Argentina, Costa Rica, Grenada, and even Cuba.

As you know, the President has requested an additional $300 million in the jobs bill to strengthen this country's immunization infrastructure, which we estimate will create between 4,000 and 5,000 new jobs. These funds would help communities to immediately strengthen delivery systems, to broaden their outreach efforts, to increase access to immunization services, to enhance parent and provider education programs, and to provide a host of other essential activities.

These endeavors alone are not enough. The legislation currently under consideration, as proposed by the President on April 1st, contains the solutions, the means, for removing the other systemic barriers to immunization.

The high price of vaccines is a significant financial barrier to obtaining vaccinations for preschool children. The absence of a tracking system has impeded local and State efforts to ensure that all children are vaccinated. A viable vaccine injury compensation program must be maintained and strengthened to increase public confidence in the safety of vaccination. Finally, information for parents on the benefits and risks of vaccines must be presented in clear, concise, and understandable terms.

This bill authorizes the purchase of all vaccines by the Federal Government to be given at no cost to providers. Our plan will eliminate financial barriers that impede the timely vaccination of children and facilitate the development of a national immunization tracking system.

The bill directs the Secretary to negotiate a reasonable price with manufacturers based on data supplied by the manufacturers regarding costs in the following areas: research and development, production, distribution, marketing, profit levels sufficient to encourage further investment in research and development, and the ability to maintain adequate outbreak control. Such data would be treated as trade secrets, or confidential information in accordance with the Freedom of Information Act, and the bill would provide criminal sanctions for violations of this provision.

We want to ensure a secure and adequate supply of vaccines and to stimulate competition among manufacturers. To this end, when possible, contracts would be put out for competitive bidding to multiple manufacturers of various vaccines. Vaccines would be provided to States for free distribution to health care providers who serve children. Such providers would not be allowed to charge pa-

tients for the cost of vaccines, but could require a fee for vaccine administration. However, no one could be denied immunization because of the inability to pay.

In addition, the bill would increase immunization levels of children receiving Medicaid by assuring appropriate reimbursement to providers for vaccine administration. Medicaid programs would take into account the reasonable cost of furnishing immunizations and to calculate payment rates for vaccine administration separately from payment rates for office visits or other services.

A few key points need to be made about the purchase and universal provision of vaccines. Critics have argued, "Why should we pay for vaccines for those who can already afford them?" We can answer that question.

First, because of patient shifting from private providers to public clinics, we are already providing free vaccines to thousands of families who can afford them. The American Academy of Pediatrics has reported that 50 percent of practicing pediatricians refer some or all children with health insurance to clinics for immunizations. Universal provision of vaccines could stop this flow of private patient shifting to public clinics and free up needed resources for the truly needy.

Second, providing vaccines based on family income would require means testing, another barrier which could be enforced only by the physicians. It would be counterproductive, in our judgment, to impose on America's physicians and health care providers a whole new set of reporting and paperwork requirements that a means-tested system would require. The purpose of this initiative is to eliminate barriers to immunization, not create more of them.

Proper immunization should be a basic right for every child in America, rich or poor, just like in most other industrialized countries. We don't "means test" the right to public education, we don't "means test" the right to clean air or clean water. Nor should we make access to the most basic form of disease prevention a matter of family income.

Also, the point must be made that by assuring a stable and strong purchasing program for vaccines, with fair prices paid, this system may stimulate rather than inhibit competition. In other words, some manufacturers actually could return to the vaccine market because of the stability and reliability inherent in the President's plan.

Finally, universal purchase is also a key to the development of the national immunization tracking system which is necessary to assist in attaining full immunization of children by their second birthday.

We cannot ensure that all children are immunized unless we know which vaccinations we need. That's why the bill provides for a collaborative Federal and State tracking system. Our system would notify parents when immunizations are due and remind them if they do not keep appointments. Children in need would be identified for special outreach efforts. Immunization levels would be monitored at the local level to track progress toward meeting State and national immunization goals.

Federal grants would be provided to States to establish and operate State immunization registries containing specific information

on each child starting from birth. Such information would include at a minimum immunization history, types and lot numbers of vaccines received, health care provider identification, demographic data, and notations of adverse events associated with immunizations. The national system will include information on all preschool children, beginning at birth, and will identify the State tracking system in which the child's immunization record is located. The national system will link all State tracking systems and transfer actual immunization records when the child relocates to a new State.

Providers would be required to report to the State tracking registry information regarding each vaccine administered. The efficacy and safety and of vaccines would be monitored by linking vaccine administration records with adverse events and disease patterns.

The bill would also require that security measures be established to assure the confidentiality of information collected. The registries, we believe, could be fully operational by October 1st of 1996.

A functioning national vaccine injury compensation program is critical to the national immunization effort. The very few children who suffer vaccine-related injuries must be compensated for those injuries, and so should their families.

In 1988, the National Childhood Vaccine Injury Compensation Act was funded through an excise tax on each dose of vaccine, and this no-fault system greatly reduced the number of lawsuits filed against manufacturers. However, the authority to pay awards expired on October 1, 1992, and the tax was suspended on January 1, 1993 by the Secretary of the Treasury. These provisions would have been extended routinely but for their inclusion in the urban aid legislation which was vetoed last year.

This new bill would reauthorize payment from the trust fund for compensable injuries attributable to vaccines administered on or after October 1, 1992. The bill also provides for the permanent extension and reinstatement of the vaccine excise tax, so that funding will continue to be reserved for the compensation program.

Additionally, the bill provides a mechanism for automatically covering new recommended vaccines under the compensation program; allows the chief special master to suspend proceedings on petitions for retrospective claims for up to 30 months rather than the 18 months in the current law; and simplifies the vaccine information materials currently in use and the process of revising those materials.

Great nations, Mr. Chairman, invest in their people—and no investment is more fundamental and more cost-effective than immunizations. We can and must develop a comprehensive program to reduce barriers to immunizations and to protect all of our children—which are, after all, the future of our country and our greatest natural resource.

The President's legislation will ensure that all children in the United States are protected against preventable infectious diseases by their second birthday. This legislation inaugurates a new partnership among parents and guardians, among health care providers, public and private, among vaccine manufacturers, and the Federal, State and local governments to ensure that all American children have the opportunity to live full and healthy lives.

The Congress now has before it for its consideration three bills that reflect President Clinton's legislative proposal—S. 732, S. 733, and H.R. 1640. To those of you who have sponsored and cosponsored the legislation, we applaud your leadership. To your colleagues who have it under consideration, we urge your support.

Thank you, and I would be happy to answer any questions you might have.

[The prepared statement of Secretary Shalala follows:]

PREPARED STATEMENT OF DONNA E. SHALALA

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American families are getting squeezed by the sky rocketing prices of vaccines. As this accompanying graph illustrates, the vaccine cost to fully immunize a child has increased significantly from 1982 to 1992. In 1982, the cost of vaccine to fully immunize a child in the public and private sectors was approximately $7 and $23, respectively. By 1992, those costs had risen to $122 in the public sector and $244 in the private sector. In part, these cost increases can be attributed to recommendations for new vaccines, to additional doses of existing vaccines, and to an excise tax used to fund the vaccine compensation program.

But these factors do not account for the net increase in the cost of existing vaccines. For example, another graph I'd like to share with you shows that in 1982, the measles, mumps and rubella, or MMR vaccine, cost $10.44 per dose in the private sector—but in 1992 the same dose cost $25.29. Even if you subtract the $4.44 per dose excise tax instituted in 1988, the price of the MMR vaccine still doubled. The diphtheria, tetanus, and pertussis vaccine or DTP, increased even more sharply—from 37 cents in 1982 to a whopping $10.04 in 1992. With the $4.56 excise tax excluded, that's a net price increase of $5.11, or almost a 14-fold hike per dose.

But what is the societal cost? According to the most recent estimates from the CDC, the failure to immunize our children on time led to the measles resurgence between 1989 and 1991. This epidemic resulted in over 55,000 cases of measles, 130 deaths, 11,000 hospitalizations, and 44,000 hospital days—with an estimated $150

million in direct medical costs. And that doesn't include the massive indirect costs stemming from lost time on the job, lost productivity, and lost wages—costs that could have been avoided by merely providing families with a vaccine that cost about $24 a dose in 1988.

I'd like you to look at another chart I have brought here today. It graphically illustrates that the United States has one of the lowest immunization rates for preschool children when compared with European countries. And note that for the United States the percentages are for children aged 1 to 4, while the European figures are for children under 3 for DTP and Polio, and under 2 for measles. Parenthetically, I would also note that data from the World Health Organization places our immunization rates for one dose of measles by twenty-four months of age behind countries such as Argentina, Costa Rica, Grenada, and even Cuba.

As you know, the President has requested an additional $300 million in the jobs bill to strengthen this country's immunization infrastructure, which we estimate will create between 4,000 and 5,000 new jobs. These funds would help communities to immediately strengthen delivery systems, broaden outreach efforts, increase access to immunization services, enhance parent and provider education programs, and provide a host of other essential activities.

These endeavors alone are not enough. The legislation currently under consideration, as proposed by the President on April 1, contains the solutions—the means—for removing the other systemic barriers to immunization.

The high price of vaccines is a significant financial barrier to obtaining vaccinations. The absence of a tracking system has impeded local and State efforts to ensure that all children are vaccinated. A viable Vaccine Injury Compensation Program must be maintained and strengthened to increase public confidence in the safety of vaccination. Finally, information for parents on the benefits and risks of vaccines must be presented in clear, concise, and understandable terms.

LEGISLATIVE PROPOSAL

This bill authorizes the purchase of all vaccines by the Federal Government to be given at no cost to providers. Our plan will eliminate financial barriers that impede the timely vaccination of children and facilitate development of a national immunization tracking system.

The bill directs the Secretary to negotiate a reasonable price with manufacturers based on data supplied by the manufacturers regarding costs in the following areas: research and development, production, distribution, marketing, profit levels sufficient to encourage future investment in research and development, and the ability to maintain adequate outbreak control. Such data would be treated as trade secrets, or confidential information in accordance with the Freedom of Information Act, and the bill would provide criminal sanctions for violations of this provision.

We want to ensure a secure and adequate supply of vaccines and to stimulate competition among manufacturers. To this end, when possible, contracts would be put out for competitive bidding to multiple manufacturers of various vaccines.

Vaccines would be provided to states for free distribution to health care providers who serve children. Such providers would not be allowed to charge patients for the cost of vaccines, but could require a fee for vaccine administration. However, no one could be denied immunization because of the inability to pay.

In addition, the bill would increase immunization levels of children receiving Medicaid by assuring appropriate reimbursement to providers for vaccine administration. Medicaid programs would take into account the reasonable cost of furnishing immunizations and calculate payment rates for vaccine administration separately from payment rates for office visits or other services.

A few key points need to be made about the purchase and universal provision of vaccines. Critics have argued, "Why should we pay for vaccines for those who can already afford them?" We can answer that question.

First, because of patient shifting from private providers to public clinics, we are already providing free vaccines to families that can afford them. The American Academy of Pediatrics reports that 50 percent of practicing pediatricians refer some or all children with health insurance to clinics for immunizations. Universal provision of vaccines could stop this flow of private patient shifting to public clinics and free-up needed resources for the truly needy.

Second, providing vaccines based on family income would require means-testing, another barrier which could be enforced only by the physicians. It would be counterproductive to impose on physicians and health care providers a whole new set of reporting and paperwork requirements that a means-tested system would require. The purpose of this initiative is to eliminate barriers to immunization, not create more of them.

Proper immunization should be a basic right for every child in America—rich or poor—just like in most other industrialized countries. We don't "means test" the right to public education, to clean air or clean water. Nor should we make access to the most basic form of disease prevention a matter of family income.

Also, the point must be made that by assuring a stable and strong purchasing program for vaccines, with fair prices paid, this system may stimulate, rather than inhibit, competition. In other words, some manufacturers actually could return to the vaccine market because of the stability and reliability inherent in the President's plan.

Finally, universal purchase is also key to the development of the national immunization tracking system necessary to assist in attaining full immunization of children by their second birthday.

We cannot ensure that all children are immunized unless we know which vaccinations they need. That's why the bill provides for a collaborative Federal and state tracking system. Our system would notify parents when immunizations are due and remind them if they do not keep appointments. Children in need would be identified for special outreach efforts. Immunization levels would be monitored at the local level to track progress toward meeting state and national immunization goals.

Federal grants would be provided to states to establish and operate state immunization registries containing specific information on each child starting from birth. Such information would include at a minimum: 1) immunization history, 2) types and lot numbers of vaccines received, 3) health care provider identification, 4) demographic data, and 5) notations of adverse events associated with immunizations. The National System will include information on all preschool children, beginning at birth, and will identify the state tracking system in which the child's immunization record is located. The National System will link all State tracking systems and transfer actual immunization records when the child relocates to a new State.

Providers would be required to report to the state tracking registry information regarding each vaccine administered. The efficacy and safety of vaccines would be monitored by linking vaccine administration records with adverse events and disease patterns. The bill also would require that security measures be established to assure the confidentiality of the information collected. The registries would be fully operational by October 1, 1996.

A functioning National Vaccine Injury Compensation Program is critical to the national immunization effort. The very few children who suffer vaccine-related injuries must be compensated for those injuries, and so should their families.

In 1988, the National Childhood Vaccine Injury Compensation Act was funded through an excise tax on each dose of vaccine, and this no-fault system greatly reduced the number of lawsuits filed against manufacturers. However, the authority to pay awards expired on October 1, 1992, and the tax was suspended on January 1, 1993 by the Secretary of the Treasury. These provisions would have been extended routinely but for their inclusion in the urban aid legislation vetoed last year.

This bill would reauthorize payment from the Trust Fund for compensable injuries attributable to vaccines administered on or after October 1, 1992. The bill also provides for the permanent extension and reinstatement of the vaccine excise tax, so that funding will continue to be reserved for the Compensation Program.

Additionally, the bill provides a mechanism for automatically covering new recommended vaccines under the Compensation Program; allows the Chief Special Master to suspend proceedings on petitions for retrospective claims for up to 30 months, rather than the 18 months in current law; and simplifies the vaccine information materials currently in use and the process of revising chose materials.

Great nations invest in their people—and no investment is more fundamental and more cost effective than immunizations. We can and must develop a comprehensive program to immunizations and to protect our children—who are, after all the future of our country and our greatest natural resource.

The President's legislation will ensure that all children in the United States are protected against preventable infectious diseases by their second birthday. This legislation inaugurates a new partnership among parents and guardians; health care providers; vaccine manufacturers; and Federal, State, and local governments to ensure that all children have the opportunity to live fully healthy lives.

The Congress now has before it, for its consideration, three bills that reflect President Clinton's legislative proposal, S. 732, S. 733, and H.R. 1640. To those of you who sponsored and cosponsored this legislation, I applaud your leadership. To your colleagues who have it under consideration, I urge your support.

Thank you and I would be happy to answer any questions.

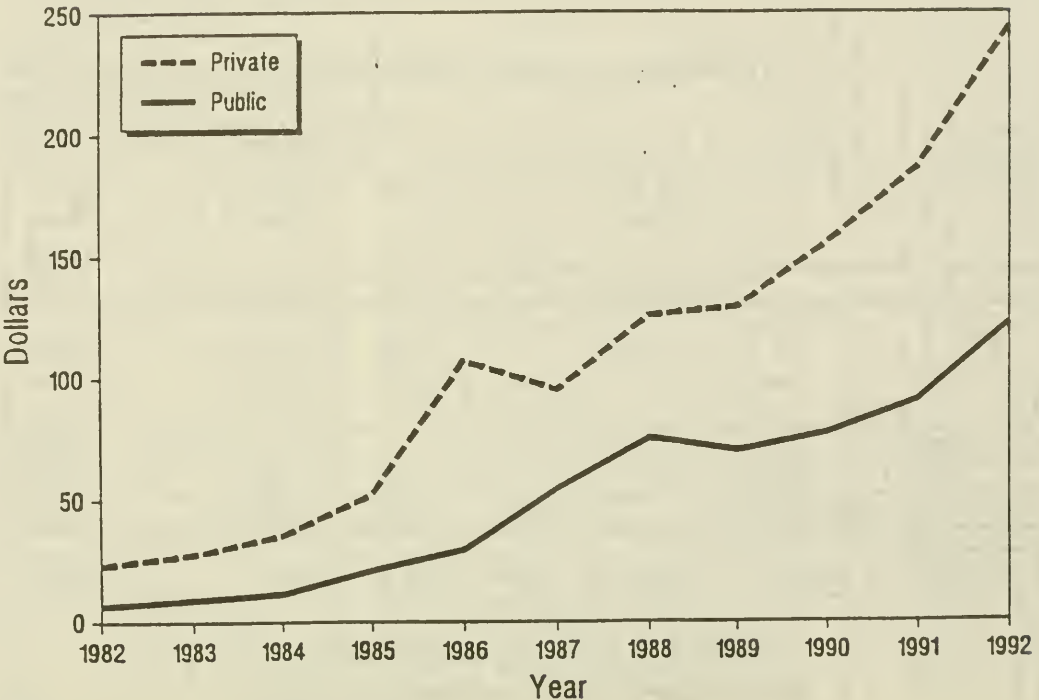
ACIP Recommended Schedule of Vaccinations for All Children

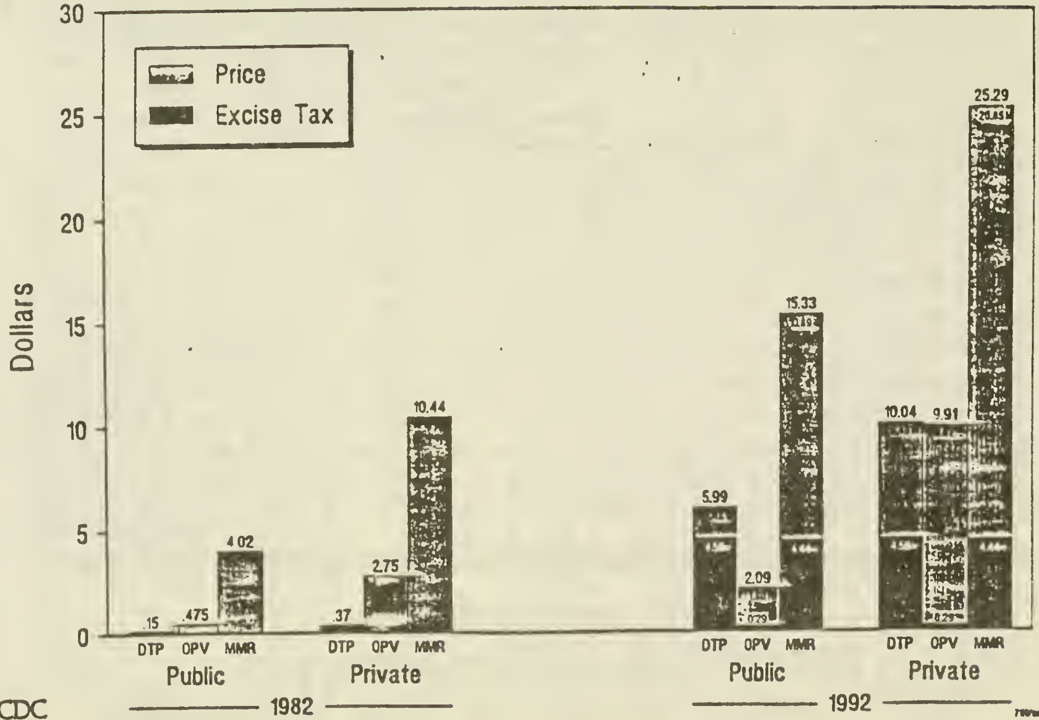
Vaccine		2 Mos[1]	4 Mos	6 Mos	12 Mos	15 Mos	4-6 Years (Before School Entry)
DTP		DTP	DTP	DTP		DTaP(DTP)[2]	DTaP(DTP)
OPV		OPV	OPV			OPV[2]	OPV
MMR						MMR[3]	MMR[5]
HbCV							
Option 1[4]		HbCV	HbCV	HbCV		HbCV	
Option 2[4]		HbCV	HbCV		HbCV		
Vaccine	**Birth**	**1-2 Mos**	**4 Mos**	**6-18 Mos**			
Hep B[6]							
Option 1	Hep B	Hep B[7]		Hep B[7]			
Option 2		Hep B[7]	Hep B[7]	Hep B[7]			

DTP: Diphteria, Tetanus, and Pertussis Vaccine
DTaP: Diphteria, Tetanus and acellular Pertussis Vaccine
OPV: Live Oral Polio Vaccine
MMR: Measles, Mumps, and Rubella Vaccine
HbCV: *Haemophilus* b Conjugate Vaccine; consult package insert for recommendation for specific product used.
HBV: Hepatitis B Vaccine

[1] Can begin at 6 weeks of age.
[2] Many experts recommend these vaccines at 18 months.
[3] In some areas this dose of MMR vaccine may be given at 12 months.
[4] HIB vaccine is given in either a 4-dose schedule (1) or a 3-dose schedule (2), depending on the type of vaccine used.
[5] American Academy of Pediatrics recommend this dose of MMR vaccine be given at entry to middle school or junior high.
[6] For infants born of HBsAg-negative mothers. (Infants weighing <2000 grams, Option 2 preferred, giving 1st dose at 2 mos).
[7] Hepatitis B vaccine can be given simultaneously with DTP, Polio, MMR, and *Haemophilus* b conjugate vaccine (HbCV) at the same visit.

Vaccine Costs to Fully Immunize a Child 1982 Through 1992, Public and Private Sectors





Price Per Dose - 1982 Versus 1992
Public and Private Sectors
Price
Excise Tax
Dollars
30
25
20
15
10
5
0
.15
.475
4.02
.37
2.75
10.44
5.99
2.09
15.33
10.04
9.91
25.29
DTP OPV MMR
Public
Private
1982
1992
CDC

Immunization Rates for Preschool Children in the United States and European Countries

(Most Recent Available Year)

Figures are in percent

Country	Year	DTP[a]	Measles[b]	Polio[c]
Belgium (estimated)	1987	95.0	90.0	99.0
Denmark	1987	94.0[d]	82.0	100.0
England and Wales	1987	87.0[e]	76.0	87.0
France (estimated)	1986	97.0	55.0	97.0
Germany (FRG) (estimated)	1987	95.0	50.0	95.0
Netherlands	1987	96.9	92.8	96.9
Norway	1987	80.0	87.0	80.0
Spain	1986	88.0	83.0	80.0
Switzerland	1986	90-98	60-70	95-98
United States[f]	1985	64.9	60.8	55.3

[a] Three doses or more. U.S. rates are for children aged 1 to 4; European figures are for children under 3.

[b] U.S. rates are for children aged 1 to 4; European figures are for children under age 2.

[c] Three doses or more. U.S. rates are for children aged 1 to 4; European figures are for children aged 1 to 3.

[d] Rate is for combined diptheria, tetanus, and polio immunizations. Pertussis (89 percent coverage) and oral polio vaccines are given at separate visits; sequential immunization against polio by both injectable and oral vaccines is recommended.

[e] Rate is for diptheria and tetanus; rate for pertussis immunization is 73 percent.

[f] Immunization rate data for the United States are shown for the total sample population of the 1985 United States Immunization Survey, the last year the survey was taken.

SOURCE: B. Williams and C. Miller, Preventive Health Care for Young Children Findings from a 10-County Study and Directions for United States Policy, 1991.

The CHAIRMAN. Thank you very much, Madam Secretary, for an excellent statement.

We will now follow a 5-minute rule that will apply to the members, and also, hopefully, to the response. We want this hearing to be accurate and complete, but we'll try and do that in fairness to all of the witnesses here today, and we'll rotate back and forth.

Senator Riegle has other business which will necessitate his departure, so I'll yield my time to Senator Riegle and recognize him for 5 minutes. I think all of us regret this timing machine more than anything else, but I would ask staff to comply with the request.

Senator RIEGLE. Thank you very much, Senator Kennedy.

Madam Secretary, let me begin by saying I appreciate your leadership on this issue. People can always drum up reasons why we shouldn't find a way to solve a serious national problem and to sort of throw obstacles in the way. You strike me as a person who is determined to try to take the obstacles down and to get this accomplished.

I am struck by the fact that other nations are finding ways to do this. You know, it isn't rocket science to figure out how to get these immunizations to these children. And when Third World countries are able to do it more effectively than we are, I think we have to face this issue and decide to solve it.

The data that I have been able to see—and I'd like your confirmation on this—from the Centers for Disease Control shows that three-fourths of the 2-year-olds who aren't fully immunized are in fact above the poverty line. Is that right?

Secretary SHALALA. Yes, Senator.

Senator RIEGLE. So most of the kids out there aren't kids in poverty—many are, but the greater number, 75 percent, of those who aren't immunized are actually children from families above the poverty line. I think this shows the difficulties of getting these immunizations to kids essentially across the board in our society.

Now, the data that I have indicate that the backgrounds of the children who are not immunized by the time they should be, just to give the public an idea and to put it into the record, some 40 percent are white children, some 65 percent are minority children, some 60 percent are children who live in cities, and some 39 percent are living in rural and suburban areas. So this is a problem that stretches across the 50 States, and it is found in all kinds of communities.

Looking at this from the point of view of how you would really change the system, I thought your testimony, by the way, was exceptionally well-done; I think you put all of the supposed objections up there, and you answered them one-by-one, in terms of how this would reduce cost and how this would enable us to get this kind of universal coverage.

A central bulk purchasing program would see to it that all providers have vaccines in their offices, ready to go, and can administer these shots. In a private doctor's office, for example, they might charge some small administrative fee to do this, but the big cost, the cost of the medicine, the vaccine itself, would, of course, be taken care of. So that would create an incentive for the doctor who is providing that primary care to go ahead and do it right

there—not send that family out the door and say, "Go find a public clinic somewhere," which they may or may not do.

Is that essentially what we're driving at here?

Secretary SHALALA. Yes.

Senator RIEGLE. Now, with respect to the $300 million in the stimulus program, that is really designed to help these overburdened public clinics, is it not, where people now go and stand in line, wait half the day, and sometimes they can't even get in on a given day because of the enormous burden out there—isn't it really designed to try to relieve that and to see to it these kids get the help they need?

Secretary SHALALA. Yes, it is, Senator.

Senator RIEGLE. When I think of urgent needs in this country, you know, we've got 50,000 nuclear warheads in our arsenal that we found the money to buy and to pay for. We've spent hundreds of billions of dollars, and frankly, not all that many questions were asked about doing it. Now we've got all these weapons that we can't use, and it's going to cost us a fortune to get rid of them.

Here, we are talking about something as fundamental as protecting our children, which after all, we talk about that being our most important natural resources, and clearly it is—if our people aren't, then the government isn't worth much, because our people truly are what our government should be aimed at helping and, in a sense, protecting. In fact, all these nuclear warheads we have presumably are designed to protect our people, and here we are with something as fundamental as a vaccination that can protect children against diseases that can kill them or handicap them for life, and in effect what we've said up until now is that, well, we can't figure out a way to do it; it's just too tough, and we can't afford it—yet we can afford every other kind of thing out there.

I think finally, with respect to the tracking system, you know, we live in a computer age, and it seems to me it shouldn't be that hard to establish a record, a permanent record. I like the idea of working with Social Security numbers, because that's a number that we take with us through our lifetimes, to see to it that we have a way of having a record on each child. Isn't the science and the practicalities now of just modern data processing sufficient that we can have these kinds of logs and maintain them so we have a way of having a record on the children of this country?

Secretary SHALALA. Yes, and most American doctors will have their computer systems up and operating because of Medicare requirements long before this new tracking system is put in place.

Senator RIEGLE. So they can just add this right onto that, so they will already have this capability.

Secretary SHALALA. Yes.

Senator RIEGLE. Now, finally—well, my time is up. Thank you.

Mr. WAXMAN. Thank you, Senator Riegle.

Secretary Shalala, I want to commend you on your statement. I thought it was an excellent statement as well. It is heartening to see the strong bipartisan support behind the initiative of this administration, and I don't think we are going to see any disagreement over the idea that we need to immunize children in this country, although I do want to point out that it has taken this bipartisan agreement behind the leadership that you and the administra-

tion have given to the whole question of making this a high priority.

We are going to hear later from the pharmaceutical companies, and they are going to argue, I believe, probably each and every one of them, that we shouldn't have the government purchase all the vaccines and then distribute them out to the clinics or even to the private doctors to be used for immunizations. I know you made reference to this in your statement, but this is a focal point for some attention. Why should we have universal purchase? Why not just let the government purchase for low-income people and then those who can afford to buy it on their own will buy it on their own, even if they pay a higher price?

Secretary SHALALA. There are a number of reasons for that. We obviously don't want to rebuild the public system so it covers all the children who are now served by their private physicians. We believe—and you will see it in our health care reform system—that we ought to build on a substantial public-private medical system that we have in this country.

What universal purchase will allow us to do is to use the current delivery system. The private doctors and the pediatricians who testify will report this, how now, for cost reasons, they are referring their children to the public clinics, which are unable to take on the responsibility for delivering without long lines and without appointments to all those children. We are losing children in the referral process. So that under the current system, middle-income parents can indeed go to a public clinic and get free shots.

And what we are trying to do is to make sure we don't break the connection between parents and their children and their own doctors. So we think that a universal purchase system, if we distribute the vaccines free, will in fact build on the existing system and keep the close connection and the continuity of the relationship between private doctors and their own patients.

Mr. WAXMAN. It is an interesting argument that you are making, because a lot of people are suggesting that what universal purchase of vaccines would mean is that the government is going to run the whole program; but in effect what you are saying is that if we can get universal purchase of vaccines, you would like to then see more people go to their private doctors rather than the public clinics.

Secretary SHALALA. Absolutely. In fact, I am arguing against a large public bureaucracy. I am arguing that while we need to rebuild the public health delivery system because it is very weak and heavily used by very poor individuals, that we should not in the process destroy the role of private pediatricians and private family physicians and their patients. They very much ought to be delivering the vaccines and having that ongoing relationship with the family.

Mr. WAXMAN. How do you answer the other argument that I know will be made, that is, if we have one purchaser of vaccines, we are going to in some way inhibit the research and development for new innovation in vaccines that are going to be more effective for the future?

Secretary SHALALA. I think we've indicated, and some of the things that are written in the bill certainly protect in the negotiations research and development. I would also say that the govern-

ment has some experience in this. Large American companies whose primary customer is the government have had a lot of experience in the negotiations, protecting the R and D. Senator Riegle mentioned the nuclear warheads, and there have not been a lot of complaints, it seems to me, from the part of the industry in this country that does purchasing and provides things for the Defense Department, that the government is insensitive to their R and D needs.

I would argue that we are sophisticated enough as a government and that my Department in particular is deeply committed to research and development in the vaccine industry, and there is just no way that we're going to permit a negotiation that doesn't protect that interest. And we also intend where we can to have multiple purchases of the same vaccine so that it won't be just one company, but as many companies as we can get involved.

We believe, too, that the stability of the government purchaser will help offer some stability to American vaccine companies.

Mr. WAXMAN. Are you giving the same kind of argument that one might give if you said the military has been the main purchaser of weapons, and that certainly hasn't inhibited development of new weapons, and that if the government is the purchaser of vaccines, it will not inhibit, and in fact it could well promote, the research and development for new vaccines?

Secretary SHALALA. It may well be. And beyond the Defense Department, there are numerous examples throughout the government of the relationship between the government and American industry and government purchasing and government involvement helping the R and D relationship. So that I just think we can do it, and for the kids of this country it is important that we do.

Mr. WAXMAN. Thank you.

The CHAIRMAN. Senator Kassebaum.

Senator KASSEBAUM. Madam Secretary, I think there is no one who can make a more thoughtful and I know dedicated effort to this initiative than yourself.

I'd like to move away from the Defense Department for a moment, because I don't think that's a very good analogy. There were some of us who thought the Defense Department didn't do a very good job with their research and development and paying for their research and development.

So I'd like to move on from that for a moment to just explore with you the premise of the administration's immunization plan. I think all of us here recognize it is important to eliminate the barriers to immunization, as you said. But where I have a problem is in believing that universal purchase will indeed do that and cost is the major barrier.

I really do feel myself that there are other factors that come into play, and one of them is the parents' lack of knowledge. I think that for many, the growth in the number of recommended vaccines may not be understood. Nor is the early age at which immunization becomes important clearly understood. And as I am sure you are well aware, there have been those in the Public Health Service who have indicated that the children most at risk of not being immunized are those who are Medicaid-eligible and for whose families, therefore, the cost of vaccines is not the problem.

You mentioned private physicians, and I think that's important. One of the problems, I would suggest—and I would like your comment on—is that these private physicians are reluctant to accept Medicaid patients because of poor provider reimbursement rates, the failure of some States to pay for required follow-up visits, and the paperwork hassles entailed in filing claims.

And I would suggest that these are things that we need to address, and with the moneys that would be spent for universal purchase, we could address some of these other barriers first.

Would you care to comment on that?

Secretary SHALALA. Yes. Thank you, Senator. Senator, I agree with you, and in fact in the stimulus package, we put in the resources to rebuild the infrastructure. We pledge that we'll straighten out the Medicaid reimbursement issues that will eliminate the paperwork that would provide a barrier.

I think the point of this bill is that what we've learned from our experience in the other States is that we have to do everything; that universal purchase cannot be the centerpiece. In fact, you have to have the infrastructure in place so that the private doctor can provide the service to the children. And to do that, you need to expand the hours of public clinics to make sure you have providers in place, to have an educational campaign that is extraordinary so that every parent not only hears about it, but feels that it is their responsibility.

So I would simply say all of the above—but we can't take one large link out. If we have learned anything about international campaigns or about national campaigns to do something as fundamental as this, it is that you have to put a public and private infrastructure in place so that no one falls between the cracks. So it's all of the pieces that have to be put in place, and what I am arguing for today is all of the pieces, and I concede your points about the infrastructure pieces that have to be in place.

Senator KASSEBAUM. It's just that I think, Madam Secretary, universal purchase does become the centerpiece. And I guess I would say for the billion dollars that is just a start, annually, we could triple the number of community health centers; we could really do some of the other things to correct what seem to me are greater barriers with the money we would spend on universal purchase.

My time, I have been notified, is about to expire, but I would just like to say that I support those who have said this is not a partisan issue. I think there are ways that we could, I hope, work on this as it moves along, in a bipartisan fashion, because I think there are many things on which we would agree.

But I have serious reservations about universal purchase. As we work together on this, I hope we can each provide some assurances to each other about whether this is indeed the answer. I know I still need to be convinced.

Secretary SHALALA. Well, Senator, if I could only repeat just quickly, if you'll just keep in mind that what we don't want to do is to build a huge public bureaucracy. What we do want to do is involve private physicians, private pediatricians, and to keep that continuity between young people, between children and their private doctors; that now, private doctors are referring patients to

public clinics because of the cost, in large part because of the cost. We need to deal with that issue as part of this bill, or 60 percent of those who are above the poverty line will continue not to have vaccinations for their children.

Senator KASSEBAUM. Thank you.

Mr. WAXMAN. Thank you, Senator Kassebaum.

Mr. Greenwood.

Mr. GREENWOOD. Good morning, Madam Secretary.

Secretary SHALALA. Good morning.

Mr. GREENWOOD. Immediately prior to my entry into politics, I was a child welfare case worker, and so was my wife. We spent a lot of time in the homes of families where there were less than ideal parenting skills, where we needed to educate the parents, we needed to coax parents and in some cases require parents to do the things that were necessary for their children.

There has been a logic proposed here by Senator Gregg from New Hampshire and Representative Klug from Wisconsin that I would like to pursue with you. We look at the fact that 2-year-olds have a 50 percent immunization record in this country. But by the time children are going to public schools, where the States require them to be immunized, that percentage leaps to 95 or 97 percent. And it seems logical, certainly on the face of it, to conclude that what is happening is that although there may be barriers to immunization, these barriers disappear when parents are told that in order to receive the service of public education, you must have your children immunized. Suddenly, the children become immunized.

So the argument has been proposed that since the Federal Government and the State governments, through their taxpayers, provide AFDC for children and the WIC nutrition program, and programs like Head Start and day care, we could simply make it a requirement of those programs that children be immunized. In fact, the caseworker would say when the mother applies for the medical assistance card for her child, "Yes, your child is eligible, and here is the card. We require that your child be immunized and that you follow up. We will work with you to do that." And the same thing could occur at day care settings and so forth.

There is a logic that says that would work. It wouldn't take a billion dollars, it wouldn't take most of what is in this bill, and it would work effectively. The logic of this argument also observes the fact that there are lots of places in this country where children have immediate access in terms of geography to clinics where there are free immunizations. The parents are not availing themselves of that service, and it is probably because they have not been required to do so.

I would like to hear your response to that argument.

Secretary SHALALA. Congressman, I think it is very important to remember that this is not a poverty program and that the problem of vaccinations in this country for preschool children is a problem for every American family, and that the high rates of children who are over the poverty line, who don't participate in the WIC program or in the AFDC program, 60 percent of the children whose families are over the poverty line don't have their vaccinations before they are 2 years old.

Mr. GREENWOOD. Sixty percent of all children over the poverty line, or 60 percent of children just above the poverty line?

Secretary SHALALA. No. These are children over the poverty line. I don't have the numbers for those who are just above——

Mr. GREENWOOD. All the way up to the top, and that would argue——

Secretary SHALALA. We have very high percentages of children from middle-income families, not just from poverty families—obviously, there are huge percentages of children who grow up in poverty in this country, larger percentages of them as a group who don't get their vaccinations. This is an American problem. This is a problem more fundamental than just looking at poor children. And therefore, the design has to be something that doesn't just look at the public delivery system, but that looks at the private delivery system at the same time.

While I believe that we ought to—and we have experimented, using the WIC program, for example, using Head Start programs, to try to get more children in, and some of these economic incentives and other kinds of incentives have worked—I think we ought to do all of the above. I am not opposed, nor is the Clinton administration, to trying every kind of positive incentive of education program. But——

Mr. GREENWOOD. Excuse me for interrupting you, but the time is short. Do you include that requirement as a criterion for entry into certain programs——

Secretary SHALALA. Yes, absolutely, absolutely.

Mr. GREENWOOD. —that there be a requirement that the children be immunized—that's all right with this administration?

Secretary SHALALA. But everything we have learned is that while that will help for a percentage of the children who grow up in poverty who are eligible for Federal programs, we need to do other things for the rest of American children.

One wealthy kid who gets measles in this country is a danger to every American child and to every American in terms of the long-term costs and the health of the children that they come into contact with. And therefore, we have to see this program as a national program for every American child and have to see the public interest in it, and therefore the design has to be focused beyond just our poverty programs.

Mr. GREENWOOD. Do you happen to know, Madam Secretary, what the rate of immunizations is for our AFDC children?

Secretary SHALALA. I actually probably have that number, and I can provide it to you.

Mr. GREENWOOD. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Madam Secretary.

I think that today, as well as the day that you made the announcement of the President's program, is really one of the important days for children in America. And I think any of us who had the good opportunity to see the President and Mrs. Clinton in the clinic in northern Virginia and meet the parents and children there, saw a successful program and know what this can really mean for children in our own country. Again, I join with others in commending you for excellent testimony, and also for your last response to some of the questions.

I think this is an area where certainly—and we gather from what the President, Mrs. Clinton, and others, including yourself, have stated—we know what works. And we have the experience in terms of many European countries. I am sure you are familiar with the case in the United Kingdom where they had national health insurance for all citizens, and they didn't have a good immunization program. And what did they do? They provided a bonus to doctors to make sure that in the various areas and regions, children would receive their immunizations. Practitioners would receive the bonus if a certain percentage of their children received immunizations. Bang, right up through the ceiling, immunization rates increased.

We aren't even proposing that in terms of this issue, but we do know what has worked in other places. We know that the cost is definitely a factor to both families and providers. We find that even in the Federal Government, we don't provide adequate reimbursement under Medicaid to doctors to provide immunizations, and that where this isn't provided, the numbers are down. So as a matter of national policy, we have had disincentives for all of our friends, rather than an incentive, to try to immunize.

And even in the handful of States that have adequate Medicaid compensation, barriers to families remain.

And as I understand it, what you are saying supports a comprehensive approach—to try to get the lowest possible cost for the taxpayers and the parents, and place a very heavy emphasis on the delivery systems—where we find that many of the European countries have had great success in involving the parents and providers.

Perhaps in the brief time that I have, you could identify even further for us—I think you have in terms of your testimony—what would be included in the President's program, and also what additional indicators there are in terms of ensuring adequate coverage. We are going to hear from someone from my own State, from Holyoke, MA, that neighbors who speak the local language participate in outreach programs, going door to door bringing the message of immunization to parents and children. Also, just very briefly in the time that I have, what can we learn from other countries? Often, we can learn from others—we know that all knowledge is not in Washington, and all knowledge is not necessarily in our country, and we find that we can probably learn a bit from some others who have had extraordinary success. So I am just wondering if you could take a minute or two and just outline these things for us.

Secretary SHALALA. Senator, as you know, much of the Third World has actually had more success than we have. In fact, in this hemisphere, there are only two countries that rank below us in the percentage of their 2-year-olds that are immunized—Bolivia and Haiti—to give you some sense of the experience in other countries.

So convinced are we that we can learn from other countries that we have recruited one of the great public health officials in this country, D.A. Henderson, who eliminated smallpox in the world some time ago, who was head of public health at Johns Hopkins. Dr. Henderson is here, and he will be the deputy assistant secretary for science policy, and he will lead the administration's effort to get every child under 2 immunized.

What he and his colleagues around the world have learned is that it really is all of the above in terms of outreach. It is edu-

cational programs, it is going to every institution, it is getting every part from the churches to the grocery stores, it is getting everyone to pass the message to parents. It is getting national leadership to make it very clear that this is a national effort.

I will be talking to our friends from Walt Disney, who are going to join me tomorrow morning to talk about what role the Walt Disney characters can play in talking directly to children. From television to the script writers to America's athletes, we intend to mobilize everyone who has conversations with parents and children to get them in and to use every American institution.

Our Social Security offices around the country—there are a large number—have volunteered to do what they can, and they are doing their own outreach for their own programs. The Department intends to mobilize itself. But the truth is a national campaign that is sustained because it has an infrastructure in place, we can do it once, but we need to repeat it so that everyone knows that the children need to come in before they are 2 to get their vaccinations.

The CHAIRMAN. My time is up. I thank you, Madam Secretary.

Mr. WAXMAN. Mr. Bryant.

Mr. BRYANT. Thank you, Mr. Chairman.

Secretary Shalala, I support the egalitarian spirit behind this, and I am willing to spend money to achieve it. It seems to me that perhaps there is still a disconnect—if 60 percent of the nonpoor kids are not being immunized, then it would appear that money is not the principal problem; and yet it would seem that purchasing all of the vaccines and providing them free would be an attempt to address the problem of affordability which, as I said, does not appear to be the principal problem here.

Secretary SHALALA. Let me respond to that. America's pediatricians have told us that they are referring large numbers of children who are not poor, because the cost of the vaccine combination, to public health clinics, and some of them never get there—transportation problems and other kinds of explanations.

One explanation doesn't work for every child depending on their income. The important point here is that you cannot assume that cost is not a problem for lower-middle-income families who have very, very young children.

The pediatricians have indicated to us that it is a problem. The fact that large numbers of nonpoor children are not immunized indicates both cost to us as well as communications. So that we aren't pointing to one explanation—cost—we are pointing to multiple explanations, and we are pointing to the need for a delivery system in both the private sector as well as the public sector to get every child immunized.

Mr. BRYANT. But the problem, I think, that persists and that I have pointed to is that if when they get to school age, 95 percent of them then get immunized, then it appears the problem is not that some private doctor is sending the kid to a public health clinic and he does not show up; the problem is something else. And I am still puzzled as to why buying the vaccine and providing it free solves the problem.

Secretary SHALALA. Because it is a combination of things, particularly for very young children and for babies. It is a combination of communication that it is necessary to do it before the children

are 2; it is a combination of having access to vaccines, which is a cost problem for many young families at that point. Our point is that we need to eliminate every barrier for parents who have very young children, to get those children in to get their vaccinations.

Mr. BRYANT. Senator Kennedy observed that in the United Kingdom, where medical care is free and apparently every barrier was down, they still did not have people getting vaccinations, and I did not know that, but apparently they had to offer a bonus to the doctors to get them to notify everybody.

Secretary SHALALA. No one can point to one explanation that accounts for this, and therefore we must do everything that has been experimented with or has been tried, but to put it all together so that we get all the children in. The important thing is not one approach versus another, but to see it as a more systemic need and to put a total effort together, to make it a community effort and a community investment.

Mr. BRYANT. Have you calculated the net cost once you subtract the costs that we will not have because we will not have so many unimmunized people? What will the net cost of the program be?

Secretary SHALALA. The universal purchase will come down to $600 million once we discount the Medicaid and other kinds of savings.

Mr. BRYANT. Thank you.

The CHAIRMAN. Senator Wellstone.

Senator WELLSTONE. Thank you, Mr. Chairman. I'll be brief.

First of all, Madam Secretary, I'd like to thank you for your leadership. I feel like I have shouted it from the mountaintop, that I think that when historians look back at this decade, the ultimate indictment is going to be the ways in which we abandoned children and devalued the work of adults who work with children. I think you are lighting a candle, and this is an extremely important initiative, and you certainly have my full support.

I have some questions, and I believe when I stepped out to meet with some students from Minnesota, that the chairman asked one of them. Let me first ask you the why of a national registry. Dr. Michael Moen from the Minnesota Department of Health is going to talk about this later on, but why a national registry as opposed to something that is more focused on those neighborhoods and those communities where we know we have a real problem?

Secretary SHALALA. These are basically State registries, but children move across State boundaries, so what we are hoping to do is to develop a State registry in every State that fits together so that we can provide the information across States as children move along. It is the basic information for the child, and the tracking system will be developed by State experts.

We've got to be able to find the child who hasn't been fully immunized, and children do move, so it is really an attempt to fit a bunch of State registries together.

Senator WELLSTONE. I must confess to you that I'm just learning about this in specific, so forgive me if this question has been asked. But I guess what I'm confused about is that at the State level, it would strike me that if there is a limited amount of money, and we are living in an age where we know we don't have an unlimited amount of resources, we are calling for States to essentially estab-

lish an across-the-board registry—why not enable States to have the capacity to have more of a focus as to where they're going to do their surveillance? I think what I am hearing from some States is that they are a little nervous about tracking each and every child. Do you see where I am heading with this question?

Secretary SHALALA. Yes, I see where you are heading. I guess I have to keep repeating that this isn't a poverty program; that we have large numbers of American children who are working class, who are middle class, who are not getting immunized; that this is a national program. Our investment in immunization, our investment in the health of our country has to be for every American, and we've got to start with very young children.

To get the information, the number of shots you need to get, the number of times you need to go back and forth, are so numerous that the registration system and the tracking system is to do the follow-up and work with parents, to get them back in at the right times. And I think I sort of read through when you have to come in—at 2 months, at 4 months, at 6 months. It is a complex system, and we need to work with parents to get them the notification, and we need it for every child.

It does us no good if part of the American children are immunized and a disease breaks out. We've got to get every child immunized.

Senator WELLSTONE. I was just handed a note that I have 2 minutes remaining.

I have a number of other questions, Mr. Chairman, which I'd like to submit in writing and will do so.

Secretary SHALALA. I'd be happy to respond.

Senator WELLSTONE. Let me just follow up, so that I am clear about the why of the question. I think that those people who have critiqued social policy in our country and have argued that all too often, means-tested programs and poor people's programs become poor programs, are correct, and I think I understand where you're heading in terms of the application of this. But I still, I guess, have this question about how it is we develop this registry. This is, of course, for the purposes of beginning to have some kind of way of accumulating our data and knowing where to go, but with a limited amount of resources, I still have that question, and I want to talk with you more about it.

Secretary SHALALA. And I would be happy to——

Senator WELLSTONE. I'm not trying to get more and more means-tested programs.

Secretary SHALALA. Yes, and to ask private doctors, private pediatricians to ask the income of their patients would simply add another obstacle. What we're trying to do is to remove obstacles. But more than anything else, we are trying to get every child in America immunized whether they are rich or poor. This is a public health program for every American child, not a poverty program.

Senator WELLSTONE. Thank you, Madam Secretary.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Senator Wellstone.

Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman.

Let me also indicate that I thought your testimony was outstanding.

Secretary SHALALA. Thank you.

Mr. TOWNS. However, I have some concerns, coming from New York, an area where many of our doctors will not take Medicaid. You mentioned the fact that with the Medicare policy, certain computers have to go in in terms of recordkeeping.

Also, many of our doctors will not take Medicare. And I am just wondering if this will not force them to opt out. I don't see this as being something that will really benefit those areas because of the problems we have now in terms of doctors not taking Medicaid. And among the reasons they give, for instance, are the amount that it pays, or the fact of all the paperwork involved. It seems to me that we are putting additional paperwork on them, and I think that the few that we have who will take Medicaid will now say, "No, I am not going to take it."

So my question to you would be why don't we spend more in terms of outreach? In the countries that are doing well, in Europe, that have 90 percent, you'll find that they spend a tremendous amount of money in outreach. So it seems to me that our problem more than anything else is outreach, and I think that's where the emphasis should be.

Secretary SHALALA. Congressman, I'm not quite sure—you mentioned a 10 percent number. It is significantly higher than that, I think, closer to 25 percent, in terms of our outreach recommendations, with a lot beyond that—that's the government expenditure—a lot of volunteers from the Ad Council and other places. So we are going to have a huge outreach effort.

Second, 90 percent of American physicians now participate in Medicare, and as you probably know, in the Medicaid program, we are in the middle of a debate within the Clinton administration about reforming that program.

Third, we are going to make it very easy for every American physician to provide vaccines by essentially giving them the vaccine. We are asking them to keep a record on the child, which they ordinarily would do, so that there could be a follow-up on the vaccine. We are going to eliminate paperwork, we are going to eliminate bureaucracy. We are going to make it easy for them to do what they very much would like to do, and that is to make sure that our youngest and most vulnerable citizens are properly immunized so they get started right and so that they do have a healthy beginning.

Mr. TOWNS. I'm hoping that you are right and that it works, and I think that we have to begin to try some things. But when I look at the pediatricians that you talked about in terms of referring patients out rather than immunizing them, I think the reason for that more than anything else is that the conventional health insurance companies, about 50 percent of them will actually pay. So I think that's a real problem there.

Secretary SHALALA. And that is why giving the physician the vaccines, particularly physicians who deal with working class people like those in your community, and low-income people, will make the difference.

I was in New York on Monday, and as you probably know, the HIP program has announced that they are going to work with us and immunize thousands of New York children. Again, they believe very strongly that free vaccines will make the difference in terms of our ability to get every child in New York and every place else immunized.

Mr. TOWNS. Well, I am happy to hear that you're really spending a little more than I thought in terms of outreach, because I really feel that outreach is the key to be able to get people to come in. I know in Georgia, there is a program that President Carter is involved in where they are giving out tickets to go see Michael Jackson in order to get people to go in and get immunized.

So I think that we have to be creative in order to make certain that it works. So I am happy to see the flexibility, because in the area that I come from, that flexibility would be needed in order to make a difference.

Secretary SHALALA. We want to leave no child behind, and to do that we have to try everything that we know to make sure we get the children in and get them into a regular relationship with the physician, so they can do more than just immunization, too.

Mr. TOWNS. Let me just make one point, and I want to make certain I understand. I know we are in the process of revamping, and I think that's great, but is there anything that we can do to encourage the physicians who will not take Medicaid to participate in this program?

Secretary SHALALA. Well, I think that as part of health reform, to the extent that we eliminate barriers, that we eliminate bureaucracy, that we make it easier to participate, that we get a national program in which everyone is insured with the same basic benefit package, that that will all help, because the doctor won't be tied to a fee-for-service, a narrow reimbursement program, and a big bureaucracy to deal with, and to that extent I think it will make a difference.

Mr. TOWNS. Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Gregg.

Senator GREGG. Thank you, Mr. Chairman.

If I understood your response to Congressman Greenwood, it was that you would have no problems conceptually with amendments that would address the issue of encouraging immunization when people who have children obtain access to Federal programs. Now, I am not limiting it just to——

Secretary SHALALA. Senator, I indicated that I favored positive incentives and connecting other kinds of programs with positive incentives. For example, in the WIC program, we have done some demonstrations where we offered 2 months of WIC rather than 1 month of WIC if parents would bring their children in, and that was a positive incentive.

Senator GREGG. You are not saying, then, that you would agree that people, in order to get WIC to begin with, should have some sort of certification that they have gotten their 2-year-old immunized, or that once they come on the system, in order to stay on the system, they have to have the 2-year-old immunized. You don't agree with that?

Secretary SHALALA. Senator, I don't want to jump into administration policy without reviewing that. What I was saying is that we certainly will consider positive incentives and connections with other government programs as part of an overall effort to raise our immunization rates. And I think we will enthusiastically review any proposal that might be made as part of an overall strategy. But I would not want to be pinned down on the specifics——

Senator GREGG. I understand that, and I think that's reasonable, but the concept makes sense.

Secretary SHALALA. Yes.

Senator GREGG. And I wouldn't just limit it to the poor or the near-poor. I don't see why people coming in for tax refunds, if they've checked off a dependency item, you might want to require that in order to get a dependency exemption you might have to certify if you have a 2-year-old that they have been immunized. But the concept of getting broader participation is, I believe, the core issue. And because you have cited D.A. Henderson's report, I would simply note that D.A. Henderson in his report didn't talk about universal purchase. He talked about a whole series of other things, all of which went to the issue of access, and that that's been the experience.

If you look at the numbers on their face, the numbers scream out that it is getting people in to get immunized that's the problem. I mean, the fact that States have universal purchase and distribution of free immunization, such as New Hampshire and 11 other States, and that there is only a 5 percent variance from those States who don't have that program, pretty much says on its face that it isn't the universal purchase that is the issue; it is the fact that people aren't taking responsibility for getting their children immunized.

In this whole process, there are going to be States like New Hampshire, which have the private sector now picking up the cost of the drugs. We have universal access and universal state purchase, and the non-Federal sector picks up 60 percent of that. Under your program, is all that money just to go back as a windfall to those insurance companies—the tens of millions of dollars that they are now obligated to pay?

Secretary SHALALA. Well, we'd have to work with the States on that. We'd have to work with the States on this universal program. There would be some opportunity for States to use the resources they have been spending in other sorts of ways. Given the budgets of most States, I am certain that they would find ways to redirect some of these resources to other programs for children.

Senator GREGG. Well, these are private contributions. These aren't State taxes. This is just a private contribution program.

Thank you.

Mr. WAXMAN. Ms. Slaughter.

Ms. SLAUGHTER. Thank you, Mr. Chairman.

Madam Secretary, your testimony was wonderful, but I think we are getting away from something here that I would like to restate. We are talking about communicable infectious disease. A bacterium or a virus doesn't give a hoot whether you are rich or poor. Obviously, the reason that we required all these inoculations by school

age was that we didn't want to decimate the entire school system with a disease. And all States have very high compliance rates.

We're talking about the children who are not protected under that school age from these same infectious diseases.

I recall when we had the great effort to do whatever we could to eradicate measles because we knew that measles often left children blind, deaf or with other handicaps, and we felt that America's future and its children were too important to allow that to go on.

I think the biggest tragedy that we are sliding over this morning is that all the vaccinations and all the inoculations that other countries are giving, far more effectively and freely than we are, were for the most part pioneered in the United States of America.

One of the things that is wrong that we haven't really talked about is that there is no education process. It is almost as though germ theory of disease does not bother us anymore because we have antibiotics now, and we'll fix it all later. And that simply is not happening, and that is not the truth.

We are losing sight here of what we are talking about, and that is an investment. If we really want to discuss this argument thoroughly, we have to ask what is the cost of not doing it.

We live in a country right now, not just with children but with elderly, where we are perfectly willing to pay $10,000 or more per hospital stay for an elderly person with the flu, but we are not willing to pay $10 to inoculate them against it. The same thing obviously is happening with the children. We just let them have the luck of the draw. Are they going to be the ones who have been born with an extraordinary immune system so they can fight some of this off, or are they, like most human beings with frailties, going to be picking up these diseases, for which we will pay?

Make no mistake about that. The option is not whether we are going to buy vaccine for these children. We are either going to pay in making sure that they are well, or we are going to pay to try to cure them or the handicaps that are left later on.

Don't ever lose sight of that. That is why we are trying to do this. And I think one of the most important points that you made that should also not get lost is that it is the working poor who suffer most. It is a good idea, I suspect, that people who are on public assistance programs can also get inoculations, but there shouldn't be a penalty. Again, this is something that we should want them to be able to have. It is important, and one thing about what we are trying to do here is to get this at a reasonable cost.

A New York State health official told me last week that they had worked out some kind of contract with Fort Drumm to be able to get some vaccine from them at almost half cost, whereupon the providers immediately doubled the cost. So I think one of the things that interests me more in what you're saying is making sure that there is a point of universal need and that there will be a strong purchasing system, so we may institute some competition, which I think would be a good thing.

But don't lose sight of the fact that what we are trying to do here is save ourselves money in the future. If you can't look at it just from the humane aspect, please look at it from the cost savings—it is cheaper to keep people well than to treat their disease.

Thank you.

Mr. WAXMAN. Thank you, Ms. Slaughter.

Mr. Slattery.

Mr. SLATTERY. Thank you, Mr. Chairman.

Madam Secretary, it's great to see you, and like all the other members of this committee today, certainly on this side of the aisle, I appreciate your leadership, and I am pleased to be an original cosponsor of the legislation in the House.

I do have some concerns about some provisions of this, and I wanted to zero in on those if I could. In response to Congressman Bryant's question about where the $1 billion is to be spent, did I understand you correctly that you envision that approximately $600 million of that will be allocated to the actual purchase of the vaccines?

Secretary SHALALA. Yes.

Mr. SLATTERY. So about $400 million of it, then, will be spent for tracking or outreach or educational efforts, or developing a better delivery system; is that correct?

Secretary SHALALA. Not quite, because in our stimulus package, we put in $300 million that helps us rebuild the public infrastructure plus does outreach, so there is a lot more of an outreach component than is apparent.

Mr. SLATTERY. So the outreach component, then, is the 300 plus million dollars in the stimulus package that is still in question, coupled with——

Secretary SHALALA. Plus the 400.

Mr. SLATTERY. —the 400. OK.

The other concern that I have is that when I look at this, it seems to me that in this matter, as in other matters dealing with the health care delivery system, that doctors are the key players. And when I look at what we are attempting to do, we are really fundamentally suggesting that the doctors need to change their behavior, need to change the way they view immunizations and be more actively involved in trying to provide these immunizations. And to achieve that, if we are going to really modify human behavior, we are going to have to incentivize that. And when I look at what we're talking about, it is difficult for me to find an incentive in this approach that is really going to motivate doctors to actively seek out opportunities to vaccinate children.

I mean, I see a recordkeeping hassle here; I see problems with maintaining the vaccines, their shelf life, and keeping them refrigerated; I see potential medical malpractice problems. I have even talked to pediatricians who are very concerned about vaccinating children without providing them with a complete medical exam.

I look at what has happened to date, and it looks to me like doctors don't really want to be troubled with all of this. And what we are in effect saying to them is we are going to give you vaccines, and hopefully, when we give you vaccines, you are going to provide more vaccinations to children. Yet when I look at what has happened in other States where we have had this universal purchase of drugs, we have seen somewhat of an increase—61 percent in Michigan, and I am advised that in Massachusetts it is roughly the same—10 percent above the national average.

I am just curious—do you believe that we have really adequately incentivized doctors to change their behavior? As Senator Kennedy earlier observed, in the United Kingdom, it was really only when they agreed to do this that it got done. I am just concerned about that point.

Secretary SHALALA. Your question is very thoughtful. We see the national immunization program for children as the opening wedge to a national commitment to prevention. It is not simply for us getting all the kids under 2 immunized. It is not an isolated program. It is a new vision of how this country's health system ought to be organized.

Mr. SLATTERY. I understand that, but again, when we think specifically, we are going to have to change the behavior of that doctor, and right now, that doctor is saying, "Go down the street to the public health clinic, because it is cheaper." But really—and I don't say this to cast any aspersions on doctors—but if there were money to be made in this, and if there were a reason to provide those vaccinations in those offices, they would probably be doing more of it.

Secretary SHALALA. If the doctor—and from our conversations with physicians, by giving the doctor the vaccine, we make that connection for the continuity of care between the doctor and the family, and we make it early enough——

Mr. SLATTERY. But there is nothing in here that would really prevent those doctors who want to provide vaccinations from saying, "Thank you very much. I am going to continue to charge my patients what I have historically charged them."

Secretary SHALALA. Well, yes, there is, in the sense that we will provide the vaccines free. They can charge a small fee for the administration of the vaccine.

Mr. SLATTERY. One more question. Please comment if you could on the concern that some drug companies have expressed with this whole idea that if the government is the single purchaser of their product, it is going to have a real chilling effect on attracting investment that is desperately needed in some cases to develop the kinds of new products that we need. I would like to hear your response to that concern that is being expressed by the drug companies.

Secretary SHALALA. First, the issue is of fair price, and I think that if investors see that one of the major purchasers—pointing out that these companies also sell their products in many cases to either other countries, or they have other products to sell, so we are not talking about companies that don't have other products; they make more than just a series of vaccines, many of them, that we are talking about being a major purchaser of——

Mr. SLATTERY. If the government were buying 90 percent or 95 percent of the products that you are producing——

Secretary SHALALA. Of one of the products that you are producing, as opposed to——

Mr. SLATTERY. Or maybe all of the products, if you are strictly in the business of producing vaccines.

Secretary SHALALA. —as opposed to other products. The issue is are they getting a fair price, is it a stable purchaser. For many American companies, it is a single buyer for a product. If you look at the rate of products that are made in this country and where

the government—either a State government or a local government—is a major purchaser that continues to get investments, the issue is are they getting a fair price that allows them to continue their R and D, to continue to be on the cutting edge. We have indicated that we have every interest in doing that, not only R and D, but obviously a fair profit, and that there would be in fact a negotiation that would protect the integrity and the economic health of the industry.

Mr. WAXMAN. The gentleman's time has expired.

Mr. SLATTERY. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Wofford.

Senator WOFFORD. Thank you, Mr. Chairman.

Madam Secretary, I fully agree with the goal, and I want to see us take the steps to reach the goal of universal immunization. I salute you for your leadership in moving us in that direction.

Is the universal purchase provision of vaccines an interim measure, in your mind, before we have a universal health insurance system in this country? My thought on this is that if we have a standard American package of health care benefits which people pay for according to their means, in a system to be designed and adopted, I hope, this year, and if preventive medicine and particularly immunization is a key part of it, then the financing of the purchase and the payment for that immunization would be part of that standard package for all. And that led me to think that this part of this bill—not the delivery system or the tracking system part, but this part of it—is a very interim measure before we get that kind of health care, universal insurance, that would emphasize preventive medicine.

Secretary SHALALA. Senator, I really can't answer that question because we obviously have not made the final decisions on the basic benefit package, though clearly we have signalled that it is going to have a huge prevention and certainly immunization component in it, or how access will be provided for every American, whether it will be done immediately or phased in.

I think that the administration was very anxious to lead with this a prevention program that provides the baseline for every American child, and we will report on the relationship between this and the package in May very quickly, about how it fits together in terms of our longer-term plans.

Senator WOFFORD. It seems to me from what I have heard, assuring that all children would be part of a universal health insurance might well be a first priority, and that therefore the proposals here would need to be folded into those proposals once they are made.

Secretary SHALALA. Certainly, every piece of legislation that has been proposed on health care by the administration will have to be fit into that new national plan. I can't give you any indication of decisions that just have not been made yet.

Senator WOFFORD. Certainly. Is there any community in America—I can't think of any State—that has taken action together, effectively, to approach universal immunization?

Secretary SHALALA. Well, there are a number of States in the Northeast, in New England in particular, that have made extraordinary efforts, and certainly there are cities, like Atlanta—and

Houston has just made a big effort to try to get their very low immunization rates up. No one is perfect. We have learned from everyone and tried to incorporate their ideas into this proposal.

Senator WOFFORD. Have those cities that have made the biggest progress relied on universal purchase within their domain?

Secretary SHALALA. Some of the New England States that have been successful have provided the vaccines free as part of their overall effort. I think that given international and national communications, a national campaign will help every community, because the word will get out in the national media for every community, and it will be a national community effort, not simply an individual State or individual city effort.

Senator WOFFORD. One last question. If the universal health system that I hope we move to includes vaccination as one of the rights, would not the $600 million in this bill for the purchasing then be better spent in strengthening the delivery and tracking system?

Secretary SHALALA. We have not yet identified the funding source for the immunization program, because that will be folded into the health care reform, so that how all these pieces fit together will be reported out when the health reform bill is folded out.

Senator WOFFORD. Thank you. I await with anticipation.

Secretary SHALALA. Thank you.

Mr. WAXMAN. Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

As a cosponsor of your proposal, Madam Secretary, I applaud both you and Chairman Waxman on your initiative on this issue.

There are some major parts of my district where the immunization rate is markedly less than 50 percent, as there are obviously in places all over the country. Recently, I convened a meeting with people who do outreach with child health care providers, with people in the community who are interested in those kinds of issues, to talk about reducing not just the cost barriers, but to address the whole outreach issue. Two questions, Madam Secretary. One, how would the Department work on the local level with State and county health agencies and not-for-profits and so on, to establish creative strategies to improve outreach, and what kinds of suggestions do you have for us as Members of Congress or for local communities to work together to complement the kinds of things that you are going to do in addition to the national strategies and national media and all that? What are you doing on the local level with county health agencies and community health agencies and so on, and what do they do to complement your efforts?

Secretary SHALALA. The counties and the States and the local communities have already done a buildup and designed action plans, and part of the stimulus package funding is to fund those action plans in which there has already been participation.

I think we believe that it will take bottom-up participation and leadership from State and local leaders and community leaders to put all of this together. We will be providing technical assistance through the CDC and through our own immunization—I don't want to call it a war room; there are too many war rooms in this town—through our own immunization strategists, but we will very much rely on passing information to local communities about what works

and what doesn't work, and about fitting—I think more than anything else, the strategy needs to fit lots of different kinds of approaches. This is an effort in which you have to make sure that no one falls between the cracks, that no child falls between the cracks, that no family falls between the cracks, so that it really has to be a multiple strategy, with community organizations working within their local communities, with State and county health officials. It has got to be an integrated strategy, but it has got to be something that's not one-shot.

My greatest concern is that we'll get everybody immunized in 1 year through this enormous effort, led by Mickey Mouse and Donald Duck and everybody else who gets energized as part of this, but that we won't have put in place a system, an infrastructure, that will repeat it year after year. And that's why we've put so much emphasis on the front end, on building that infrastructure, that delivery system, so that the visibility efforts will fit into that and so that we begin to change everybody's minds about when children should be their shots.

Mr. BROWN. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. If there are no further questions, we want to thank you very much, Madam Secretary. It has been a very full morning, I know, for you, but I think the responses that you have given have made a very powerful and constructive record. We are enormously grateful for your presence here, and we'll do everything we can in our committee to expedite the consideration of the Act.

We thank you very, very much.

Secretary SHALALA. Thank you. To all of you, thank you.

The CHAIRMAN. Our next panel includes Dr. David Smith, director of the Texas Department of Health, who is representing the Association of State and Territorial Health Officers. Dr. Smith is a pediatrician who tackled the problem of low immunization as senior vice president of Parkland Memorial Hospital in Dallas. He now is a State health officer, and has pushed legislation through the legislature to improve immunization services in the State. We welcome him.

Dr. Dean Sienko is the medical director of the Ingham County Health Department in Lansing, MI, and he represents the National Association of County Health Officials here today. I know Senator Riegle wanted to add a very special welcome to you, Dr. Sienko.

Dr. Ed Thompson is the acting State health officer in the State of Mississippi and is also president of the Council of State and Territorial Epidemiologists. Dr. Thompson is well-respected for his work in childhood immunization. We are glad he could join us today.

Mr. Michael Moen is director of the division of disease prevention and control at the Minnesota Department of Health. He has served in many capacities with the department of health over the years, and he has a particular interest in childhood immunization. We welcome his testimony.

Finally, I'd give a warm welcome to Ms. Gladys LeBron, who is director of CEDE, a community-based organization serving Puerto Rican families in Holyoke, MA. Accompanying her is Ms. Danielle Gordon, immunization project director. Ms. LeBron oversees the

community outreach project, training community workers to go out into their neighborhoods with health information, assisting families to obtain health care and needed services. We are delighted that you could both join us today. I am familiar with this program, and if you want to talk about a hands-on program that involves the members of the community in an imaginative and creative and hardworking way, this is really it. The community workers in that neighborhood know their neighbors, understand them, believe in them, and talk their language. I think this organization has really shown an enormous dedication to the many, many families in that community.

Senator Riegle.

Senator RIEGLE. Senator Kennedy, thank you.

I just wanted to recognize Dr. Dean Sienko who is here, and to thank him for his leadership and the very important role he plays in Michigan. I think his testimony today will be very important.

The CHAIRMAN. Thank you.

Dr. Sienko, we'll start with you.

It is the intention of the chair, with the understanding and support of the members, that we will hear from all of the panelists first. Marian Wright Edelman had been scheduled to testify, and we made an extraordinary effort to get the satellite time. Since several members of this panel have planes to catch, the intention of the chair is to hear from each of the panelists and then to hear from Marian Wright Edelman via television. And then, since her testimony is related both to what Dr. Shalala and the others have discussed and what this panel will talk about, we'll go to questions for members of the panel before moving on to the next panel.

So that's the way we will proceed, and I'll ask Dr. Sienko if he'd be good enough to start off.

STATEMENTS OF DR. DEAN SIENKO, DIRECTOR, INGHAM COUNTY HEALTH DEPARTMENT, LANSING, MI, REPRESENTING NATIONAL ASSOCIATION OF COUNTY HEALTH OFFICIALS; DR. DAVID SMITH, DIRECTOR, TEXAS DEPARTMENT OF HEALTH, AUSTIN, TX, REPRESENTING ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICERS; DR. ED THOMPSON, JR., ACTING STATE HEALTH OFFICER AND MISSISSIPPI STATE EPIDEMIOLOGIST, JACKSON, MS, AND PRESIDENT, COUNCIL OF STATE AND TERRITORIAL EPIDEMIOLOGISTS; MICHAEL E. MOEN, DIRECTOR, DIVISION OF DISEASE PREVENTION AND CONTROL, MINNESOTA DEPARTMENT OF HEALTH, MINNEAPOLIS, MN; GLADYS LeBRON, DIRECTOR, CENTRO DE EDUCACION DURANTE EL EMBARAZO, CEDE, HOLYOKE, MA, ACCOMPANIED BY DANIELLE GORDON; AND MARIAN WRIGHT EDELMAN, PRESIDENT, CHILDREN'S DEFENSE FUND, WASHINGTON, DC.

Dr. SIENKO. Thank you, Mr. Chairman.

My name is Dr. Dean Sienko. I am representing the Ingham County Health Department in Lansing, MI, the Michigan Advisory Committee on Immunizations, and the National Association of County Health Officials.

My testimony will describe how local health departments contribute to our Nation's immunization effort and outline opportunities to improve immunization compliance within our population.

Over 2,900 local health departments vaccinate 28 million children annually. About one-half of all American children are vaccinated in our clinics. In Michigan, most counties provide immunizations free-of-charge, without copay or sliding fee scales. At my health department, we have witnessed growing demands for our services. The number of immunizations that we provided from 1990 to 1992 increased 46 percent. Our resources will be stretched even further as newer vaccines come to market.

Our immunization clients are employed people, people with Medicaid, and individuals without health insurance. An expanding number of people with health insurance come to us for immunizations as their private practitioners are discontinuing such services or charging beyond the average citizen's means to pay.

We have found that 37 percent of our immunization clients have private health insurance, another 38 percent have Medicaid.

The demands on our immunization clinics translate into longer waiting lines, overcrowded waiting rooms, and unnecessary frustration among our consumers. Undoubtedly, such circumstances contribute to the substandard immunization coverage for many of our Nation's children.

We estimate that roughly 60 percent of our country's preschoolers are age-appropriately immunized. CDC studies reveal rates much lower than this in large urban areas. If we are to reach the U.S. Public Health Service Year 2000 goal to have 90 percent of 2-year-olds age-appropriately immunized, then improvements in our immunization infrastructure will be necessary. Fortunately, many of these infrastructure problems are considered in the President's immunization bill.

If I were to receive increased resources to improve my county's immunization rates, I would employ the following strategies. First, I would expand immunization clinic hours to include evenings and weekends. One reason would be to help people who do not have sick leave benefits. Their visits to the immunization clinic require uncompensated time off from work. If we could offer services during hours that are more conducive to our patients' schedules, our immunization coverage rates would improve.

Second, I would expand services in satellite locations. We frequently hold clinics in outlying areas of the county or within our poorest neighborhoods. However, the demand for such services quickly exceeds our capacity to meet it. Increased resources would allow us to enhance capacity and meet the demand in these locations.

Third, I would enhance both internal and external outreach efforts. Internally, we could couple immunization services to other health department functions. For example, with a computerized tracking mechanism, we could assess immunization status and refer or offer direct services through our WIC clinic or other maternal and child health programs. Externally, we could enhance surveillance, education, promotion and referral efforts in the community at large and within those communities where immunization rates are lowest. Along these lines, we could work more closely

with day care facilities to ensure compliance with immunization recommendations.

I believe that your proposed legislation will give us the means to execute many of these strategies. In my written report, I offer comments specific to the proposed legislation on 1) the explicit inclusion of local health departments as part of the free vaccine distribution network and universal purchasing system; 2) the potential for increased burden on our system should private providers be dissatisfied with the administrative fee reimbursement or immunization registry reporting requirements; 3) defining the responsibility for registering children within 6 weeks of birth and the follow-up of children who are behind schedule, and 4) our gratitude for the intention to simplify the vaccine information pamphlets and to extend the National Childhood Vaccine Injury Compensation Program; and finally, our concerns about the requirement to have a Social Security number as a condition of a child receiving vaccine. In many jurisdictions, undocumented people are often among those least vaccinated. Prohibiting their participation could be counterproductive to local disease control efforts.

In summary, local health departments are at the front line of the immunization effort in this country. We already immunize large numbers of the population, and we have established relations with segments of the population that are most in need of improved immunization coverage. And we have ideas and solutions to respond to the year 2000 challenge.

I submit that any national strategy that takes advantage of our vast network of cost-effective clinics and resourceful staff will be able to meet this challenge.

Thank you for the opportunity to present these thoughts before the committee.

Senator RIEGLE. Thank you, Dr. Sienko. I know you have a plane to catch, and we appreciate very much your being here and your leadership in Michigan.

Dr. SIENKO. Thank you.

Senator RIEGLE. Let me now go to Dr. David Smith, who is here from Austin, TX.

Dr. SMITH. Thank you, Senator Riegle. It's my pleasure to be here and to support a bill that I suppose, after Secretary Shalala's presentation, could be called the "No More Excuses" bill.

I think what we are doing here is trying to eliminate all the excuses that we've had from all different sectors and to make sure we realize the place it's going to happen is certainly within the family and the community first, and then only with the help of places such as Austin and Washington, to hopefully make some sense out of this and not get in the way.

I also want to point out that the State of Texas, which has the dubious distinction of having some of the worst statistics in the Nation—in fact, overall, I think about 30 percent of our children under the age of 2 are adequately immunized—having been both a National Health Service Corps physician practicing in Brownsville, being a pediatrician, and also in Dallas during the outbreak, I have unfortunately both managed the problem and tried to do something about it over time, and we aren't doing enough.

We have new call words in Austin now. We used to say frequently that we had to "Remember the Alamo." I would challenge us now as a State, and certainly as a Nation, that if we can't fix measles, then there is little we can do in health care reform and the problems we are facing, and we need to understand that.

I also join with our Governor, Ann Richards, who has sent her support for this legislation to Secretary Shalala, and I am here to add my endorsement. In addition, I am here representing the Association of State and Territorial Health Officers, and share with my colleagues in the public health infrastructure at the local and national levels the need to pay attention to all public health as we look at this issue.

I am here, though, to quickly tell a tale more of what happened in Dallas in 1989-90 which reflects the challenge if we can't fix measles. In 1989-90 in Dallas County, we had almost 2,500 cases of measles in that community. It hit both sides of the Trinity River. For those who don't know, that means it hit north Dallas as well as south Dallas, rich Dallas as well as poor Dallas, and it didn't bother as far as barriers to time or age or distance. Quite frankly, we also had a number of adults infected.

Interestingly, that problem and that tragedy taught us several things, the first of which is that a number of the individuals who did become infected did later go to the hospital. Almost 240 individuals were hospitalized. A study that we did at the University of Texas Southwest Medical College showed that the inpatient cost alone, just inpatient cost, for that outbreak was $3.5 million. We could have immunized easily four times the number of children for about $200,000. The cost benefit here is staggering. We need to get on with it because we are paying every, single day.

Twelve people died. A number of those were adults, interestingly. We sent two children, one of whom actually went to Michigan, for a heart-lung bypass, ECMO, extracorporeal membrane oxygenation, at a cost of over $200,000 for just one child. We could have easily prevented that.

We also know several things from this particular outbreak, and it has now held true for similar work that we've done analyzing the problems in Houston and most recently in Starke County, which is the second poorest county in the United States, in far south Texas. It has touched all aspects of Texas culture as we have looked at this problem.

We have learned these things. No. 1, a 700 percent increased demand has been placed on our public sector in Dallas County by people who traditionally would go to the private sector. One of the commonly cited reasons in fact is cost. It is not the only one. I think we all too often want to pick a fraction or a part of this bill apart and eliminate it from the process, but it was an issue, and it was a significant issue. And our already overburdened public system at the local and State levels could not meet the excessive demand that was placed upon it.

I would also point out that we determined other barriers do exist, and what I was pleased to hear from Secretary Shalala was the acknowledgment that it will take flexibility to meet individual community needs. And I think Representative Wyden said this well. Each community is different, and we're going to have to under-

stand those, and States will need flexibility with these resources to attack the needs and the problems that we are facing. I would just like to quickly touch on those because I think they are relevant.

The first is that in our State, we don't have a lot of infrastructure. We do have to build it up. We are very pleased with the proposal for the $300 million to do something about it. In many countries in our State—in fact, over 170—the only thing we've got out there is a Dairy Queen, and if we don't decide to use those as a place to shoot, we are going to have a problem; maybe we should.

In our State, like many States—and I think we need to be harsh—tracking is an issue. In our State, we track lottery tickets better than we do children's immunization status. We have a lovely little code. We put the technology in place in every Circle K, 7-Eleven, and convenience store in the State, and we did it in 6 months. We can do it with immunizations.

I would also finally like to say, though, that we do need to look at issues of convenience, making sure we have a system that is in place and oriented to comprehensive care and prevention. Cost is an issue, I would reinforce, and that every community is different. And finally—and Secretary Shalala mentioned this—I would not use the word "education" anymore. We need to use "outreach." But also, I think we need to look at marketing. We need to be ready for prime time, because when we put our messages on today about public health, they are usually at 2:00 on Saturday morning, or I'm on a radio talk show at 5:30 on Sunday. We need to be on prime time, and we know when we've done it—when we're right next to Nike and McDonald's during the Super Bowl on Super Bowl Sunday.

Thank you.

Senator RIEGLE. Thank you, Dr. Smith, for very impressive testimony.

[The prepared statement of Dr. Smith follows:]

PREPARED STATEMENT OF DAVID R. SMITH

Chairman Waxman, Chairman Kennedy, Senator Riegle, distinguished committee and subcommittee members, my name is David Smith. I am the Texas Commissioner of Health and head of the Texas Department of Health. I also am representing the Association of State and Territorial Health Officers.

I appreciate the opportunity to talk with you about a topic that is a number one health priority in Texas: immunizations.

Texas Governor Ann Richards has already communicated her support for this "Comprehensive Child Immunization Act of 1993" to Secretary Shalala. I am here to add my endorsement.

I strongly support the major points addressed in this legislation, namely: universal purchase of vaccines, improved access to immunizations, the establishment of a nationwide tracking system and the revitalization of the National Vaccine Injury Compensation Program.

My State leads the Nation in the number of cases of vaccine-preventable diseases. In fact, in some areas of our State the immunization rate is lower than in some Third World Countries. While the estimated national rate for immunization of 2-year-olds is 60 percent, in Texas it's 30 percent. We're not bragging about this. We're not proud. But, we are determined to do something about it.

We're hopeful that a new piece of State legislation which recently came out of a House/Senate conference committee will be approved. While this legislation does not give us all of the ammunition we wanted, it is an excellent start. We call it the "no more excuses" bill.

It mandates that every child in Texas be immunized. It also mandates that hospitals and Physicians check immunization records of their young patients, and administer any needed vaccines. It allows us to provide reimbursement to private phy-

sicians for administering vaccines. It states that immunizations will not be denied because of an inability to pay. And, it allows us to operate our public health clinics during hours that are more convenient to working parents, including poor working parents.

With the new Texas legislation and this new Federal initiative—putting solid resources behind our efforts—we are increasingly confident that we will be able to achieve our goal of immunizing 90 percent of the 2-year-olds in Texas by the year 2000.

Perhaps, it would be helpful, in offering my support for this legislation, that I offer some beliefs and observations from my perspective.

1) It is my belief that every child in this country should be immunized: we should look at this legislation as a bill of rights for children's health care.

2) It is also my belief that this right should be inalienable and available, regardless of the ability to pay.

3) We have got to simplify the way we, as government agencies, communicate the need for immunization and the recommended immunization schedule to parents and others responsible for young children. We can't continue to Rubik's Cube the information and expect them to figure it out, or to even want to figure it out.

I submit that the way we communicate this information shouldn't be—but is—a barrier to compliance. I'm talking about the need for brevity, for plain concise language, in a form readily understandable by the parents of the children we need to serve.

The proposed tracking system in this legislation is extremely valuable for several reasons, but one of the main ones, I believe, is that it will allow us to better communicate the immunization need to parents. We can help them remember, especially as immunization schedules become more complex and new vaccines are added.

4) Another barrier to immunizations, which may not seem obvious at first, is the complexity of the consent forms required by the Federal Government before an immunization can be given in a public clinic. I normally do not get excited about such details, but it is gratifying to see that this legislation includes the opportunity to simplify these forms.

Certainly, it is important for parents to understand the care given to their children. But, currently, a parent who takes an 18-month old in to a public clinic for the appropriate immunizations is confronted with 16 pages of consent forms . . . 16 pages of very small print. It is critical that we streamline this information, so that it is not formidable but still informative for parents. It is also vital that other relatives or guardians be allowed to bring children in for immunization when the parents cannot.

5) In establishing this system of purchase, distribution, and tracking, it is vital that Federal agencies work together with the States and require only the reporting data necessary to ensure program accountability and document results. We do not need to increase the cost of this vital program with excessive reporting requirements. To achieve the best return for our investment, please don't ask us to document the process. Ask us to immunize the children and document the results.

6) And in connection, while I confess that each of us always thinks the best level for control is the level at which we find ourselves at the time, please allow funds for the improvement of the public health infrastructure to be directed by each State for each State.

A major strength of this legislation is that it recognizes the vital role states have in developing strategies to address public health needs.

In other words, don't hold me responsible for Texas unless you allow me the flexibility and control to actually be responsible. Then, hold me fully responsible. Allow us to capitalize on doing what we do best at the level that's best equipped to handle it. Allow us the flexibility to shift and emphasize according to need. This is not a question of turf; it's a question of efficiency and effectiveness.

7) The obligation we have to our children does not lie in the public sector alone; nor does it lie in the private sector alone. We have to have a delivery infrastructure that encourages both the public health clinics and the private physicians. We need to remove any barriers which discourage private physicians' full participation in our efforts to immunize.

We don't need a system where private physicians refer children to public health clinics for immunization. That's like me walking in to a Ford dealership to buy a car and being told to go to another Ford dealer across town. What are my chances of doing that? What are my chances of actually staying interested in Fords? What are the chances of me making the effort?

We're talking about an immunization program, not a progressive dinner. We cannot continue sending people on a scavenger hunt for health.

When we've got 'em, let's don't let 'em get away. I believe this—in essence—is the wish of this administration and the intent of this bill.

Let us remember that this war will be waged in the communities of this Nation, not in Washington, DC. and not in Austin, TX. We have to have the flexibility to employ nontraditional delivery methods. Raving the vaccine without a system of delivery, without the people to give it, isn't going to do anyone any good. In a community where the closest thing we have to a health care facility is a Dairy Queen, we've got to look for other ways to deliver. We've got to talk about school-based or church-based health care. We've got to talk about mobile systems. We've got to take the care to the people where the people are and quit trying to make them come to us.

We can't throw this national party where the people ain't, and we can't throw the party without someone to cut the cake. We've got to have the professional health staff to get the job done. We've got to have more nurses, and we've got to be able to keep them.

Many States, including Texas, will need the flexibility to use funds to meet these staffing needs and to look for and establish non-traditional delivery systems at the community level . . . to make immunizations available and convenient.

8) We have to market the product. We have to advertise. To promote. And, we have to do it professionally. In this age of instant mass communication technology and methodology, we cannot continue to rely on seminars, overheads and one-on-one communication to get the word out. Public health communication in this country has been the medical equivalent of the "Not Ready for Prime Time Players". Well, this immunization initiative is definitely a prime time program, and our communications to make it successful have to be prime time, too.

We've got to sell the product.

But, before any aspect of this immunization effort can be maximally effective, I believe there are several conditions we need to recognize.

First, we as decision makers and we as a nation of parents, have got to view immunization as a priority need. We cannot continue to look at measles, mumps and whooping cough as normal childhood diseases which every kid goes through. We cannot continue to think they're just part of growing up—some sort of plights of passage—that aren't that serious. These illnesses are serious, even deadly, and we have no excuse for not eliminating them in this country. We've got to get away from the idea that a disease has to be deadly to be disastrous.

Second, we cannot continue to wait for devastation before we see doing something about it as a priority. It's a sad commentary on our vision when we experience some calamity of national attention, followed by everybody and their uncles clamoring for action, for reform. It doesn't take a genius to witness a pile-up at an unmarked intersection to conclude the need for a signal light.

We have a chance here to exercise real vision . . . to do something to prevent calamity.

Third, we have got to continuously remind ourselves that prevention is the cheapest form of health care we have. And, immunization is prevention at its best . . . our most cost-effective health service.

To illustrate, allow me to mention three outbreaks of measles in Texas in the past few years:

In Dallas, in 1989–90, it cost $3.5 million to hospitalize 238 patients. It would have cost $3,700 for 238 doses of the MMR vaccine.

In South Texas, in 1991–92, it cost $2.4 million to hospitalize 595 patients. It would have cost $9,100 for the vaccine.

In Houston, in 1988–89, it cost $8.5 million to hospitalize 550 patients. It would have cost $8,400 for the vaccine.

In the Dallas outbreak, more than half of the $3.5 million hospitalization cost was borne by the government or government-sponsored agencies.

In short, in these three examples alone, $14.4 million was spent to treat because $21,200 was not spent to prevent.

One of the major points we supported that we did not get in the Texas legislation I mentioned earlier was a provision that health insurance companies would be required to reimburse for immunizations on a non-deductible basis. I'm not an actuary. I'm a pediatrician. Maybe that's why I'm missing the point. I simply cannot see the wisdom of an insurance company refusing to reimburse a few dollars for an immunization, but be willing to cover hospital stays for measles complications that can range from $850 to $20,000 a day.

Another disturbing finding in the Dallas example . . . of the 238 patients hospitalized, some 169 were children. Of these, about half had been to a health care provider prior to exposure; providers who missed opportunities to immunize. We had 'em; we let 'em get away.

Equally disturbing is that about 40 percent were enrolled in at least one of our Federal assistance programs-food stamps; Women, Infants and Children; Aid to Families with Dependent Children; or Medicaid. We could have immunized them there. Again, we had 'em; we let 'em get away.

We cannot continue to miss opportunities to prevent illness, doctor bills, hospital bills, suffering, death, loss of income, and lost productivity.

We have got to have cooperation among our various government programs, especially among entitlement programs, such as food stamps, WIC, Medicaid and AFDC.

In Texas, we estimate that half of the 2-year-olds who need to be immunized participate in the WIC program. So why not incorporate our immunization program with WIC? In fact, we have started doing just that in El Paso, and we are excited by the reception from the WIC program and by the prospects for increased immunization rates this cooperative effort affords us.

Let's get them while we've got them and not send them across town and bet so heavily on them getting there. Neither a 2-year-old nor the parents should have to understand and appreciate a governmental organizational chart to get what he or she should have.

Let's stop saying we can't, and start figuring out ways to do it. The "Comprehensive Child Immunization Act of 1993" is a solid and impressive step in this direction. The State of Texas and ASTRO stand ready to work with you to enact this legislation in 1993.

Thank you for this privilege, and in closing, I would emphasize that Texas stands ready and willing to be a charter participant in any aspect of this initiative you see fit, especially in the efforts to establish a national tracking system.

Senator RIEGLE. Next, Mr. Ed Thompson, Jr., who is here from Jackson, MS.

Dr. THOMPSON. Thank you, Senator.

I am Dr. Ed Thompson, chair of preventive health services for the Mississippi State Department of Health, and currently that State's interim State health officer.

At the national level, I am president of the Council of State and Territorial Epidemiologists and a member of the Centers for Disease Control's Advisory Committee on Immunization Practices. I do not, however, present any official ACIP position on this issue.

As a practicing public health professional responsible for the direction of a State immunization program, I want to express appreciation for the interest and support being given to children's immunization by the President and by the Congress. I would like to voice strong support for much of the content of the Comprehensive Child Immunization Act of 1993.

Two provisions in particular will be of significant help. The simplification of vaccine information materials will generate a nationwide sigh of relief throughout our public health system, and the ability to use Social Security numbers to track children's immunization status is something we in the States have recommended for some time, and it will be of major help to us in tracking children.

Another provision of the bill, the collaborative Federal and State efforts to track children's immunizations, can be highly valuable, perhaps even decisive, in our efforts to reach the goal of protecting 90 percent of our children by age 2. In Mississippi, we have identified the implementation of a statewide immunization tracking system as one of the most important things we need to do to reach our year 2000 goal.

There is a cautionary note that needs to be raised, however. The emphasis needs to be on supporting tracking systems in the States. The national registry proposed in the bill will contribute much less to raising immunization levels. It needs to be kept simple and

streamlined, and common sense and the realistic evaluation of its relative yield need to be stressed.

In addition, there are serious concerns in the States about some of the requirements with regard to adherence to Federal tracking models and systems specifications regarding registry design. I can address these further in response to questions the members may have at the conclusion of my remarks.

One provision of the bill, the universal purchase of vaccines, is not, in my opinion as a public health practitioner, a good use of resources and will not contribute significantly to raising childhood immunization levels. To support that opinion, I must give some background on immunizations in Mississippi.

Mississippi has the lowest per capita income of any State. We have one of the highest proportions of minority populations in the Nation; 36 percent of our population is African American. In many ways, Mississippi is the rural counterpart of the inner city, with substantial demand for public health services and relatively limited resources to meet that demand.

Mississippi has one of the highest immunization levels in the Nation. In 1992, 72.2 percent of our children had completed a basic series of four DTP, three OPV, and one MMR by age 2, and that is based on a statewide population-based probability sample. One of our public health districts has already reached the year 2000 goal of 90 percent coverage, and these levels are the same for African American and white Mississippians.

Mississippi intends to be the first State to reach the Nation's year 2000 goal, and we believe we can do it by 1994. We have accomplished the immunization levels we have and can reach our 90 percent coverage goal without providing vaccine to private providers.

In analyzing the reason why 28 percent of our 2-year-olds are not fully immunized, we have not found availability of vaccine or its cost to be a significant barrier. MMR is the most expensive vaccine we give, yet in 1992, 86 percent of Mississippi children had received MMR by 24 months of age. Availability of vaccine is not the problem. Like all States, we purchase our public health vaccine through Federal contracts, at prices significantly below the retail prices paid by private providers. We are able to provide vaccine to any child in Mississippi through the health department at minimal cost for those who can afford it and at no cost to those who cannot.

We have enough vaccine, or nearly so, as long as new vaccines and cost increases are provided for. Giving vaccine is the problem. We need more nurses and other staff to give the vaccine, track children and do outreach. We need computers and software to do tracking and trigger outreach. We need, in short, to further strengthen the public health infrastructure for vaccine delivery, not just buy more vaccine.

Part of the reason that vaccine availability and cost are not a real barrier is that States provide much of the funding for vaccine. In Mississippi, nearly 80 percent of children receive all or most of their immunization in health department clinics. Roughly half the cost of the vaccine we use each year is paid for with State dollars, even though we are a resource-poor State. State legislators can understand and appreciate the need for vaccine. It is easier to get

State support for vaccine than for infrastructure, which is more difficult to sell at the State level.

The cost of making free Federal vaccine available to all providers is high. As a practicing public health official at the State level where immunizations are actually given, where the rubber meets the road, I respectfully recommend that these funds be directed to infrastructure instead, especially for outreach and tracking.

Thank you for the opportunity to speak on this issue, and I'll be happy to answer any questions the members may have.

Mr. WAXMAN. Thank you very much, Dr. Thompson.

[The prepared statement of Dr. Thompson follows:]

PREPARED STATEMENT OF F.E. THOMPSON, JR.

Messrs. Chairmen, ranking members, and members of the committee and subcommittee. I am Dr. Ed Thompson, Chief of Preventive Health Services for the Mississippi State Department of Health, and currently Mississippi's Interim State Health Officer. At the national level, I am president of the Council of State and Territorial Epidemiologists. I am also a member of the Centers for Disease Control's Advisory Committee on Immunization Practice; I do not, however, present the ACIP's position on this issue, but appear today as an individual member of that body.

As a practicing public health professional responsible for the direction of a State immunization program, I want to express my appreciation for the interest and support being given to children's immunization by the President and the Congress. The increased resources already provided for childhood immunizations, and those proposed in the legislation being considered by this committee are a clear indication of both the President's and the Congress's intent to protect our children against diseases no child should have. Our goal for the Nation for the year 2000 is for 90 percent American children to have completed a basis series of immunizations by their second birthday. The measure being considered today can help us reach this goal.

I would like to voice strong support for much of the content of the Comprehensive Child Immunization Act of 1993, as contained in House Bill 1640 and Senate Bills 732 and 733. I would like to raise a cautionary note about one provision of the act, and I would also like to respectively suggest that the resources provided in another major component of the proposal could be better targeted. Two provisions in particular are much needed and will be of significant help. The simplification of vaccine information materials provided in subsection (e) of section 5 of the bill will generate a nationwide sigh of relief throughout our public health system. The unduly complex materials currently mandated are a barrier to timely immunization, a needless expense, and divert time and effort away from actually immunizing children. The ability to use Social Security numbers to track children's immunization status, provided in subsection (b) of new section 2143, is one of the most valuable provisions of the bill. This is something we in the States have recommended for some time, and it will be a major help to us in tracking children. It may well be the single best thing in the bill, and it's much appreciated.

Another provision of the bill, the collaborative Federal and State efforts to track children's immunizations described in new section 2143, can be highly valuable, perhaps even decisive, in our efforts to reach the goal of protecting 90 percent or more of our children by aged. A good tracking system allows reminder notices to be sent when immunizations are due, and other notices to be sent if a dose is missed or overdue. It identifies inadequately immunized children for special attention and outreach efforts, measures immunization levels in a clinic, an area, or a State, and allows for evaluation of immunization program efforts. In Mississippi, we have Identified the development and implementation of a statewide immunization tracking system as one of the most important things we need to do to reach the year 2000 goal.

There is a cautionary note that needs to be raised, however. The potential value in raising immunization levels lies in State and large substate regional tracking systems, and this is where the emphasis needs to be: on supporting tracking systems in the States. The national registry or tracking system proposed in the bill, while of some help, will contribute much less to actually raising immunization levels, and needs to be kept simple and streamlined. Most importantly, common sense and a realistic evaluation of its relative yield need to be stressed. In addition, while some degree of standardization and interchangeability of data is important, there are serious concerns in the states about some of the requirements with regard to adherence

to Federal tracking models and systems specifications regarding registry design. I can address these further response to questions the members may have after the conclusion of my remarks.

One provision of the bill, the universal Federal purchase of vaccines addressed in new section 2141, is not, in my opinion as a public health practitioner, a good use of resources, and will not contribute significantly to raising childhood immunization levels. To support that opinion, must give some background on immunizations in my own State of Mississippi.

Mississippi is a largely rural State, and has the lowest per capita income of any State in the Nation. We have one of the highest proportions of minority population in the Nation: 36 percent of our population is African-American. In many ways, Mississippi is the rural counterpart of the inner city. We are a State with substantial demand for public health services, and relatively limited resources to meet that demand. In light of these factors, Mississippi has had to develop a strong immunization program.

Mississippi has one of the highest immunization rates in the Nation. In 1992, 72.2 percent of our children had completed a basic series of four DTP, three OPV, and one MMR. This figure is based on a Statewide, population based survey of a probability sample consisting of 6 percent of the 1990 birth cohort, drawn from birth certificate records, and surveyed prospectively. Figure 1, in Appendix A, depicts these results by State and by public health district. One of our districts has already reached the year 2000 goal of 90 percent completion. These levels are the same for African-American and white Mississippians. With the help of the new resources provided in other measures now before the Congress, and some of those proposed in this bill, Mississippi intends to be the first State to reach the Nation's year 2000 goal. We believe we can do it by 1994.

We have accomplished the immunization coverage we have, and we will reach our 90 percent coverage goal, without providing vaccine to private providers. In analyzing the reasons why 28 percent of our 2-year-olds are not fully immunized, we have not found availability of vaccine, or its cost, to be a significant barrier. MMR is the most expensive of the vaccines we give, yet in 1992, 86 percent of Mississippi children had received MMR by 24 months of age. Availability of vaccine is not the problem. Like all States, we purchase our public health vaccines through Federal contracts at prices significantly below the retail prices paid by private providers. We are able to provide immunizations to any child in Mississippi who wants to receive them through the health department at minimal cost ($5 per dose) for those that can afford it, and at no cost to those who cannot we have enough vaccine, or nearly so, and as long as new vaccines and cost increases are provided for, we need resources in other. areas to raise our immunization levels. Giving the vaccine is the problem. We need more nurses and other staff to give the vaccines, track children, and do outreach. We need computers and software to do tracking and trigger outreach. We need, In short, to strengthen the public health infrastructure for vaccine delivery, not just buy more vaccine.

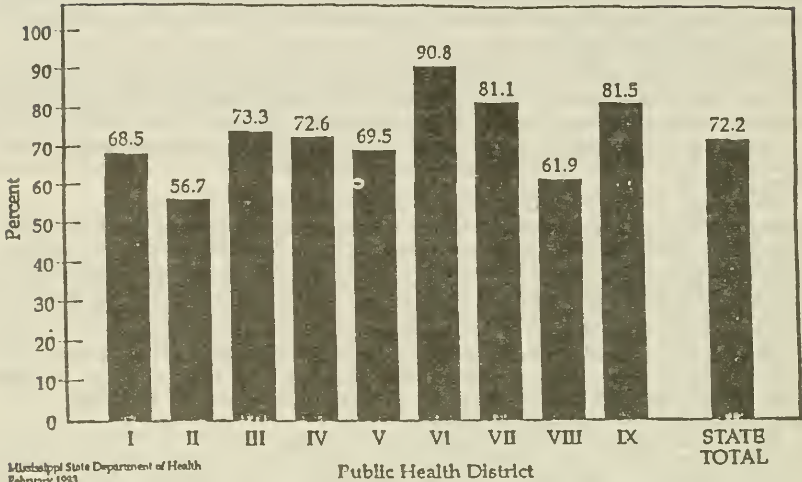
Part of the reason that vaccine availability and cost are not a real barrier is that States are willing to provide much of the funding for needed vaccines. In Mississippi nearly 80 percent of children receive all or most of their immunizations in Health Department clinics, as shown in Figure 2 in Appendix B. Figure 3 in Appendix C shows Mississippi's Health Department vaccine funding over the last 7 years. Roughly half the cost of the vaccine we use each year is paid with State dollars, even though we are a resource-poor State. We anticipate the willingness of our State legislature to bear the State's share of vaccine costs will continue. State legislators readily understand and appreciate the need for vaccine, and it is easier to get State support for vaccine than for infrastructure, which is more difficult to "sell" at the State level.

The cost of making tree Federal vaccine available to all health care providers is high—over a billion dollars annually. As a practicing public health official at the State level, where immunizations are actually given, "where the rubber meets the road," I respectfully suggest that these funds be directed to infrastructure, especially for outreach and tracking, rather than universal vaccine purchase. From our experience at the State and local level, that is what's needed to really raise immunization levels for our children.

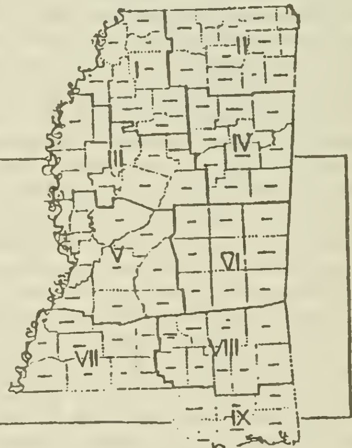
Thank you for the opportunity to speak on this issue. I will be happy to answer any questions the committee and subcommittee members have.

Mississippi Immunization Status

1992 Survey Of Two Year Olds
Completion Status By District



The Healthy People Year 2000 immunization goal is to increase childhood immunization levels to at least 90 percent of two-year-olds (a 20 percent increase)



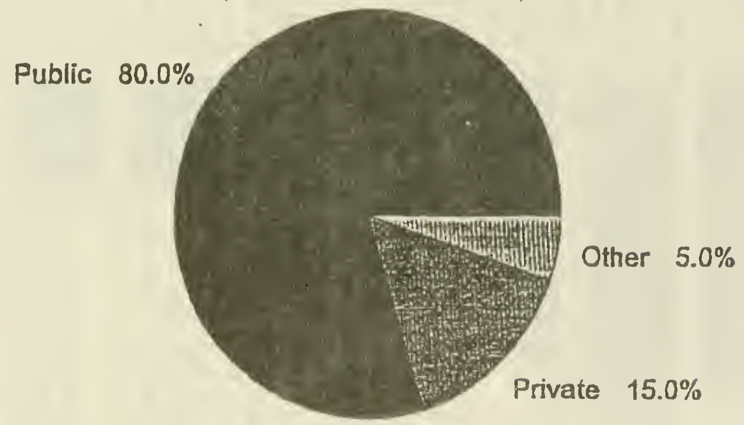
Mississippi State Department of Health
Public Health Districts

Northwest Public Health District I
Northeast Public Health District II
Delta Hills Public Health District III
Tombigbee Public Health District IV
West Central Public Health District V
East Central Public Health District VI
Southwest Public Health District VII
Southeast Public Health District VIII
Coastal Plains Public Health District IX

Figure 1

APPENDIX B

Distribution of Immunization Provider
Mississippi, 1992 Two-year Old Survey



Unweighted Results

Figure 2

APPENDIX C

MISSISSIPPI STATE DEPARTMENT OF HEALTH

Vaccine Cost by Fund Source

	87	88	89	90	91	92	93
State	907,514	719,163	1,397,485	1,490,354	2,032,480	2,590,994	2,070,957
Federal	600,265	918,998	1,393,149	1,910,404	1,944,493	2,503,610	2,535,500
Other	193,077	129,077	202,963	240,212	322,601	366,585	338,468
Total	1,700,856	1,767,238	2,993,597	3,640,970	4,299,574	5,461,189	4,944,925

Figure 3

Mr. WAXMAN. Mr. Moen.

Mr. MOEN. Thank you, Mr. Chairman and members of the committee and staff. I'd like to applaud your efforts in putting forth this legislation we are discussing today. I offer the following comments in the spirit of helping make this legislation focus on the real immunization problems confronting us.

I would like to discuss with you two issues. First, we must be more specific on how we measure immunization rates in this country. The current one-number methodology treats children who have had no immunizations the same as children who have three doses of DTP, two doses of polio, and one dose of measles, mumps, rubella. While both groups of children are technically behind in their immunizations, there is a substantial difference in terms of disease risk, reasons for being behind, and the interventions necessary to address the problem.

The current one-number methodology at best oversimplifies the issue and at worse seriously misdirects our efforts to improve immunization rates in this country.

The second issue pertains to immunization registries. We believe immunization registries can be useful and have several purposes in tracking children's health over time. However, we believe there has been inadequate consideration of the costs or the benefits of a national statewide immunization registry.

Regarding the first issue, we continue to describe the immunization levels of our preschool children by use of a single number—the percentage of children who have completed a primary series of four doses of DTP, three of polio, and one of MMR by 24 months of age. Unfortunately, the single-number approach does not accurately portray that immunization levels are a moving and changing target throughout the life of a child.

In Minnesota, we have ascertained the immunization rates of all 69,000 kindergartners in the State who were born in 1986-87. For purposes of comparison, we define success by whether the child had received the recommended dose within 2 months of the time it should have been administered.

The attachments to my testimony display charts and graphs of some of this information and the rates of immunization in Minnesota using this methodology. Eighty-six percent of the children in Minnesota do receive their first dose of DTP and polio by 4 months of age. As additional doses are added, however, the numbers adequately immunized quickly but begin to rebound as children receive additional recommended vaccine doses.

By 24 months of age, 90 percent have received three doses of DTP, 93 percent have had two doses of polio and 82 percent have had MMR. While these are the most important of the primary immunizations a child should receive, because only 64 percent of the children have received the fourth dose of DTP, we often refer simply to this latter number as the percent of children who have been vaccinated at this age. As you can see, the single number hardly represents our experience, does not portray true disease risk in these children, and does not allow us to understand what or where the problem is.

Looking at vaccines over the life of the child can also identify problems at the local level. We have information on the immuniza-

tion rates over time in the city of St. Paul, and in the city of St. Paul, fewer than 80 percent of the children receive their first doses in a timely manner. However, we can go down further. We can go down to the ZIP Code level in St. Paul. In ZIP Code 55105, over 90 percent of the children receive their initial dose within 2 months of the recommended age. If we look at another ZIP Code in the city of St. Paul, we see quite a different picture; less than 70 percent are actually receiving immunizations.

We have similar information for every county in the State of Minnesota. This effort has allowed us to focus the activity in communities at the problems, activate and arm those communities to first understand what their problem is and then to act.

Local immunization registries in conjunction with other interventions can be cost-effective and can play an important role in improving immunization rates in a community. However, a national population-based immunization registry is premature at this time and will divert resources from areas with the greatest problems.

We need to keep our eye on the ball, and the ball in terms of disease risk is low immunization rates, especially for those early doses of DTP, polio and MMR in specific populations with the worst problems.

We support the thrust of this legislation and believe it can result in significant improvements of immunization rates in this country if the interventions and resources are directed to where the problems are.

Thank you.

Mr. WAXMAN. Thank you very much, Mr. Moen.

[The prepared statement of Mr. Moen follows:]

PREPARED STATEMENT OF MICHAEL E. MOEN

Mr. Chairman, members of the committee and staff, I'd like to applaud your efforts in putting forth this legislation we are discussing today. I offer the following comments in the spirit of helping make this legislation cost-effective end focus on the real immunization problems confronting us. I would like to discuss with you two issues. First, we must be more specific on how we measure immunization rates in this country. we must be able to distinguish children who have had no immunizations from children who have had 3 doses of diphtheria, tetanus, pertussis (DIP), 2 doses of polio, and 1 dose of measles, mumps, rubella (MMR). While both groups of children are technically behind in their immunizations, there is a substantial difference in terms of disease risks, reasons for being behind, and interventions to address the problem. The second issue pertains to immunization registries. There has been a great deal of discussion regarding the use of immunization registries for determining immunization levels in this country. Immunization registries have several purposes, including tracking the health of children over time. We believe there needs to be additional discussions, however, about the cost of a national or statewide immunization registry.

Regarding the first issue, we continue to describe the immunization levels of our preschool children by use of a single number: the percentage of children who have completed a primary series of 4 doses of DIP; 3 doses of polio; and 1 MMR by 24 months of age. These numbers are frequently used to describe immunization rates in individual states or cities. Unfortunately this single number approach does not accurately portray the complex process of immunizing children. immunization levels are a moving and changing target throughout the life of a child and especially during the time from birth through age 3. Our success at immunizing preschool children must be measured by their age-appropriate receipt of vaccine not just on their completion rates for the primary series by 24 months of age. Ensuring that children start on time and receive their third dose of DIP by 6 months of age is critical to prevent the serious complications of pertussis infections during the first year of life. The importance of timely administration of these early doses of vaccine can be lost by focusing only on the immunization status of children at 24 months.

In Minnesota we have conducted a retrospective survey of all 69,000 kindergarten children to determine their immunization rates from birth to school entry. These are children who were born in 1986 and 1987. We have conducted validation studies and determined that their school records accurately document the dates upon which they received their immunizations. By comparing these dates with the birth of the child we can present a composite history of the immunization of each child. Our goal is to create a system that ensures that infants of all geographic areas, racial and ethnic groups, and socio-economic strata receive age-appropriate immunizations, such that 90 percent are up-to-date when measured within 2 months of the dates on which they were to be vaccinated. Thus, we have evaluated the preschool immunization levels of our kindergartners at the live goal points described in Attachment 1. Attachment 2 displays the immunization rates for the State of Minnesota using this methodology. As you can see, immunization rates vary tremendously by the age of the child and the type of vaccine. In Minnesota, 86 percent of children receive their first dose of DIP and polio by 4 months of age. As additional doses of vaccines are added, the numbers of children adequately immunized drop sharply but begin to rebound quickly as those children receive the additional recommended vaccine doses.

By 12 months of age, 79 percent of children in this cohort have received 3 doses of DTP and 89 percent have received 2 doses of polio. By 24 months, 90 percent have received 3 doses of DTP 93 percent had 2 doses of polio, and 82 percent MMR. While these are the most important of the primary immunizations a child should receive, because only 64 percent of children have received the fourth dose of DTP, we often refer to this latter number as the percent of children who have been vaccinated at this age. As you can see, this single number hardly represents our experience in Minnesota. Because of laws that require children to be immunized prior to school entry, over 98 percent of children in Minnesota receive all required vaccines by school entry.

Lack of immunizations at different ages of a child's life suggest very different problems. A 2-month-old child who has not received first dose or second dose DTP or polio, very likely has not received any well-baby care subsequent to delivery. Provision of these early doses of vaccine are clearly one of the most important functions of any well-baby visit. Lack of completion of the series, in particular fourth-dose DTP, suggests quite a different problem. This is particularly evident when comparing the percent of children who receive MMR who do not receive the fourth dose of DTP. Inasmuch as these two vaccines can be given simultaneously at the same clinic visit, the question arises as to why children who are receiving MMR are not receiving their fourth dose of DTP.

By conducting surveys of all kindergartners in Minnesota, we can determine immunization rates by specific geographic areas. Attachment 3 displays the immunization levels for children in the city of St. Paul. Fewer than 80 percent of children receive their first doses of vaccine in a timely manner and, except for second dose polio, which reaches 83 percent, these children do not rise above 80 percent for any vaccine. Breaking the city into zip codes provides additional information which is key to targeting efforts to improve immunization rates in this city. Attachment 4 displays immunization rates for zip code 55105 in St. Paul. Over 90 percent of children In this area receive their initial dose within 2 months of the recommended age. However, even in this relatively affluent community there is room for further improvement in the timeliness of fourth dose DTP.

Attachment 5 displays immunization rates for zip code 55103 in St. Paul. Clearly this area is where we need to focus our efforts.

Attachment 6 displays rates for Olmsted County, home of the Mayo Clinic. Attachments 7 and 8 display immunization rates in two different schools in Olmsted county. In this county with generally good immunization levels, Hawthorne Elementary represents a pocket where efforts to improve immunization rates need to be directed.

In order to successfully attack the problem of low immunization rates, we must focus our limited resources to where the problem is and not to where the problem is not. The methodology described above allows us to pinpoint immunization problems and direct resources to those areas. We collected this data, analyzed it, and prepared a composite for each county in Minnesota in 8 months at a cost of approximately $220,000. Using Immunization Action Plan (IAP) funding, local community health departments in Minnesota have convened community task forces to develop strategies to address the low immunization rates in their areas. This process will focus resources and interventions to problem areas and avoid the dilution of emphasis and resources that occur with a "shotgun approach.

Local immunization registries in conjunction with other interventions can play an important role in improving the immunization rates of a community. By assisting

providers and parents in keeping track of when the next vaccine dose is due, a registry can serve an important purpose. Registries that are locally-supported by the community can be cost-effective, particularly in areas with low immunization rates. The Minnesota Department of Health supports immunization tracking and registries, particularly at the provider or community level. we have experience in the development of registries in the area of cancer and in public immunization clinics, and have received a grant from the Robert Wood Johnson Foundation to develop additional immunization registries in Minnesota. In addition, key staff in the department, such as Dr. Osterholm, have served on grant review committees for immunization registries for the Robert Wood Johnson Foundation. We draw upon this experience with, and commitment to, registries when we say that a national immunization registry is premature at this time and will divert resources from areas with the greatest problems.

Local provider-based immunization registries that provide "on line," "real time" information are important and cost beneficial in areas where there are documented immunization problems. However, the expanse of a national population-based "on line," "real time" immunization registry is hardly justified at this time.

We support the thrust of the legislation and believe it can result in significant improvement of immunization rates in this country if the interventions and resources contained in the bill are directed to where the problems are. I believe we can improve immunization rates in this country if we build on the work that has begun through the IAP initiative; which involves communities in identifying where problems exist and which directs resources toward problem areas. Additional information on immunization rates can be gathered quickly and inexpensively using existing survey methodology and existing data sources. This information can assist States and communities to direct their efforts to problem areas. Adding registries and additional vaccines to public health's armamentarium to attack low immunization rates is a good strategy. Making those two strategies the sole strategy, or applying them in areas where they're not needed, diverts important and limited public health resources from the areas where additional work is needed.

ATTACHMENT 1

Goal of the Minnesota Immunization Action Plan

By the year 2000 create a system that ensures that infants of all geographic areas, racial and ethnic groups and socio-economic strata receive age-appropriate immunization against diphtheria, tetanus, pertussis, poliomyelitis, measles, mumps, rubella, *Haemophilus influenzae* type B, and hepatitis B such that 90% are up to date when measured within two months of the date(s) on which they were to be vaccinated.

Immunization Goals by Age

Goal 1 (4 months)
DTP 1
Polio 1

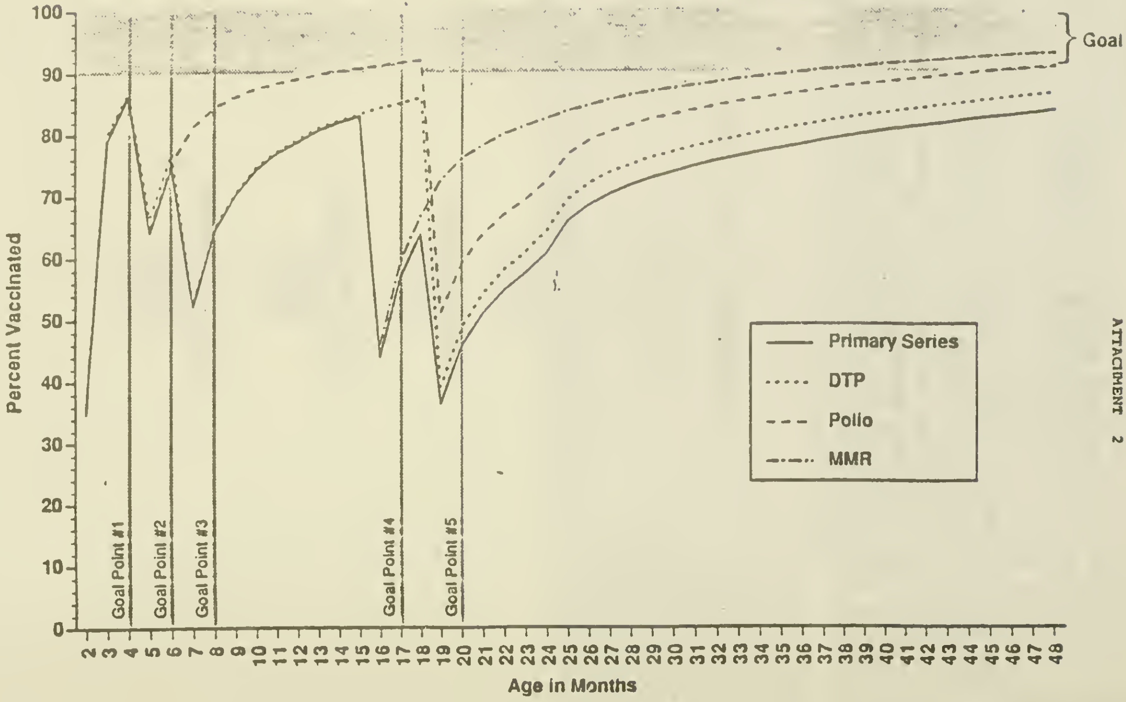
Goal 2 (6 months)
DTP 2
Polio 2

Goal 3 (8 months)
DTP 3
Polio 2

Goal 4 (17 months)
MMR
DTP 3
Polio 2

Goal 5 (20 months)
MMR
DTP 4
Polio 3

ATTACHMENT 2



ATTACHMENT 3

Percent of Children with Age-appropriate Vaccination by Age in Months, Kindergarten Survey 1992-93
St. Paul

N = 4840

Goal

Percent Vaccinated

100
90
80
70
60
50
40
30
20
10
0

Goal Point #1
Goal Point #2
Goal Point #3
Goal Point #4
Goal Point #5

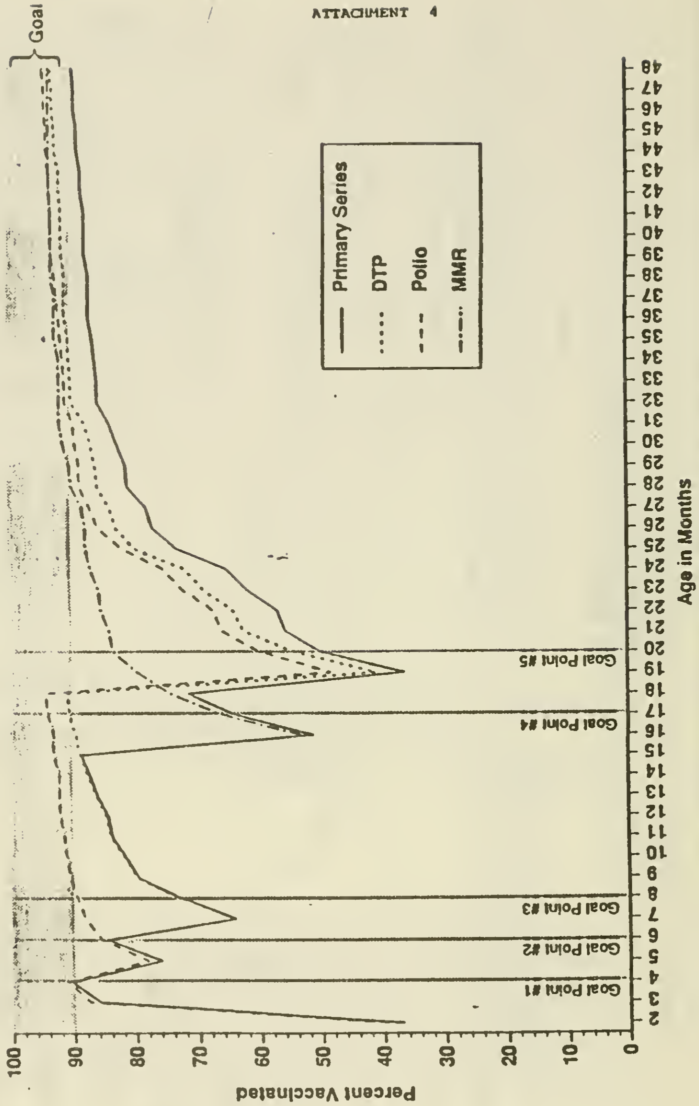
Primary Series
DTP
Polio
MMR

2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48

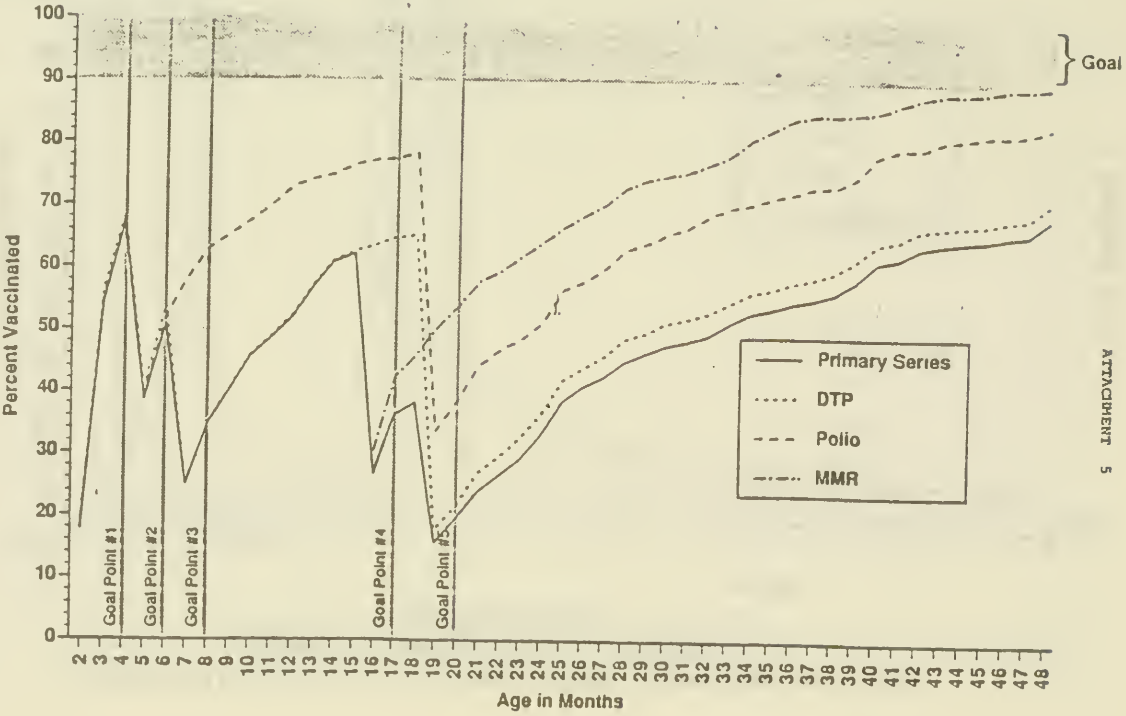
Age in Months

ATTACHMENT 4

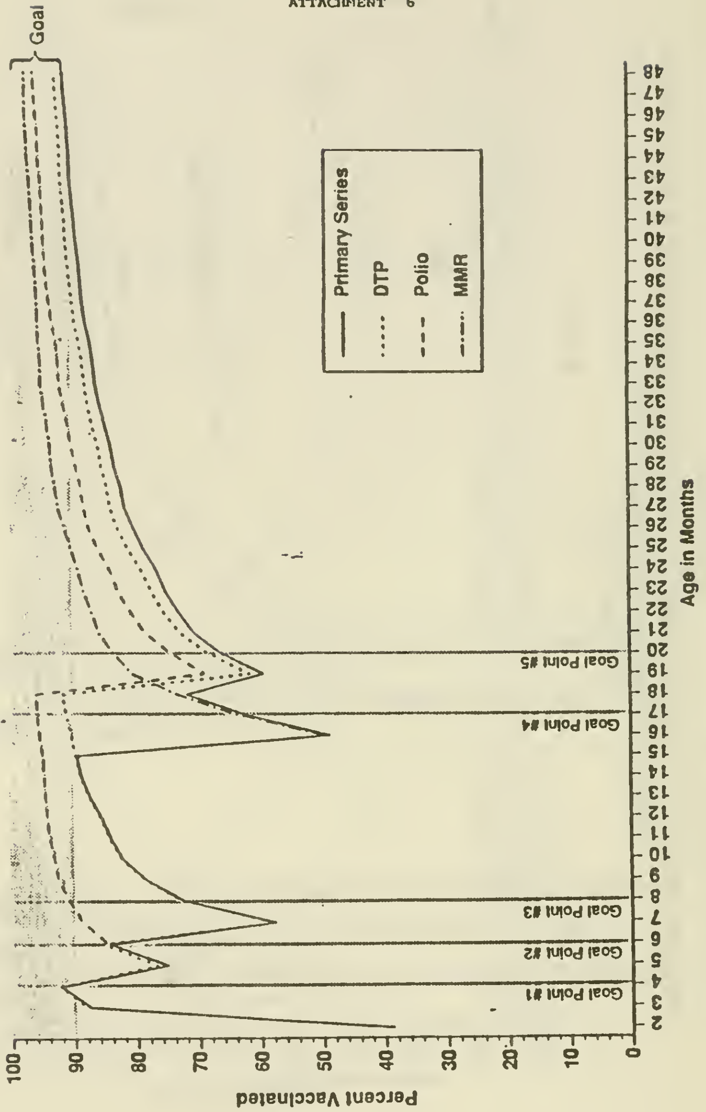
Percent of Children with Age-appropriate Vaccination by Age in Months, Kindergarten Survey 1992-93
St. Paul - 55105



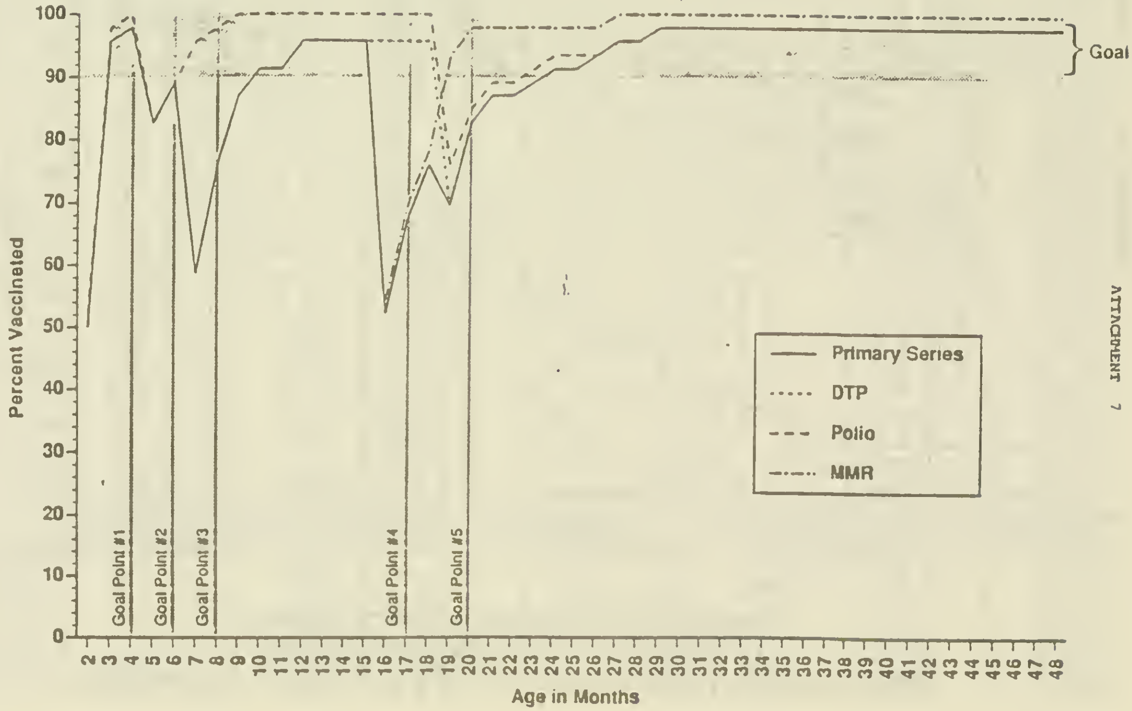
ATTACHMENT 5



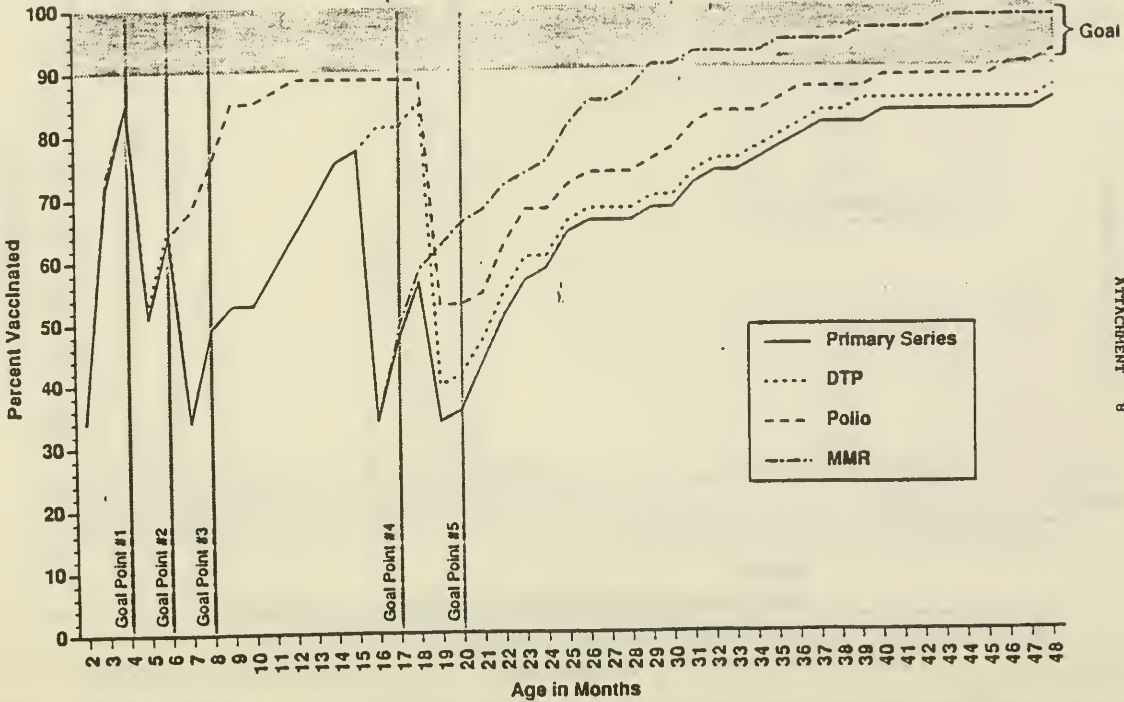
ATTACHMENT 6



ATTACHMENT 7



ATTACHMENT 8



Mr. WAXMAN. Ms. LeBron.

Ms. LEBRON. Thank you, Chairmen, and members of the committee. I thank you all for allowing me to come here today to speak on the immunization project that we have in the city of Holyoke, MA. It is an honor.

I'd like to introduce on my right Ms. Danielle Gordon, the coordinator of the Holyoke immunization project.

I will be talking in regard to the strategies that have taken place with our program, which is funded through the Department of Public Health. CEDE is a community-based project under the Nuevo Esperanza Housing Development Agency, and our strategies are grassroots level strategies.

As I go through my testimony, I will be touching on what kinds of strategies were used in this community. We are serving and working with a predominantly Puerto Rican community in this city. Our approach has been door-to-door outreach.

In our first year, when we began our first phase for the project that is a demonstration of the Department of Public Health, what we did was to go out and do an assessment. This was through a randomly-chosen sample, and we did door-to-door knocking in order to identify families whose children were not fully immunized.

Let me just say that we found that 70 percent of these children were not immunized, and this was just a random sample, so we can figure out the rest.

I want to continue by saying that each community needs to apply its own personal outreach that fits into its own community. Besides door-to-door outreach, we have been able to do media advertising through our local ratio stations and community and local newspapers to outreach to families so that they know what is available.

The first year, what we did was to just assess these families, look at the records of what they had available, and then compare with the providers. And like I said, it was found that 70 percent of these children were not fully immunized.

We are in the second phase of our project now, and we are doing the second components, which is what people suggest. There was a series of questions that were asked to the families. And I heard here today certain things that are very true. There were barriers, and these barriers are the ones that we are working with in this second phase.

One of the barriers that I'd like to mention was health insurance. Massachusetts has done a great job in providing immunization free-of-charge, but we need to understand that the administration of these immunizations still has a cost. So that is a barrier right there alone.

The accessibility of hours and days is a barrier, and language, transportation and child care are some of the barriers that were encountered as well. This project is based on empowerment and also on the involvement of members of the community. The suggestions were that we should have rotating clinics throughout the four wards of the community to provide these clinics. Right now, we will begin our first one on Saturday, April 24th, from 12 to 4. We have subcontracted with Providence Hospital Prenatal Clinic from Holyoke, MA, and they will be the providers.

In closing, I just want to say that we are not health professionals, but we are health educators who are taking this to heart in reaching our grassroots residents to understand and educate at the same time. This process took place as they were doing the assessment; they were also educating people at the same time, and working on the barriers.

We are doing follow-ups with the families, getting them into clinics, and assuring them that they can have the accessibility that they need.

Thank you.

Mr. WAXMAN. Thank you very much. That is a report of a good success story.

[The prepared statement of Ms. LeBron follows:]

PREPARED STATEMENT OF GLADYS LEBRON

Thank you Mr. Chairman and members of the committee for the opportunity to be here and to talk with you about the importance of childhood immunizations. I am the Director of C.E.D.E., or the Center for Education During Pregnancy, which is a community organization concerned with health education and support for Latinos, and in particular for pregnant and postpartum Latina women. With me today is Danielle Gordon, who is the coordinator of a C.E.D.E. immunization project.

C.E.D.E. is based on a holistic approach and believes in using outreach strategies to help people facing barriers to health care services. C.E.D.E. is an organization of community workers, not trained health professionals—it works because it is an integral part of the community it serves, and is strongly committed to community empowerment through better health education.

C.E.D.E.'s outreach strategies include going door-to-door, canvassing areas by posting flyers, and having a strong physical, visible presence in the neighborhood. As we provided case management services to young women and families in Holyoke, we became aware that many children were behind in their vaccinations and that some lacked primary care providers.

In 1991, the Massachusetts Department of Health approached C.E.D.E. to begin a demonstration project to assess the immunization status of children in our community, and to identify barriers to immunization. This followed an outbreak of measles in 1990 that affected other areas of New England, when it was found that many children were not fully immunized.

C.E.D.E. took on the assessment project with 4 part-time outreach workers who worked in the 4 predominately Puerto Rican wards of Holyoke. The outreach workers went door-to-door in these neighborhoods, were interviewed on radio, and were featured in local newspapers. They asked parents a series of questions and examined children's vaccination records kept by the family. The outreach workers also compared each family's vaccine records with those kept by the family's medical provider. Each time the outreach workers found children who were behind in their immunizations, we worked to get those children to a health clinic for their vaccinations—making appointments, often providing the transportation to the clinics and back.

The results of our survey were very disturbing; we found out that 70 percent of 2-year-olds were not fully immunized. The main barriers to immunization were language difficulties, inconvenient hours for administration of vaccinations, lack of health insurance and concern for the cost of immunization, misunderstandings about the potential risks of vaccination, and a lack of support and transportation to enable families to get to a provider for immunizations.

In Massachusetts, we are more fortunate than many to have vaccine available to providers without cost, and families in clinics pay for administration on a sliding fee scale. Even though no one can be turned away from vaccinations if they can't pay the administration fee, it is not easy for families to discuss these issues and advocate for themselves. We work with parents to help them understand this.

Just to give you some idea about the kind of problems we face, we recently assisted a mother who has a child suffering from meningitis, which could have been prevented by timely immunization. Although this mother clearly understood the importance of vaccines, she had two other children who were behind in their immunizations. No parent would knowingly put their child at risk, but the barriers to immunization are so daunting that even parents who are trying hard to assure their children's protection are not always successful.

In another case, a mother was suffering from AIDS and faced a constant struggle between trying to obtain the medical services she needed, while trying to make sure that her child also received the necessary immunizations. Before we were able to help them, both the mother and the child were lacking needed services. These stories are not uncommon—our immunization project deals with these kinds of problems every day.

As a result of our interviews, C.E.D.E. is now embarking on a new project, based on the suggestions of parents. Beginning this weekend, we will provide free immunization clinics one weeknight and one weekday, rotating through the 4 wards of Holyoke we serve in community centers and accessible locations. We have subcontracted with Providence Hospital to administer the vaccines. To announce these clinics, C.E.D.E. has made a major effort in public outreach, including putting posters up throughout the neighborhoods, distributing informational packets to local agencies, placing public service announcements on radio, TV and in newspapers, doing bullhorn announcements in the street; and a massive distribution through the public school system of 7,800 flyers sent home to parents. This has been a major collaborative effort for our organization, involving all of our staff and outreach workers.

In conclusion, I would like to stress to you the importance of this community-based health care outreach, education and support to improving immunization rates in communities. It is most important that each community apply their own strategies to see what works in each neighborhood. Only by reaching out and understanding what parents and families face, can we be helpful in overcoming the barriers to immunization and help our children grow strong and healthy. Thank you, am happy to answer any questions you may have.

Mr. WAXMAN. I am going to add to this panel another witness who unfortunately is not able to be here with us, and that is Marian Wright Edelman, who is president of the Children's Defense Fund and a leading advocate on behalf of our Nation's children. She has been an inspiration for this legislation, and I think this hearing would not be complete if we didn't have an opportunity to hear from her.

We have fortunately been able to tape a statement from her, and I'd like to have the monitor run right now so we can hear from Ms. Edelman.

Ms. EDELMAN. I am deeply grateful for the opportunity to testify today from Indianapolis, where 8,500 Head Start directors, teachers and parents are meeting, in strong support of the Comprehensive Child Immunization Act of 1993.

Recently, with the help of American soldiers in Somalia, UNICEF announced that it would vaccinate more than 80 percent of that devastated country's children against measles in just a few short months. In contrast, here at home we have just emerged from a measles epidemic that struck nearly 60,000 Americans, mostly preschool children, and cost millions in unnecessary hospitalization costs.

Failing to invest in universal childhood immunizations really does increase both our Nation's social and fiscal deficits, and it increases unnecessary child suffering.

The Children's Defense Fund supports immediate action to include this universal childhood immunization legislation in the President's budget reconciliation package. We think that immunizing children should not and cannot wait for a national health plan, which we also support very strongly and hope will move quickly.

We hope you will act and will include all of the components of this comprehensive immunization initiative, because they all are crucial. We know that education and outreach will not succeed if parents are frustrated by systems barriers or costs. We know that public health service delivery changes will not work alone as long

as children still have private physicians—and we hope they will. We know that a national tracking system will only work if all providers, both public and private, participate as a condition of universal vaccine distribution.

Since our Nation's failure to vaccinate all our children has multiple causes, the response must include multiple remedies, and the President's proposal does so.

Millions of times a year, children miss opportunities to be vaccinated. Too often, doctors delay their shots because they have a runny nose or a sore throat. Many pediatricians send children away from their offices without immunizations because families cannot afford to pay the steep price of the vaccine, even if they can afford the doctor's administration fee.

For many parents, it is a choice between immunizing the child right away at a cost of $60, or going to a public immunization clinic for free. According to one State study, more than 70 percent of pediatricians and family physicians now refer patients to public clinics for immunizations because of financial considerations.

The system unwisely forces families to run around from provider to provider to find low-cost immunization services. Many parents must take extra time off work and find transportation to inconvenient locations for free vaccine, rather than putting the vaccine where the children can get their health care—in their family doctors' offices. This system makes it more difficult for parents to do and get their children's health needs met.

This was not a serious problem before vaccine prices rose for immunizing a child from less than $11 in 1977 to more than $230 today. While there are many reasons for the price increase, including price inflation, new vaccines and excise taxes, the fact is that many families have simply been priced out of the market. Even middle class parents are increasingly driven by rising vaccine costs to see the immunization as a step that can be deferred.

With less than half of private insurance plans covering the cost of immunization services and the rising number of uninsured children, more families are being forced to rely on public clinics for their children's health care.

Under a universal vaccine distribution system, which the Children's Defense Fund strongly supports, a system that has been in place for some vaccines in the New England States for 20 years and is used in every other Nation in the world, we think that this problem will be significantly alleviated. Vaccine would be added to education, fluoridated water, fire protection, and other activities recognized as best delivered for everyone's benefit on a universal basis.

We believe that a comprehensive approach is essential. Many opponents of this legislation have argued that universal vaccine purchase and distribution alone will not solve the problem. We agree. That is exactly why the administration has put forth a comprehensive strategy with universal purchase as a cornerstone.

Universal distribution will fix the problem of children missing opportunities to be vaccinated in their doctors' offices. It will be the foundation for a universal tracking system, and it will make it much easier to reach parents and reduce the overwhelming burdens on the public health system. But it cannot solve all these

problems alone. That is why the administration's proposal is also asking for resources to reach parents and expand public health services.

Some believe that simply adding new dollars to the infrastructure components of the solution will solve the problem. While this is a key step and a key element of the administration's strategy, it is not sufficient alone to address the problem. For the past several years, this has been the principal Federal response to the immunization problem.

First, vaccine price increases have tracked appropriations increases so that Federal funding increases have been offset by higher vaccine costs.

Second, focusing on the public sector alone will not stem the flow of children from private health providers to public clinics for immunizations. In fact, a strategy that focuses solely on the public sector could exacerbate the current trends by increasing the cost of vaccines for the private sector and forcing more children and their families into public clinics. We simply will not be able to solve the immunization crisis without fully enlisting the participation of private pediatricians and family physicians.

So, while we do support increasing and strengthening the public infrastructure, it alone is not enough.

Another proposed alternative to a universal system is to create a new means-tested or Medicaid-like program to distribute vaccine to private physicians. Some advocate a means test in order to avoid subsidizing the well-to-do, despite the fact that means-testing would have a very high administrative cost for modest benefit.

For example, the haemophilus influenza B vaccination for a 12-month-old infant costs about $10, far less than the cost to process the paperwork needed to check a family's resources. In order to have a means test in the private sector, either doctors would have to apply the income test, or families would have to go to a separate agency. Few doctors would be willing to conduct income tests, and millions of families would be lost from the system by the need to go through a separate process for a crucial but modest benefit. Another barrier would be erected when our goal is to eliminate such obstacles.

About 70 percent of families with children under 6 have total incomes below $45,000, about 300 percent of the poverty level for a family of four. To ensure equity, revenues needed to pay for childhood immunizations should be raised through the tax system, placing the least burden on those with lower incomes, not by adding more administrative costs in the doctors' offices.

Finally, the vaccine manufacturers claim that this legislation will stifle vaccine research and development. We disagree. The legislation specifically requires the Secretary to negotiate a price for vaccines that includes production costs, research and development expenses, and sufficient profits to encourage future vaccine research and development in addition to the funds they currently receive from NIH. The legislation assumes that the negotiated price of vaccines will be the average of current public and private market prices—$122 in the public sector versus $245 for a full series of vaccines per child at the private market price. As a result, the manufacturers should see no loss of revenue. They will, however,

lose the ability to unilaterally increase prices at rates far higher than inflation.

The President has shown leadership on this critical issue of childhood immunizations and recognizes that it is unacceptable for our children to lag behind many other industrialized nations and indeed, developing nations, in seeing that its children are healthy.

Congress must follow this leadership and take the needed action to immunize every American child. If we do not seize this opportunity, we will see another cycle of falling immunization rates and resurgent childhood diseases, unnecessary child illness and death, and unnecessary expenditures on treatment and hospitalization.

This Comprehensive Child Immunization Act of 1993 is good for children, it is good for families, it is good for our Nation, and it is long overdue. It lightens the load for public health and strengthens the role of pediatricians and family physicians in children's health care. And it provides assurances for the vaccine manufacturers for fair and reasonable prices and reasonable profits for their products.

I urge Congress to take immediate action on this most basic, cost-effective investment in children's health and not let proprietary interests prevent us from doing the right thing for our children.

I thank you for the opportunity to testify. I regret I am not there in person. CDF staff is there to answer any questions you may have, and I will be glad to answer them myself in writing if you submit them to me.

Thank you.

[The prepared statement of Ms. Edelman follows:]

Prepared Statement of Marian Wright Edelman

Messrs. Chairmen and members of the Senate Labor and Human Resources Committee and the House Health and Environment Subcommittee, I am honored to be testifying before you today from Indianapolis where 8,500 Head Start directors, teachers, and parents are meeting on expanding and improving the Nation's best early childhood development program. The greatest challenge before our Nation is to provide a head start, a healthy start, and a fair start to every child so they arrive at school ready to achieve and learn the skills necessary to compete in a global economy.

Yet when we look at immunizations and other measures of our children's well-being, we have fallen far behind not only our industrialized competitors, but many developing nation's as well. Over the past 10 years, as immunization rates rose in the developing nations of Latin America, Africa, and Asia, American children became less and less likely to be protected against vaccine preventable diseases. While China, one of the poorest nations in the world, immunizes more than 90 percent of its children, nearly half of American 2-year-olds are not fully immunized. With the help of American soldiers in Somalia, UNICEF announced that it would vaccinate more than 80 percent of that devastated country's children against measles in just a few short months. In contrast, here at home, we have just emerged from a measles epidemic that struck nearly 60,000 Americans, mostly preschool children, and cost millions in unnecessary hospitalization costs.

Our failure to protect children against preventable diseases is a disgrace not only because of the needless suffering it creates, but because of its shortsightedness. Every dollar we invest in immunizing a child saves at least $10 in later health care costs by preventing disease. Failing to invest in childhood immunizations worsens both our Nation's social and fiscal deficits. In order to lay the groundwork for a solid economic future, we must make investments in proven, cost-effective programs like immunizations. It is these cost-effective, preventive health measures that must be the foundation of reforming our health care system.

The Children's Defense Fund is delighted that the President and the Secretary of the Department of Health and Human Services have made immunizations a high priority. We urge you to take quick action and to pass this legislation in the budget

reconciliation package. Immunizing children cannot and should not wait for a national health plan. While CDF supports moving national health reform quickly, particularly comprehensive coverage for all children, any phase-in will delay the implementation of a program we know works. We literally cannot afford to wait. The President's initiative is comprehensive. It will help parents through increasing education and outreach services. It will hire more nurses and open more clinics to rebuild the public health system which has suffered from a decade of neglect. It will create a national vaccination registry or tracking system to monitor our children's immunization status. And it will eliminate cost barriers for parents as well as the hassles of having to go to more than one doctor by creating a universal vaccine purchase and distribution system.

Each of the components of the immunization initiative are crucial. We know that education and outreach will not succeed if parents are frustrated by systematic barriers to providing for their children's needs. Public health service delivery changes will not help those children who have a private physician. And a national tracking system will only work if all providers, both public and private, participate as a condition of universal vaccine distribution. Since our Nation's failure to vaccinate all our children has multiple causes, the response must include multiple remedies. This bill encompasses the essential components to a lasting solution and has our full support.

THE PROBLEM

While nearly all American children are immunized at the time they enter school, millions of preschoolers don't get their shots on time, leaving them vulnerable to preventable diseases. There are many reasons children don't get immunized on schedule. They include the rising cost of vaccine to families, missed opportunities to vaccinate, inadequate resources in public clinics, and some children's lack of access to regular health care. The Nation needs a comprehensive immunization policy that will protect every child against preventable diseases.

Millions of times a year, children miss opportunities to be vaccinated. Too often doctors delay their shots because they have a runny nose or sore throat. Many pediatricians send children away from their offices without immunizations because families cannot afford to pay the steep price of the vaccine, even if they can afford the doctor's administration fee. For many parents, its a choice between immunizing the child right away at a cost of $60 or going to a public immunization clinic for free. According to one state study, more than 70 percent of pediatricians and family physicians now refer patients to public clinics for immunizations because of financial considerations.

This system unwisely forces families to run around from provider to provider to find low cost immunization services. Parents must take extra time off work and find transportation to inconvenient locations. For free vaccine rather than putting the vaccine where the children get their health care—in their family doctors' offices. We simply cannot expect high vaccination rates if we leave such barriers to immunizations in place.

Further, these referrals contribute to the immunization crisis both directly and indirectly: direct when a child referred out of the private doctor's office never makes it to the public clinic, and goes unimmunized; and indirectly, when the family gets to the public clinic and is deterred by long waiting lines or inconvenient hours. In a recent California study, 60 percent of children in public immunization clinics had been referred there by their private family doctor. In either case, immunizations are being separated from children's overall health care and "medical home," which contributes to lower quality health care and inadequate tracking of children's vaccination status.

A decade ago, this was not a serious problem because vaccines were much cheaper. Since 1977, the price of vaccines to fully immunize a child has climbed from less than $11 to over $245. While there are many reasons for the price increase, including price inflation, new vaccines, and excise taxes, the problem is that many families have been priced out of the market. For many families—especially lower-middle income families—the cost of vaccines makes immunizing their children in a doctor's office prohibitively expensive. Even middle income parents are increasingly driven by rising vaccine costs to see the immunization as a step that can be deferred.

In addition to vaccine costs and the attendant disruption of care, low immunization rates are also attributable to an overburdened and underfunded public health system, the lack of a comprehensive tracking system, and inadequate parental and provider education. With less than half of private insurance plans covering the cost of immunization services and the rising number of uninsured children, more families rely on public clinics for their children's health care. Yet public clinics are hav-

ing a hard time trying to serve more people, with fewer resources. Increasing funds for these clinics is critical to provide immunization services to more children.

Finally, experience from States that currently have universal programs underscores the importance of a full scale tracking system which can monitor vaccine usage and child immunization status, and send reminder notices to parents when their child is due for their next shot. Many parents need help remembering the schedule for all 18 shots. We also need to provide the outreach and flexibility in service delivery to reach the many families who because of geographic, language, transportation or other barriers are unable to bring their children in for shots.

THE ADMINISTRATION'S IMMUNIZATION INITIATIVE: A COMPREHENSIVE STRATEGY

The Administration is making its first investments in public health service delivery and education and outreach to families. The President's proposed $300 million supplemental appropriation for immunizations and additional investments in the fiscal year 1994 budget will allow clinics to stay open on evenings and weekends to serve working families, to open new clinics in convenient locations, and bring immunization services to programs like WIC that serve families with young children. The new investments will nearly double the federal commitment to immunization services.

The second component of the President's initiative is the Comprehensive Child Immunization Act of 1993 (H.R. 1640 and S. 732/733). The key elements of the legislation are:

Universal Vaccine Purchase and Distribution: The President's immunization bill will make vaccines available to all children and assure that no child goes unimmunized because his or her family could not afford the vaccine. This system is already in place in the New England States and Washington State. The vaccine would be distributed by the manufacturers directly to doctors and clinics. While doctors may still charge a small fee to administer the vaccine, no child could be refused a vaccination because the child's family could not pay the administration fee.

Cost Containment of Vaccine Prices: As part of a universal vaccine distribution system, the Federal Government would negotiate prices for vaccines with the manufacturers. A negotiated system would control vaccine price inflation while still providing sufficient revenues for fair profits and aggressive research and development of new vaccines by the manufacturers.

Research and Development of New Vaccines: The legislation encourages research and development of new vaccines. The bill specifically requires that vaccine prices reflect production costs, research and development expenses, and sufficient profits to encourage future research and development.

Immunization Tracking and Surveillance: The bill would establish a system that tracks the immunization status of preschool children. This system would make possible the sending of reminder notices to parents, the targeting of outreach and education efforts, and the identification of high-risk communities. The tracking system will be state-based to provide the States with maximum flexibility.

Reauthorization of the National Vaccine Injury Compensation Program: The program provides compensation for the small number of children who have adverse effects after receiving vaccines.

Simplification of Vaccine Information Pamphlets: Doctors and clinics are now required to give long, cumbersome vaccine information materials to families before providing immunizations. The legislation will allow the Department of Health and Human Services to develop simpler and easier to understand materials to parents.

Under a universal vaccine distribution system, the government purchases vaccines from private manufacturers and distributes them to immunization providers free of charge. This system has been in place for some vaccines in the New England States for 20 years and is used in nearly every other nation in the world. Vaccine would be added to education, fluoridated water, fire protection, and other activities recognized as best delivered for everyone's benefit on a universal basis.

A universal system would be simpler than the current two-tier system to administer. The Federal Government would contract with vaccine manufacturers to purchase and distribute vaccines to individual health providers. Physicians would simply place vaccine orders to the manufacturers and immunize their patients with the free vaccine. No payment would be made between providers and the vaccine companies. And no charge would be placed on families for the vaccine. As a universal program, no income test would be applied; all children would be eligible to receive the free vaccine.

There would be a vastly reduced financial barrier to immunizing a child in a doctor's office under a universal vaccine distribution system. So, rather than referring children to public clinics, private physicians could immunize the children in their

offices and not have to worry about vaccine costs. Not only would this system reduce missed opportunities, but it would also reduce demand on public immunization clinics and free public health resources to better serve low-income families and those with no regular source of care. As a condition of receiving free vaccine, physicians would be required to participate in an immunization tracking system. This system would follow the immunization status of children from birth. When a child is due for a vaccination, the system would send a reminder notice to the family. A reminder and recall system is needed particularly to help a family with no regular source of care to know when their child needs immunizations. But, it helps all parents who have a difficult time keeping track of the 18 doses needed to fully immunize a child from birth to school-entry. The system would also provide detailed information on communities with low coverage rates in order to better target parent outreach and education activities and would also identify physicians whose patients are not appropriately immunized to target provider education as well.

WHY A COMPREHENSIVE APPROACH IS ESSENTIAL

Opponents of this legislation argue that universal vaccine purchase and distribution alone will not solve the problem. That is exactly why the Administration has put forth a comprehensive strategy with universal purchase as a cornerstone. Universal distribution will fix the problem of children missing opportunities to be vaccinated in their doctor's offices, it will be the foundation for the tracking system, and it will make it much easier to reach parents and reduce the overwhelming burdens on the public health system. But it cannot solve all the problems alone. That is why the Administration is also asking for resources to reach parents and expand public health services.

Some believe that simply adding new dollars to the infrastructure components of the solution will solve the problem. While this is a key step, and a key element of the Administration's strategy, it is not sufficient to address the problem. Over the past several years, this has been the principal Federal response to the immunization problem. It has not worked, because while new resources are desperately needed by the public health system, this approach alone does not fix the weaknesses of the current system. First, vaccine price increases have tracked appropriations increases so that federal funding increases have been offset by higher vaccine costs. Second, focusing on the public sector alone will not stem the flow of children from private health providers to public clinics for immunizations. In fact, a strategy that focuses solely on the public sector could exacerbate the current trends by increasing the cost of vaccines for the private sector and forcing more children and their families into public clinics. We simply will not be able to solve the immunization crisis without fully enlisting the participation of private pediatricians and family physicians.

Another proposed alternative to a universal system is to create a new means-tested or Medicaid-like program to distribute vaccine to private physicians. Some advocate a means-test in order to avoid subsidizing the "well-to-do", despite the fact that means-testing would have a very high administrative cost for modest benefit. For example, the haemophilus influenza B vaccination for a 12-month old infant costs about $10, far less than the cost to process the paperwork needed to check a families resources. In order to have a means test in the private sector, moreover, either doctors would have to apply the income test or families would have to go to a separate agency. Few doctors would be willing to conduct income tests, and millions of families would be lost from the system by the need to go through a separate process for a crucial but modest benefit. Another barrier would be erected when our goal is to eliminate such obstacles.

However, it is important to understand that about 70 percent of families with children younger than 6 have total incomes below $45,000—about 300 percent of the poverty level for a family of four. Concern about unnecessarily subsidizing wealthy families is misplaced. To ensure equity, revenues needed to pay for childhood immunization should be raised through the tax system placing the least burden on those with lower incomes, not by adding more administrative costs at the doctor's offices.

Finally, the vaccine manufacturers claim that this legislation will stifle vaccine research and development. We disagree. The legislation specifically requires the Secretary to negotiate a price for vaccines that includes production costs, research and development expenses and sufficient profits to encourage future vaccine research and development in addition to the funds they currently receive from NIH. The legislation assumes that the negotiated price of vaccines will be the average of current public and private market prices—$122 versus $245 for a full series of vaccines per child at the private market price. As a result, the manufacturers should see no loss of revenue. They will, however, lose the ability to unilaterally increase prices at rates far higher than inflation.

The President has shown his leadership and vision on this critical issue. Congress must accept the challenge issued by the President and think boldly about the solutions needed to immunize every American child. If we do not seize this opportunity, we will see another cycle of falling immunization rates and resurgent childhood diseases unnecessary child illness and death, and unnecessary expenditures on treatment and hospitalization. The Comprehensive Child Immunization Act of 1993 (H.R. 1640 and S. 732/733) is good for children and their families and good for our Nation. It is long overdue. It lightens the load for public health and strengthens the role of pediatricians and family physicians in children's health care. And, it provides assurances for the vaccine manufacturers for fair and reasonable prices and reasonable profits for their products.

I urge Congress to take a quick action on this most basic cost effective investment in children's health and not let proprietary interests prevent us from doing the right thing for children. Thank you.

Mr. WAXMAN. As Marian Wright Edelman indicated, she is not here to answer questions, but all members will have an opportunity to submit questions to her in writing and get a response for the record, and I am sure Dr. Sienko would be willing to do the same.

But you all are here from this last panel, and I want to pursue some questions with you. First, let me be sure that I have everyone's position clear. All of you support Federal programs to assist States, local governments and poverty clinics in providing immunizations, and all of you support expanded Federal resources to provide immunizations, and all of you support assistance for expanded outreach, longer clinic hours, and more accessible services. Is that a correct statement?

Dr. SMITH. Yes.

Dr. THOMPSON. Yes.

Mr. MOEN. Yes.

Ms. LEBRON. Yes.

Mr. WAXMAN. Dr. Smith, you support universal purchase of vaccine. You have heard testimony from other witnesses that this is not necessary or even a good idea. How would you respond? Why are the State health officers and the county health officers supporting this proposal?

Dr. SMITH. Speaking for myself as a State health officer and a pediatrician, looking at the data, I think it gets back to the point of Secretary Shalala's response to this, that there are many different aspects to this, and one of them is cost. And I think to stand by and say that it isn't one of the factors is ignoring some data that is out there, whether it is coming directly from the provider groups, my colleagues, pediatricians, family practitioners, nurse practitioners, P.A.s and others, and then the trends that we have seen from other parts of my own State, where in fact we talk to families or we see the trend where in fact a larger burden is being placed on the public sector, and that direction is being created in large part by cost. The information there leads to believe it is part of the problem. It is not the only one, and I think we have stated that clearly, too, but I think when you are trying to create a "no more excuses" bill and eliminate any possibilities and try to go forward with a good program which we needed yesterday, you do that, you move on, and we evaluate it as we go forward. And I think since our background is in epidemiology and evaluation, we want to be held accountable if we have those tools and flexibility, and we should continue to evaluate the effectiveness of this legislation as we need forward—but we do need to do something today.

Mr. WAXMAN. Thank you.

Dr. Thompson and Mr. Moen, in some States, we have seen doctors referring private patients to public clinics because of the cost of the immunizations, and slowly, by default, this sort of private to public shift is creating a universal purchase system, but one without the efficiencies of planning and price negotiations, and one in which children get lost in the cracks between services.

How would you respond to this shift without universal purchase, and what can we do to encourage full immunization in such circumstances?

Dr. THOMPSON. We have already responded to the shift in Mississippi, because 80 percent of Mississippi children receive most of their immunizations in public health department clinics, and another 5 percent receive their immunizations in community health centers, leaving only 15 percent that receive the bulk of their immunization in the private sector. And yet the vast majority of these children have a regular pediatrician who cares for them.

They are able to come to public health clinics, efficiently receive their immunizations, and go right back to their private doctor. Far from fragmenting health care, in many ways, this has been efficient, because it brings many parents who would never otherwise see the public health system in operation into our clinics for a brief and efficient visit and then back to their private physician.

It is something that we have been able to absorb; it has not been an undue burden on us. And I would say that if I could get Mississippi's share of even the $600 billion suggested for the purchase of vaccine, I could guarantee that we could have a private physician's patient in and out of the health department in about five minutes; we could almost have them drive through, and they might not even have to slow down very much.

Mr. WAXMAN. You have an 85 percent universal system now in Mississippi; what you are doing, though, is having the clinics pay for the immunizations for the patients of private doctors. Wouldn't it be more convenient for those private doctors to be able to have the lower price vaccine and not have to make the patients have to travel to the clinics?

Dr. THOMPSON. It might be more convenient for the doctor, and it might be somewhat more convenient for the parent. But our experience has been that while some private pediatricians very carefully adhere to all the recommendations of such groups as the National Vaccine Advisory Committee about simultaneous administration of as many vaccines as possible at a single visit, so that children to complete their vaccines on schedule, many other private physicians do not do so, and for reasons that pertain more to the private practice of medicine than to the child's direct health care needs, will often space out immunizations and expect the parents to return for five or six or even seven visits rather than completing the basic series in four visits, as it can be done. The result is that children are not fully protected at age-appropriate times for their immunizations.

Mr. WAXMAN. That is a pretty indicting statement of doctors, that they have their patients come back for extra visits, presumably because they are getting fees for extra visits, rather than do all the immunizations in the few visits that it would take to do it.

It sounds to me like it's an argument for public medicine instead of private medicine.

Dr. THOMPSON. I don't mean to imply that the motivations of physicians who space immunizations out more widely than is recommended are financial. In many cases, it is their sincere and honest belief that it is better for the child to come back for additional visits and be seen more frequently for well-child visits. That's debatable.

With immunization, sometimes one of the biggest problems we have is that the worst enemy of good is often better; sometimes, if we could just get them in for immunizations, we could stand not to have them come in for quite so many well-baby visits.

Mr. WAXMAN. Mr. Moen, did you want to respond? I did direct the question to you as well.

Mr. MOEN. In Minnesota, we have a very different situation than in Mississippi. Eighty percent of the vaccines in Minnesota are given by the private sector; 10 percent are given by a combination of public-private, and 10 percent are given in the public sector. In addition, 30 percent of the children in Minnesota zero to 6 are covered by prepaid health plans, HMOs, which under State law cannot charge fees for immunization or well-baby care visits, and the percentage is higher in the metropolitan area, obviously, that out of State.

We have seen some movement in some rural areas in particular of individuals going to the public clinics, but in fact our vaccine usage has not increased, and that rate of shift between public-private has remained somewhat constant.

We could use some additional vaccines in particular areas where some of the prepaid health plans are not, for example, as prevalent, and people are paying for immunizations out-of-pocket. However, our main concern with some of the issues involving the legislation is not necessarily the universal purchase or the universal furnish of vaccine. I think that is something that, as I said, even though for a number of children, cost is not an issue, it would certainly be nice to have the free vaccine. The issue we're concerned about is that to the extent you remove bureaucracy and red tape and barriers through the universal plan, I think you create it through the national registry program, and I think more thought needs to be brought to that so we don't add more red tape, more paperwork, and more bureaucracy to make that work, while at the same time we are trying to decrease it with the universal plan. Some of our concerns are more on that side of the issue.

Mr. WAXMAN. Thank you.

Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman.

First, Dr. Smith, in your testimony, you indicated your support for Texas State legislation that has just come out of conference committee. As I understand it, the legislation mandates that every child in Texas be immunized, and in fact, it mandates that hospitals and physicians check immunization records of their young patients and administer any needed vaccine.

Does this legislation require that children be immunized as a condition of their participation in any programs in Texas?

Dr. SMITH. No, it does not. It was debated, just as it has been here. In fact, we went the route of looking at some incentives also that we could put in place. We are looking at using WIC and other programs to expand the vouchers even to two or 3 months, and we are actually beginning to do immunizations on all WIC sites. We are very different from Mississippi, too. We have about 340,000 children born each year, so it is a large issue. The private sector is a significant player. We are even going to try to get some programs like WIC to parallel that with our initiatives in immunization and tie them into the private sector.

It was pushed away. We actually had talked quite a bit about it. The reason and the concern was that if you put it as a stipulation or a penalty, number one, a lot of our kids who aren't being immunized are not part of those programs, which has already been stated, so that it wouldn't be effective for those families who are above income levels—and unfortunately, in Texas, it is quickly to be above an income level——

Mr. GREENWOOD. Let me interrupt you if I may. I apologize for that, but with limited time, we have to do this sometimes. Do you know of any data that would describe the rates of immunization for children above and below the poverty line, for instance, for those children who are eligible for AFDC or involved in WIC programs? Do you have any statistics of that nature?

Dr. SMITH. We have some of that, and I believe that there is some also available in limited quantity through CDC. But we do have some in the State that we could share.

The other factor, though, that I'd like to point out is that we have the problem of infrastructure. If you made that a condition, the challenge back to us by all groups, including pediatricians and others, is do we have the ability to come up and be able to shoot those children if we make it a stipulation. The concern was that we did not have enough infrastructure out there to live up to the demand we just placed on families, so let's go ahead and do that first.

Mr. GREENWOOD. I think I heard you say that you are working on providing immunizations at WIC centers.

Dr. SMITH. That is correct.

Mr. GREENWOOD. Do you have a problem with at least requiring that immunizations be completed where you can provide them—in other words, if you can get physicians to come to the WIC centers, the Head Start centers, the day care centers, is it okay then to say, "OK, now, if you want to participate, get your shot"?

Dr. SMITH. That is part of the flexibility that I think you need to give States and local authorities to in fact try some of those things, because in fact we are going to at least require that they bring in their records so we can review them, and we will offer onsite, and that's a flexibility that I think we need to look at and evaluate at the State and local levels, and we would press for that kind of flexibility.

Mr. GREENWOOD. Thank you.

I'd like to address some questions to Mr. Moen. I am looking at the graphs that you have provided us. You made some points in your testimony about the differences between ZIP codes. It looks to me like maybe St. Paul 55105 has pretty good rates of immuniza-

tion, and 55103 has pretty low rates. First of all, am I reading these charts correctly?

Mr. MOEN. That's correct.

Mr. GREENWOOD. second, can you tell us something about the demographics of those two ZIP codes?

Mr. MOEN. Yes. 55103 is the inner city section of St. Paul, perhaps not dissimilar from many inner city locations throughout our country; 55105 is a more affluent section of the city of St. Paul where incomes, I'm sure, are much higher. And that's exactly the point, that we need to bring that specificity, because as the city of St. Paul mobilizes their resources, their physicians and their public clinics to start attacking this problem, they need to know where to focus, and in Minnesota, we are trying to focus where the problem is.

Mr. GREENWOOD. That's what I'm trying to do. The thing that's troubling me is that these statistics seem to bear what I think is intuitive to most people. That is, that the lowest rates of immunization and the biggest problems are in the areas of greatest poverty, of the least advantage and so forth. Those are the places where we are going to find much greater percentages of kids participating in AFDC, Head Start, WIC and similar programs. Yet you heard the Secretary disagreeing with that thinking, and saying that 60 percent—I can't believe that this is accurate—but she said 60 percent of the kids in this country who aren't immunized are above the poverty line. Since the national average is 50 percent, that would argue that below the poverty line you have very small percentages of unimmunized kids. That can't be true, can it?

Mr. MOEN. And in fact that illustrates my point why the one-number methodology for measuring immunization rates is in fact misleading. Even in our ZIP code 55105, if you look at the completion of the series as defined by the one-number methodology, which includes fourth dose DTP, it is extremely low. However, if we look at the overall rate of immunizations for all the doses, there is a very different picture that emerges.

So I think it may be in fact true that, as I said in my opening comments, we are treating a child who has had no vaccines the same as a child who has had three doses of DTP, two of polio, and one of MMR. The disease risk is very different, and yet we are talking about them in the same context.

Mr. GREENWOOD. One follow-up or final question. What are your feelings, sir, with regard to the notion of requiring parents to immunize their children in a timely fashion in order to continue their eligibility for day care, Head Start, WIC, or EPSDT where we can provide immunization.

Mr. MOEN. In Minnesota, we have actually changed our State law so it is a requirement for attendants at day care centers that you do show proof of immunization similar to our school entry immunization.

Mr. GREENWOOD. This is sometimes characterized as punitive. Do you find that there are children who are missing out on day care as a result of that stipulation, or do they in fact just get the shots and then go to the day care?

Mr. MOEN. I think the requirement attached to day care has not had an adverse effect in terms of persons staying away. I think

some of the requirements that have been discussed pertaining to some entitlement programs may have a different effect. In St. Paul, we have actually added an immunization registry into the WIC clinic, and I think that's a combination of immunization clinic at the WIC clinic, and immunization registry in the WIC clinic, and the immunization rates and the immunizations being given in the WIC clinic now exceed the immunizations being given in the immunization clinic.

I think these are the types of local interventions that can be put together at the local level if we arm these communities with specific data and empower them to move forward and stay away from kind of national, one-shot kinds of approaches.

Mr. WAXMAN. Would the gentleman yield?

Mr. GREENWOOD. Yes.

Mr. WAXMAN. I'd like to direct a question to Dr. Smith, because you are representing the State and Territorial Health Officers. Do most States have requirements that before you can enter school, before you can enter day care, before you can get your WIC allotment or whatever, that there be an immunization? Is this a usual practice in the States?

Dr. SMITH. I am not totally familiar with all the States, but of course, when it relates to school entry, that's pretty uniform. Day care, a number of States including my own have a requirement for licensed day care that in fact you also have to show proof of immunization.

When it comes to WIC, I think a number of us are looking at this as yet another opportunity—not a way to be punitive, but as an opportunity—for us to knock a barrier down, since they are already going there. Our problem in the past has been, and it has also been a problem of policy in the Agriculture Department, is that we are allowed to do everything but shoot using money through WIC. And that's a crazy policy, by the way. We need to change that. We can screen, we can counsel, and we can refer. Well, we shouldn't be referring; we should be shooting. And most of us are looking at opportunities——

Mr. WAXMAN. Immunizing at the center itself.

Dr. SMITH. That's correct. And we are taking advantage of those. I think it gets back to the point of this legislation. I don't see it prohibiting any of that. I want to make sure we have the flexibility, but that we do go forward with that kind of flexibility.

I think you asked if there was a requirement to do that through WIC, and I don't think there is any requirement there. I think, though, good public health officials are taking advantage as are community-based people and private practitioners to use these places to immunize kids.

Mr. WAXMAN. Well, it certainly makes a lot of sense to me to have immunizations available at those locations and ask for certification that the children have been immunized, as a way to have a double check at a location and a nexus in time to make sure that the immunizations are taking place.

I would be interested if you would ask other State officials whether their experience is the same as yours and whether they think there ought to be a Federal law mandating it, or whether

most States already do it, and therefore it would not be necessary. I am impressed by that.

Dr. SMITH. We'd be glad to get back to you on that. I was handed a note that all States do in fact, with licensed day care, besides schools, have requirements. We'd be happy to get back with you on some recommendations in that regard from ASTHO.

Mr. WAXMAN. Thank you.

Mr. Greenwood.

Mr. GREENWOOD. The term "punitive"—you just used again—comes up in this instance, and I would ask this question. Why don't we refer to the requirement that kids be immunized in order to go to school as punitive? I don't see any clamor to repeal that punitive criterion. In fact, it seems obvious on the face of it that these barriers vanish into thin air at the door of the public school system; they vanish, and the kids get their immunization.

I cannot understand for the life of me why it is that, if we say that we care so much about getting kids immunized, we don't simply push that door back where it belongs, not at age 5 or 6, but at age 2. We push the door back, watch the barriers vanish, the kids get immunized and the problem is solved without spending $1 billion.

Dr. SMITH. In response again—I think I already alluded to this—I think States would like to try and look at that flexibility for programs. I think the thing we are cautious about ourselves is that if we put that law on the books, whether it is at the State or the Federal level, do we have the capacity, whether the vaccine or the people to provide the immunization, to make sure they get it?

Right now——

Mr. GREENWOOD. It is there at the gate to the school.

Dr. SMITH. Yes, but you've got children now backed up before school age that we aren't getting to. The question is at what point is the system at capacity, and at what point do you have to add capacity. In many of our States—and I know it is true in mine—we are at capacity or beyond, so somehow, I've got to get the private sector back in, which is what I am going to have to do in my State—and they have endorsed our bill, as you are probably aware. And in addition, I have got to get public capacity where I don't have that.

It is a capacity issue in addition, and part of that is also the vaccine availability. And I think if that were there, most of us would be willing to try the others, because that would go hand-in-hand, plus some incentives, which is giving the extra month of vouchers for WIC, or—and we've got to remember this, too, that human behavior does respond to nonincentives. We don't sell Nike and McDonald's on television through punitive action. And I really do want to push for marketing. We need to go prime time. We change behaviors on television, and we know that's a fact, so why aren't we in fact pushing this harder and making it important on our airwaves?

Mr. WAXMAN. You all raise very good questions, and I think it would be worthwhile to continue to pursue them with you, and we'd be pleased to receive for the record any further comments that the other State representatives have.

Thank you very much. We appreciate each of your testimony.

Mr. WAXMAN. The members of our next panel are representatives of various manufacturers of childhood vaccines.

Dr. R. Gordon Douglas is president of the Merck Vaccine Division of Merck and Company, Inc. Mr. David Williams is president of Connaught Laboratories, testifying on behalf of Lederle-Praxis Biologicals, with Dr. Ronald Saldarini, the organization's president and chief executive officer. And finally, we will hear from Mr. Jean-Pierre Garnier, president of SmithKline Beecham Pharmaceuticals.

We appreciate your being here today. Your prepared statements will appear in the record in full. We'd like to ask each of you to limit your oral presentation to no more than five minutes.

Dr. Douglas, we'll start with you.

STATEMENTS OF DR. R. GORDON DOUGLAS, PRESIDENT, MERCK VACCINE DIVISION, MERCK AND CO., INC., WHITEHOUSE, NJ; DAVID WILLIAMS, PRESIDENT, CONNAUGHT LABORATORIES, INC., SWIFTWATER, PA; RONALD SALDARINI, PRESIDENT AND CHIEF EXECUTIVE OFFICER, LEDERLE-PRAXIS BIOLOGICALS, WAYNE, NJ; AND JEAN-PIERRE GARNIER, PRESIDENT, NORTH AMERICAN PHARMACEUTICALS, SMITHKLINE BEECHAM, PHILADELPHIA, PA

Dr. DOUGLAS. Mr. Chairman and members of the committee, my name is Gordon Douglas, and I am president of the Vaccine Division of Merck and Company. Merck commends the diligence of these comments in pursuing solutions to one of our greatest health care challenges—full immunization of all of our children by age 2.

Merck has been committed to the eradication of infectious diseases through the research and development of vaccines for 100 years. But the ability to prevent disease is a hollow triumph if we fail to get vaccines into the arms of our children.

President Clinton deserves credit for bringing the issue if childhood immunization to the forefront, but the administration's proposal to expand the government's free vaccine program for the poor to include wealthier Americans is a flawed prescription. It is based on a misdiagnosis of the Nation's true immunization challenges, and it will not get us to our goal of full immunization.

Available research clearly demonstrates that the roadblocks to immunization are delivery failures, not vaccine cost or supply. I cannot emphasize this point strongly enough, because without a clear, factual definition of barriers, we cannot work together to construct a comprehensive, effective solution.

The administration misleads the public by stating that the vaccine price increases drove the cost to immunize a child in the public sector from $6 in 1982 to $90 in 1992. The CDC data shown on this chart clearly show that 80 percent of the increase is a result of adding the Federal excise tax to fund the National Vaccine Injury Compensation Program, and the introduction of new vaccines that produce against two serious infections—Hib meningitis and hepatitis B.

Almost 100 percent of our children get all their recommended shots by age 5. This is not a function of Federal spending, but rather of State laws which mandate immunization for school entry. CDC data show that the average immunization level in the 11

States that currently distribute taxpayer-funded vaccines—63 percent—is little better than the national average of 58 percent.

In 1982, eight other States considered adopting universal purchase, and after examining the results in the record, all eight rejected the concept. Our challenge is to increase unacceptably low immunization rates among children at age 2.

Mr. Chairman, the fact is a high percentage of children in this younger age group are being immunized appropriately. These are the children who have access to appropriate health care. The system for them is working. The children who really need help are the poor and near-poor without health insurance. Many in this most vulnerable population already are covered through Federal vaccine programs.

We know that government programs purchase more than enough measles, mumps and rubella vaccine to immunize all of America's needy infants; yet only about half get shots on time.

The National Vaccine Advisory Committee concluded in its 1991 report that all 13 barriers to immunization were related to the delivery system, not to vaccine supply. These problems are articulated by thousands of voices from frontline service providers. We agree with them that the best way to raise preschool immunization rates is to make immunization services more accessible and to overcome parental ignorance and apathy through education.

In 1955 as a medical resident, I worked on a ward with 20 patients, victims of the last polio epidemic, clinging to life in tank respirators, the old "iron lungs." Most patients today have never seen polio. Our triumph in eradicating disease creates a complacency about risk.

A recent General Accounting Office report found that allowing States to create Medicaid vaccine replacement programs and increasing Federal funds for education and tracking could actually reduce Federal spending, while improving immunization rates.

Merck's Medicaid program for vaccines facilitates the specific recommendations of the GAO for a State replacement option. In brief, the program encourages more immunizations of Medicaid-eligible children in the private physicians' offices; it saves Medicaid program money, thus freeing dollars for investment and outreach, delivery, and increasing physician reimbursement fees.

Unfortunately, without changes in the Medicaid law, States require a waiver to participate in a replacement program of this sort. We believe this program, expanded to provide immunizations to those at up to 200 percent of poverty, will go a long way toward assuring that our kids get their shots and will save taxpayers billions of dollars that otherwise would be spent on the administration's vaccine purchase program.

Thank you.

Mr. WAXMAN. Thank you very much, Dr. Douglas.

[The prepared statement of Dr. Douglas follows:]

PREPARED STATEMENT OF R. GORDON DOUGLAS, JR.

My name is Dr. R. Gordon Douglas, Jr. I am president of the Vaccine Division of Merck and Co., Inc. Merck appreciates the diligence of these Committees in pursuing solutions to one of this Nation's greatest health care challenges: full, age-appropriate immunization of our children.

The purpose of today's hearing is to discuss viable solutions to the immunization crisis facing this Nation. I believe we should couch any deliberation in an accurate description of the problem. While we unequivocally support the goal of universal immunization, we reject the approach contained in the Comprehensive Child Health Immunization Act of 1993 put forth by the White House. Universal purchase is not synonymous with universal immunization. In fact, the concept of universal purchase, where the government buys vaccine for distribution to the entire population of children—needy or well-to-do, insured or uninsured—does not address the established barriers to immunization in America.

I cannot emphasize this point strongly enough, because without a clear, factual definition of barriers, we cannot work together to construct a comprehensive, effective solution.

Merck has recommendations to share with the committees today, recommendations which packaged together can assure success in meeting the Administration's goals while saving the taxpayers billions of dollars. We believe that State vaccine replacement programs for families up to 200 percent of the poverty level, combined with first-dollar insurance coverage for vaccinations, meet the litmus test of fiscal responsibility and will hurdle the real barriers to immunization.

VACCINES REDUCE HEALTH CARE COSTS AND SAVE LIVES

Vaccines clearly are the most cost-effective way to prevent disease and reduce health care costs. Vaccines have eradicated smallpox internationally and virtually eliminated polio in the Western Hemisphere. Measles, mumps and rubella have been reduced by more than 95 percent in this country. The Centers for Disease Control and Prevention (CDC) estimates that for every $1 invested in vaccines, $10 can be saved in potential health care costs.

Childhood vaccines yield a particularly high return to society. These products help prevent unnecessary disease and the related suffering, physical and mental disabilities, emotional trauma, hospitalization and death at a fraction of what it costs to treat diseases. Childhood diseases also represent a financial drain on adult Americans and the national economy through lost days of parental employment, the cost of doctor visits and the emotional wear and tear that comes with caring for a sick child.

A recent cost-benefit analysis of immunization against Haemophilus influenzae type b, which causes serious infections in children, calculated the cost of the disease to society at $2.6 billion and savings at $88.22 per child vaccinated. Infant bacterial meningitis has been reduced by 80 to 90 percent in just 2 years since the introduction of the HIB vaccine. (Pediatric Infectious Disease Journal, April 1990) For Merck's vaccine against measles, mumps and rubella, MMR-II, the cost-savings ratio is $1 to $14. The CDC estimates that more than 77.5 million cases of measles and 25,200 cases of mental retardation have been averted, and 7,750 children's lives saved, through immunization with 0-II over the past 27 years.

MERCK'S COMMITMENT TO VACCINE RESEARCH AND DEVELOPMENT

Vaccines have been an important part of Merck's business for nearly 100 years. Beginning in 1894 with the first U.S. antitoxin against diphtheria, our dedication to vaccine research and development has yielded a product portfolio and research pipeline that are the strongest in the industry. Among the many contributions we have made to human health through immunization are vaccines for smallpox, rabies, meningitis, pneumonia, measles, mumps, rubella, hepatitis B and tetanus.

Other Merck vaccine innovations include a combined measles, mumps and rubella (MMR-II) vaccine and RecombivaxHB, the world's first genetically engineered product to prevent hepatitis B. We have been working for 28 years on a vaccine to prevent chickenpox ('VARIVAX') and are in the later stages of development of a new vaccine combining 'VARIVAX' with MMR-II. A killed hepatitis A vaccine is expected to be licensed in the near future.

Industry currently has under development vaccines for numerous other diseases, including hepatitis C, which causes liver disease; otitis media, a middle ear infection caused by a variety of organisms; herpes simplex virus types 1 and 2 which cause fever blisters and genital sores, respectively; Lyme disease; respiratory syncytial virus, an acute respiratory infection that can be fatal in infants; rotavirus, a major cause of diarrhea and dehydration; meningococcal meningitis; streptococcus pneumonia; and AIDS.

Basic research ongoing at this time may lead to new vaccines for leprosy and gonorrhea and diseases caused by Epstein-Barr virus, chlamydia and cytomegalovirus. In addition, new technology like naked DNA may revolutionize our approach to all

vires and facilitate the development of vaccines against such diseases as cancer and arthritis.

One of our most exciting research initiatives now underway is a vaccine that would combine DTP vaccine (for the prevention of diphtheria, tetanus and pertussis), a high potency inactivated polio virus vaccine, Haemophilus influenzae type b vaccine and hepatitis B vaccine into a hexavalent product. We will follow this with the addition of the acellular pertussis component to replace the whole cell pertussis in current DTP vaccines.

No one company has all the critical antigens necessary for this combined vaccine—or super shot—which has long been a goal of industry and the public health community. A super shot would remove two significant barriers to full immunization—the discomfort of multiple injections for children and the anxiety for their parents and repeat visits for additional shots. Too often, children are not brought back for subsequent vaccinations because of the trauma of the injection. To expedite a more rapid development of this product, the Merck Vaccine Division recently created a partnership with Connaught Laboratories.

Yet another intriguing research project underway involves encapsulating vaccines in microsomes, or microscopic beads, that the body breaks down over time. By altering the chemical composition of these beads, we hope to time the release of antigens in the body, making it possible—again, with one shot—to provide protection against diseases that now require multiple injections at varying intervals.

VACCINE COST DOES NOT EXPLAIN FAILURE TO IMMUNIZE OUR CHILDREN

Mr. Chairmen, there should be no question about Merck's commitment to eradicate preventable infectious disease through the development of new vaccines and improvements in vaccine delivery. But having the capability to prevent disease through successful research is worth little if we do not immunize against disease through effective vaccine delivery.

In advancing a universal purchase plan, the Administration would have us believe that our immunization problems are predominately economic. The Secretary's call for government-negotiated "reasonably priced" vaccines as the solution to our deplorable failure to immunize our children on an age-appropriate schedule clouds the real issues. It implies that the industry has set prices that are not reasonable and that we raise these prices regularly—neither of which is true. Pricing is a short cut way to explain why all American children are not immunized by the recommended age of 2 years. But it is a short cut that leads to a dead end.

In comparing today's cost for complete immunization to that of 12 years ago1 the Administration misleads the public by implying that the entire increase is due to price inflation by vaccine developers. Centers for Disease Control data (Figure 1) demonstrate that 80 percent of the cost increase is the result of added protections of an excise tax and two new vaccines. Specifically:

(1) In 1988 the Federal Government added an excise tax to each dose sold to fund the National Vaccine Injury Compensation program for a total added cost of $23.50 for three vaccines; and (2) As a result of research and development, children now are being immunized with new vaccines that protect against two serious infections: Hib meningitis and hepatitis B. The cost of these additional vaccines is $43 for seven doses.

We at Merck are pleased to have had a leading role in the discovery and development of these two new vaccines. Furthermore, we believe that Merck has done its part by containing vaccine costs. Since its introduction in 1972 to the present, price increases for Merck's MMR-II have remained at or below the CPI (Figure 2). In fact, for the past 2 years there have been no price increases at all, despite increasing costs to us and inflation. At the Federal Government price of $10.89 per dose, MMR-II is a bargain, preventing three potentially serious and debilitating diseases in infants.

Perhaps the greatest testament to the fact that price is not a significant barrier to immunization is the experience of the 11 States that currently provide taxpayer funded vaccine. CDC data show that the average immunization level of these states—63 percent—is little better than the national average of 58 percent (Figure 3). The State of Connecticut, which has a high per capita income and a universal vaccine purchase program, has an immunization rate of only 59 percent, barely matching economically disadvantaged Alabama's 57 percent, rural Kansas's 58 percent and falling far short of Tennessee's 69 percent. Furthermore, Connecticut and Vermont, the universal purchase State with the highest immunization rate, currently are experiencing measles outbreaks.

It is worth noting that while these States often are cited as models, most do not have congested urban areas with large minority populations. It is these areas that

have consistently suffered the most during epidemics and which have the lowest immunization rates. Thus even the universal purchase States' modest average improvement in rates does not necessarily reflect the potential for other States.

In 1992, eight other States considered adopting universal purchase systems. But after examining the realities and the record, all eight rejected the concept.

INEFFICIENT DELIVERY IS THE TRUE BARRIER TO IMMUNIZATION

When Ventura, CA, recently set out to improve its immunization rate it did everything right. Vaccine was free. Public health nurses were available in strategically placed clinics during hours geared to accommodate working parents. Materials promoting the program were printed in two languages and widely distributed throughout the community. Vans drove the streets with loudspeakers blaring immunization messages. Net result: not a single child showed up for vaccination. Universal purchase deals solely with the issue of vaccine cost, when in reality the problems obviously are much more complicated.

To begin with, not all children are equally at risk for failure to be immunized. Ninety-seven to 98 percent are fully immunized by age 5 when they begin school. This success is not a function of federal spending, but of State laws. We know that a high percentage of children in the private sector are being immunized appropriately. For example, the return rate for MMR-II distributed to private physicians' offices—which is one measure of actual use—is about 3 percent. Dr. Alan Hinman at the Center for Preventive Services of the CDC recently wrote that universal purchase would "essentially subsidize vaccination for the middle class and well-to-do, who seem to be getting immunized on 1schedule." (Am. J. Dis. Child 145(5);559-562(May 1991))

I would like to elaborate briefly here on the Administration's statement that universal purchase is necessary in part because increased costs of vaccine have damaged our private delivery system. The most-often quoted source for this statement is a survey of family practice physicians and pediatricians in Dallas County, Texas, as reported in the February 2, 1991 issue of PEDIATRICS.

Careful evaluation of this survey reveals significant shortcomings in methodology that promote misleading findings and a flawed conclusion. Specifically:

The survey's cover letter explained that the survey was undertaken because of increased usage of health department clinics, which may have predisposed physicians in their responses.

Physician recall for a period spanning nearly 10 years was the only "documentation" used to quantify changes.

The authors suggest that the changes noted in the article occurred while the state's child population was stable for immunization purposes. In fact, the U.S. Bureau of Census reports at least a 30 percent increase in those populations most likely to use public clinics, Hispanic and Black.

Perhaps the greatest contradiction to the authors' conclusions, however, is in the actual distribution of vaccine sales. If the PEDIATRICS article's conclusions were valid, dramatic shifts should have been readily apparent with respect to vaccine distribution. Yet during the survey years, the proportion of privately administered doses of MMR-II actually increased in Texas from 43 percent in 1985 to 51 percent in 1987. Further, in states comparable to Texas in terms of population, vaccine delivery systems and experience during the measles epidemic (Pennsylvania, California and New York), the proportion of doses delivered in the private sector likewise increased.

THOSE MOST AT RISK ARE AMERICA'S POOREST

Tragically, the most vulnerable population is the very population already covered through federal vaccine programs: America's poorest children. We know that in any given year, government programs purchase more than enough MMR-II to immunize all of America's needy infants. Merck provides each dose at a discount of 50 percent under the price to the private sector. Yet nationally, only about half of these children actually get their shots and in some areas, the delivery rate is as low as 10 percent.

The government wastes tens of millions of scarce tax dollars annually and fails to reach our poorest, most vulnerable kids because it has failed to assure effective delivery. The real problem with current government programs is that they lack—on a local level—the infrastructure, organization skills and sufficient personnel needed to effectively get already-purchased vaccines to America's needy children.

Having worked with immunization programs and health care agencies throughout the United States, we have heard about the many problems on the front lines. Near Trenton, NJ, for example, there is a refrigerated warehouse stocked with a complete

inventory of required childhood vaccines waiting to be administered to the poor for free. Yet poor children throughout the State—particularly in the cities—remain unprotected, unable to get past the real barriers of ignorance, indifference and access. As Dr. Franklin S. Ward, a physician in New York City wrote in a March 11, 1993 letter to the New York Post, "I can tell you that the president is wrong as to why people don't get vaccinated . . . . We're dealing with people's personalities and people's ambitions and motivations. The cost of the vaccine has nothing to do with it—anybody can get it for nothing if they want to."

A government study following the measles outbreaks in 1989 and 1990 underscores this point. The 38 percent of kids in the Medicaid population, particularly Hispanic and Black preschool children in urban areas, were disproportionately affected by the epidemic. The principal cause for the measles epidemic, according to the report, was failure to deliver existing vaccine to children at the recommended age. Given the expansions in Medicaid eligibility, the study concluded adequate steps had not been taken to assure vaccine delivery under the program.

The U.S. Department of Health and Human Services National Vaccine Advisory Committee (NVAC), which conducted this careful analysis, listed 13 specific barriers as the major causes of this national tragedy. Vaccine cost was not one of them. The NVAC report cited inadequate delivery infrastructure, specifically, insufficient staff and too few hours in public clinics, and insufficient education and outreach as the main impediments to vaccination.

One situation in particular creates a "domino effect" for the Medicaid population: the exodus of office-based physicians from the program. Low Medicaid reimbursement fees lead physicians to refer patients to public health clinics. The resulting demand overburdens these clinics and discourages families from seeking services. And the result is that kids don't get immunized.

The issue of inadequate education is significant, ironically in large degree, because of our successes in developing new vaccines. In 1955, as a medical resident at Bellvue Hospital in New York City, I worked on a ward with 20 patients, victims of the last polio epidemic, who were clinging to life in tank respirators, the old "iron lungs." Most young parents in America today have never seen polio and by now the iron lungs have rusted away in junk yards, due entirely to an effective vaccine. Our triumph in eradicating one disease creates a complacency about the risk of others. This complacency, unfortunately, has been reinforced by the government's lack of emphasis on public education around the importance of childhood immunization.

UNIVERSAL PURCHASE PLACES INNOVATIVE RESEARCH AT RISK

In addition to its demonstrated inability to achieve full immunization, a national universal purchase program ultimately would erode the foundations of a successful research environment. Here it is important to note the technical complexities confronting the vaccine industry.

Vaccines are discovered and developed through a partnership between the government which excels at basic research, and industry, which excels at developmental research and manufacturing. While the government facilitates some clinical studies, it does not generally conduct process research and development (PR&D), quality control or regulatory development.

These later functions are delicate, time-consuming, resource-intensive processes involving live viruses and bacteria. It takes, on average, 10 to 12 years from discovery until a vaccine is approved for market. The average manufacturing cycle for a vaccine is 6 months to 1 year. Ten years ago there were 11 companies making vaccines in America; today, only four remain. Merck is one of only two United States-based firms still in the vaccine business. Inadequate profitability and increased liability were the key factors cited by companies as they went out of the vaccine business.

Even once a vaccine is approved, a company faces a changing and uncertain marketplace. Years ago, for example, the public health community asked vaccine developers to put their resources into the discovery and development of a vaccine against pneumococcal pneumonia. Merck responded with 'Pneumovax23', which today remains an underutilized vaccine. We probably never will recover the investment we made in getting this vaccine to the public.

In addition to the heavy time invested by our top scientists and engineers, over the past 30 years Merck has invested more than $1.1 billion on vaccine research, more than half of which was spent investigating products that never made it to market. Most recently, we have invested an initial $150 million in phase one of a new, state-of-the-art, biotechnology manufacturing facility at our West Point, Pennsylvania site.

Companies that invest heavily in research and development need the freedom to set their own research agendas. A federally-controlled process of price bidding and market division, combined with the vagaries of the federal budget process cannot assure the reliable, stable, long-term infusions of capital that companies like Merck need to commit to fund vaccine discovery, development and manufacturing.

The Administration's rhetoric alone around universal purchase and vaccine companies has contributed to a dampening of the potential for vaccine and pharmaceutical research. U.S. pharmaceutical and biotechnology industries so far have lost at least $120 billion in market value during the last several months.

That the current market strangles the influx of new investment capital to biotechnology companies has a direct, negative impact on a competitive environment for vaccine research and development. After more than a decade of companies exiting the business, we have begun to see a resurgence of interest in this area. New companies and strategic alliances promote more vigorous competition and the rapid development of new products.

Dr. Samuel Katz of the Duke University Department of Pediatrics, an internationally recognized expert on childhood immunization, addressed this issue of competition in a recent issue of PEDIATRICS. Dr. Katz noted that universal purchase would hamper this currently favorable situation because if companies are unable to see the possibility of reclaiming research investments and securing some profit, they will "very quickly again move out of the vaccine business."

VACCINE "PROMOTION" EQUALS CONSUMER, PHYSICIAN EDUCATION

Mr. Chairmen, I would like to set the record straight on both the nature and extent of the Merck Vaccine Division's "promotional" activities. Merck's responsibility as a vaccine developer and manufacturer extends far beyond providing vaccine in a vial. We warehouse millions of doses of vaccines for the government's emergency stockpile. We handle product returns of vaccine whose dating has expired. We report on adverse reactions. We have developed and implemented vaccine tracking systems. And every year, we spend millions of dollars to educate consumers about the importance of immunization. Our goal is to market and promote vaccines in a way that appropriately informs the physicians and other health-care workers, as well as parents, on use, risks and benefits of our vaccines.

I have included with this testimony several typical education pieces, including the Vaccine Information Pamphlet (VIP) which we print and distribute to pediatricians at a cost of $1 million per year.

MEETING THE REAL CHALLENGES OF UNIVERSAL IMMUNIZATION

As a Nation, we must focus on solutions that meet the real challenges of universal immunization. The Administration's proposal, while its goal is admirable, directs scarce tax dollars and social resources at the wrong sources of our problem. America's low vaccination rate is principally a problem of distribution, not price. This is what the government's own research tells us. This is the message from public health experts throughout the United States. This is what the experience of States with universal purchase plans teaches us as well.

President Clinton deserves credit for bringing this issue to the forefront of health care reform. But unfortunately, the universal purchase debate has served to distract us from the larger issues that actually impact vaccine delivery—issues such as the failures in the infrastructure, the lack of sufficient public education about health care, the complacency of parents toward immunizing their children and the need for first dollar insurance coverage for immunizations.

We at Merck believe that to improve the health of our children, government and the private sector must work together and draw upon the strengths of one another. In terms of improving immunization rates, this means focusing our collective energies on three goals:

1. Reaching children early;
2. Pursuing scientific innovations to reduce barriers to immunization; and
3. Developing a national tracking system.

GOAL NUMBER 1: EARLY IMMUNIZATION

We have a long way to go to achieve this first goal. While our record of immunizing school-age children is excellent—the concern is for those children who remain at risk before they reach the schoolhouse. What lessons can we apply from the success of school immunization requirements to increase immunization rates by age two? Surely there are ways to gain compliance on such a critical public health objective that are not punitive. If we can immunize children before they reach 2 years

of age, when they are the most vulnerable, the health benefits down the road will be incalculable.

Data show that those children who rely on Medicaid and public health clinics for vaccinations are the most likely to remain unimmunized. We need to support vaccine delivery in public clinics and private physicians' offices and encourage doctors to vaccinate, rather than refer, patients. To the extent that the President's economic stimulus package funds the expansion of public clinics, community outreach and multi-cultural education programs, we strongly endorse his recommendations.

The problem of referrals is a serious one. Research shows that vaccinations referred often are vaccinations deferred—parents frequently do not follow through from the private office to the public clinic.

We have responded to this problem with the Merck Medicaid Program for Vaccines, which encourages more immunizations of Medicaid-eligible children in private physicians' offices. Under this program, Merck will send each participating physician a "seed" shipment of vaccines at no cost. The States will pay Merck directly for vaccines actually used for Medicaid children and we will replace supplies directly to the physician. Thus physicians have no out-of-pocket costs to carry and will always have vaccines available.

There are benefits from this program to both Federal and State governments. First, it obviates the need to set up a national or State warehousing and distribution system for vaccines. It saves Medicaid programs substantial monies since all vaccines distributed through the program will be at the CDC rate—which is the lowest price for our products.

California estimates that participation in this program would save $4.5 million annually for distribution of MMRII alone. Virginia, which implemented the program in March, anticipates annual savings to Medicaid of $800,000 per year, again just for MMRII. New Jersey projects savings of $600,000 if they were able to participate.

All of the States we have spoken with have pledged to reinvest these savings to improve their vaccine infrastructure and to increase physician fees paid for immunization of Medicaid children. Finally, this program facilitates development of a nationwide tracking system.

Senator Daniel P. Moynihan, as Chairman of the Senate Committee on Finance, asked the General Accounting Office (GAO) to examine possible ways to reduce Medicaid vaccine costs for immunizing children and for ways to improve immunization rates among preschool children. GAO's recommendation, just released last month, was a vaccine replacement program that mirrors the Merck proposal. Specifically, GAO found that:

Most State Medicaid programs could save money if low-cost vaccines acquired through CDC contracts were made available to all health care providers administering vaccinations to poor children.

The report goes on to say that:

Savings on vaccine costs will do little to improve preschool immunization levels unless funds are provided for educating parents and tracking and following up on the immunization status of children. . . .

We are very optimistic about the Merck Medicaid Program for Vaccines's potential for removing additional roadblocks to immunization at actual savings for the States. Unfortunately, without formal changes in the Medicaid law, states require a waiver to participate in a replacement program of this sort. Despite the established value of this program and the promise of the Administration to expedite waivers required for the states to participate, five States (California, New Jersey, New York, Florida, and Arkansas) actually have waiver requests sitting at the Department of Health and Human Services. Language to allow all States this option was included in the tax bill vetoed by President Bush last fall. Senator Danforth has introduced a free-standing bill, S. 151, this session.

Ignorance is a tremendous barrier to early immunizations. Aggressive community education initiatives that promote full and early immunization will help to eliminate this obstacle. As a company, we are investing $5 million in grants over 3 years in the Merck Immunization Initiative to support creative local projects that educate people about the importance of immunization and make immunization services more accessible. I have included a complete summary of the Merck Immunization Initiative projects as an appendix to these remarks.

But we must do more than educate. To improve immunization rates among the poor, where the need is greatest, we should provide Medicaid immunization coverage for families living at a level of up to 200 percent of poverty. An enhanced Federal match to ease the burden on the States for this coverage is a much fiscally sounder and goal oriented commitment of tax dollars than subsidizing coverage for the wealthier. In addition, we need insurance reforms that provide first-dollar cov-

erage for all childhood immunizations. Such reforms alone could reach a substantial percentage of America's children under age 2.

GOAL NUMBER 2: SCIENTIFIC INNOVATION

Vaccines against more diseases and more efficient methods of inoculation are critical components of improved immunization. I have dealt in some detail with the research and development initiatives currently underway in the Merck Vaccine Division and the exponential risks and intense resource demands inherent in vaccine initiatives. We must maintain a market environment that encourages risk-taking.

GOAL NUMBER 3: TRACKING

Merck is committed to facilitating implementation of a national tracking system. We offer the full range of our experience and resources in this area to the Administration and the public health community.

SUMMARY

Messrs. Chairmen, I want to thank you again for the opportunity to testify today. Much of the Administration's dialogue on immunizations to date has been heavy on emotional rhetoric and short on hard fact and has done little to advance the cause of universal immunization in America. And immunizing our children, after all, is the goal we all seek to attain.

Because universal immunization is our goal, we cannot support the Administration's recommendations. As I have illustrated, the very "Findings" on which the legislation stands are flawed. The solution—a multi-billion dollar entitlement program to treat a problem caused predominately by failures in delivery—suggests a strong need to go back to the drawingboard.

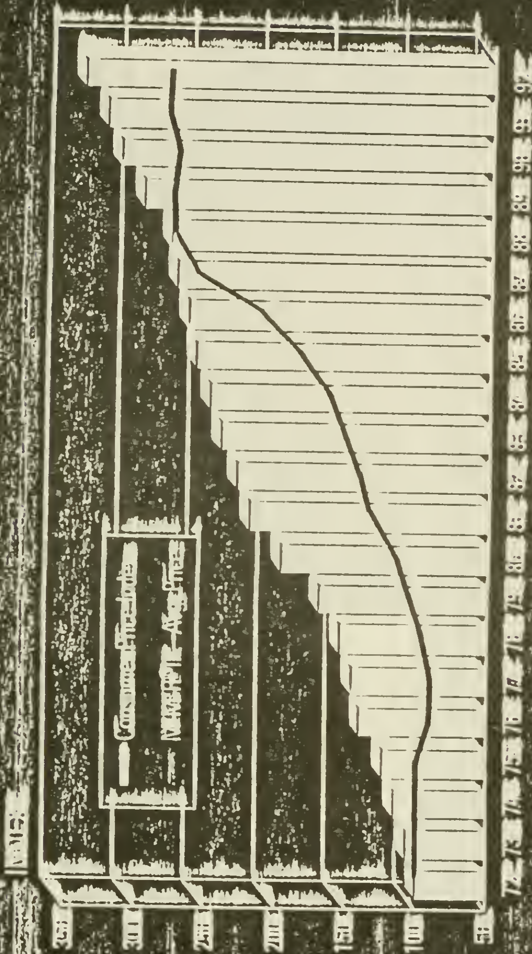
We look forward to a continued dialogue on this issue and a deliberate consideration of alternatives such as we have proposed today.

RECOMMENDED IMMUNIZATIONS BY AGE 2

Costs in the Public Sector (CDC)

1982

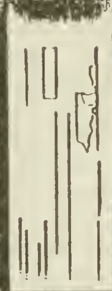
1992



Retrospective Survey Results of Immunization Status
of Children at Second Birthday
by Immunization Project: School Year 1991/92
United States (Excluding Territories)
(Reports Received by 09 March 1993)

PROJECT	GRADE	4:3:1	3:3:1	DTP4	POL	MMR	ANY
ALABAMA	K	57.0				81.0	
ALASKA	K	52.7	59.4	56.6	68.5	73.7	95.0
ARIZONA	K	48.7	64.9	53.1	78.9	70.7	93.4
ARKANSAS	K	42.0	53.4	44.4	58.3	73.9	96.0
CALIFORNIA	K	48.2	62.7	54.1	77.6	70.2	94.9
CONNECTICUT	K	59.4	71.2	62.0	83.4	78.3	88.6
COLORADO	K	60.8					
DELAWARE	K	53.2	65.4	55.4	87.0	82.4	96.5
DISTRICT OF COLUMBIA	K	38.7	55.2	43.4	73.8	61.6	85.1
FLORIDA	K	49.3	62.2	53.8	72.2	70.8	95.8
GEORGIA	K	50.64	63.76	52.96	70.27	76.65	94.43
HAWAII (PUB SCH)	K	60.9	71.2	78.1	80.8	80.8	96.3
IDAHO	K	49.4	59.6	52.6	66.2	72.2	93.9
ILLINOIS *	K	60.7		63.6	76.1	69.4	
CHICAGO-PUBLIC SCH	K	27.3	34.7	35.6	49.8	47.2	82.4
INDIANA	K	56.0		59.0	75.0	76.0	98.0
IOWA	K	51.73	59.75	53.4	63.92	78.01	95.76
KANSAS	K	58.4		61.2	77.4	79.9	
KENTUCKY	K	60.3		63.1	69.6	83.0	
LOUISIANA	K	58.0	58.0	61.0	71.0	77.0	97.0
MAINE	K	65.29	75.29	72.61	82.81	85.19	98.64
MARYLAND	1	56.6	69.5	62.2	79.8	80.5	97.7
MASSACHUSETTS	K	64.97	75.61	69.57	84.93	84.25	97.79
MICHIGAN	K	61.0		68.8	72.7	80.7	
MINNESOTA	K	61.4	68.3	64.7	73.7	82.8	97.4
MISSISSIPPI	1	58.0	68.8	62.8	66.5	78.5	97.9
MISSOURI	K	44.1	61.2	48.8	71.6	70.8	94.0
MONTANA	K	53.2	77.0	53.6	65.5	80.4	
NEBRASKA	K	65.0	77.0	70.0	84.0	85.0	99.0
NEVADA	1	41.6	56.8	44.5	67.2	71.2	94.7
NEW HAMPSHIRE	1	78.9				89.0	
NEW JERSEY	1	50.2	65.0	58.3	82.5	64.5	97.2
NEW MEXICO	K/1	54.8	53.4	65.0	60.5	76.5	95.4
NEW YORK STATE *	K	55.8	70.4	59.8	79.4	81.8	97.7
NEW YORK CITY	K	37.8	46.4	47.8	56.8	70.5	95.3
NORTH CAROLINA	1	58.1	72.0	60.0	79.1	81.7	97.7
NORTH DAKOTA	CUR	58.3	63.1	61.0	65.8	74.8	99.4
OHIO	K	51.0	57.0	59.0	69.0	78.0	96.0
OKLAHOMA	K	44.1		45.4	62.0	75.5	
OREGON	1	47.2	58.8	50.5	69.2	72.5	94.4
PENNSYLVANIA	K	58.1	74.6	62.2	78.7	79.4	100.0
PUERTO RICO	K	38.4	61.1	41.5	79.2	67.2	96.7
RHODE ISLAND	K	67.6	79.7	72.1	88.9	85.0	98.4
SOUTH CAROLINA	DNC						
SOUTH DAKOTA	DNC						
TENNESSEE *	CUR	69.5					
TEXAS *	NR						
HOUSTON	K	17.9	49.6	20.5	64.3	59.5	84.3
SAN ANTONIO	K	47.6	70.8	50.8	82.9	76.3	99.8
UTAH	K	35.8	46.6	37.9	64.5	57.5	78.5
VERMONT	K	68.2	79.9	73.3	85.4	90.8	94.5
VIRGINIA	K	57.8	68.74	65.2	76.61	78.78	96.46
WEST VIRGINIA	K	48.1	61.1	51.5	68.8	77.3	97.8
WASHINGTON	K	50.5	66.2	54.8	75.9	76.0	97.1
VIRGIN ISLANDS	K	38.0	40.0	39.0	41.0	43.0	68.0
WISCONSIN +	K	60.9	77.0	63.0	77.9	83.7	96.5
WYOMING	K	58.0		61.5	79.7	80.9	

K - Kindergarten
1 - First Grade
+ - Excludes Milwaukee
* - State reports exclude corresponding city reports
NR - Reports not received
CUR - Current information, i.e., not retrospective
DNC - Did not conduct survey



Mr. WAXMAN. Dr. Williams.

Mr. WILLIAMS. Thank you very much.

First off, let me say I am not a doctor; I appreciate the extra title, but it is Mister Williams. And good afternoon.

My name is David Williams, and I am president and chief operating officer of Connaught Laboratories. I appreciate the opportunity to be here today to talk about this very important Act.

Connaught Laboratories, Incorporated is based in Swiftwater, PA, and is solely dedicated to biological products, which means that most of our products are vaccines. It is the very company that Mr. Slattery was referring to. We do exist.

We do support the administration's objective of fully immunizing all children by age 2. We think that Senator Gregg summed it up best when he said that this country does an excellent job of immunizing our children by the time they enter school. If we can properly immunize most of our children by age 5, we certainly can immunize them by age 2.

We haven't achieved near universal levels at school entry age because all vaccines are free. We have done it because we do it well; there is a motivation, and we set out to get it done, and we accomplished it. We need to use those same resources that we used at school entry to get children immunized at age 2.

The Comprehensive Child Immunization Act of 1993 has three major parts: supply and price, a follow-up section, and motivation and infrastructure. We believe, however, that the legislative priorities are a bit upside-down in this regard.

No. 1, most of the funds will be consumed through the acquisition of vaccines by universal purchase; second, a substantial amount will follow for tracking and, as a result, insufficient funds will be left for motivation—which we heard earlier is going to be the key—and infrastructure changes which will follow right behind it, and have been concluded by all health experts to be absolutely necessary for full immunization.

We recommend that universal purchase, which will do little to improve immunization rates, not be included in the final legislation. Universal purchase does not equal universal immunization. Part or all of the money saved could be invested in the areas of education, outreach, and infrastructure improvements.

The administration, however—and it didn't come up this morning—but they may State that the vaccine is needed for tracking—we have heard this before—that is, that doctors must be free vaccine in return for supplying tracking information to the CDC. To that, we have a few questions.

What will happen if the doctor doesn't supply the vaccine? Will the vaccine be withheld, and is that creating another barrier to immunization?

And then, most importantly, there is a sunset clause in the legislation. If it is so important today, why is it not going to be important when universal purchase no longer exists?

We feel that the lack of free vaccine will not dissuade providers from participating in a well-developed, well-run tracking program that not only goes for the good of society, but also brings patients back for additional services.

Any number of studies, including the report by the National Vaccine Advisory Committee, have outlined the major barriers to immunization. Cost and supply are not amongst them. In addition, universal purchase programs simply don't raise immunization rates enough. Immunization levels, we heard earlier, in the 11 States that have it, are disappointing.

The quotes that came out in the newspaper, in the Washington Post here in town, heard from many health care providers, and the quotes ranged from Dr. Polumbo, who is in a private clinic here in Washington, DC., who said, "Vaccines are available; the problem is the kids are not available." And a public health official in New Jersey, Dr. Larry Lockhart, was quoted in the Bergen County Record to say: "Vaccine cost is not an issue; putting doctors and pediatricians in the community and having a good program is what is needed."

In addition, the CDC data shows that more than enough vaccine is already currently purchased by the private and public sectors to fully immunize every child in this country on time. The vaccine is already there. So why not concentrate the scarce resources that are available today on those programs that have proven to make a difference?

Study after study documents what will work—more education for parents and health care providers; outreach—we can't emphasize that enough; infrastructure improvements, such as improved clinic hours; and less obstructive policies, like the requirement for appointments. Those are the things that drive patients away.

In Connaught's opinion, reforming Medicaid is the key to the success. Improper Medicaid is what is driving patients from private offices to the public clinics. We feel that if we can fix that problem, we're going to go a long way toward fixing immunization rates.

Connaught has a program similar to Merck in terms of providing vaccine at low cost to Medicaid programs, and I would like to draw your attention to that in our written testimony.

However, a fundamental drawback of the universal purchase concept is its failure to account for the economic realities that influence manufacturers to remain in the vaccine market and pursue vaccine development and research. The prospects of insufficient returns on investment will discourage companies from engaging in vaccine research and development. I have already talked to several biotech companies who are reevaluating their programs. We think universal purchase shouldn't be part of this program. We hope that the members of this committee look beyond universal purchase toward legislation that will in fact break down the real barriers to immunization and achieve the goal that we all share, and that is immunizing all of our children by age 2.

Thank you very much.

Mr. WAXMAN. Thank you, Mr. Williams.

[The prepared statement of Mr. Williams follows:]

PREPARED STATEMENT OF DAVID J. WILLIAMS

Good morning. My name is David Williams and I am president and chief operating officer of Connaught Laboratories, Inc. I appreciate the opportunity to provide Connaught's views on H.R. 1640, the Comprehensive Child Immunization Act of 1993. Connaught Laboratories, Inc. based in Swiftwater, PA, is dedicated solely to the development and manufacture of vaccines and other biological products.

We support the Administration's objective of fully immunizing all children by age 2. This country does an excellent job of immunizing our children for school entry when almost all of them are immunized. We do it at 5 years of age, not because we do it free, but because we do it well. Having proven that it can be done by age five, we just need to use these same resources and immunize our children by age 2.

The Comprehensive Child Immunization Act of 1993 has three major parts to it.
(1) Supply and price—the universal purchase of all childhood vaccines that will require at least $1 billion a year of taxpayers money
(2) Follow-up—which is being addressed by a tracking and registry system, and
(3) Motivation and infrastructure—which is being addressed by the continuation of outreach, education and infrastructure programs already underway as part of other HHS initiatives.

We think this legislation is upside down in that:

most of the funds will be required for universal purchase which will do little to improve immunization rates

a substantial amount follows for tracking and registry—which won't be fully operational until the next century

insufficient funds are left for the motivation and infrastructure parts of the legislation that most people feel could bring about the biggest improvement in immunization rates.

Our recommendation is that universal purchase, which will do little to improve immunization rates, not be included in final legislation and that part of the money then saved be invested in the area of education, outreach and infrastructure improvements.

A. WHERE WILL TAXPAYERS' DOLLARS GO?

Purchasing the entire vaccine supply for rich and poor alike is estimated to cost at least $1 billion a year. Currently, the public sector buys vaccines at a substantial discount averaging 50 percent less than the private sector price. Should the government become the only purchaser of vaccines, the CDC price per dose would have to rise for all children, in order to subsidize those who can readily afford them. This money could be better spent on programs that address the real problems.

B. UNIVERSAL PURCHASE: NOT A CURE FOR THE PROBLEM

The United States does an excellent job of immunizing children who are about to enter school. According to the Centers for Disease Control and Prevention (CDC), over 96 percent of U.S. children are properly immunized by the time they reach school-age. If vaccine cost is a major barrier at two, why is it no longer a barrier at age 5?

A closer look at immunization levels for children younger than age 2 proves that a variety of factors other than cost are keeping children from vaccines. Unfortunately, less than half of our children are completely immunized by their second birthday. These unimmunized children are often the ones most vulnerable to vaccine-preventable childhood diseases and their complications. Because companies like Connaught have substantially discounted their vaccines to the public sector for many years, vaccines are readily available to children without charge.

In fact, approximately 50 percent of vaccines are purchased by the public sector at deeply discounted prices already provided by the manufacturers. Yet according to CDC, the children who have greatest access to free and low-cost vaccines have the lowest age-appropriate immunization rates. The point is that children are not being brought by their parents to be immunized.

When serious outbreaks of measles and other diseases occurred during the late 1980's and early 1990's, minority children were disproportionately affected, with Hispanic and African-American preschool children, particularly in urban areas, facing seven to nine times the risk of contracting measles when compared with Caucasian children. Significantly, low-income, minority, inner-city children most often depend on acute-care clinics and other public-sector agencies, where vaccines are already available without charge, for their primary health care and immunizations.

CDC data also show that more than enough vaccine is currently purchased by the public and private sectors to age-appropriately immunize every child in this country. In fact, with the exception of Hepatitis b which was recently added to the schedule, 110 percent of the vaccine needed for full immunization is bought each year.

We need to learn from the experience in the 11 States with universal purchase programs. Many of these State programs have been in place for over 25 years, and the results have been mixed, but disappointing. The 1991 immunization rate for

children 2 years and under was 49 percent in Idaho, 50 percent in Connecticut, 51 percent in Washington, and 56 percent in South Dakota.

Although immunization levels in some universal purchase States are slightly better than the national average, it is probably due to other factors. For instance, New England States have few inner city areas and the preponderance of children are vaccinated by private physicians.

Any number of studies, including a report by HHS' National Vaccine Advisory Committee which has been studying immunizations for several years have outlined the critical barriers to pediatric immunization. Cost is not one of them. In addition, leading health officials are convinced that universal purchase does not address the root of the problem. According to former U.S. Surgeon General C. Everett Koop, M.D." . . . the real problem is inadequate education and access to, not availability of, vaccines." Dr. Francis Polumbo, a pediatrician who works in a large Northwest Washington practice where most patients have health insurance and well-educated parents, recently told the Washington Post that "Vaccines are available. The problem is that the kids are not available." A March 28, 1993 Bergen County (N.J.) Record article entitled "Unused Vaccines" quotes Larry Lockhart, Associate Commissioner of the New Jersey Department of Human Services, as saying, "The vaccine cost is not an issue. It's putting doctors and pediatricians in the community and having a good system".

C. THE REAL BARRIERS TO PEDIATRIC IMMUNIZATION

A 1990 article in the Journal of Health Care for Poor and Underserved by Dr. Walter Orenstein et al., described a survey of 54 immunization program managers on pediatric immunization barriers.

The most frequently mentioned barriers were appointment-only systems (93 percent), insufficient staff (70 percent) insufficient clinic hours (56 percent) and requirements for prior physical examinations (56 percent). Similar conclusions are reached in a paper entitled "The Measles Epidemic: The Problems, Barriers and Recommendations," which was adopted by the National Vaccine Advisory Committee in 1991.

The findings in the H.R. 1640 legislation state that there has been a shift in immunizations from private physicians' offices to public clinics. We know of only two sources of data on this issue: manufacturers' records and an American Academy of Pediatrics (AAP) study completed in September, 1992. The companies' actual shipping records do not suggest that such a shift from the private to the public sector has occurred. Since numerous studies document that the best immunization services are provided in private physicians' offices—where children are more likely to have a "medical home"—Connaught strongly supports efforts to eliminate barriers in private physicians' offices. However, we do not believe that the conclusions of the AAP report can be supported by the study methodology. The AAP study consisted of a self-administered mail survey of 1246 fellows of the Academy. The study is problematic for a variety of reasons, including an over-representation of residents, interns, and physicians involved in administrative and teaching positions.

Survey respondents were also more likely to be employed in hospitals than the general pediatric physician population. Furthermore, the survey is based on the physicians' "perceived" recall of referrals over a 10-year period, and the questions related to the cost of vaccines did not adequately differentiate between the cost from the manufacturer and the cost to the patient, which includes physicians' fees. Because of the problems with the sample, the long time-frame for recalled perceptions and vague way key questions are phrased, we do not believe that this study can be applied to pediatric trends in general. In fact, Connaught supports the need for further studies of this nature with representative samples and multi-year tracking so trends can be accurately detected.

E. EXAMINING IMMUNIZATION COSTS

Despite the fact that cost is clearly not a major barrier, vaccine prices have been the focus of much undue attention over the past few months. There is no question about the cost-effectiveness of vaccines. As the President has noted, we save $10 for every $1 spent on vaccines. However, the reasons for increases in the cost of immunizations have been misrepresented. Eighty percent of the cost increase to fully immunize children over the past decade is due to:

—Two new vaccines added to the immunization schedule to protect against hepatitis B and haemophilus influenzae type b(Hib), a leading cause of meningitis. The Hib vaccine alone is estimated to save $400 million per year in health care costs.

—A Federal excise tax added to the price of pediatric vaccines to fund the National Vaccine Injury Compensation Program, a Federal program designed to provide an orderly and swift mechanism to compensate those few who suffer unavoidable adverse reactions to the childhood vaccines that protect our children. The excise tax accounts for $23.50 of the cost increase over the past decade.

Vaccine production has become increasingly complex. It often takes 10 to 12 years to bring a new product to the market. Skyrocketing costs to develop and manufacture vaccines account for the remaining price difference between 1982 and 1992. Manufacturing costs have risen because of:

—A proliferation of government regulations by FDA, CBER, OSHA (Federal and State) and environmental agencies, such as DEP and EPA. For example, the cost to manufacture our DTP vaccine rose nearly 500 percent since 1982. The overwhelming majority of this increase is due to government regulations and requirements. Substantial capital investments were required to comply with new government requirements and regulations, covering such areas as validation, aseptic techniques, and good lab and clinical practices.

—Sharply rising costs of insurance which remains necessary for liability not covered by the National Vaccine Injury Compensation Program. Due to an extremely litigious climate for vaccine manufacturers in the early 1980's, Connaught was unable to obtain adequate private insurance. To stay in business, we were forced to become primarily self-insured and our insurance premiums for what little insurance we can purchase today have risen 750 percent since 1982. During the same period, deductibles rose by 2,000 percent.

Despite the tremendous increases in our costs, Connaught's prices in the public and private sectors have also stabilized and for some products, dropped significantly. Connaught's DTP public sector prices dropped from a high of $7.69 per dose in 1987—prior to enactment of the National Vaccine Injury Compensation Program—to $1.42 per dose in 1992 (exclusive of the $4.56 per dose Federal excise tax). Private sector prices have followed the same pattern. Connaught also passes along economies of scale to private physicians who purchase in large quantities.

We have analyzed international prices and when you compare apples to apples, the cost of fully immunizing a child in the United States and European Community is relatively the same. There will always be some individual product price anomalies in international comparisons. The focus on pricing has also obscured its relativity in terms of overall health care costs. Pharmaceutical products account for 5 percent; vaccines are five one-hundredths of one percent of total health care cost.

F. THE NATIONAL CHILDHOOD VACCINE INJURY ACT: A CALL TO ACTION

The National Childhood Vaccine Injury Act has helped play a major role in stabilizing both the supply and price of vaccines. Products liability has been the single most potent determinant of the cost of—and attitudes about—vaccines in the last 10 years. It not only significantly increased the overall cost of immunization, it also created a climate of fear among parents and led to an informed consent process that is complicated and frightening.

Ultimately, working closely with physicians, manufacturers and parents, the Federal Government enacted this program that went into effect in 1988 and was funded by the Federal excise tax placed on each dose of vaccine. Unfortunately, the excise tax expired on December 31, 1992 along with authorization to use previously collected taxes to pay for claims based on vaccinations after October. Immediate legislative attention is needed to reinstate both the Act and the excise tax and amend the program to coyer new vaccines.

G. SOLVING THE PROBLEM WITH SCARCE TAXPAYER DOLLARS

In addition to reinstating the National Vaccine Injury Compensation Program, we need to concentrate scarce taxpayers dollars on programs that have proven that they can get vaccines to children, and children to vaccines. Solving the immunization problem will require that government, industry, parents and health professionals work together in a multi-faceted campaign. Study after study has documented some of the most important areas to address including:

1. EDUCATION FOR PARENTS AND HEALTH CARE PROVIDERS

Immunization, in ending the mass epidemics that once routinely killed or harmed our babies, may be a victim of its own success. Parents no longer see these preventable diseases as something to fear. We need educational programs that reinstitute—and even go beyond—the degree of appreciation of immunization that parents had

in the past. Educational programs for health providers on current vaccinations and appropriate contraindications are also important.

2. INNOVATIVE DELIVERY MECHANISMS

We need to create a public health environment that welcomes parents and children, rather than keeps them away. To that end, we may have to go directly to them, rather than wait for them to come to us. There are a number of pilot programs having success in that area.

The Children's Health Fund has created a clinic on wheels in New York and other cities; the National Immunization Campaign has a multi-faceted organizing and outreach effort on national and grassroots levels. In addition, there are several government demonstration projects in New York, New Jersey and Illinois in which immunizations are combined with other services, such as food stamp purchase and welfare, to meet multiple needs simultaneously.

3. INFRASTRUCTURE IMPROVEMENTS

We wholeheartedly support the Clinton administration's intention to infuse more funds into the public health infrastructure. Such funds will directly address the most common barriers, such as improved staffing, expanded hours, and better transportation.

4. IMMUNIZATION TRACKING SYSTEMS

A national immunization registry to insure that each child's immunization record is automatically updated, wherever and whenever a vaccine is administered, is long overdue. We firmly support the Administration's efforts to establish such a system and only wish it could be implemented sooner. A national immunization registry needs to be comprehensive and include the private sector, so that the immunization status of all children is accessible and updated as vaccines are administered. However, universal purchase is not a prerequisite for effective tracking systems. Any tracking system must be designed with a minimal "hassle factor" so that doctors aren't driven away from delivering immunization altogether. The Administration states that free vaccine is needed for tracking, i.e., doctors will get free vaccine in return for supplying tracking information to the CDC.

We have a few questions: (1) What will happen after the sunset clause kicks in and universal purchase stops? and (2) What if doctors don't supply the tracking information—will free vaccine be withheld? Is that another barrier? We think it will create another barrier to immunization and the free vaccine will play little to no role in tracking. Free vaccine will not be enough of an incentive to make providers participate in an overly burdensome information gathering system. Nor will lack of free vaccine dissuade providers from participating in a well developed, well run tracking program that not only does good for society but brings back the patients for follow-up services and treatment. It is clear from this provision that the Administration believes that the distribution of free vaccine to providers will be adequate inducement to ensure that providers perform their "tracking" duties under the bill. It is just as likely to drive providers out of providing immunization services. It is more likely that the States will have to develop some penalty system or make the performance of these duties a condition of licensure for providers, in order for States to get and maintain their Federal grant money and for the tracking system to work.

5. ELIMINATE MEDICAID OBSTACLES

There are a variety of delivery systems for Medicaid-eligible children throughout the country. Some States have been successful in achieving high rates of immunization for Medicaid-eligible children, while others have not. The States which have the best records are those which have little paperwork hassle and reimburse at high enough levels to cover vaccine costs and a reasonable administration fee. In Connaught's opinion, if this were fixed, much of the concern about the price of vaccines will be eliminated. Thus far, however, there has not been a comprehensive analysis of success factors to help forge a blueprint for success. We applaud the Administration's intention to seek long-term funding to rebuild the infrastructure but believe that it will be necessary to include a careful analysis as the keystone for success. However, several key issues are universally mentioned as necessary for Medicaid reform. Eligibility requirements should be standardized to establish accurate numbers of children who are receiving vaccines through Medicaid programs. Currently, disincentives to physician participation are created by inadequate reimbursement rates and excessive paperwork.

Another disincentive to private physicians is the difficulty of obtaining Medicaid-priced vaccine for Medicaid patients. Connaught believes that Medicaid-eligible children should receive Medicaid-priced vaccine and has a long-standing commitment to work on a State-by-State basis to accomplish that goal. To that end, we are offering several States a Medicaid Replacement Program that seeks to provide public sector vaccine to private physicians for their Medicaid-eligible patients in as efficient a way as possible. In addition, we believe that states should be able to buy vaccine for all Medicaid-eligible children at reduced prices.

Connaught also believes that all necessary childhood vaccines should be made accessible to the public sector at a discounted price and that appropriations should cover, for use by the medically needy, all vaccines—including Haemophilus Influenzae type b and Hepatitis B—that are indicated for use and recommended by the Public Health Service's Immunization Practices Advisory Committee (ACIP) and by the Red Book Committee of the American Academy of Pediatrics. Currently, that is not the case.

6. PRIVATE INSURANCE COVERAGE FOR IMMUNIZATIONS

In the private sector, much needs to be done to encourage timely immunization. While many managed health care programs now cover immunizations, less than half of conventional, employment-based carriers do so. As a result, many underinsured patients must find their way to the public health sector for immunizations. The Commonwealth of Pennsylvania has addressed this issue by passing a law that requires all commercial group and individual policies that provide medical coverage for dependent children to provide first-dollar coverage for immunizations, including professional fees for administering the vaccines. Benefits for immunization services are exempt from deductible or dollar-limit provisions. We think this is a model approach that can have a significant impact on reducing the cost of immunization to the Federal and State Governments.

I. SUMMARY

We applaud the Clinton administration's intention to ultimately include childhood immunizations as part of a basic benefits package under Health Care Reform. However, using scarce taxpayers' dollars as a stopgap measure with no proven utility in raising immunization levels will have serious long-term repercussions that could jeopardize our entire industry.

Among Thomas Jefferson's private papers is a letter he wrote to Dr. Edward Jenner, the father of vaccination who is best known for inoculating himself with the first smallpox vaccine. Jefferson describes Jenner's discovery of the first vaccine by saying that "Medicine has never before produced any single improvement of such utility".

It is in this spirit of worthwhile innovation that Connaught must be allowed to continue to be responsible to the children in the United States and around the world. The only way we can do this is to continue developing new and improved vaccines.

A fundamental drawback of the universal purchase concept is that it does not account for the economic realities that influence manufacturers to remain in the vaccine market, adjust prices in accordance with the demands of competition, and pursue vaccine development and research. If most or all pediatric vaccines were purchased under Federal or State contracts at bulk-purchase discounts, a company that did not win a contract award for a year or 2 would be unlikely to continue to invest in vaccine development or to a commitment of manufacturing resources.

Risks are extremely high and returns are too small to justify such investment. Thus, the result would likely be the elimination of manufacturers from the competitive market, which in turn would eliminate incentives for competitive price reduction and increase the risk of vaccine shortages. In addition, the prospect of insufficient returns on investment will discourage companies from engaging in vaccine research and development and may diminish efforts to improve existing or develop new vaccines. Vaccine prices reflect the ever increasing manufacturing costs but also the need to achieve reasonable returns on previous vaccine research and developments. We are on the verge of an explosion of new vaccine technology, with new combination vaccines that protect against more diseases with fewer injections, and with many new products in the pipeline such as those against otitis media and Respiratory Synctial Virus infection, the leading cause of childhood hospitalization in this country.

Unfortunately, the universal purchase program proposed in the Child

Immunization Act, may put an end to this kind of research and hurt considerably companies like Connaught—which focuses almost entirely on vaccines—in the proc-

ess. Even more unfortunate is the fact that universal purchase will not fix the problem. This Kind of expenditure of taxpayers' dollars is both unwise and unjustifiable.

We hope that the members of these committees will look beyond universal purchase toward legislation that will, in fact, break down the barriers to pediatric immunization and achieve the goal, which we all share, of full immunization of every child by two. Thank you.

Mr. WAXMAN. Dr. Saldarini.

Dr. SALDARINI. Thank you, and good afternoon.

I am Ron Saldarini, president of Lederle-Praxis Biologicals. I have submitted written testimony, and I don't intend to read it; I would just like to make a few additional comments for the record.

As I came into this meeting room today, it occurred to me that I have been associated with the vaccine business for the last 8 years, and I believe I have been participating in some type of committee hearing like this probably five or six times over the past 8 years. These are very meaningful subjects and very important to the health and welfare of our Nation's children.

One of the things that was always consistent as I look back on those committee hearings was the tone that one always heard from people representing public interest groups, people representing the government, and even people representing the industry, and that tone was one of great expectation.

I think uniformly throughout those hearings, everyone expected that because we were now in a new era, which we refer to as "biotechnology," that the promise for vaccine development was really very, very big, and people felt good about it. And everybody looked to the industry to help provide those new vaccine developments.

And I guess as we have been deliberating these very important immunization initiatives over the past several years, one thing is very clear—the industry, and Lederle-Praxis, to be sure, in particular, has not been idle; in fact, we have been very busy. And we have reached or achieved some of these expectations because just my own company has introduced three new vaccines in the last 4 years.

We introduced a brand new one, called haemophilus influenzae type B, in 1990. We know that it has already significantly impacted the total economic costs associated with disease to the tune of about $2.5 billion a year, which is Centers for Disease Control statistics.

We know that we have reached a noticeable improvement in pertussis immunization, which has been a source of concern for many of these committees over the past 10 years, and we have introduced a new vaccine for that, called acellular pertussis vaccine. What is becoming very clear is that as biotechnology moves us forward, there will be many new product introductions, and we will run out of arms and legs on a child, and therefore, we must find better ways to deliver the product, and that has been referred to often as "combination products." And we have just introduced our first combination product, which combines real childhood vaccines—diphtheria, tetanus and pertussis—with haemophilus influenzae, so that we have effectively reduced the number of immunizations required from eight tc four, and that has just happened in this last month.

So I am trying to emphasize the fact that I feel that this company and this industry have had a very successful relationship, we hope, and we feel we have been faithful to the public sector by of-

fering very, very low cost products to the public sector so they can be directed to those parties who truly are needy. And we have offered at least half of our volume in that cause of everything that we produce.

We feel we have had an effective partnership with the private sector as well, because we spend a lot of time and effort not only trying to provide pediatricians with an understanding of what is coming in vaccine development, but also with the educational materials that are required to help them relate to their patient base, which is very, very important.

And yet throughout all of this, we are faced with a constant concern over the pricing of these products, and this is particularly true for existing products. And I wouldn't want to mislead anybody and say that the prices of these products has not gone up; in fact, they have gone up. And I would also add that in large measure, the moneys that were in those prices that people constantly refer to have been redirected into this business.

In my company, just as with my colleagues, this redirection has indeed resulted in three new vaccines in the last 4 years, and has resulted in a measurable improvement in research and development pipelines which will take advantage of the biotechnology era, and over the next several years, we are going to see many, many more products come this way as a result of this reinvestment.

I feel that if we move in the direction that this bill—at least, the part of this bill that deals with universal purchase—takes us, it will have an impact on our overall research and development effort. We feel the marketplace is a better place than having the government making decisions with respect to vaccine products, vaccine research, the way we do clinical studies, the kinds of investments we make, and we think it will also have a potentially negative impact on the overall capital market in terms of attracting investment.

So I would argue that historically and currently, we are the world's leader in vaccine innovation. Please consider this bill carefully because it may not keep us that way.

I would add one more point——

Mr. WAXMAN. Dr. Saldarini, the rest of your statement will be in the record——

Dr. SALDARINI. If I may, Congressman, one more point, because it is ironic to me that the Clinton administration has, in our opinion, wisely rejected a single-payer approach for its health care reform initiatives, and it has opted to go with the competitive marketplace—that is, in everything but vaccines. There, where we have demonstrated our capability to deliver new products, there, the single-payer approach seems to be important, and I would like us to give that consideration.

Thank you, sir.

Mr. WAXMAN. Thank you, Dr. Saldarini.

[The prepared statement of Dr. Saldarini follows:]

PREPARED STATEMENT OF RONALD SALDARINI

I am Ron Saldarini, president of Lederle-Praxis Biologicals, a Division of the American Cyanamid Company. Lederle-Praxis is one of two remaining U.S.-based vaccine manufacturing companies. Our business is promotion of health through prevention, for the moment mostly in the form of childhood vaccines but with the hope of developing an array of effective adult vaccines in the future.

Lederle-Praxis is proud of its accomplishments in childhood immunization. At present, it is the sole supplier of oral polio vaccine, and one of two companies providing diphtheria, tetanus and pertussis vaccines, combined into one DTP shot. We were the first company to introduce an acellular pertussis product to the American market as a result of demands from pediatricians, parents and the public health community for a less reactive vaccine to prevent whooping cough. In addition, we received in 1990 the first approval for a vaccine for infants to prevent meningitis caused by the haemophilus influenzae type B organism—the first new infant vaccine since oral polio vaccine, 30 years earlier.

The haemophilus, or Hib, vaccine provides dramatic evidence of the value of childhood immunization and the necessity for continued research and development efforts. Meningitis resulting from infection with the haemophilus bacterium was the cause of about 800 infant deaths annually and about the same number of cases of mental retardation or other permanent neurological damage. The government's own statistics from the Centers for Disease Control (CDC) were that the disease resulted in economic loss to the United States of $2.5 billion every year. It was only through new biotechnology techniques that we and other companies could find a way to stimulate the immature immune systems of infants to create protective antibodies against this disease. Once the vaccine was approved, the disease was virtually eradicated over the course of about a year and a half.

Just a few weeks ago we received the good news from the Food and Drug Administration that we had received approval for a combined DTP and Hib vaccine, again the first such product to be approved. This combination of four antigens will effectively halve the number of injections required to immunize children against those diseases. Against this backdrop of success in our research program and in introduction of new products, we appreciate the invitation to address this joint hearing, but we approach this hearing with mixed emotions. As someone who has spent a number of years in the vaccine business, I am gratified to see the attention which childhood immunization is receiving in this Administration. Finally, policymakers in Washington and elsewhere, along with the media and the public generally, seem to appreciate the value of prevention and, more specifically, of immunization as a cost-effective strategy for health care. However, while the spotlight on immunization is welcome, we fear that politics, public relations and symbolism may be pushing aside sound policy considerations in addressing what everyone agrees is a distressing problem—the chronic low rates of age-appropriate immunization among our children, particularly in the inner cities and other challenging locations.

The legislation sponsored by Congressman Waxman and others in the House and by Senator Kennedy and Senator Riegle in the Senate is at the root of our concern. Lederle-Praxis supports in concept virtually all the provisions of this legislation. We endorse improved tracking, outreach and delivery of vaccines as a means of enhancing immunization rates across the board and especially in those hard-to-reach inner city or remote rural sites. In fact, the only significant portion of the legislation which we cannot support is the provision for the government to purchase all childhood vaccines.

As we have said many times before, universal purchase is not the answer to the problem of low immunization rates. If it were, the 11 States currently following that formula would demonstrate markedly better immunization rates, as well as lower disease rates. The reverse is true. Immunization rates are not substantially better in universal purchase States, and in some notable instances, disease rates are higher in those States purchasing all vaccine for distribution free-of-charge not only through public health clinics but also through private pediatricians' offices.

Aside from this overwhelming public policy reason for not pursuing universal purchase, we believe that the current environment of vigorous research and development cannot continue if we have only one customer and that is the Federal Government. Our specific concerns about the universal purchase proposal are as follows:

As drafted, the legislation does not address the real problems underlying low immunization rates. As noted in a recently released GAO report requested by the Chair of the Senate Finance Committee, improvement in immunization programs depends on (1) education of parents, (2) tracking of each child's immunization status and (3) follow-up with children requiring further immunization.[1] Even though the legislation deals with funding for each of these matters, there is no guarantee that the States receiving grant funds will approach these tasks in a systematic coordinated fashion. Universal purchase is little more than a diversion from these fun-

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[1] GAO/HRD-93-41, Report to the Chairman, Committee on Finance, U.S. Senate, "Childhood Immunization: Opportunities to Improve Immunization Rates at Lower Cost," (March 1993).

damental undertakings, and there is no evidence to lead one to believe that it will measurably enhance the immunization effort.

The universal purchase proposal is antithetical to the Administration's health care reform initiative. We have been told that universal purchase is a transitional device, complete with a sunset provision, but we believe it in fact represents a destructive departure from the philosophy underlying the Administration's health care reform initiative. The Clinton administration has expressly rejected a single-payer system and has instead chosen a market-driven managed competition system. Having rejected a single-purchaser model for the overall health care system, however, the Administration has chosen to make the Federal Government the sole purchaser of vaccines. To render the government our sole customer is effectively to make industry a prisoner of bureaucratic decisionmaking. Why take this extraordinary step with a segment of the pharmaceutical industry which has historically provided the public sector with one-half of all product needs at sharply discounted prices in order to ensure that the needy would be served? It contradicts every impulse that we have come to expect from the Administration's health care deliberations. Regulate us if you must, but do so in the context of larger health care reform where those fundamental marketplace principles may be allowed to operate.

Universal purchase of childhood vaccines at this juncture may create an unintended subsidy for the insurance industry and may provide disincentives to insurance coverage for well-baby care. Statistics indicate that about one-third of insurance policies currently provide for well-baby care, including immunizations. If vaccines are now to be provided free of charge, the insurers will be absolved of a cost which they have contractually agreed to bear. More importantly, the pressure for mandated first-dollar coverage of well-baby care, including immunizations, may be decreased by enactment of this legislation. As proponents of the legislation would agree, there are substantial reasons to mandate insurance coverage of well-baby care that includes immunizations.

The legislation creates a new entitlement for middle-and upper-income parents at a time when other entitlements are at risk. Under current budget rules, $90 billion in entitlements are slated for reduction over the next five years, roughly the same period in which this legislation would spend almost $5 billion to provide free vaccinations to all children, regardless of wealth. The more than $1 billion a year that is proposed for universal purchase could go far toward any of the following

priority items to serve the needs of the poor: full funding of Head Start; full funding of WIC; or bringing Medicaid coverage up to 185 percent of poverty. If this unprecedented shift of public resources from the needy to the 'well-to-do had been proposed by a Republican Administration, there would be well-justified howls of protest from Congress, as well as from a variety of public interest advocates.

Universal purchase is not necessary to facilitate a tracking program which includes private pediatricians. Among the rationales offered for universal purchase is the perception that private physicians must be enticed to participate in a Federal tracking system by the lure of free vaccines. Personally, I am not prepared to accept this cynical, defeatist attitude. Physicians are obliged as part of their duty to patients and to the public health to participate in various reporting programs, and there is no reason to believe that pediatricians would resist involvement in this very important initiative. Most private pediatricians' offices now have computer capacity, and Lederle-Praxis has offered to design and provide free of charge to pediatricians a software package that should be compatible with the program being developed by CDC for tracking purposes.

Research and development efforts will be seriously affected by universal purchase. Virtually every vaccine company in this market could offer impressive reports of their research and development programs, in terms of both past successes and future prospects. We at Lederle-Praxis are confident of our capacity to bring to market a very complicated, multi-antigen product to prevent acute, recurring ear infection, one of the most common and costly reasons for visits to pediatricians during the early years of childhood. We are not, however, confident that funding for such projects will be available if the government is our single customer. There is no need to recount the numerous examples, experienced by every company, of instances in which inefficiencies or bureaucratic thinking by the government has impeded our ability to provide safe and effective products to the public. If the government, rather than the marketplace, becomes the arbiter of manufacturing protocols, research priorities, and investment decisions, both quality and progress will suffer.

At the outset, I mentioned the fact that our Hib vaccine, introduced in 1990, was the first new infant immunization for 30 years. During that 30-year-period, Lederle-Praxis and other manufacturers competently and reliably produced the traditional regimen of childhood vaccines—OPV, DTP and MMR. Only with the advent of biotechnology have we been able to expand the universe of diseases preventable

through childhood vaccines. I fear that adoption of a universal purchase program, under which the government is our single customer, will return us to the relative dark ages of vaccine development. I cannot envision a system in which the government participates with today's vaccine developers, and essentially overrides the marketplace, in making investment, research and product decisions except by reference to that earlier period when research and development took a backseat to mere manufacturing.

We at Lederle-Praxis believe that many more diseases of childhood—and for that matter of adults—can be conquered through immunization. The promise of the future will not be realized if we sacrifice continued progress for short-term political and symbolic gains. In the strongest possible terms, I urge Members of Congress to consider carefully the relative benefits and risks of this ill-conceived strategy.

My company could understand a push for universal purchase if history were different. We could understand it:

—if the government had any reason to say that we had ever been a bad partner in the effort to immunize our nation's children;

—if we had sought to gouge the public sector with high prices;

—if we, like foreign-based manufacturers, had abandoned the U.S. market when we were no longer able to obtain liability insurance in the mid-1980's;

—if we had ever failed to respond to the government's request to shift production or provide vaccine when shortages threatened;

—if there were any reason to believe that our research and development programs were broken and in need of a government fix; or

—if any State had ever markedly improved its immunization rates by adopting universal purchase.

Instead, we see a situation in which we have been a faithful partner to the Federal Government and a good friend to individual States. (Even States like Hawaii and South Carolina, cited by the Administration as examples of States we denied discounted vaccines, would agree that we willingly and openly shared our views with them, and we believe we earned their respect and in all likelihood could reach accommodation with them.)

We have regularly supplied the government with half the country's vaccine needs at sharply reduced prices, have held relatively steady our private sector prices in recent years, and have pledged to freeze current prices. We have remained in a very difficult market when others have left, and we would like to think we will still be here when they have left again. Our research and development are second to none. We have not panicked, or carped or bolted the market when the government let lapse the excise tax which funds the compensation system that is critical for large corporate enterprises lacking liability coverage.

In short, we have given just about everything the government has asked. But we draw the line when the government says it wants to own us, which is the effect of universal purchase. The immunization system in this country may be broken, but not with respect to quality of vaccines, assuredness of supply at reasonable prices, or prospects for innovation and improvement. Let us fix the delivery system and not risk destroying those parts of the immunization program that have worked well and will continue to do so if the government permits.

Mr. WAXMAN. Mr. Garnier.

Mr. GARNIER. Thank you, Mr. Chairman, and members of the committee and subcommittee. My name is Jean-Pierre, and I am president of SmithKline Beecham Pharmaceuticals for North America.

SmithKline Beecham is a transnational health care company whose principal activities are the discovery, development, manufacture and marketing of pharmaceuticals, vaccines, and other health care goods and services.

As far as vaccines are concerned, we are a major supplier of polio and measles vaccines outside the United States, and we market Engerix-B, the first biotechnology-derived hepatitis B vaccine in the U.S. and around the world. Every second of every day, 15 people around the world are inoculated with one of our vaccines.

We consider our R and D efforts second to none. We are working on Lyme disease, AIDS, and we recently introduced the world's

first hepatitis A vaccine in Europe. As you know, hepatitis A is a major killer in the world. And we presently plan to offer a full range of pediatric vaccines in this country. So we are a fairly new comer in the U.S. in terms of pediatric vaccines, and therefore I think we bring a different perspective.

We believe we bring in fact a useful worldwide perspective on the types of measures that will help achieve the goals we all share.

I am pleased to appear before you today as you consider an issue of great importance—the immunization of our children by the age of 2. I will identify the approaches we favor, and comment on those which we believe need modification.

Few tasks are more important than the one before us, because nothing speaks more for any Nation than how well it protects its children. America's record is not what it can and must be. There is no question that we can get the job done; we have a world class vaccine industry, dedicated health professionals, sophisticated distribution networks, and the economic capacity to do it.

SmithKline Beecham applauds the objectives of the universal immunization proposal, and we favor many aspects of the administration's proposal, particularly the following: establishment of an immunization tracking system; enhancing education and outreach programs; securing the National Vaccine Injury Compensation Program by making it permanent, and finally, continuing vaccine infrastructure enhancements.

While we support these important points, there are other areas where we believe modifications are in order. Universal government purchase creates several concerns.

First, universal purchase would eliminate the private market which, incidentally, under managed care, for instance—and soon, managed competition—works quite well in ensuring immunization of young children. One need only look at the Kaiser Permanente program in California, where childhood immunization at the age of 2 is at 95 percent.

Second, elimination of the private market will greatly increase government outlays for vaccines, first by reimbursing vaccines for many Americans who could afford them, and second because prices to the public sector—currently, the CDC prices—which are now subsidized by the higher prices derived from the private sector, will indeed increase.

Sole-source procurement will create a major barrier to entry for new players in the vaccine market such as SmithKline Beecham. If universal purchase is coupled to a winner-take-all bidding approach, the nature of vaccine manufacturing is such that the firms that lose the bid will exist the market. Vaccine production cannot be shut down for months or years and restarted on the next bid.

Creation of a system giving all the business to a sole-source supplier could lead to a shortage of essential vaccines if that supplier encounters production or quality control problems. Precisely this has happened in the recent past.

The current proposal also fails to address the inadequate compensation of physicians who are expected to immunize Medicaid beneficiaries. This has resulted in some patients being shifted from private physicians' offices to public clinics. As a consequence, many children are not being immunized.

The March 1993 GAO report notes that, "even when States have established vaccine replacement programs, not all physicians have participated because of what they perceive as very inadequate reimbursement for vaccine administration."

And finally, the proposal should be changed to include an important role that should be performed by the private insurance market. Insurance companies should be required to contribute to the solution by covering the immunization of children they already insure. Plus it is good business for them; they avoid costs in the future.

While we do not endorse every facet of the administration's proposal, we do not favor the status quo. Rather than turning the industry on its head, we essentially would like to talk about a better approach. Let me summarize SmithKline Beecham's recommendations on how each of these issues may be addressed.

First of all, we advocate that CDC prices—currently the lowest prices in the marketplace—be made available to all State Medicaid programs.

We recommend that the CDC winner-take-all system be replaced by an apportioned bidding system, allocating a share of the bid to all bidders that meet the lowest price.

We support expanded purchase to provide Medicaid immunization coverage for all children whose family incomes are 185 percent of poverty. We also support coverage of the physician fees to ensure needed follow-up visits to complete immunizations.

We recommend that private insurance be required to cover all American Academy of Pediatrics recommended childhood immunizations and that preventive care services be made part of the basic health care benefit.

Our proposal achieves the results that the administration seeks, but at a much lower cost. If the Federal Government were to purchase vaccines for all children, and if a 95 percent immunization rate were reached, we estimate that the cost would be around $700 million to $1 billion annually. Under our proposal, the vaccine cost would be $240 million, a saving of more than half a billion dollars every year. The savings could be applied to the public education effort, the infrastructure and tracking programs, and to Medicaid reform and expansion.

Contrary to the universal purchase, our proposal preserves multiple vaccine developers and manufacturers, therefore avoiding potential serious disruptions of supply. Our proposal also focuses on the root causes of low vaccination rates, at a substantially lower price tag for the taxpayers.

Our proposal represents a workable plan for achieving full immunization of our children, while avoiding the pitfalls of universal purchase and the severe inadequacies of the current system.

This completes my testimony. Thank you for your attention.

The CHAIRMAN. Thank you very much.

[The prepared statement of Mr. Garnier follows:]

Prepared Statement of J.P. Garnier

Chairmen and Members of the Committee and Subcommittee, I am Jean-Pierre Garnier, President of SmithKline Beecham Pharmaceuticals-North America.

SmithKline Beecham is a health care company with annual sales of more than $9 billion. Our principal activities are the discovery, development, manufacture and marketing of human and animal pharmaceuticals, over-the-counter medicines and health-related consumer products and clinical laboratory services.

We are a major supplier of polio and measles vaccines outside the United States, and we market Engerix-B, our hepatitis B vaccine in the U.S. and around the world. Every second of every day, fifteen people around the world are inoculated with one of our vaccines. Recently we introduced the world's first hepatitis A vaccine in Europe and we presently plan to offer a full range of vaccines in this country.

We believe we bring a useful worldwide perspective on the types of measures that will help achieve the goals we all share.

I am pleased to appear before you today as you consider an issue of great importance -- the immunization of our children by the age of two. I will identify the approaches we favor, and comment on those which we believe need modification.

Few tasks are more important than the one before you, because nothing speaks more for any nation than how well it protects its children. America's record is not what it can and must be. We have much to do if we are to look back with pride at the end of this decade to a nation whose children are protected as well as any in the world against communicable illnesses.

There is no question that we can get the job done. We have a world class vaccine industry, dedicated health professionals, sophisticated distribution networks and the economic capacity to do it.

SmithKline Beecham applauds the objectives of the universal immunization proposal, and we favor many aspects of the Administration's proposal, particularly the following:

- Establishment of an immunization tracking system through state registries to ensure that children receive their scheduled immunizations at the earliest appropriate age.

- Enhancing education and outreach to improve parents' awareness of the importance of immunization.

- Securing the National Vaccine Injury Compensation Program by making it permanent.

- Continuing vaccine infrastructure enhancements.

While we support these important points, there are other areas where we believe modifications are in order. Universal government purchase creates several concerns:

- First, universal purchase would eliminate the private market, which under managed competition works quite well in ensuring immunization of children. One need only look at the Kaiser Permanente program in California, where childhood immunization is at 95%.

- Second, elimination of the private market will increase government outlays for vaccines, because prices to the public sector, which are now subsidized by the higher prices derived from the private sector, will increase.

- Sole-source procurement will create a major barrier to entry for new players in the vaccine market, such as SmithKline Beecham. If universal purchase is coupled to a winner take-all bidding approach, the nature of vaccine manufacturing is such that the firms that lose the bid will leave the market. Vaccine production cannot be shut down for months or years and restarted on the next bid.

- Creation of a system giving all the business to a sole source supplier could lead to a shortage of essential vaccines if that supplier encounters production or quality control problems. Precisely this has happened in the recent past.

The proposal also needs to correct inadequate compensation of physicians who are expected to immunize Medicaid beneficiaries. This has resulted in some patients being shifted from private physicians' offices to public clinics. As a consequence, many children are not being immunized. The March 1993 GAO report notes that, "even when states have established vaccine replacement programs, not all physicians have participated, because of what they perceive as inadequate reimbursement for vaccine administration."

And finally, the proposal should be changed to include an important role that should be performed by the private insurance market. Insurance companies should be required to contribute to the solution by covering the immunization of children they already insure.

While we do not endorse every facet of the Administration's proposal, we do not favor the status quo. Rather than turning the industry on its head, creating a public utility concept, with a promise to turn us back on our feet with implementation of managed competition, we have a better approach.

Let me summarize SmithKline Beecham's recommendations on how each of these issues may be addressed:

1. We advocate that CDC prices be made available to all state Medicaid programs.

2. We recommend that the CDC winner-take-all system be replaced by an apportioned bidding system, allocating a share of the bid to all bidders that meet the lowest price.

3. We support expanded (not universal) purchase to provide Medicaid immunization coverage to all children whose family incomes are 185 per cent of poverty. We also support coverage of the physician's fees to ensure needed follow up visits to complete immunizations.

4. We recommend that private insurance be required to cover all American Academy of Pediatrics recommended childhood immunizations and that preventive care services, including Immunizations, be made part of the basic health care benefit.

These are our principal recommendations. A more comprehensive explanation of our approach, and a rationale for them, is attached to my testimony.

Our proposal allows the government to help those most in need. It maintains a role for private insurance, ensuring that all privately insured children will be covered.

Our proposal achieves the results the Administration seeks, but at lower cost. If the Federal government were to purchase vaccines for all children and if a 95% immunization rate were reached, we estimate that the cost would be $695 million annually. Under our proposal, the vaccine cost would be $240 million, a saving of $455 million. The savings could be applied to the public education effort, the infrastructure and tracking programs, and to Medicaid expansion.

SmithKline Beecham appreciates this opportunity to offer our perspectives on improving immunization rates in this country. While we support the objectives of universal immunization, we believe that during this time of limited resources, a more targeted, public-private partnership is required. Any plan must ensure the participation of multiple manufacturers while at the same time providing the lowest cost vaccines to the public market. The Senate bill provides that the Secretary

shall grant multiple contracts, but there must be greater certainty in order to ensure enough volume to justify investment in manufacturing and research. Without these assurances, SmithKline Beecham will have difficulty entering a winner-take-all system where there is universal purchase.

Our proposal represents a workable plan for achieving full immunization of our children, while avoiding the pitfalls of universal purchase and the severe inadequacies of the current system.

We are ready to work with you to refine a new immunization policy, and we look forward to the day, hopefully in the very near future, when no child in this country goes without proper immunization.

SMITHKLINE BEECHAM PHARMACEUTICALS FEDERAL IMMUNIZATION PROPOSAL

Executive Summary

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

2. Provide the CDC price to all state Medicaid programs.

3. Replace the CDC winner-take-all system with an "apportioned" bidding system which would allocate a share of the bid to all bidders that meet the lowest bid price.

4. Give states the option of developing a cost-effective way to distribute vaccine products to Medicaid programs at the CDC price.

5. Require all private insurors to provide coverage of all American Academy of Pediatrics (AAP)-recommended childhood immunizations in their plans as well as preventive care services and include immunizations as part of basic health care benefits in any plan that is adopted to provide universal health care coverage.

6. Simplify the regulatory approval process for vaccines, particularly the new combination products, with clearer guidelines and expedited approval.

7. Require a multi-pronged approach to improve access, outreach, education and delivery of immunizations, including a national immunization tracking and surveillance registry.

8. In order to ensure the pricing stability of the market place, the Vaccine Injury Compensation Fund should be restored and expanded.

PRINCIPLES FOR A FEDERAL IMMUNIZATION PROGRAM

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

Principle 1: Elimination of Financial Barriers to Immunization

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

Principle 2: Preservation of Healthy Private Market

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

Principle 3: Guaranteed Participation in Public Market

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

Principle 4: Improved Access and Outreach

Experts agree that improved access and outreach are critical to increasing this nation's childhood immunization rates, and universal purchase of vaccines alone will be insufficient to increase vaccination rates.

Principle 5: Restoration of Liability Protection

Immediate restoration of the Vaccine Injury Compensation Fund and tort reform in the longer run are key to containing the cost of vaccines.

RECOMMENDATIONS

Issue 1: Elimination of Financial Barriers

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

Recommendation:

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

Rationale:

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

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

SB's combined private-public approach addresses virtually all of the affordability problem by:

- expanding Medicaid coverage to 185 percent of poverty to cover almost 52 percent of children; and
- requiring all private insurers to cover immunizations.

We estimate significant savings from this targeted approach. If the government were to purchase vaccine for all children, we estimate the cost to be about $695 million per year. If instead Medicaid eligibility were expanded to 185 percent of poverty, we estimate the cost to the government for vaccine products to be only about $240 million, or a savings of $455 million.

Issue 2: Availability of Low-Cost Vaccines to the Needy

Many state Medicaid programs do not take advantage of lower CDC prices for vaccine products.

Recommendation:

Allow state Medicaid programs the right to purchase vaccines at the CDC bid price.

Rationale:

To make sure all states have access to the most favorable prices for vaccines, an expanded CDC-administered bidding program makes sense. The Medicaid program could garner significant savings from CDC pricing for childhood vaccines. By combining the broadened eligibility with the most favorable vaccine pricing, we estimate that state Medicaid programs currently using a fee-for-service system to provide immunizations potentially could save about 50 percent on vaccine acquisition costs at existing CDC prices.

Issue 3: Guaranteed Participation in Public Market

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

Recommendation:

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

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

Rationale:

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

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

Because vaccine manufacturing requires major investment in a sophisticated production plant and the establishment of teams with multidisciplinary expertise in the large-scale production of biological products, it is essential to preserve a market with multiple manufacturers. This combination of resources would be extremely difficult to assemble to offer an alternate supply if a sole supplier experienced the problems outlined above.

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

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

Issue 4: Mechanism for Providing Vaccines to Medicaid Programs

How would the "apportioned" bid system actually work to provide CDC vaccine prices to expanded state Medicaid programs?

Recommendation:

A number of distribution approaches could be used by states. Alternatively, the CDC could contract with private wholesalers to distribute vaccine products on behalf of the states. States should be given the option to select the approach that makes the most sense for them.

Here are three possible approaches:

1. State replacement: Where states currently buy vaccines directly from CDC, warehouse, and distribute them to Medicaid physicians, they would continue to do so, according to an apportionment scheme which may be administered by CDC.

2. State-contracted distribution: States would allow private wholesalers to bid for the right to distribute vaccines it purchases to Medicaid physicians within the state, according to an apportionment method (see attachment).

3. CDC-contracted distribution: CDC would contract with private wholesalers who would compete--possibly on a regional basis--for contracts to distribute vaccine products to state Medicaid programs. Physicians would purchase inventory under extended credit terms rather than receive free replacement products.

Caution should be exercised when considering the individual manufacturer "free replacement" or "consignment" approach proposed by some manufacturers. This program is targeted at high volume Medicaid physicians--not necessarily all physicians who could immunize Medicaid patients--and is intended to create a de

facto monopoly of the distribution channel within that state at the expense of retail pharmacies and physician supply houses. This de facto monopoly can then be naturally extended to include the vaccines for private patients as well as non-pediatric vaccines. The long term consequence of such a program is increased cost of vaccines as a result of the distribution monopoly within the state. Last but not least, the manufacturer replacement approach could not accommodate the federal apportionment program outlined above without a supplemental effort by the federal or state government

Issue 5: Preservation of Healthy Private Market

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

Recommendation:

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

Rationale:

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

The elimination of a private market is not inthe public's interest, either from a financial or a health-status standpoint. The elimination of the private market will raise prices in the public sector because private market vaccine prices are subsidizing the public vaccine market. If public market prices do not go up, then the number of manufacturers will go down as those on the cusp of entry decide not enter the vaccine business.

Last, providing free vaccines to the insured or to those who can afford it simply takes away scarce, critical federal resources from Medicaid expansion and education, access and outreach efforts that experts agree are critical to higher immunization rates.

SB's combined private-public approach addresses virtually all of the affordability problem by:

- expanding Medicaid coverage to 185 percent of poverty to cover almost 52 percent of children; and
- requiring all private insurers to cover immunizations.

We estimate significant savings from this targeted approach. If the government were to purchase vaccine for all children, we estimate the cost to be about $695 million per year. If instead Medicaid eligiblity were expanded to 185 percent of poverty, we estimate the cost to the government for vaccine products to be about $240 million, or a savings of $455 million.

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

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

Recommendation:

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

Rationale:

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

Issue 7: Improved Access and Outreach

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

- lack of education about the benefits of childhood immunization
- missed opportunities for vaccine delivery due to the failure to sufficiently link immunization services with other private and public sector (e.g., private physicians, the WIC program, unemployment benefits) interactions with persons who are not immunized

- inadequate tracking of vaccine delivery and the failure to fully fund methods of providing immunization services to underserved populations (e.g., public health clinics, outreach programs)

- cultural misconceptions regarding vaccines, and hypersensitivity to perceived vaccine risks

Recommendation:

Require a multi-pronged approach to include:

- easier and increased access to public health clinics and outreach programs

- education programs to eliminate the misconceptions about immunization and ensure that information about the need for and methods of obtaining vaccines is widely disseminated

- coordination of Federal, state and local immunization programs to ensure that no opportunity to immunize a child is missed

- establish a national immunization tracking and surveillance registry at CDC to collect and analyze data on childhood immunizations

Issue 8: Restoration of the Vaccine Injury Compensation Fund

The affordability and the long-term price stability of vaccines are adversely affected by the expiration of the Vaccine Injury Compensation Fund.

Recommendation:

Without the protection of the Vaccine Injury Compensation Fund, the long-term price stability of vaccines cannot be guaranteed because manufacturers will need to provide for the uncertainty of enormous legal awards. Likewise, physicians will need to additional malpractice protection. The fund should be restored immediately and the newer vaccines (HiB for bacterial meningitis, and HBV for hepatitis B) should be included.

STEPS TO IMPLEMENT THE APPORTIONED DISTRIBUTION SYSTEM

1. The CDC or other federal entity would solicit from and award bids to manufacturers to provide vaccines products in volumes sufficient to immunize all Medicaid and other public sector patients. In the case of multiple bidders, multiple contracts would be awarded on an "apportionment" basis, e.g. 40% to the lowest bidder, 30% to second lowest and 30% to high bidder.

2. States that already have their own distribution system would be allowed to continue it so long as their systems could meet the terms of the CDC apportioned bid.

3. States without their own distribution systems would be required to develop their own system or contract with a private distributor to provide a system to distribute vaccines to physicians for Medicaid patients and to public clinics. Such as system would ensure that:

- products would be distributed to public clinics and Medicaid physicians in accordance with the apportionment in the federal contract;

- physicians receive adequate supplies of vaccine to immunize all their Medicaid patients;

- free vaccine products are supplied to physicians solely for their Medicaid patients; and

- data regarding public clinic and Medicaid utilization is transmitted to the distributor so that products can be replaced as needed.

4. Manufacturers would provide a one-month initial inventory of goods based on the CDC contract for distribution to public clinics and physicians for Medicaid patients.

5. Physicians would immunize Medicaid patients and file Medicaid claims for administration and office fees; claims would capture appropriate information to allow replacement.

6. The Medicaid agency or its claims processor would report monthly to the distributor on the vaccines used per physician with a requisition to purchase more vaccine; public clinics would make a similar monthly report.

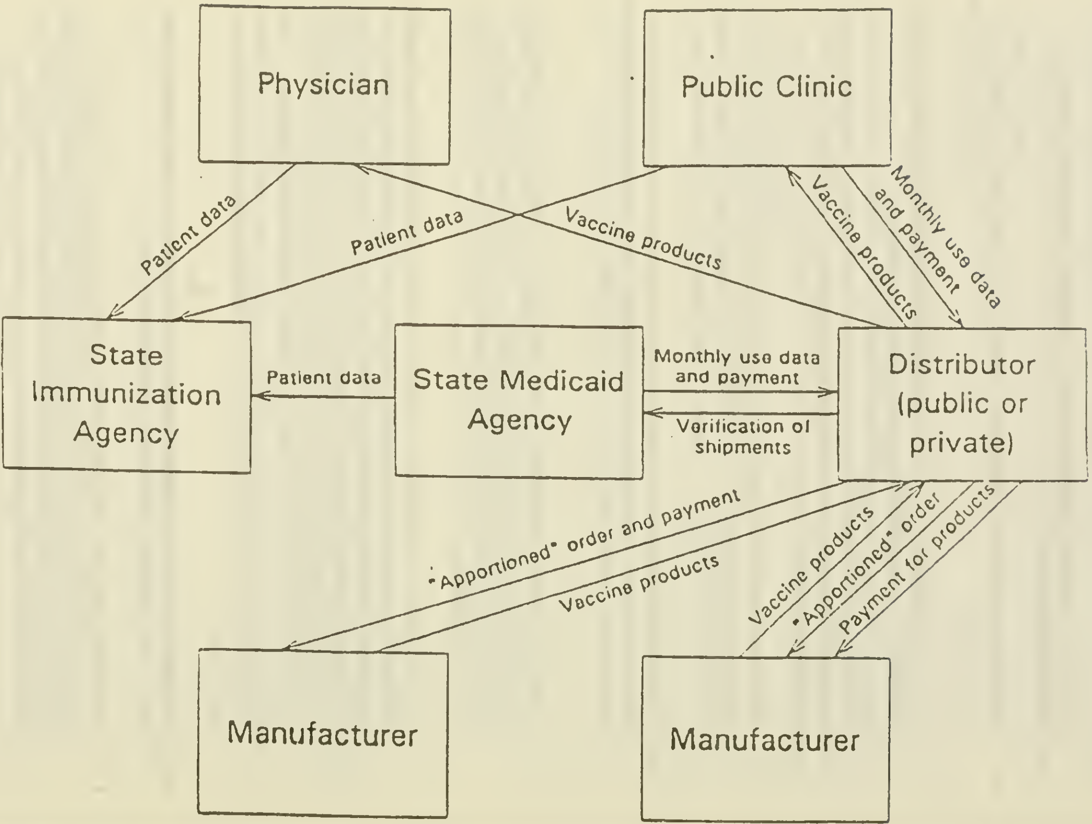
7. Based on the information provided by the state, the distributor would order replacement products from the appropriate manufacturers (ensuring the apportionment described above) and manufacturers would ship the vaccine to the distributor.

8. The distributor would replace the vaccine used by clinics and physicians for Medicaid patients at least monthly, although the distributor would have to be able to provide additional vaccine to clinics and physicians who run out of vaccine between monthly shipments; alternatively, if the state agencies captured product specific data, they could report utilization data to both the manufacturer and the distributor to enhance distribution efficiency.

9. Manufacturers would ship vaccine in the "apportioned" amount to the distributor.

10. The appropriate state agencies would pay the distributor the contract price for vaccine products purchased from manufacturers.

11. To enable states to track immunization, physicians would be required to report to the state immunization agency patient-specific immunization data for private patients; Medicaid and public clinics would be required to report the same data for their patients.



Physician
Public Clinic
Patient data
Patient data
Vaccine products
Vaccine products
Monthly use data and payment
State Immunization Agency
Patient data
State Medicaid Agency
Monthly use data and payment
Verification of shipments
Distributor (public or private)
"Apportioned" order and payment
Vaccine products
Vaccine products
"Apportioned" order
Payment for products
Manufacturer
Manufacturer

The CHAIRMAN. Thank you all very much. I apologize for missing the earlier presentations, and I will review the statements at the conclusion of the hearing.

Mr. Garnier, you have given us the cost and the savings. Could you elaborate on that for us in submitting further information and analysis in terms of the comparison?

Mr. GARNIER. Yes, we have in fact.

The CHAIRMAN. That would be very useful and helpful.

Mr. GARNIER. Yes, we will do that.

The CHAIRMAN. As I understand, Dr. Garnier, your company has considerable experience internationally, does it not, and therefore has operated in markets where the government is the sole purchaser? Is that true?

Mr. GARNIER. Yes.

The CHAIRMAN. And are there such markets in which you compete, and if so, is it safe to assume that the company is still able to make a profit in those areas?

Mr. GARNIER. The company's profits, of course, are dependent on a number of successes in various markets. We operate in all different markets, some where we negotiate vaccine prices with the government, and some where we do not.

The vaccine business is not a business that can be earmarked in every country in terms of profitability, because it has a huge fixed cost. The cost of manufacturing and research and development is a fixed cost, and it really doesn't vary with the volume so much of vaccines you sell; so I don't want to necessarily analyze country by country. But I think that in all cases, the solution is possible in terms of allowing the company to make a profit.

Simply stated, however, if you look at the market dynamics, in some markets, market dynamics have actually driven the cost lower, so it is of benefit to the consumers, compared to some government-controlled price countries.

The CHAIRMAN. But nonetheless, it is safe to assume at least where you are operating in different countries around the world where the government is the sole purchaser, or some combination of different negotiations, that you are able to compete with other companies, and you are able to make a profit.

Mr. GARNIER. Clearly, with the exception of our sales to UNICEF, which are sales of a product which is charity, more or less.

The CHAIRMAN. And if this legislation is enacted, and a fair price for your products is offered, do you believe your company's efforts in research and development be compromised?

Mr. GARNIER. Senator, it really depends on how those prices would be negotiated—and not just on the price level, but also on how the bidding system would function. We stress the importance of allowing multiple manufacturers to participate in a given market. We have had no assurances that this would actually occur.

Now, if there is a negotiation that allows predictability——

The CHAIRMAN. I think that is a constructive suggestion to encourage multiple manufacturers, but I think we may need to do more than this. But go ahead, please.

Mr. GARNIER. So if you combine apportionment with reasonable pricing, clearly, there is a probability of ensuring a sufficient

stream of profits to the company. However, I want to stress a remark that one of my colleagues made about biotechnology companies. I happen to sit on the U.S. board of biotech companies, and I can tell you that for them, it is a very difficult task to come in, not having a basis of revenue to draw from, and enter a new market under this set of conditions. That is why there are different situations for different players.

But looking from the outside in, I would confirm what you said, Senator—if the implementation of the pricing negotiation and the guarantee of multiple participants in each market are granted, that will go a long way to facilitate this.

The CHAIRMAN. In your written testimony, you caution us against the individual manufacturer contract—as I understand it, the free replacement or consignment approach that has been proposed. Could you State your concerns about that?

Mr. GARNIER. We feel that the distribution of vaccine is an easy issue to resolve in terms of making free vaccine available to pediatricians. We don't need universal purchase to make that happen. There are several formulas which are possible. We just want to warn against the fact that if States would enter into negotiations with one sole manufacturer under this distribution system, it would create a monopolistic situation, and we are opposed to that. There is already an existing network of distribution in this country which is very effective, and instead of reproducing the same network over and over again in order to be able to compete—and therefore, incidentally, later on passing on those costs to the public—we feel that there are better solutions.

The CHAIRMAN. Thank you very much. I'll submit my other questions.

Mr. WAXMAN. Mr. Greenwood.

Mr. GREENWOOD. Thank you, Mr. Chairman.

I would address my question to any or all of the panelists who can respond. Earlier, I asked Dr. David Smith, representing the Association of State and Territorial Health Officers why we can get kids immunized in time for school, but not when they are 2, which is when they ought to be immunized. Part of Dr. Smith's response was that a contributing factor is the inadequate supply of the vaccines. I wonder if any of you heard that portion of his response and if you have any comment to make in that regard.

Mr. WILLIAMS. I think I addressed that in my testimony. Each year, the Centers for Disease Control publishes information on the amount of vaccine that is put into the distribution system. Each year over the last five or 6 years, that amount has averaged about 110 percent of the vaccine necessary to immunize every child on time up to the age of 5, with the exception of hepatitis B, which is a new vaccine and on the upswing in terms of utilization.

So we really see no supply problem for vaccines in this country. And we are not at capacity. If more vaccine were needed, we would be in a position to provide it.

Mr. GREENWOOD. Does anyone have a different comment?

Dr. SALDARINI. No. I would just confirm what David is saying, and that is what orders are placed on us, the vaccines are delivered from those of us who have contracts with the CDC, and there has never been a supply issue.

Mr. GREENWOOD. Let me move on to another point——

Dr. DOUGLAS. I'd like to add to that point. We have traditionally sold about 6 million doses of MMR in the United States to vaccinate 4 million children once before the second dose recommendation. There has always been plenty of vaccine.

Mr. GREENWOOD. OK. In her testimony, Secretary Shalala stated that "universal purchase, by assuring a stable price for vaccines, will stimulate rather than inhibit competition." The Secretary stated that, and I am quoting here, "some manufacturers actually could return to the vaccine market because of the stability and reliability inherent in the President's plan."

I'd like your comments on that. Do you think this is a likely outcome of this proposal before us?

Dr. SALDARINI. I suppose I would ask if the Secretary has any companies that she has talked to that have expressed a willingness to come back into the business under that type of scenario. I think that prospect would be a very difficult one to entertain.

Mr. GREENWOOD. So you would contest that part of her testimony?

Dr. SALDARINI. I think "contest" is perhaps too strong a word, but I'd certainly be willing to debate the issue with her. I'm just not entirely sure. I think it depends a lot on the circumstances of the individual companies—not my company.

Dr. DOUGLAS. Can I add to that?

Mr. GREENWOOD. Sure.

Dr. DOUGLAS. We do not see Federal Government purchase as creating a stable environment to induce the long-term investment in research and development and in manufacturing. It takes 10 to 15 years to make a new vaccine, and one tries to predict what the playing field is going to look like in the future when one makes investments today.

We have seen, for example, reductions in other entitlement programs by the government; we saw a reduction in the NIH budget this year for R and D, or at least a very low increase. And these kinds of things give us great pause for concern. We would rather deal with an open marketplace, even if that marketplace included managed competition, etc., where we have a better prediction of what the future will bring.

Mr. GREENWOOD. There has been some discussion today with regard to the increasing cost of immunizations over the past 10 years. I think the implication has been that the increased cost has been the result of profit-taking. Can any or all of you comment as to the costs which have been built into the increase over time?

Dr. SALDARINI. I tried in my comments earlier to indicate that. The cost of vaccines for sure has gone up and on existing products, which has been an issue that has often come up in committee hearings or in any kind of dialogue where I have been involved, or with other manufacturers. What I am trying to say is that those dollars were required in order to allow the industry, certainly my company, to begin the investment process required both in research and development and new facilities construction, in order for us to start making products that we felt biotechnology, the new technology, could actually help us create.

And in fact, as I have tried to point out, the fruits of five to 10 years' worth of labor have now begin to be borne in the form of a new vaccine for haemophilus, a new vaccine for pertussis, and a new combination product that is pivotal. And that investment, from my company's standpoint, has been in excess of $300 million, which is a substantial amount of money and which, if we had not had an open marketplace to deliberate on, we might not have made those decisions.

Mr. GARNIER. May I comment on this question, too?

Mr. WAXMAN. If I might just interrupt, because we are being summoned to the House floor for a vote, and Mr. Greenwood's time has expired, and I want to pursue this issue as well. So perhaps we can get some of the answers you want to give to some of the questions that I am going to ask that are related to it.

As I hear what all four of you are saying, you like the idea of a vaccine program, you like almost everything in this administration's bill because it will reach more kids with immunizations, but you don't like the idea of the government buying all the vaccines from you because you are afraid you are going to get less money. Is that an accurate statement?

Dr. SALDARINI. It's not entirely accurate in the way you put it. We are going to have less flexibility, I think, we feel, in terms of making decisions about research, research projects, vaccine projects and so forth.

Mr. WAXMAN. Government isn't going to tell you what to do in terms of your budgets on research. Government is simply going to say: You are selling a vaccine. We want to purchase it so everybody in this country will have it available to them, and we're going to negotiate the price and pay you that price.

Dr. SALDARINI. One of our concerns about the government taking over this role is that while this may be a very strong issue this year—and most assuredly, it deserves to be a strong issue—in next year's budget, we are already faced with a budget deficit, we are already faced with entitlements that are being cut in 1993 to Medicaid. This is part of President Clinton's plan, as I have understood it, to cut back on certain entitlements associated with Medicare and Medicaid.

We are concerned that, as Dr. Douglas has indicated, we spend 10 to 15 years looking out, and if the government funding is not reliable in years to come—and it well could be that our flexibility is limited, and you may be losing an opportunity to introduce valuable new products to the American health community.

Mr. WAXMAN. I hear what you are saying, but I want to express some skepticism, because what I hear you saying is that you are worried that you won't be able to continue a program where you sell vaccines to the public for a lower price than what you sell to the private payers of vaccines, and what you are able to sell to the private payers is at a higher rate, and if you have to use the same price, you are going to reduce your revenues, and therefore, if you reduce your revenues as you look down the road, you won't have some of those revenues to use for other purposes.

But the reason I'm skeptical is that I have been around for a while, and I recall in 1986 your company, Dr. Saldarini, a representative testifying before my subcommittee saying the only rea-

son there were increases in the price of the vaccine was because of the liability situation.

Dr. SALDARINI. Well, to be sure, liability was a part of it, Congressman——

Mr. WAXMAN. No, not a part of it. The statement was due entirely to the liability claims situation. The increase in DTP vaccine was taking place in 1986, and your president said that the price of vaccine included $8 a dose for liability reserve. And then we pass a vaccine compensation program, but the price of vaccine was never reduced, and during this whole time, there has never been another liability problem. What happened to that $8 a dose that went to liability cost?

Dr. SALDARINI. The $8 a dose—as the Vaccine Injury Compensation Act took effect over time, that price has dropped. And the price of the product in those days was about $11.40, and today it is $5.41, so as we have seen a reduced liability exposure, which the National Vaccine Injury Compensation Act has helped us——

Mr. WAXMAN. Have you dropped your price by $8, which was the cost for the liability?

Dr. SALDARINI. Absolutely, absolutely.

Mr. WAXMAN. It is your testimony that the price of your vaccine has dropped $8 after the Vaccine——

Dr. SALDARINI. No, not $8. The price of my vaccines has dropped from $11.40 in 1986 to $5.40 in 1992. So it is not an $8 drop, but it is a significant drop, and it reflects our experience with the National Vaccine Injury Compensation Act.

Mr. WAXMAN. The compensation program is one that I am certainly proud of; I think it has worked well. It held down the costs you were incurring for liability expenditures, yet I haven't seen the kind of recouping for the public of the lower prices.

Now, what are your proposed price increases for this next year?

Dr. SALDARINI. Our price increases for 1993 are frozen, and our price increases for 1994 are within the framework of the Consumer Price Index, and that's on a product-by-product basis.

Mr. WAXMAN. So if you froze your prices and had the government purchase them at that price, you know what your incomes will be for the next several years, and you could then make your plans accordingly.

Dr. SALDARINI. I understand where you are coming from, Congressman, but I am saying to you that from our perspective, if the government rather than the marketplace becomes the arbiter of our activities in R and D, in manufacturing and so forth, I think over time, in our opinion, the quality of the programs will suffer, and I think that will have a damaging effect on our ability to bring vaccines further forward.

Mr. WAXMAN. It's certainly something we have to be concerned about, but then we look at so many other countries where they have a national program to immunize all their kids, the government purchases the vaccines, they pay you a set amount—as I understand Mr. Garnier's testimony, the companies still make a profit. And if we are paying higher prices for vaccines in this country, the American public wants to know why and what in fact we're getting out of it. That's the question that I think we have to look at.

Thank you.

The CHAIRMAN. Thank you very much.

I just have one final question. Dr. Williams, in your testimony on page 3, you say, "If vaccine cost is a major barrier at 2, why is it no longer a barrier at age 5?"

What is the difference in cost for school entry vaccination of an unimmunized child compared to a child who is fully immunized by the age of 2?

Mr. WILLIAMS. There is no difference in the price of a vaccine whether you are selling it for someone who is going to be 2 months of age or 5 months of age; the cost of the vaccine is going to be the same.

The CHAIRMAN. Then this refers not to what the total costs are for a 2-year-old and a 5-year-old; you're just talking about——

Mr. WILLIAMS. What I am referring to there is that it has been held up that cost is a major barrier, and that children are not being immunized at various ages because they cannot afford vaccine; and it has been held up primarily age the age of 2.

Well, my question to you is what happens between age 2 and age 5? When it is mandatory for them to become vaccinated to enter school, those children find a way to pay for vaccine. So that the systems of today are providing the vaccines at today's cost that allow those children to get into school. That's the point we're making.

The CHAIRMAN. Well, still, obviously, the costs are a lot more if you have a child immunized the way they should be at the age of 2, isn't that true, than the amount that would be necessary at the age of 5?

Mr. WILLIAMS. They will be slightly less, but the amounts are still, we think, in line with the overall immunization cost.

I think it is a point very definitely worthy of making.

The CHAIRMAN. Senator Riegle.

Senator RIEGLE. Thank you.

Gentlemen, in Canada, as I understand it, the country contracts with vaccine manufacturers, negotiating to purchase all of the vaccines. You are familiar with that, I'm sure. They have an immunization rate for one-year-olds of 85 percent, while ours is at about 48 percent; so they are obviously getting that job done better than we are. But I am told that the cost to fully immunize a child in Canada is about half what it is in the United States. Is that generally the case? What price do you sell vaccines to Canada for?

Mr. WILLIAMS. I think in Canada, it isn't 50 percent, but it's much closer to that. They have a different liability——

Senator RIEGLE. Fifty percent in terms of the cost?

Mr. WILLIAMS. They have a liability system in Canada that is far different than the liability system in this country. I think the point that has to be made on Canada is not so much a point of cost, but a point of outreach and infrastructure. This is a country that has one of the best outreach programs and one of the best infrastructures in the world.

Senator RIEGLE. We don't disagree on that, but let me stay on the cost issue, because I really resent you moving off that point when that's the point I am raising with you. So let me just stay on the cost issue.

I want to know the difference in cost—and I'd like an answer from each of you—between what you sell those vaccines for in Canada versus what you sell them for in the United States. Do you sell them to Canada for less than you sell them here in the United States?

Mr. WILLIAMS. There is a difference——

Senator RIEGLE. There is a difference? How big a difference?

Mr. WILLIAMS. We'd be pleased to provide that information.

Senator RIEGLE. You don't know that number?

Mr. WILLIAMS. I don't have it with me.

Senator RIEGLE. Do you have any idea?

Mr. WILLIAMS. I think it is in the 15 to 20 percent range, and I'll be pleased to provide that to you.

Senator RIEGLE. Does anybody else here have any information?

Dr. SALDARINI. Yes. The vaccines that I sell in Canada are equivalently priced——

Senator RIEGLE. What does that mean?

Dr. SALDARINI. "Equivalent" meaning that sometimes, exchange rates might change momentarily——

Senator RIEGLE. But other than that, dollar for dollar, it is the same?

Dr. SALDARINI. The prices are essentially equivalent; that's correct.

Senator RIEGLE. Would that be true of your company, Mr. Garnier?

Mr. GARNIER. In our case, I want to stress that negotiations with governments on vaccine price are not the most rational and logical approaches to pricing products, and therefore, when we negotiate with different countries, we arrive at different prices.

For instance, the marketplace, which really determined the price in the U.S., is actually benefiting the consumers as far as Engerix-B, the hepatitis B vaccine, is concerned. Our price in the U.S. is below the price in the U.K., where we have a negotiated agreement with the government; it is below the price in Spain, and it is below the price in Italy. It happens to be above the price in Canada by about 35 percent.

So I think that these comparisons between countries are very difficult to take at face value.

Senator RIEGLE. Well, that may be. That's what I am trying to get to.

Mr. WILLIAMS. One of the problems——

Senator RIEGLE. If you could just wait a minute, I am questioning this gentleman; I might come back to you, but you've already had a chance to speak, and I would like to hear from the others.

With respect to the price you charge in Canada, are you selling below cost in Canada, or do you make a profit on that sale in Canada?

Mr. GARNIER. We are making a profit in Canada. But again, you can't look at every country as an incremental stream of revenue. The fixed costs have to be paid by somebody. Therefore, it is a little difficult to simplify the profit discussion to whether we are covering our cost of manufacturing. Of course, we are covering our cost of manufacturing.

Senator RIEGLE. I didn't ask you if you were covering your cost of manufacturing. I asked you if you were making a profit. And I assume in scoring your profit is the cost of manufacturing, it is the cost of selling—it is all costs, isn't it? You are still making money on the prices you charge in Canada. I think that's what you just said. Is that right or wrong?

Mr. GARNIER. Yes. I'm not going to try to tell you that we aren't making a money by selling in Canada. Yes, we are, but the way we measure our profitability, again——

Senator RIEGLE. But you sell there for——

Mr. GARNIER. —if I may, is by consolidating all our revenues and comparing them to the fixed costs we have to pay every year for research and the rest.

Senator RIEGLE. Now, do you manufacture some of those vaccines you sell in Canada here in the United States?

Mr. GARNIER. No; as a matter of fact, the vaccines sold in Canada are manufactured partially in Belgium.

Senator RIEGLE. Partially in Belgium. None are manufactured in the United States?

Mr. GARNIER. No.

Senator RIEGLE. So you have to bring them from Belgium here, and also to Canada; is that right?

Mr. GARNIER. Right, that's correct.

Senator RIEGLE. OK. But you bring them to Canada, and you sell them at a much lower price, even though you make a profit; and you sell them at a higher price in the United States, and I assume you make even a bigger profit.

Mr. GARNIER. No—actually, yes, you are correct, but why do we limit our comparison to the United States and Canada? Why don't we compare to the U.K. and Spain and Italy?

Senator RIEGLE. Well, I am happy to do that. The reason that I am picking that is because we live right beside Canada. I think the travel costs are about the same. I think the difference is that they have a different strategy for buying the vaccines. And we are talking here about using a strategy similar to theirs—in other words, buying the vaccines as a government exercise so we can do exactly what they have done. They have gotten a better price out of you.

What can I do, short of doing that, to get the same price out of you that you give Canada?

Mr. GARNIER. I think that it is fair to say that in the case of hepatitis B, we introduced our product 3 years ago, and the price has declined substantially since, so every year we have had to make more favorable concessions to the marketplace. This is market dynamics.

Senator RIEGLE. Yes, but you are dodging my question, with all due respect. The question is if today you are selling that vaccine in Canada at a lower figure, what do I have to do, or what does this government have to do, to get at least as good a price out of you as Canada is getting? I mean, why should we concede to you a higher profit when the country living right next door has figured out how to get you to sell them exactly the same vaccine at a lower price? Why should we spend money we don't need to spend that they aren't spending, so you can have more profit? Is that fair?

Mr. GARNIER. No, but let me try to address the question. The reason we are uncomfortable having a discussion like this obviously is because the criteria upon which governments negotiate with us the price of our vaccines vary enormously, so it is very difficult to answer your question because we are not comfortable with the process that is being used in Canada and the U.K. and so forth——

Senator RIEGLE. Let me just ask you this. What am I missing? If a vaccine is made in Belgium, and it is shipped over to Canada, to Windsor, or right across the Detroit River into Detroit, MI, how is the manufacturing cost any different—or how is any cost any different? The only thing that I see is different is the fact that price is different; they're getting a better price, and we're getting a worse price.

Mr. GARNIER. But you have to relate it to the cost of living of the country and the exchange rate. When we started to sell our vaccine of Engerix-B in Canada, in fact, the price translation between the U.S. and Canada was essentially the same.

Our policy is to try to sell the same product at the same price in all the Western countries. And what happened over three or 4 years is the exchange rate has an enormous impact, and I can show you variations of 30 to 40 percent solely attributable to foreign exchange losses. So we are not trying to get the products sold at different prices in different countries. By the way, there is nothing unusual about this for vaccines or pharmaceuticals. All products sold in all countries go through the same process.

Senator RIEGLE. Let me just finish in the time that I have. The data that I have show that Canada is much more effective in holding down the cost and the price for these vaccines by using their national buying mechanism than we are here. That's just what the facts show. It isn't just with your company; it is with all companies. The average cost of vaccinations up there is far less because they have used the strength of their buying consortium to get a better price out of you.

Now, I know you'd rather not deal with that. I'm sure you wish that weren't so, and you like the system here. But let's at least be honest about what is going on. And the fact is, you are still able to sell at a profit in Canada. You haven't stopped selling up there. You are selling up there because you are making money. You aren't making as much money as you are making here, so I can see why you'd just as soon not have us change the system here, because it is more profitable for you now the way it is here at the present time. But from a public interest point of view, I hope you can understand why, if the Canadians have figured out how to get more vaccine for less money, or the same amount of vaccine for far less money, and to vaccinate their people less expensively, we ought to be smart enough to find a method and a means here to do exactly the same thing, because frankly, we don't have the extra money to give you anymore.

Thank you.

The CHAIRMAN. Senator Kassebaum.

Senator KASSEBAUM. Thank you, Mr. Chairman.

I apologize for coming late to this discussion, so I guess I would only add a bit, just following on Senator Riegle's questioning.

This is the question you hear most as you visit around your State. You hear it from pharmacists, you hear it from constituents: Why do drugs cost less, for instance, in Canada or some other country abroad than here? I think that we all have to feel comfortable with an answer to that.

I think we can also ask, however, how many blockbuster drugs have been developed in Canada? Does one think of Canada as a place where research has been done necessarily to the degree that it has been done here?

I think the other side of that coin is the ability to have the innovation and research that is important in the development of drugs. Now, whether that explains the difference in costs here and abroad, I am not sure, but I think that we are going to have to be able to answer this question to the satisfaction at least of those who are really trying hard to understand what factors go into drug pricing. Maybe there is research that is being done in Canada and would continue being done there; whether that even weighs into that price differential or not, I'm not sure. Does anybody have an answer?

Mr. WILLIAMS. I might make a couple of points, Senator. I think that one of the ways we look at our measles-mumps-rubella vaccine is that we sell it almost exclusively in the developed world. There is very little either demand for it or want for it in the underdeveloped world. Our average price outside the United States is slightly more than our average price in the United States.

Now, there are countries where we sell it at a lower price than we do in the United States. There are countries, like Germany, where we sell it considerably higher than we do in the United States. A lot of that has to do with variations in exchange rates that have occurred since the introduction of the product, when a price was fixed, and in many countries you cannot then change the price. And many of these complexities have been mentioned previously in the panel. But we look at the total return on non-U.S. sales of vaccine, and therefore we can accept these variations as they occur naturally and you can't do very much about.

Mr. GARNIER. If I may add also, the consequence if we were to take one of the lowest, or in fact, the lowest-priced country for Engerix-B or hepatitis vaccine, and if we were to align ourselves with that price, we would have a considerable loss for the company. This is the idea of having to cover your fixed costs. You cannot look at one market and say, "The price is low here, so how come we don't get it?" At some point, the fixed costs that we are incurring, most of it for research, have to be covered by our total worldwide revenues. In the case of SmithKline Beecham and Engerix-B, as I said before, the U.S. happens to be a very reasonably priced market if you compare it to Spain, Italy, the U.K., Germany, Japan; all those markets have a higher price.

So it is a little unfair to pick on the lowest country where we do get incremental profits from that country and say, "Why don't you align your price to the lowest country and start to live like this?" We would not be able to reinvest in research as we currently do. So one has to be careful in how we look at the worldwide picture for the pricing of our products.

Senator KASSEBAUM. Thank you.

The CHAIRMAN. The only point is why the Americans have to be the ones to pick up the tab. What I am hearing from you is, "Look, we may be selling this at cheaper prices, but unless we can get real profits out of some countries, we aren't going to be able to afford this kind of work." I think the frustration that we are hearing from parents all over this country is that they have been paying more, and they want to find out why that is the case. And I think the burden is really on the companies to demonstrate their prices are fair—we'll put the comparisons in the record. I hope you'll provide for us a detailed account, country-by-country, where you are selling each of the products, which we will make part of the record. And we'll put in the record this same information as well for the other companies that are producing other essential vaccines for children. I think it is important to have that as a matter of public information.

We want to thank you all for being here. You might wonder sometimes whether you are welcome, but I think this is an enormously important issue, and there are strong views. Just speaking personally, I am a strong supporter of the administration's proposal, but as one whose family has probably benefited more from the innovation and the creativity and the work that has been done by many of the pharmaceutical companies in a number of different situations, I think I can speak for many Americans. We are obviously very grateful for the progress that has been made by medical research.

We are in this together, in the same boat, quite frankly, because we've got this issue of underimmunized children. We've got health insurance reform coming along, and we want to be able to work with you on that as well to insure access to preventive health care. We are going to have some differences as we look for solutions, but we are going to have to try to work through those. But hopefully, you have some sense of the concern that millions of families have regarding immunizations and the difficulty they face in obtaining them for their children. Resolving the public policy questions is of great importance and urgency. We are very interested in the suggestions that have been made, and we'll go over those in greater detail.

Senator Riegle.

Senator RIEGLE. Senator Kennedy, if I may just add one final comment myself, and that is that I appreciate the forward movement of the science in vaccines and in medicines, generally, and I would not want that to be misunderstood. I want to see us develop a system here that provides for a fair rate of return and for the money that is needed for continued research and development.

I came out of the private sector before coming here, and I think I understand how it works in that respect, so I don't want anything that I have said to be contrary to that.

By the same token—and let me make it just as plain as I know how to put the words, because we are going to go through health care reform, and you can either help us or you can work against us, and I hope you will help us and that we'll work together—we are not going to be able to tolerate these differentials such as they exist now. We cannot have a situation where these bulk buying programs in an adjacent country like Canada, a developed country,

where those drugs are available at a much lower cost than they are here in the United States. And there aren't going to be any exceptions made for anybody, so you might as well just figure that out and decide in that respect to become team players with this country.

It is a very sensitive issue. We're talking about getting children immunized, and we cannot afford to pay premium expenses for that that aren't justified and that aren't being paid in Canada or in a lot of other countries. The fact that you've got these other pricing anomalies in other countries, so be it. We don't run the affairs in those countries. But we are going to have to change the system here, and you should be helping us. And you can make it more difficult, or we can figure out a way to work together. I'd like to work together. But if anybody is thinking that maintaining the status quo and those kinds of differentials is working together, then that isn't going to work.

Dr. SALDARINI. Senator, I appreciate your comments, and I certainly do want to work with the committee on the initiatives of the Health Care Reform Task Force. I would just make one point to your comment, and that is we are an American company; we are manufacturing here, and we are selling here, and we sell from here abroad.

Thank you.

Senator RIEGLE. We want you to be able to continue to do that, and we want the best price here in the United States. There are no transportation costs, no transportation premiums of anything made here that is kept here. It costs more to send things out of here than it does to keep them and consume them here.

The CHAIRMAN. I would say that we appreciate the companies that have stayed here. Many have moved abroad, but that's an issue for another day. In any event, I certainly appreciate those that have stayed in the vaccine production business.

And as a personal note, let me just say that my sense is that about half of the major pharmaceutical companies are really doing a bang-up job on research, and the other half are just drawing down on this perception but aren't doing the kind of creative work, and are taking a ride on the increase in the price of pharmaceuticals. That is my view; I might be wrong, but I don't believe that I am. I think most of us who have been dealing with this issue over some period of time on both sides could name them.

And one of the problems that we're going to have is that the industry will need to participate in the solutions. The good companies that are really on the cutting edge, doing the job—really out there in terms of investing and doing the kinds of things that all of us expect and hope for—they have got to help the Congress in terms of the other groups that are just along for the ride, because they are dragging them down. It is going to be very tough in terms of legislating to try to achieve the cooperation of all involved. But that isn't a phenomenon unique to the pharmaceutical industry—it's true about politicians as well, and others. So that is the part of the frustration—and we won't get into it today deeply—but we want to work for the best outcome, and we won't tolerate those who aren't really committed to achieving the goal of immunizing all children.

We'll try and work with you, and I hope you will join with us to help our Nation reach this important objective.

Thank you very much.

The CHAIRMAN. Our next panel includes Dr. Ed Marcuse, president of the Washington Chapter of the American Academy of Pediatrics, and director of ambulatory services at Children's Hospital and Medical Center, at the University of Washington, in Seattle; and Dr. Richard Duma, executive director of the National Foundation for Infectious Diseases in Bethesda, MD.

I want to thank both of you. We have your written statements, and they will be made part of the record in their entirety, and we hope you can comply with the time limitations.

Dr. Marcuse.

STATEMENTS OF DR. ED MARCUSE, PRESIDENT, WASHINGTON CHAPTER, AMERICAN ACADEMY OF PEDIATRICS, AND DIRECTOR, AMBULATORY CARE SERVICES, CHILDREN'S HOSPITAL AND MEDICAL CENTER, UNIVERSITY OF WASHINGTON, SEATTLE, WA; AND DR. RICHARD J. DUMA, EXECUTIVE DIRECTOR, NATIONAL FOUNDATION FOR INFECTIOUS DISEASES, BETHESDA, MD

Dr. MARCUSE. Thank you.

My name is Ed Marcuse. I am a pediatrician at Seattle's Children's Hospital, and I am here today representing the American Academy of Pediatrics.

Senator, I think everyone's appetite for rhetoric has been sated, and I have handed in some written remarks, and I will just make a few points.

The Academy enthusiastically supports the Comprehensive Child Immunization Act of 1993. We are pleased for the priority on immunization. We see it as the first step toward reaching the goal of assuring basic health care for all of America's children.

Simply put, our Nation's immunization system for infants today is like a car with four flat tires. One flat is the major out-of-pocket expenses for immunization. A second flat is that the immunization services are not readily accessible. A third is that the immunization schedule is complex, and American families move. And the fourth is the immunization simply has not been a high priority.

As you have heard, we can now protect children against nine diseases. This requires 15 doses of five vaccines, administered in the first 2 years of life.

A car with four flat tires is not going to get very far down the road unless we change all four tires at the same time. We have to increase the demand, we have to develop a tracking system, we have to make immunization accessible to all children, and we've got to remove all the financial barriers to vaccines. Fixing only one or two of these is going to leave us with a car with one flat tire, and we are still not going to be able to make the trip we need to.

In Washington State in about 1989, we knew that 46 percent of our 2-year-olds were getting immunized on time, and that's just with the old vaccines—DTP, MMR and OPV. In the decade before that, prices had gone up 10 to 12 times in the public sector, and there had been a shift of patients from the private sector into our health departments, which were ill-equipped to handle more pa-

tients. We had some pertussis outbreaks. It was the beginning of the measles resurgence in the country.

We looked around the country to figure out what we could do. We looked to New England, we looked to Massachusetts, and we saw that they had universal purchase programs, and pediatricians and family practitioners administering vaccines in their offices. I personally did a survey in Washington State, and 93 percent of our pediatricians said they had administered health department-purchased vaccines in their offices. Pediatricians really do believe in comprehensive care and really do want to immunize kids.

So, with bipartisan support, our legislature allocated the funds to buy the vaccine. The first year, it was bumpy. There are 10 requirements or so that pediatricians and other primary care docs have to fulfill in order to use State vaccine. They have to limit administration fees to $10; they have to give the vaccine without charge if the family can't afford it and post a sign in the waiting room that says that; they have to develop a tracking and recall system and do several other things.

The first year was bumpy. There were delivery problems. Health departments ran out of vaccine. There were misunderstandings and disputes. But by the end of the year, we had solved that, and the system now works. Not every doctor in the State participates, but overall, last year we gave 835,000 doses of publicly-purchased vaccine, and 70 percent of that is administered in private offices by physicians. It is working.

We believe that immunization is a shared responsibility between the community and the parents. Protecting the public health, controlling communicable disease, is a fundamental responsibility of government. Our Nation's measles resurgence was due to failure to immunize. Forty-three percent of the measles cases occurred among unimmunized preschoolers, and the cost for that was borne by the entire Nation. No Nation in the world has achieved satisfactory immunization levels vaccinating only disadvantaged children.

We have a two-class immunization system in the United States today, and the middle class who can afford vaccine is paying for it three times over. They are paying a higher price than the public sector price for vaccine. They are paying for the Medicaid fees through Social Security taxes, and in addition, they are paying the taxes that fund our local health departments.

We think we need to have a system that will use all providers, public and private, to get our kids immunized. Doing this just in the public sector, we can't get the job done. We can enlist all the private providers and the public providers through this legislation.

Thank you.

Sentor Riegle. Thank you very much.

[The prepared statement of Dr. Marcuse follows:]

PREPARED STATEMENT OF ED MARCUSE

My name is Ed Marcuse, M.D. I am a pediatrician at Seattle's Children's Hospital and am here today representing the America Academy of Pediatrics. I have recently completed a term appointment on the National Vaccine Advisory Committee, am a member of the Academy's Committee on Infectious Diseases ad currently serve as President of the Washington Chapter of the America Academy of Pediatrics.

The Academy enthusiastically supports "The Comprehensive Child Immunization Act of 1993." Basic health care for all American children is a goal that is long over-

due. We view the priority placed on immunizations as a important first step in reaching that goal.

From the pediatric perspective, immunizations delayed are immunizations denied. Barriers leading to such delays cross all income levels ad exist in every State. Our immunization program is falling our children because access to vaccines has been hampered by costs, by problems in service delivery, by a lack of appropriate information ad by our inability to keep track of children's immunizations. Countries which provide for universal childhood immunization delivery ad tracking do far better than our current best efforts. And as you well know, the costs of our failure to immunize our children are borne by the entire country in unnecessary medical costs, outbreak control, costs of life-long ability, and lost productivity of affected children ad their parents.

Today, we can protect infants from nine diseases: diphtheria, tetanus, whopping cough, polio, measles, mumps, rubella, hemophilus B and hepatitis B. To accomplish this requires that we administer to every infant a total of 15 doses of 5 vaccines before their second birthday. We have never had an immunization delivery system capable of doing this. As you have heard, only 40 to 60 percent of U.S. infants receive all of the 8 needed doses of DTP, OPV and MMR—vaccines recommended by 2 years of age that have been available for over 20 years. Far fewer receive the newer vaccines.

Simply put, our Nation's immunization system for children is like a car with four flat tires:

because immunization is a major out-of-pocket expense for too may,

because immunization services are not readily accessible,

because the immunization schedule is complex and America families move, and

because immunization is not a high priority for many young families.

A car with four flat tires isn't going to go very far very fast until we fix all four flats. To protect our children and really the potential savings in medical costs, we must: ensure that immunization is in fact truly accessible to all children in all areas of the United States; remove all financial barriers to this cost-effective preventive service; develop a tracking and recall system to cope with the complex schedule and our mobile population; ad, increase the demand for immunization services. I believe that the Comprehensive Child Immunization Act of 1993 is the new set of tires we need to get our country's immunization program going.

Fixing one or two or three of these problems still leaves us with one or more flat tires. We must address all four issues simultaneously.

WASHINGTON STATE EXPERIENCE

As the 1980's drew to a close it was apparent that the immunization program in Washington State had four flat tires. By 1989, we recognized we were not doing the job as the costs of vaccines skyrocketed ad new vaccines were added to the schedule. Although we had not quantitated the problem,it was our impression that the immigration of children from the private to public sector to receive immunizations that was occurring across the Nation was occurring in Washington state as well. We were aware that the number of cases of measles was increasing and we experienced outbreaks of pertussis. We knew that in New England States such as Massachusetts health departments purchased vaccine and distributed it to private physicians to administer. In planning to change our immunization program we surveyed Washington pediatricians in 1989 and learned that 93 percent would administer vaccines supplied by the health departments in their offices. Working in the spirit of a long tradition of public-private immunization partnership, in 1990 our State expanded its vaccine purchase program to cover 100 percent of children born each year. Immunization of children was a bipartisan priority for our State legislators; they appropriated funds to purchase under Federal contract (as had the New England States) all recommended vaccines for 70,000 children born in the State each year.

We traveled a very bumpy road that first year. To receive State purchased vaccines physicians have to agree to:

limit their administration fee to $10 or less

give the vaccine for free if a parent could not pay an administration fee and post a sign about this practice

have a tracking ad recall system

get a parent's signature for informed request for each dose of vaccine

report summary statistics

monitor the temperature of stored vaccine

There were misunderstandings ad disputes about these things. And there were major supply and delivery problems. Health departments filled only partial orders, ran out of some vaccines, kept physician office personnel waiting for long times to pick up supplies. But during that year our local health departments learned how to do the job. The next year it worked.

Last year (1992), Washington State purchased 835,101 doses of vaccine—70 percent of them were administered by private providers.

Not every private provider participated. Some dropped out at the start and are not yet ready to participate. Some don't want to be hassled by one or another of the State's requirements for participation. Several say they are waiting to sign on until the State buys all vaccines including hepatitis B. We estimate that today at lease 65 percent of our State's total childhood vaccine needs are now being met by this program. We do not know what proportion of the remaining 35 percent are met by private purchase of vaccines or remains unmet.

Since beginning the program we have not experienced a shift from private to public sector. In several areas practitioners tell me they match their administration fees to those of the local health department to avoid any incentive for fragmentation of care. (Pediatricians really believe in comprehensive child health care—that is the way they want to practice.)

But we have a long road left to travel. Only about 60 percent of our 2-year-olds are fully immunized. We believe the reason is we have changed only one of the four flat tires. So we have set about changing the other three. But we need help with the resources.

> Tracking ad recall: We have a coordinated effort between the State Health Department, two local health departments, health professionals, volunteers and an impressive coalition of private hospitals to develop an immunization registry.
>
> Increase access to immunization: Each of the State's 32 health districts is implementing a plan to increase the availability of immunization services. Local communities are increasing the hours of clinics, offering evening and weekend clinics, often supported by Junior League or service clubs.
>
> Increase demand for timely immunization: In several areas, including Seattle the hospitals where a baby is born have agreed to send out individualized immunization reminders to their infants—the first step in establishing a registry.

We think we have made a good start. The Comprehensive Child Immunization Act of 1993 will provide the motivation and opportunity to fully implement these initiatives and get all four flat tires on the road.

ISSUES ADDRESSED IN THE COMPREHENSIVE CHILD IMMUNIZATION ACT OF 1993

Access

Clinics, particularly in inner cities too often have policies that function as barriers to accessing immunizations. These include: no evening/weekend appointment hours usually due to staffing constraints, long waiting times both in clinic and for appointments requiring excessive time away from work for a parent. The irony is that the private sector has removed may of these barriers through extended office hours, efficient scheduling of appointments, and by making immunization available in hospitals, hospital outpatient clinics, and in community health centers—but at a much higher cost for the vaccine to the family. Current immunization plans and this bill provide funding to address these problems.

Costs of immunization

Vaccine costs to the private sector are considerably higher than the costs of those very same vaccines purchased by the public sector—1.7 times higher for DPT and MMR, 4.6 times higher for OPV. The cost to the private sector for one child's vaccines from birth to school entry is about $250 without any administration fee. (See tables.) Since immunizations are generally not covered by health insurance, the cost must be paid by parents out of pocket, causing financial hardship to many working, middle class families.

Today, in many communities, private physicians often feel obliged to offer their paying patients the option of receiving vaccines at health department clinics which have access to lower cost vaccine purchase under federal contract. Dallas County Texas has experienced a 700 percent increase in children receiving vaccines in public clinics.

Vaccine costs are also having a negative impact on this Committee's tireless efforts to improve Medicaid coverage and eligibility. While may Medicaid-eligible children now have what we call a medical home—an ongoing, comprehensive source of medical care—in areas where Medicaid reimbursement is less than the cost of these vaccines, physicians are forced to refer these children to public clinics for their im-

munizations. At best, this fragments their care, delays their immunization, and complicates record keeping for these families. At worse, these children never make the trip to their local clinic.

We have U.S. Public Health Service' immunization recommendations that advise new vaccines ad new vaccine schedules yet may public clinics cannot implement these recommendations largely due to the lack of adequate funding. This means that many children are denied a second MMR or meningitis or hepatitis B vaccines that are simply not available for children dependent on public programs for their immunizations.

Tracking system

The tracking system established by this bill will perhaps prove to be the most important part of our Nation's long term vaccine strategy. The recommended schedule of immunizations is complicated and it is changing because science and technology are making available marvelous safe and effective new vaccines.

Even if we remove the barriers of cost and access to immunization and significantly strengthen our outreach capabilities, we will not recognize our progress if we do not put in place a practical tracking system and develop a nationwide immunization registry.

The complexity of today's immunization schedule and the mobility of our population require this new tool to get the job of immunizing our children done. We need to merge the record-keeping experience of public programs, such as medicaid and Maternal and Child Health, with existing computer technology and private sector needs to create a practical system that can function in a busy clinic or office without adding significant cost. Most European countries have tracking systems that begin at birth ad are designed to assure continuing participation of the infant in a system of health care. We now have legislation that provides motivation and opportunity to develop such a system in the United States.

Immunization receives low priority

Many U.S. children live in poverty. For their parents, shelter, food, and protection from violence are all of higher priority than is preventive health care. Even for the more affluent, immunization is not always a high priority. Parents of young children lead hectic lives, juggling work, child care, shopping, meals, laundry. Immunizing their child on time often does not rank high enough to make the cut, particularly if immunization services are not readily accessible.

May parents simply do not recognize these diseases as a threat to their children—in contrast to substance abuse or environmental hazards.

We pay a high price for our immunization failures. In 1989 there were more than 16,000 cases of measles in the United States with 41 deaths. The number of measles cases rose in 1990 to more than 27,700. Forty-six percent of the cases were in unimmunized preschool children. In 1991, there were more tha 60 measles deaths nationwide. CDC has reported more than a three-fold increase in the number of cases of rubella in 1990 as compared with 1989. Recently, pertussis cases have increased 17 percent, with rates highest in children under one year of age. This bill makes immunization a high national priority and educational efforts aimed at parents and providers will raise levels of awareness.

The case for universal purchase

Protecting the public health by controlling communicable diseases is a fundamental function of any government. Immunizations of children is a responsibility shared by a child's parents and the community. No nation has achieved satisfactory immunization levels vaccinating only disadvantaged children. This bill recognizes this responsibility ad provides vaccine for all children.

Today, we have a two-class immunization system, where one class subsidizes the other for the costs of vaccine. Those who are immunized in the private sector pay for the vaccine three times over: first, they pay up to four times the price for the vaccines themselves, subsidizing the artificially low public sector price; second, through social security taxes which fund Medicaid; ad third, by paying the State and Federal taxes that fund local health departments. In essence, working families with young children, who have the least insurance coverage ad least disposable income, are subsidizing public clinics. Such a two-class immunization does not serve well children in either class. To immunize all our Nation's children on lime requires utilizing all available qualified providers—private offices, hospitals, public health departments, and community clinics. All must be utilized to provide the cost-effective preventive care to children who need it at every opportunity.

Requiring private providers to means test each patient to determine from which vial to draw the vaccine would destroy the public private partnership we need to get the job done. The cost of failure to immunize in my community are ultimately

borne by the Nation. A measles outbreak in Los Angeles or Dallas can quickly spread to Boston or Yakima. We must find a way to facilitate timely immunization of all U.S. children in every community. This requires a negotiated federal purchase price for childhood vaccine. As stated in the bill the price should:

1) ensure incentives for private sector research;
2) preserve multiple manufacturers in the marketplace; and
3) allow fair profit margins for manufacturers.

In exchange for the provision of vaccines provider charges would only reflect a reasonable administration fee.

Vaccine compensation amendments

I would be remiss if I did not briefly comment on the section of the bill that deals with vital amendments to the Vaccine Injury Compensation Program. The viability of the childhood immunization program is closely tied to the National Vaccine Injury Compensation Act.

This program is now in "limbo" due to the expiration of the excise taxes on January 1 of this year. This compensation program has stabilized vaccine prices, encouraged private physicians to continue providing immunizations, enticed new manufacturers into the marketplace, and has fairly compensated families who's child may have been unavoidably injured by vaccines. Without a immediate restoration of this vital program, vaccine prices may rise (to cover manufacturers' liability), patients may be shifted to public clinics because of physician renewed liability concerns and more parents may delay immunizing their children if no recourse for adverse reactions is available. The losers, obviously, during this period of "limbo" are our children.

Once the program is restored, then we must focus our attention on the other needed amendments also spelled out in this bill including: the addition of new vaccines; the simplification of the parent information materials; and extension for filing periods.

As the debate for national health care reform continues, we can do no less than insist that childhood immunizations be assured for all our children.

VACCINE COSTS – PUBLIC VS PRIVATE

COST TO IMMUNIZE A CHILD TO AGE TWO IN WASHINGTON STATE

COST OF A WASHINGTON CHILD'S IMMUNIZATION IN THE PUBLIC SECTOR FROM BIRTH TO AGE 2 1993

VACCINE SUPPLIED OFF FEDERAL CONTRACT

VACCINE	COST (1/93)	DOSES	MIN TOTAL	MAX TOTAL
DTP	5.99	4 MIN/3 MAX	23.96	17.97
DTaP	11.01	4TH DS ONLY	N/A	11.01
OPV	2.16	3	6.48	N/A
e-IPV	7.59	3	N/A	22.77
Haemophilus b	5.37	4	21.48	21.48
MMR	15.33	1	15.33	15.33
Hepatitis B*	10.36	3	31.08	31.08
* TEMP STATE PRICE		TOTAL	98.33	$119.64

COMPARE

COST OF A WASHINGTON CHILD'S IMMUNIZATION IN THE PRIVATE SECTOR FROM BIRTH TO AGE 2 1993

PRIVATE VENDOR SUPPLIED VACCINE

VACCINE	COST (1/93)	DOSES	MIN TOTAL	MAX TOTAL
DTP	10.04	4 MIN/3 MAX	40.16	30.12
DTaP	15.56	4TH DS ONLY	N/A	15.56
OPV	9.91	3	29.73	N/A
e-IPV	17.79	3	N/A	53.37
Haemophilus b	15.13	4	60.52	60.52
MMR	25.29	1	25.29	25.29
Hepatitis B	21.46	3	64.38	64.38
		TOTAL	220.08	$249.24

COST DIFFERENCES BETWEEN PUBLIC VS PRIVATE SUPPLIED VACCINES

1993		MIN TOTAL	MAX TOTAL
PRIVATE	$	220.08	$249.24
PUBLIC	– $	98.33	$119.64
SAVINGS USING PUBLIC VACCINES	$	121.75	$129.60

COST TO IMMUNIZE A CHILD TO AGE TWO IN WASHINGTON STATE

VACCINE COST WITH ADMINISTRATION FEE

COST OF A WASHINGTON CHILD'S IMMUNIZATION IN THE PUBLIC SECTOR FROM BIRTH TO AGE TWO 1993					
VACCINE SUPPLIED OFF FEDERAL CONTRACT					
VACCINE	COST (1/93)	ADMIN. FEE*	DOSES	MIN TOTAL	MAX TOTAL
DTP	5.99	10	MIN 4 /MAX 3	63.96	47.97
DTaP	11.01	10	4TH DS ONLY	N/A	21.01
OPV	2.16	10	3	$36.48	N/A
e-IPV	7.59	10	3	N/A	52.77
Haemophilus b	5.37	10	4	61.48	61.48
MMR	15.33	10	1	25.33	25.33
Hepatitis B #	10.36	10	3	61.08	61.08
# TEMP STATE CONTRACT			TOTAL	$248.33	$269.64

* Medicaid Fees are: $4.07 for Hlth Depts (Admin. only), as of 7/1/92.

COMPARE

COST OF A WASHINGTON CHILD'S IMMUNIZATION IN THE PRIVATE SECTOR FROM BIRTH TO AGE TWO 1993					
PRIVATE VENDOR SUPPLIED VACCINE					
VACCINE	COST (1/93)	ADMIN. FEE*	DOSES	MIN TOTAL	MAX TOTAL
DTP	10.04	10	MIN 4 /MAX 3	$80.16	60.12
DTaP	15.56	10	4TH DS ONLY	N/A	25.56
OPV	9.91	10	3	59.73	N/A
e-IPV	17.79	10	3	N/A	83.37
Haemophilus b	15.13	10	4	100.52	100.52
MMR	25.29	10	1	35.29	35.29
Hepatitis B	21.46	10	3	94.38	94.38
			TOTAL	370.08	$399.24

* $2.71 X Unit Price of Vaccine for MEDICAID/EPSDT Providers (Admin. & supplies).

COST DIFFERENCES BETWEEN PUBLIC VS PRIVATE SUPPLIED VACCINES			
1993		MIN TOTAL	MAX TOTAL
PRIVATE	$	370.08	$399.59
PUBLIC	− $	248.33	$269.64
SAVINGS USING PUBLIC VACCINES	$	121.75	$129.95

Senator Reigle. Dr. Duma, we'd like to hear from you now, please.

Dr. DUMA. Messrs. Chairmen and members of the committees, my name is Richard J. Duma. I am an infectious disease specialist and executive director of the National Foundation for Infectious Diseases, a nonprofit foundation which has as its goals education of the public and professionals about, prevention of, and support for research in infectious diseases. The Foundation commends the committee for holding these hearings to address a major health care problem, namely, appropriate immunization of all our children.

NFID has been heavily committed to promoting immunizations, not only of infants and children, but also for adults—the forgotten segment of the population in these deliberations.

At the risk of attacking "motherhood and apple pie," let me State that those of us intimately familiar with and engaged in the problems of immunizing people are very concerned that the current proposal for universal purchase of vaccines for all our children is being perceived by many as the solution to immunization problems. Public support for this may be great because it is a "freebie"—but is it really? I doubt if the public realizes what the long-term consequences might be—that it may be at the expense of more badly needed programs involving vaccine delivery and education.

The notion of universal purchase to provide free vaccine to all our children is popular among the naive—this is to say, among those who have never given a shot or chased a family of kids to get them immunized.

In this country, the major problems responsible for unsatisfactory immunization rates of infants and children, and adults as well, is not the vaccine cost—far from it. The major problems are education, attitudes, delivery, and tracking.

NFID has conducted a number of programs in which vaccines and their administration have been offered free of charge, but encountered little to no use of those vaccines unless we educated, pleaded, promoted, and virtually delivered recipients to vaccination sites.

Ladies and gentlemen, we live in a country in which we graduate thousands of high school students who, upon graduation, get married and have children. The vast majority of these young people have not learned in school what the word "vaccine" or "immunization" means, and yet they are expected to properly care for themselves and their children.

Nothing in our school systems educates students about common preventable infectious diseases. Even among the educated, we are combating apathy, indifference and complacency.

In this Sunday's Washington Post, an excellent article by staff reporter Barbara Vobejda, which I commend to your reading, concerns volunteer attempts at door-to-door home immunizations in Atlanta, in which as an incentive to become immunized, people were offered, as you have already heard, free tickets to hear Michael Jackson. The article states that, "the most daunting obstacle is not the cost of the vaccines; it is finding the children that need them, persuading parents to bring them in, and encouraging public health clinics to make the process easier." Volunteers found some

parents oblivious to the need for immunization, others too burdened to battle the public system.

Even physicians in this country lack the training, drive and motivation necessary to promote immunizations. Our medical schools do a great job in training physicians to care for the sick, but not in how to prevent diseases. We need to insist that all our medical schools emphasize preventive medicine more than they do, especially vaccines and immunization strategies.

Combined with education of the public and professionals, we desperately need to improve the infrastructure of our public health care systems which currently is in shambles. The public health clinics need more trained people to administer vaccines and counsel the public. Also, very importantly, the public health clinics need the assistance and involvement of the private medical sector if they are to successfully immunize all our children.

Much has been said of tracking. It seems incredible in this day of computers, Social Security numbers, bulk mailings and mass communications that we can't keep track of our children's immunization records. But we do have to worry about the uneducated, the apathetic, the disinterested, the unavailable, the difficult-to-reach people. If we could identify them and serve them notice, we could probably achieve 100 percent immunization rates. For those identified as indigent, for whom money truly is an obstacle, free immunization could be provided.

As an aside, for those who are insured, we must get insurance companies to accept and underwrite preventive medicine. Our insurance system is long overdue in including in their policies appropriate cost-effective immunizations and preventive medicine practices.

Finally, just when the science of immunology and vaccines are at the threshold of great discoveries, and just when many new promising biotech companies are entering the arena of vaccinology, the notion of government control over vaccines threatens to stifle their involvement and their new developments. The bright people these companies contain, as well as the venture capitalists that support them, may soon be departing.

We have witnessed a terrific decline in vaccine producers and developers between the 1950s and 1990s, and only recently have we seen an interest by many companies, old and new, to reinvest in this field. It is a very sensitive industry.]

There are many new vaccines right around the corner that exceed anything we ever dreamed possible a century ago, and U.S. industry is playing a major role in their development. We do not want to find ourselves in a few years bargaining with a foreign power for the purchase of vaccines who see development, manufacture and quality control may not meet our own standards. Our government must do everything it can to preserve the vaccine expertise which exists in the Nation today. Thoughtless denunciation of vaccine producers and frightening away venture capitalists are not in the best interest of the public.

I urge each member to carefully consider the issue. We don't want to kill the goose that laid the golden eggs. The fate of vaccine research and development truly is in your hands.

In summary, quite frankly, the current cost of vaccines today is probably the least of our problems in regards to poor immunization rates. Our scarce dollars and resources should be expended on improved delivery, accessibility, education of both professionals and the public, and development of a reliable tracking system. This is where the action is.

Thank you.

Senator RIEGLE. Thank you very much.

[The prepared statement of Dr. Duma follows:]

PREPARED STATEMENT OF RICHARD J. DUMA

MISTERS CHAIRMEN AND MEMBERS OF THE COMMITTEES:

MY NAME IS RICHARD J. DUMA. I AM AN INFECTIOUS DISEASE SPECIALIST AND EXECUTIVE DIRECTOR OF THE NATIONAL FOUNDATION FOR INFECTIOUS DISEASES (NFID), A NON-PROFIT PUBLIC FOUNDATION, WHICH HAS AS ITS GOALS EDUCATION OF THE PUBLIC AND PROFESSIONALS ABOUT, PREVENTION OF, AND SUPPORT FOR RESEARCH IN INFECTIOUS DISEASES. THE FOUNDATION COMMENDS THE COMMITTEE FOR HOLDING THESE HEARINGS TO ADDRESS A MAJOR HEALTH CARE PROBLEM -- NAMELY, APPROPRIATE IMMUNIZATION OF ALL OUR CHILDREN.

NFID HAS BEEN HEAVILY COMMITTED TO PROMOTING IMMUNIZATIONS, NOT ONLY OF INFANTS AND CHILDREN, BUT ALSO OF ADULTS -- THE FORGOTTEN SEGMENT OF THE POPULATION IN THESE DELIBERATIONS.

AT THE RISK OF ATTACKING "MOTHERHOOD AND APPLE PIE," LET ME STATE THAT THOSE OF US INTIMATELY FAMILIAR WITH, AND ENGAGED IN, THE PROBLEMS OF IMMUNIZING PEOPLE, ARE VERY CONCERNED THAT THE CURRENT PROPOSAL FOR UNIVERSAL PURCHASE OF VACCINES FOR ALL OUR CHILDREN IS BEING PERCEIVED BY MANY AS THE SOLUTION TO OUR IMMUNIZATION PROBLEMS. PUBLIC SUPPORT FOR THIS MAY BE GREAT BECAUSE IT IS A "FREEBIE" -- BUT IS IT REALLY? I DOUBT

IF THE PUBLIC REALIZES WHAT THE LONG TERM CONSEQUENCES MIGHT BE. THAT IT MAY BE AT THE EXPENSE OF MORE BADLY NEEDED PROGRAMS INVOLVING VACCINE DELIVERY AND EDUCATION. THE NOTION OF UNIVERSAL PURCHASE TO PROVIDE FREE VACCINE TO ALL OUR CHILDREN IS POPULAR AMONG THE NAIVE -- THIS IS TO SAY AMONG THOSE WHO HAVE NEVER GIVEN A SHOT OR CHASED A FAMILY OF KIDS TO GET THEM IMMUNIZED.

IN THIS COUNTRY, THE MAJOR PROBLEMS RESPONSIBLE FOR UNSATISFACTORY IMMUNIZATION RATES OF INFANTS AND CHILDREN — AND ADULTS AS WELL -- IS NOT THE VACCINE COST -- FAR FROM IT. THE MAJOR PROBLEMS ARE EDUCATION, ATTITUDES, DELIVERY, AND TRACKING. NFID HAS CONDUCTED A NUMBER OF PROGRAMS IN WHICH VACCINES AND THEIR ADMINISTRATION HAVE BEEN OFFERED FREE OF CHARGE, BUT ENCOUNTERED LITTLE-TO-NO-USE OF THOSE VACCINES UNLESS WE EDUCATED, PLEADED, PROMOTED, AND VIRTUALLY DELIVERED RECIPIENTS TO VACCINATION SITES.

LADIES AND GENTLEMEN, WE LIVE IN A COUNTRY IN WHICH WE GRADUATE THOUSANDS OF HIGH SCHOOL STUDENTS WHO UPON GRADUATION GET MARRIED AND HAVE CHILDREN. THE VAST MAJORITY OF THESE YOUNG PEOPLE HAVE NOT LEARNED IN

SCHOOL WHAT THE WORD VACCINE OR IMMUNIZATION MEANS, AND YET THEY ARE EXPECTED TO PROPERLY CARE FOR THEMSELVES AND THEIR CHILDREN. NOTHING IN OUR SCHOOL SYSTEMS EDUCATES STUDENTS ABOUT COMMON PREVENTABLE INFECTIOUS DISEASES. EVEN AMONG THE EDUCATED, WE ARE COMBATING APATHY, INDIFFERENCE, AND COMPLACENCY.

IN THIS SUNDAY'S WASHINGTON POST (APRIL 18, 1993), AN EXCELLENT ARTICLE BY STAFF REPORTER BARBARA VOBEJDA, WHICH I COMMEND TO YOUR READING, CONCERNS VOLUNTEER ATTEMPTS AT DOOR-TO-DOOR HOME IMMUNIZATIONS IN ATLANTA, IN WHICH AS AN INCENTIVE TO BECOME IMMUNIZED PEOPLE WERE OFFERED FREE TICKETS TO HEAR MICHAEL JACKSON. THE ARTICLE STATES THAT "...THE MOST DAUNTING OBSTACLE IS NOT THE COST OF THE VACCINES. IT IS FINDING THE CHILDREN THAT NEED THEM, PERSUADING PARENTS TO BRING THEM IN, AND ENCOURAGING PUBLIC HEALTH CLINICS TO MAKE THE PROCESS EASIER. VOLUNTEERS FOUND SOME PARENTS OBLIVIOUS TO THE NEED FOR IMMUNIZATION, OTHERS TOO BURDENED TO BATTLE THE PUBLIC SYSTEM.

EVEN PHYSICIANS IN THIS COUNTRY LACK THE TRAINING, DRIVE, AND MOTIVATION NECESSARY TO PROMOTE IMMUNIZATIONS. OUR MEDICAL SCHOOLS DO A GREAT JOB IN

TRAINING PHYSICIANS TO CARE FOR THE SICK, BUT NOT IN HOW TO PREVENT DISEASES. WE NEED TO INSIST THAT ALL OUR MEDICAL SCHOOLS EMPHASIZE PREVENTIVE MEDICINE MORE THAN THEY DO, ESPECIALLY VACCINES AND IMMUNIZATION STRATEGIES.

COMBINED WITH EDUCATION OF THE PUBLIC AND PROFESSIONALS, WE DESPERATELY NEED TO IMPROVE THE INFRASTRUCTURE OF OUR PUBLIC CARE HEALTH SYSTEMS WHICH CURRENTLY IS IN SHAMBLES. THE PUBLIC HEALTH CLINICS NEED MORE TRAINED PEOPLE TO ADMINISTER VACCINES AND COUNSEL THE PUBLIC. ALSO, VERY IMPORTANTLY, THE PUBLIC HEALTH CLINICS NEED THE ASSISTANCE AND INVOLVEMENT OF THE PRIVATE MEDICAL SECTOR IF THEY ARE TO SUCCESSFULLY IMMUNIZE ALL OF OUR CHILDREN.

MUCH HAS BEEN SAID OF "TRACKING." IT SEEMS INCREDIBLE IN THIS DAY OF COMPUTERS, SOCIAL SECURITY NUMBERS, BULK MAILINGS, AND MASS COMMUNICATIONS THAT WE CAN'T KEEP TRACK OF OUR CHILDREN'S IMMUNIZATION RECORDS. BUT WE DO HAVE TO WORRY ABOUT THE UNEDUCATED, THE APATHETIC, THE DISINTERESTED, THE UNAVAILABLE, THE DIFFICULT TO REACH PEOPLE. IF WE COULD IDENTIFY THEM AND SERVE THEM NOTICE, WE COULD PROBABLY

ACHIEVE 100 PERCENT IMMUNIZATION RATES. FOR THOSE IDENTIFIED AS INDIGENT, FOR WHOM MONEY TRULY IS AN OBSTACLE, FREE IMMUNIZATION COULD BE PROVIDED.

AS AN ASIDE, FOR THOSE WHO ARE INSURED, WE MUST GET INSURANCE COMPANIES TO ACCEPT AND UNDERWRITE PREVENTIVE MEDICINE. OUR INSURANCE SYSTEM IS LONG OVERDUE IN INCLUDING IN THEIR POLICIES APPROPRIATE COST EFFECTIVE IMMUNIZATIONS AND PREVENTIVE MEDICINE PRACTICES.

FINALLY, JUST WHEN THE SCIENCE OF IMMUNOLOGY AND VACCINES ARE AT THE THRESHOLD OF GREAT DISCOVERIES, AND JUST WHEN MANY NEW PROMISING BIO-TECH COMPANIES ARE ENTERING THE ARENA OF VACCINOLOGY, THE NOTION OF GOVERNMENT CONTROL OVER VACCINES THREATENS TO STIFLE THEIR INVOLVEMENT AND THEIR NEW DEVELOPMENTS. THE BRIGHT PEOPLE THESE COMPANIES CONTAIN, AS WELL AS THE VENTURE CAPITALISTS THAT SUPPORT THEM, MAY SOON BE DEPARTING.

WE HAVE WITNESSED A TERRIFIC DECLINE IN VACCINE PRODUCERS AND DEVELOPERS BETWEEN THE 1950'S AND THE 1990'S, AND ONLY RECENTLY HAVE WE SEEN AN INTEREST BY MANY COMPANIES - OLD AND NEW - TO REINVEST IN THIS FIELD.

IT IS A VERY SENSITIVE INDUSTRY.

THERE ARE MANY NEW VACCINES RIGHT AROUND THE CORNER THAT EXCEED ANYTHING WE EVER DREAMED POSSIBLE A CENTURY AGO, AND U.S. INDUSTRY IS PLAYING A MAJOR ROLE IN THEIR DEVELOPMENT. WE DON'T WANT TO FIND OURSELVES IN A FEW YEARS BARGAINING WITH A FOREIGN POWER FOR THE PURCHASE OF VACCINES, WHOSE DEVELOPMENT, MANUFACTURE AND QUALITY CONTROL MAY NOT MEET OUR OWN STANDARDS. OUR GOVERNMENT MUST DO EVERYTHING IT CAN TO PRESERVE THE VACCINE EXPERTISE WHICH EXISTS IN THE NATION TODAY. THOUGHTLESS DENUNCIATION OF VACCINE PRODUCERS AND FRIGHTENING AWAY VENTURE CAPITALISTS ARE NOT IN THE BEST INTEREST OF THE PUBLIC.

I URGE EACH MEMBER TO CAREFULLY CONSIDER THIS ISSUE. WE DON'T WANT TO KILL THE GOOSE THAT'S LAID THE GOLDEN EGGS. THE FATE OF VACCINE RESEARCH AND DEVELOPMENT IS IN YOUR HANDS.

IN SUMMARY, QUITE FRANKLY, THE CURRENT COST OF VACCINES TODAY IS PROBABLY THE LEAST OF OUR PROBLEMS IN REGARDS TO POOR IMMUNIZATION RATES. OUR SCARCE DOLLARS AND RESOURCES SHOULD BE EXPENDED ON IMPROVED DELIVERY, ACCESSIBILITY, EDUCATION OF BOTH PROFESSIONALS AND THE PUBLIC, AND DEVELOPMENT OF A RELIABLE TRACKING SYSTEM. THIS IS WHERE THE ACTION IS.

Senator RIEGLE. Dr. Duma, as I understand it, the National Foundation for Infectious Diseases is a nonprofit public foundation. Is that correct?

Dr. DUMA. That's correct.

Senator RIEGLE. And you are the executive director.

Dr. DUMA. That's correct.

Senator RIEGLE. Can you tell me what percentage of the foundation's endowment and operating funds come directly or indirectly from contributors in the pharmaceutical industry?

Dr. DUMA. It would probably be in the area of maybe 30 percent, something in that order.

Senator RIEGLE. It wouldn't be higher than 30 percent?

Dr. DUMA. It might be. I can't give you the exact figure right now, but it is less than 50 percent.

Senator RIEGLE. Where does the rest come from?

Dr. DUMA. It comes from various foundations. It has come in the past from the Rockefeller Foundation, from the Theresa Thomas Foundation, from the American Foundation for Microbiology and others; it has come from the Federal Government; it has come from a wide number of contributors throughout the Nation.

Senator RIEGLE. Is there any single group that would be as large as the 30 percent or so that you get from the pharmaceutical industry?

Dr. DUMA. No, not one single group, because by IRS regulations, we really can't have one single group dominate any contributions.

Senator RIEGLE. The reason I ask that—and no disrespect to you—but I found a real overlap between what you were saying, and sort of downplaying the importance of the price as a factor with respect to vaccine cost, and what I heard the last panel say. I mean, I know you are here as a separate panel, but there was just such an overlap that I was very struck by it.

From all the data that I have seen, to dismiss, quite frankly, the notion that vaccine cost isn't really the problem, that it is education, that it is this or that, that it is everything else—that could almost come from somebody in the pharmaceutical industry. I'm not saying that isn't your view; you have obviously stated it as your view.

Dr. DUMA. I am just giving you my honest opinion in terms of my 30 years of experience in infectious diseases.

Senator RIEGLE. I'm sure you are, I'm sure you are. But I assume by the same token, you can see the degree to which that runs parallel to what we just heard from the pharmaceutical industry, too, can't you?

Dr. DUMA. I am sure it runs parallel to many other testimonies that you have heard from a variety of other groups. It seems like many people are saying basically the same thing.

Senator RIEGLE. I have not heard that today. I think what you have said has been closer to what I heard them say than anybody else I've heard, but that's just how it sounded to my ears.

Dr. Marcuse, let me ask you this. With respect to the issue of price of vaccines, and the degree to which that is or isn't a relevant factor as a disincentive for families and parents getting their children vaccinated on time and the sufficient number of shots, what has been your finding? Does price matter here, when people come

in to get their shots? I mean, is there an economic factor at work here, or is that all just myth?

Dr. MARCUSE. There is certainly an economic factor. There are other factors, but that is a big factor. The cost for vaccines alone to immunize a child through age 2 in the private sector is somewhere around $240. For most young parents, that's an out-of-pocket expense. It is not covered by insurance. Only half the indemnity insurance plans cover immunization. And the price difference is enormous. For polio vaccines, $2.16 in the public sector, and $9.91 in the private sector. A kid needs four doses of that. That's $30 more just for polio. For Haemophilus conjugate vaccine, it is another $30; for DTP, it is another $20—just for that one set of three vaccines from one manufacturer, it costs $80 more per child for the first 2 years of life.

In Washington State, we have 70,000 kids born each year. With a little multiplication, you get up to $3 or $4 million more money.

Senator RIEGLE. The problem here is that I think how it looks sort of depends upon where you stand. In other words, I think for people who are in higher income situations and who are in more favored circumstances, that amount of money may not seem like much. I mean, it may not be particularly relevant in their personal experience. But I think for rank-and-file citizens, and particularly to lower-income families—and more and more families are in that category; we've got more and more families now where it takes two people working to earn as much as one person could earn 20 years ago—these expenditures on the margin are very significant, because that isn't the only bill they have to pay. They have to buy shoes, they have to buy clothes, they have to buy car insurance, they have to put a roof over the family's head, and so forth.

So the figures that I have show me that the private sector catalog price of the vaccines, all of which have to be administered over a period of up through, say, age 4 to 6, just the vaccines alone, $232.72. But that's just the beginning. There has got to be a cost as an overlay on that—I'm talking about if you're going to go into a private doctor's office to get this, the doctors aren't going to do this for free, and they aren't doing it for free, for the most part—maybe occasionally, they do—so we are talking about a figure that is much higher than that.

The economics are a factor here, and I guess I'm a little taken aback when I hear the argument made by those for whom it may not be a problem, whether they are in the pharmaceutical industry or outside of it, and where a few hundred dollars may be a big deal—a few hundred dollars is a big deal, especially when it becomes a barrier to getting children protected. And I think clearly, it is. A lot of these families have two, three, and four children. So you can multiply this times the number of children, and then it becomes a very significant cost barrier.

I realize in Washington, where we live with millions and hundreds of millions and billions and trillions that a few hundred dollars may not sound like much, but I think that's part of what has gone wrong around here, it's part of the detachment of Washington from what is going on in the lives of real people. And I'm troubled about it. I was troubled about the answer that I got from one witness on the issue of why the costs of these vaccines are so much

less in Canada than they are here in the United States, and that we should sit around and congratulate ourselves for the fact that we are paying more than they are for the very same thing, and therefore doing a less effective job dollar-wise of protecting our people. They have their immunization rate in Canada now up to 85 percent for their 2-year-olds, and we are down at 48 percent, and part of it is because we spend a lot more doing it. And there is really no excuse for it, as I see this data.

Thank you.

Senator Kassebaum.

Senator KASSEBAUM. I think the economic factor is a consideration, and I think all of us would agree with that. I think how it weighs in in the overall picture of eliminating these barriers to immunizations is what is important.

Dr. Marcuse, I would like to ask you, because you have had some real experience with that, in light of the fact that we have talked about the barriers to delivery and education and the problems in Medicaid reimbursement rates, timely repayment, and paperwork hassles and so forth, I would like to ask why Washington decided to go with the vaccine purchase before improving—and maybe you had; maybe this is not a problem—some of these other barriers we've talked about—through more of outreach programs with community health centers and so forth. Have you found that providing free vaccines has made the difference?

Dr. MARCUSE. Senator, we set about doing all four things. Vaccine purchase was a major initial step. At the same time we did that, we increased Medicaid reimbursement for vaccine administration, and in our State, poor Medicaid reimbursement is not the problem.

In various of our 32 health districts, we have done many things to increase availability of vaccines. We have the beginnings of a tracking system, but only the beginnings of a tracking system, and we have tried to begin to increase public demand.

We very much feel that all four of those things need to be done simultaneously. Making vaccine available alone won't solve the problem, but without making vaccine available, the problem can't be solved.

We have been very successful in preventing a shift of our patients from the private sector into the public sector, and while today our assessment capabilities to figure out what proportion of kids are fully protected are limited, we can't say that we're much better than 60-65 percent of our kids immunized by age 2. We think we've got the infrastructure in place to begin to build on that.

Senator KASSEBAUM. When did you start that program?

Dr. MARCUSE. Of providing vaccines?

Senator KASSEBAUM. Yes.

Dr. MARCUSE. It began in 1990. The first year was rocky, and we've really only had 2 years.

Senator KASSEBAUM. Is Carol Washburn still assistant secretary for health in the State of Washington?

Dr. MARCUSE. Yes.

Senator KASSEBAUM. I know that she testified before the National Vaccine Advisory Committee that immunization rates in the State are still low despite the universal purchase——

Dr. MARCUSE. I do regard 65 percent as low. We would like 90.

Senator KASSEBAUM. —and that the pediatricians are reluctant to administer free vaccines unless they can charge an administrative fee. That's not a problem?

Dr. MARCUSE. As I said, Senator, in our community, 70 percent of the State-purchased vaccines are administered by pediatricians who have agreed to limit their administration fees. The reluctance of physicians to participate—and not all do participate—relates to a number of things.

First, unfortunately, all recommended vaccines are not available through Federal purchase. We don't have money for hepatitis B, and that's a major reason pediatricians don't participate.

Senator KASSEBAUM. Well, hepatitis B has just been approved, has it not, as a needed vaccine?

Dr. MARCUSE. About a year ago.

Senator KASSEBAUM. And of course, I think that goes back to education. With my children, we never would have thought of a hepatitis B vaccine when they were babies. My grandchildren, I suppose, now will receive this vaccine. But I think again, this goes back to the education process and, for many young parents, the almost fear, perhaps, sometimes of the unknown. I think there are a lot of concerns in just trying to understand from a medical standpoint the pluses and minuses of this.

Kansas this coming weekend is launching an "Operation Immunize" program, in which they are going out into the State with mobile units, going to shopping malls, utilizing the National Guard and other volunteer groups, doing a lot of public service advertising, trying to have an outreach effort to help people to understand why immunization is important.

I think that programs such as this are what should come first. All of the problems that I believe are attendant in universal purchase will be subsumed if we assume that universal purchase is the key to our immunization problem, and the other areas where we really need to focus will get lost. We don't really understand some of the full ramifications of universal purchase.

I appreciate what you are saying—it all has to be done at the same time. This is, of course, what the Secretary said this morning as well. But I think those of us who question whether universal purchase is the right approach, I would suggest to Senator Riegle, who has now left, aren't just necessarily trying to make a case for the pharmaceutical companies. I think there are a number of people in the public health field, a number who have served as governors, such as Senator Gregg, who have understood our immunization problem from a different perspective. I really think if we are going to come together in shaping a successful answer to that problem, we have to take all these things into consideration, rather than trying to just blame it on one aspect or another, such as vaccine cost.

Dr. DUMA. If I can interject or add something to that, Senator, I certainly agree with you. I think that those people in the trenches who have been involved in immunization programs and actually administering vaccines find that you have to do all sorts of things to reach out, to bring people in, to get them involved and be immunized. It is a very complicated area, and we have done all sorts of

things, and it does require involvement of television, the media, getting at it with ice cream trucks if you need, and giving vaccines. There are all sorts of tricks that have to be employed to get people to participate.

The Senator mentioned that $300 is not much—it is a lot to a lot of people—but it isn't the money. It is a question of is that cost a barrier, at least in the current situation. We have a significant amount of vaccine that is available free of charge to many people who need it, and we have a significant portion of the population who can afford it and who are paying for it, and everybody gripes about paying a few hundred dollars for vaccinating the complete immunization program for their children. But that isn't the real barrier. The real barriers are some of the other things that we have already mentioned here.

Senator KASSEBAUM. Well, this "Operation Immunize" which Kansas is doing is free for everybody. So again, it is trying to bring people in, and that is going to be difficult in and of itself. I think there are going to be a lot of young parents who will wonder about hepatitis B, is this really necessary. Again, it really involves many different things other than, I would argue, just universal purchase.

Dr. DUMA. Well, you mentioned and it has been mentioned about physicians in terms of referring their families or children that they are taking care of to the public health sector for immunizations, and I was interested, at least, when Dr. Edelman mentioned that it was for financial reasons, basically. I don't know whether it's the financial reasons of the patient or the doctor. I think when you really look at it, there are many physicians other than pediatricians who are administering vaccines, that the administration fees are inadequate in many of these situations, the complexity of forms that have to be filled out, the explanations and the complicated forms in terms of consent forms between you and the patients and so forth. There are a lot of barriers at those levels that, even if the vaccine were made available free-of-charge, I'm sure there are many physicians who would just simply turn their backs on it.

Senator KASSEBAUM. Dr. Marcuse.

Dr. MARCUSE. There are pediatricians all over the country who feel that, reluctantly, they must advise their patients that vaccines are available at a lower cost at the health department, because it is a major cost factor.

There are several pediatricians in my community who set their administration fees to match the local health departments so there will be no incentive for fragmenting care. We do need to do all of these things simultaneously. Diseases like measles, mumps, rubella and diphtheria have no more relevance for most people in the United States today than black plague, leprosy, malaria, and things they have read about in textbooks. We need to make these threats real enough that people will understand the importance of immunization, but it is still in part a public health responsibility, because a case of measles in Kansas can spread to Yakima, WA overnight.

Senator KASSEBAUM. Thank you very much.

Senator Gregg.

Senator GREGG. Thank you. I just want to clarify the record a little bit, because I did hear one of the Senators mention that they had not heard anywhere, other than from Dr. Duma and from the

drug companies that universal purchase wasn't very important in the essence of the problem. There have been a number of studies which have basically said that it isn't universal purchase and distribution of this drug that is going to solve the problem. In fact, the National Vaccine Advisory Committee's 1991 report in JAMA didn't even mention the concept of universal purchase as being one of the critical problems. They cited a whole series of problems, most of which dealt with poor delivery, such as missed opportunities, appointment-based system, long waiting lines, transportation, education, poor Medicaid system. And then GAO has already done a report in this area in 1993 which says savings on vaccine cost, the price of vaccine, is not the issue and will have little to do with improved preschool immunization levels unless funds are provided for educating parents, tracking, and following up on the immunization status of children.

And the statistics speak for themselves on this issue. The fact is that when you've got 95 percent of the kids in grade schools immunized, then it is obvious that it isn't the availability of the commodity that is the problem; it's the fact that people are not taking advantage of the availability. And when you've got universal availability States such as New Hampshire and the State of Washington, which still have—in the State of Washington, according to the testimony—35 percent of the kids not being immunized, it is the people coming to use the available drug supply which is the issue here. And what we are going to end up doing if we go down the road of universal purchase and distribution is we are going to end up saying, well, we've taken the magic wand of the Federal Government to this problem, and we have solved it. And as a result, we are not only not going to solve it, but we are going to end up undermining the systems which we should be putting in place to solve it. And we are also, in my opinion, going to end up undermining in the long run the research effort in the area of the private sector that is being made to produce better vaccines.

So I think we are coming at this backwards, and it is not unusual for the Federal Government to do that, but as a practical matter, in this instance, we can't afford to come at it backward. We have got to get the drugs out there, and the way you do that is by getting into the issue of how you get the parent to act responsibly and to come in and use the available drugs, and how you create a system which educates the parents as to the need to be responsible and immunize their children. Until we address that, this concept of nationalizing the drug system is a mistake, in my opinion.

Dr. DUMA. Senator, if I could add something to that that is in my unabridged testimony that I submitted, there was a very comprehensive article entitled, "Childhood Immunizations," that was very severely peer-reviewed and published in the New England Journal of Medicine in December of 1992——

Senator GREGG. Is that a tool of the drug companies, the New England Journal of Medicine? What percentage of their money comes from the drug companies?

Dr. DUMA. If you look at the ads, they probably own the whole thing. [Laughter.]

Dr. George Petier, who is professor of pediatrics and head of infectious diseases at Brown University, stated in the article—and

you can read it—"Of particular importance in the current era of escalating health care costs is the fact that effective childhood vaccines are highly economical and thus represent efficient use of society's resources." He goes on to say, "Four major reasons for low rates of immunization among young children have been identified. First, many opportunities to vaccine children are missed; second, deficiencies in health care delivery systems in the public sector, including insufficient staff and policies that serve as barriers, have limited the administration of vaccines. The remaining factors are the inadequate access to medical care and lack of public awareness in some communities."

Nowhere is cost mentioned as a barrier in his article.

Dr. MARCUSE. Excuse me, but Dr. Petier happens to be from Rhode Island and a colleague, and that is a State that happens to utilize distribution of vaccine to private physicians in order to get kids immunized.

With regard to the National Vaccine Advisory Committee report, Senator, with respect, I chaired the committee that wrote that report; there is a section in that report on barriers to vaccine which are financial barriers and include cost of vaccine. We specifically dealt with the issue of the cost of the vaccine, the lack of reimbursement for administering vaccine, and specifically included in the report on access, a statement saying that universal purchase of vaccine should be explored as one of the alternatives. Nowhere do we say it is a panacea, but it is one of the things that should be explored, and that is in that access report, sir.

Senator GREGG. Well, I would just note that it is being used here as a panacea.

Dr. MARCUSE. Well, I really think my analogy, sir, of four flat tires works, that changing one tire won't fix the problem. You have got to do all four. And I think this bill includes fixing all four.

Senator KASSEBAUM. Well, we are exploring it, since that was one of the recommendations.

I very much appreciate, Dr. Marcuse and Dr. Duma, your patience for this long day, but it has been important testimony, and we appreciate your being with us.

Dr. MARCUSE. Thank you.

Dr. DUMA. Thank you.

[Additional material follows.]

Additional Material

STATEMENT

OF THE NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS

Thank you for the opportunity to express the views of the National Association of Community Health Centers (NACHC) on the importance of President Clinton's Initiative to safeguard children against vaccine preventible disease through the Comprehensive Childhood Immunization Act of 1993.

During the last 100 years, great strides have been made in reducing the impact of infectious disease throughout the world. With broad public acceptance of the power of vaccines through the near eradication of diphtheria and poliomyelitis in the United States and the decline in other contagious childhood diseases, we, as citizens, developed a prevailing view that children are entirely protected from common childhood disease, and therefore that our efforts could be relaxed. The truth is that we still permit what Dr. Martin Smith of the American Academy of Pediatrics calls "Sacrificial Death"; that is, the death of children from vaccine preventable disease.

Nearly seven million people - including almost 2 million pre-school children and another 1.5 million children of school age - across the country rely on the national network of over 600 Community and Migrant Health Centers across the country for their comprehensive primary health care and prevention services. Health centers provide these services to people who are economically disadvantaged, or geographically or culturally isolated. Studies have demonstrated the effectiveness of these health centers in reducing the numbers of preventable illnesses in the communities they serve. Community health centers are well positioned to respond to growing concerns about the immunization status of children across the nation.

We fully support the principle that the cost of vaccines should not be a barrier to the receipt of childhood immunizations. NACHC, which supports the availability of free

vaccines for all children, believes that all C/MHCs should be considered a part of the public sector vaccine distribution programs in every state and territory. Further we believe that childhood immunizations, while an important public health issue in itself, should be considered as a component of primary care rather than be uncoupled from it. Therefore, the best way to address the issue of improving childhood immunization rates is to build and design systems that assure access for all children to community-based primary care.

In this context, we fully support the Clinton Administration's initiative to both make childhood vaccines more available and affordable to all, and to support the infrastructure needed to deliver the immunizations to all who need them.

In 1991 the National Association of Community Health Centers accepted the challenge issued to us by U.S. Surgeon General Antonia Novello to meet the nations' plan to reach a level of 90 percent age-appropriately immunized children by the year 2000. Based on a six-point plan, the Association initiated a "National Immunization Campaign" to achieve this objective.

To date, we have developed "Accepting the Challenge: A Primary Care Manual for Immunization Services", which we have distributed widely among private and public providers of immunization services. In close collaboration with the staff of the Centers for Disease Control Infant Immunization Initiative, the Bureau of Primary Health Care of the Health Resources and Services Administration, and the Aetna Foundation as a private partner, NACHC recently conducted a national conference to identify local obstacles to increasing immunization rates and strategies to breach them.

Participants at the conference identified "Action Steps" that reaffirmed two major categories of obstacles. The first is infrastructure: delivery, access, tracking mechanisms. The second is public will: the acceptance of responsibility by parents or guardians to assure age-appropriate immunizations, and the commitment of government to remove legislated barriers, especially the vaccine consent forms.

To achieve a 90 percent immunization rate for children two years and under, we must have the service delivery capacity to deliver the vaccines. Universal purchase will ensure vaccine for all, but the doses may sit in warehouses because we lack the service delivery means. To achieve the capacity, we must create access: access at the point in time when people need it; locations that are easy to reach; translation capacity; and outreach workers to provide services.

We must institute marketing capacities that target hard to reach population segments; develop cultural competencies; provide peer-to-peer education; and produce motivational incentives.

The current infrastructure often relies on parents, pieces of paper, and/or memory to know the status of a child's vaccinations. Among mobile people, especially migrant and seasonal farmworkers and homeless families, accurate information is often unattainable because of lack of records or language barriers. As a result, reports indicate that some children are often over immunized. We need to develop in-house tracking capacities that can be integrated with local, state and national date systems. A major obstacle to achieving this are patient confidentiality laws. It is imperative that the government mandate a system that allows information transfer and protects the privacy of a patient.

Finally, as we build capacity infrastructure, we build the means to achieve the preeminent goal of the National Vaccine Advisory Committee, which is wholeheartedly endorsed by the National Association of Community Health Centers: "Childhood immunizations should be given as part of comprehensive child health care. This is the goal toward which the nation must strive if America's children are to benefit from the best disease prevention our health system has to offer."

President and Mrs. William Clinton
The White House
1600 Pennsylvania Ave.
Washington, D.C. 20500

Dear President and Mrs. Clinton:

I am writing on behalf of my son Scottie and the many others who have died, or, cannot walk, read, write, or speak for themdelves, because of the devastating injuries they've suffered from childhood vaccinations.

Your administration's plan to vaccinate "all" children may appear on the surface as being very good, and I do not question the sincere intent. After all, I and the parents of the disabled mentioned above didn't doubt vaccines' safety or efficacy either, and allowed our innocent children to be vaccinated in good faith, only to have our world crash down around us by the profound injuries our children sustained.

I must painfully tell you there is a very grim side to the vaccine issue and I respectfully ask that you take a long hard look at the other side, the "true side" of current vaccines and vaccine procedures before you embark upon a mass vaccination program. Please note: I have used the term vaccination, not, immunization, because unfortunately, the vaccines are not nearly as safe or effective as society has been led to believe they are. Thus, leaving large numbers not "immunized" against the disease for which they've received vaccine. Indeed, they were exposed to the risks of the vaccine, without protection. A classic example is the government's recommendation of the re-vaccination for measles. Please see the enclosed May 19, 1992, Dayton Daily News, OpEd, (Ex. # 1) by: Dr. Kristine Severyn, whose professional opinion is clearly spelled out that "vaccines may do more harm than good."

And in the context of professionalism, I bring to your attention a news item ~~enclosed~~ from the February 7, 1993,

Milwaukee Journal, (Ex. 2), in which your Health and Human Services Secretary, Donna Shalala was asked how she was preparing to tackle the issues facing her department Her answer was: "The same way I did in Wisconsin. I get smart people and listen to them."

President and Mrs. Clinton, that will be the best news in a long time, providing, the smart people that Dr. Shalala chooses to listen to regarding the planned vaccination program will be advisors (outside) of the government, the Academy of Pediatrics, the American Medical Association and the realm of vaccine manufacturer(s). Because, unfortunately, these entities have built-in conflict of interests, the tragic consequences of which have been well proven over the years resulting in ill-conceived vaccine programs.

An example is the present unconscionable recommendation to administer as many different vaccines as possible at one visit, without any assurance children will not suffer irreparable harm. "Common sense" tells us, it could be devastating to expose a 15 month child to "9" vaccines at one time, and most assuredly, "impossible" to determine which of the multiple vaccines is responsible for the injury, or death, when such an event occurs. Obviously, the current advisors don't care, since this totally shields their good friends, the vaccine administrator and manufacturer from any accountability ... or, liability. So, please be assured, these recommendations are by design ... not, by mistake.

My deep concerned curiosity for vaccine safety began 31 years ago, after Scottie (at 6 months of age) turned from a beautiful bright-eyed alert and observing baby with excellent head control ... into an infant who lost his vision with near constant seizures and whose head flopped around like a rag doll. Scottie literally "wilted" before my eyes

after the third combined DPT and polio shot, which rendered him a permanent nonambulatory spastic quadriplegic, with severe mental retardation and visual impairment. His present physical capabilities are less than that of a nine month infant. In contrast, his understanding in most common areas is that of about age seven years. He is dependent upon total 24 hour care which is provided in our home, by my husband Jim and myself, since his 145 pound weight requires both of us to "lift" him, for his care.

The Children's Defense Fund has stated that for every $1.00 spent on vaccines, up to $10,00 is saved. Has this group ever substantiated the calculation of these purported savings? If so, did they take into account the following...

1. How do you measure the so-called savings for "pain and suffering" the vaccine damaged and their families are forced to endure?
2. How do you measure the cost of destruction to entire families due to the insurmountable expenses incurred by the vaccine injured's needs?
3. How do you measure the emotional and physical taxing impact of the rigorous 'round-the-clock schedule (for a life-time) on other siblings ... and on a marriage?

So much for the Children's Defense Fund's, cost savings.

A top government vaccine official was quoted in the news as saying, with the current [vaccine] system, access to immunization has become a privilege, and he believes that every child has a right to be vaccinated, just as everybody has a right to clean water. Frankly, that's a preposterous statement, since vaccines are a long cry from being clean as water. And, he knows it!

Past performance reveals mighty serious negligence right within our federal regulating agency, the Food and Drug Administration. If you question this, check with the near 500 persons who were afflicted with Guillian-Barre paralysis during the mass "swine flu" vaccine fiasco back in 1976. Or, just ask the seven families who lost loved ones due to contracting polio ... from polio vaccine. Please see the enclosed January 27, 1993 Baltimore Sun news item on this matter. (Ex.#2) My blood boils with rage to read: "...government ...in this case approved use of a live-virus vaccine that did not meet government standards...these people are paralyzed because people didn't follow the law, both the government and the company."

If you folks and the persons you've appointed to your administration are serious about true health care for children, then you must not ignore the poor track-record of past administrations' vaccine studies. I must tell you, the absolute "true facts" of one of the largest and most important studies done in our country on "pertussis" vaccine, which was tax-funded, has yet to be published. I refer to what is commonly called the "UCLA" study, because it was conducted at the University of California, Los Angeles, from September 30, 1977, to December 31, 1979. This was a Food and Drug Administration project, directed by FDA's Dr. Charles Manclark. Assisted by Drs. Baraff, Cherry and Cody at UCLA.

This study project was called, "Rates, Nature and Etiology of Adverse Reactions Associated With DTP Vaccine." The contract number is: USPHS/FDA-223-77-1203

It behooves you President and Mrs. Clinton, to have Dr. Shalala request and read thoroughly the "raw data" of the above mentioned study ... "before" even considering the proposed mass immunization plan. You all, owe it to

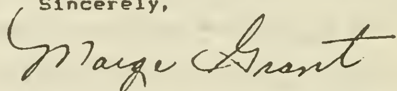
our children. Naturally, first you need to know the truth ... and then, we shall expect nothing less from you, but to exercise that truth in your vaccine endeavors. We cannot, and do not fault you for the past administrations' serious inequities relative to vaccines. However, you'll have no excuse ... should you take the same path, or even worse, if you proceed without heeding to the "red flag" which I have just raised. ~~Please note exhibits 4 and 5 are excellent articles from The Fresno Bee and the special report called "The Vaccine Machine" in Gannett News, on the above mentioned UCLA study. (Both published in December, 1984).~~

I would be happy to meet with you and Dr. Shalala and, or, to provide you with individuals who have personal vaccine expertise, to discuss this crucial issue of mass immunization.

I served on the national Advisory Commission on Childhood Vaccines the first two years of its inception. This is the commission which advises the secretary of of Health and Human Services on vaccine policy. I am co-founder of Wisconsin's Citizens For Free Choice In Immunizations and president of the parents' DPT SHOT organization, which is short for: Determined Parents To Stop Hurting Our Tots.

I look forward to your early response.

Sincerely,



Mrs. Marge Grant, (DPT SHOT)
Determined Parents To Stop
Hurting Our Tots

cc: Dr. Shalala

Various members of the Senate and House

OpEd Page

DAYTON DAILY NEWS
May 19, 1992

Vaccines may do more harm than good

By Kristine M. Severyn

Ohio parents of 6th graders are currently being notified that their children must receive a second dose of MMR (measles, mumps and rubella) vaccine before they may enter 7th grade this fall.

As a registered pharmacist, with an additional Ph D in biopharmaceutics, I was taught that vaccines work all the time, with extremely rare adverse effects. My extensive research in this area indicates that neither is true.

The Ohio Department of Health spokesman quoted in the April 6 *Dayton Daily News*, "Get shots or forget 7th grade," said there were 2,720 cases of measles in Ohio in 1989. What he omitted was the 72.5 percent of these cases occurred in previously vaccinated people. This is representative of outbreaks around the U S, where the majority of measles cases often appear in vaccinated people, sometimes among 100-percent-vaccinated populations.

The Advisory Committee for Immunization Practices (ACIP), which recommends national vaccine policy, reported, in "Measles Prevention: Recommendations . . ." *Morbidity and Mortality Weekly Report* 38 (S-9), Dec 29, 1989, that "Among school-aged children, outbreaks have occurred in schools with vaccination levels of greater than 98 percent. These outbreaks have occurred in all parts of the country, including areas that had not reported measles for years."

Routine measles vaccination may have caused this problem. Prior to mandatory measles vaccine, measles was "generally considered to be benign" in school-aged children, according to the U S. Food and Drug Administration. Since the widespread use of measles vaccine in young children, the incidence of the disease has shifted to adolescents and young adults, where it may be more serious than if it had occurred while they were children.

Additionally, mothers who caught measles as children acquired lifelong immunity and passed measles antibodies to their babies during pregnancy, giving the newborn baby a temporary immunity for a year or longer. We are now finding that vaccinated mothers do not have this strong lifelong immunity, and cannot pass immunity to their babies, leaving them susceptible to measles in the first year of life.

Despite my receiving measles vaccine in 1983, I had no immunity to measles less than eight years later, as measured by blood antibody levels. The manufacturer claims that "vaccine induced antibody levels persist for at least eight years, without substantial decline."

In spite of inadequate effectiveness, the numerous publications that note high failure rates of measles vaccine booster shots, and the ACIP's acknowledging that "further studies are needed to determine the duration of vaccine-induced immunity," our state public health officials mandate a second dose of MMR vaccine.

To make matters worse, they include two additional vaccines — mumps and rubella — which ACIP states have problems with effectiveness and can be harmful. They also ignore warnings by the vaccine manufacturer not to re-vaccinate with three vaccines when only one may be needed.

Ohio Department of Health Director Dr. Edward G. Kilroy states, "No complications or deaths occurred in Ohio children" from measles disease. Unfortunately, recipients of MMR vaccine have not fared so well.

The federal government's Vaccine Injury Compensation Program (VICP) recently reported that there were 378 claims — 351 injuries and 21 deaths — to the program related to MMR vaccine or one of its components — measles, mumps or rubella.

In Ohio there were 16 MMR — or component — vaccine damage claims to the VICP (15 injuries and one death).

The VICP reported on May 31, 1991, that the federal government had paid $10,351,731 thus far to victims of MMR vaccine or one of its components. Considering that many people are unaware of the VICP — some victims have sued outside the VICP — or more often, people do not know that vaccines can cause injuries, the total victim count and dollar amount due to MMR vaccine may be higher.

Dr. Kilroy labels vaccine-induced injury or death as "only temporal," meaning the child was predestined to die or be damaged near vaccination day anyway.

The Taiwanese government takes these "temporal" reports of vaccine death seriously, recently suspending use of the DPT (diphtheria, pertussis, tetanus) vaccine after the deaths of five infants within three days of receiving doses (*Dayton Daily News*, March 11).

Aren't U S. children worth the same concern by our own government health officials? Don't children damaged or killed by vaccines deserve the same sympathy and attention as children who happen to catch a communicable disease?

Unbeknownst to most people, the rigorous standards used by the FDA to evaluate new drugs are not applied to new vaccines, resulting in vaccines actually being "tested" on our children.

The MMR vaccine package insert states that there is a 12-20 percent incidence of severe side effects, i.e., transient or permanent crippling rheumatoid arthritis, in post-pubescent females receiving rubella vaccine. This was confirmed in a large National Institute of Medicine study released in July 1991.

Government health officials unfairly cite the worldwide death rate of measles to justify compulsory vaccination in the U S. The death rate from measles in the U.S. is far below that of Third World nations.

Another misleading ploy is crediting vaccines with the drop in all communicable diseases. However, history indicates that the incidence and death rates of many of these diseases were already reduced prior to the introduction of vaccines.

Concern about health care for children is understandable. However, withholding potentially harmful vaccines does not mean denial of appropriate medical care for children. Government health officials are pressured by drug companies to add more and more doses to their required list of vaccines, despite the risks of dubious benefits.

Since the individual parent will be responsible for the care of a vaccine-damaged child, it should be the parent's right and responsibility to make an informed decision, in consultation with their physician, about which vaccines are appropriate for their family.

Most of the world, even those countries with compulsory vaccination laws, and 20 U S. states, allow parents to choose whether to vaccinate their children. All of Western Europe, Canada, Japan, New Zealand and Australia allow philosophical exemptions. With few exceptions, those denying this right are the former Communist Eastern Bloc countries.

I encourage you to contact your elected officials in Columbus and tell them that you, like most of the developed free world, want freedom of choice in vaccines.

OTHER VOICES

This column gives readers a format to share ideas, opinions and experiences. Columns should be of interest to the general public, timely and concise. Length should be between 400 and 1,000 words. Send to Other Voices, *Dayton Daily News*, P.O. Box 1287, Dayton, Ohio 45401. Include your address and a telephone number where you can be reached during business hours.

■ KRISTINE M. SEVERYN, R.Ph., Ph.D., is a registered pharmacist in Ohio and Kentucky who belongs to a number of professional societies. She lives in Centerville.

THE BALTIMORE SUN—WEDNESDAY, JANUARY 27, 1993

7 polio victims' families win damages from U.S.

From Staff and Wire Reports

The family of a Maryland man who died of polio eight years ago will collect damages from the federal government as a result of an appeals court ruling in a liability case focusing in part on the safety of the live-virus vaccine.

The 4th Circuit Court of Appeals in Richmond, Va., upheld a Baltimore judge's ruling against the U.S. government in seven consolidated cases — including that of Westinghouse engineer William F. Miller Jr. of Glen Burnie, who contracted polio from his infant daughter after her vaccination.

Mark S. Moller, a New York lawyer who was co-counsel for the victims and their families, said the amount of the damages to be collected by widow Deborah Miller and the couple's two children — daughter Kristin, now 9, and Michael, 11 — was sealed under court order but he described it as "very substantial."

The other lawyer representing the plaintiffs, Stanley P. Kops of Philadelphia, said the ruling — upholding a decision by U.S. District Judge Frederick Motz in Baltimore — could cost the government more than $20 million in damages. Of wider importance, the lawyers said, is that the decision holds the federal government accountable if it violates its own rules — in this case, approving use of a live-virus vaccine that did not meet government standards.

"It tells the government, you make the law, you have to follow the law," Mr. Kops said. "This is all about the rule of law. We are a nation that is governed by law. These people are paralyzed because people didn't follow the law, both the government and the company."

Mr. Moller said five of the cases involved batches of vaccine made during the late 1970s, and two involved later batches.

Lederle Laboratories manufactured the vaccine in all seven cases and has settled out of court, said Craig Engesser, a spokesman for the company, which is a division of Wayne, N.J.-based American Cyanamid.

Government lawyers involved in the case could not be reached for comment yesterday.

Mr. Miller was infected with the polio virus while changing the diaper of his daughter, shortly after her vaccination. Symptoms developed in February 1984, after a two-month incubation period, leading to complete paralysis and then death 11 months later. Mr. Moller was unable to say with certainty why Mr. Miller's own childhood vaccination did not protect him from the virus when he came in contact with the diaper wastes.

Another plaintiff in the case, Randy Musgrove of Morrison, Tenn., also contracted polio in changing a child's diaper but has survived — with partial paralysis. The other five cases involved children in various states who contracted the disease and suffered paralysis after taking the oral vaccine.

Some aspects of the protracted litigation reached the U.S. Supreme Court, which decided in 1988 to revive a case that had been thrown out by a Philadelphia court after the government claimed immunity. After that decision, the seven cases from around the country, including the Philadelphia case, were consolidated in Baltimore to resolve common issues, Mr. Kops said.

The high court, in a unanimous decision written by the late Justice Thurgood Marshall, ruled that immunity only exists when an agency or official exercises policy-making discretion or judgment, not when it fails to follow its own safety standards.

The Reagan administration argued at the time that exposing the government to suits for defective vaccines could hinder efforts to control diseases. Judge Motz in Baltimore sided with the plaintiffs, finding that officials who approved the vaccine did not follow federal guidelines concerning strength and manufacturing of the vaccine.

Senator KASSEBAUM. That concludes the hearing.
[Whereupon, at 3:15 p.m., the proceedings were concluded.]

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