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✓ PRESS CONFERENCE WITH DONNA SHALALA,
SECRETARY OF HEALTH AND HUMAN SERVICES
DR. DAVID SATCHER, CENTERS FOR DISEASE CONTROL AND PREVENTION
DR. DAVID KESSLER, ADMINISTRATOR, FOOD AND DRUG ADMINISTRATION
AND OTHERS

2:30 P.M. EDT

TUESDAY, JULY 19, 1994

TRANSCRIPT BY: FEDERAL NEWS SERVICE
620 NATIONAL PRESS BUILDING
WASHINGTON, DC 20045

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MODERATOR: Good afternoon, and apologies to Rush Limbaugh. Our telephone
call-in guest is Secretary Shalala today. She will be making brief remarks on
the immunization initiative. As you know, there was a press conference
earlier today by some members of Congress.

Secretary Shalala will be followed by Dr. David Satcher, who will then
take over the program and introduce our other guests.

Secretary Shalala?

SEC. SHALALA: There are few issues closer to my heart than the children
in this country -- (audio difficulties) --

MODERATOR: Secretary Shalala, if you could speak more clearly and loudly
-- (laughter) --

SEC. SHALALA: Last year we worked with Congress to pass a major
initiative designed to raise the immunization rate for preschoolers to 90
percent, but more importantly, to keep them there, and that's why we have to
put a new system in place; in fact, the first system for immunization that
we've ever put in place for those that are younger than two years old. This
is a public and a private partnership. It's headed by Dr. Satcher and the
Centers for Disease Control. No one ever said it was going to be easy, but

the CDC has provided systems and technical training for the delivery of vaccine supplies to the most remote corners of this world.

MODERATOR: Secretary Shalala?

SEC. SHALALA: Yes?

MODERATOR: Can you start the statement from the beginning? Some of the press missed the beginning.

SEC. SHALALA: Okay. Can you hear me now?

MODERATOR: Yes.

SEC. SHALALA: I'm in Florida, in a state that doesn't have all its children immunized. In fact, hundreds of miles below us are a serious of countries in Latin America that have higher immunization rates than Florida or the United States as a whole. Only Bolivia and Haiti have immunization rates below our for their preschoolers. Last year we passed a good piece of legislation designed to raise the immunization rate for preschoolers to at least 90 percent, but just importantly, what that legislation did was allow us to put the infrastructure in place to keep our immunization rates high. Months and months of hard work have gone into this effort. Working with the GSA, with the states and with the private sector, this is very much a public-private effort. It's headed by Dr. David Satcher, who will speak to you in a moment, but I'd like to make a couple of points about our expertise in this area.

Number one is that we will meet and we will master the challenges that are cited in this GAO report. It does take awhile to get the system in place; we believe we have the time to do that.

CDC has done this before. It has provided systems and technical training for the delivery of vaccine supplies to the most remote corners of this earth. They did it without Federal Express couriers, without the state-of-the-art computer hardware and software which this new system that we're putting in place incorporates. You can't tell me that an organization with that kind of track record in Subsahara Africa, in Latin America, all around the world, can't deliver and store vaccines and get them to Little Rock, to Portland, to St. Louis, and to my own hometown of Madison, Wisconsin.

The greatest risks to us are not those cited by the GAO. It would be any kind of delay in raising the immunization levels among our preschoolers. We need to get those immunization levels up to protect the children in this country, we're pledged to do it. We have very creative partnerships to put the infrastructure together and to make sure the parents know what they need to do, and I'm fully confident that we're going to be able to put this new system in place.

We have the most talented people in the world who have done it in other parts of the world, and I'm certain that we can do it in this case.

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We're almost there now, and we're just going to get the job done. I'll leave you now to my colleagues, Dr. Satcher and Dr. Kessler, and the other talented people in the Department.

MODERATOR: Thank you, Dr. Shalala.

Dr. David Satcher, director of the Centers for Disease Control and Prevention.

DR. SATCHER: Thank you. Let me begin by introducing the other people on the platform, three of whom will be following me and speaking and three who are with us to respond to questions.

Dr. David Kessler is director of the Food and Drug Administration -- to my far left -- and he will be responding to questions.

Dr. Walt Orenstein is director of the Childhood Immunization Initiative at the Centers for Disease Control and Prevention. He's here to respond to questions.

Mr. Roger Johnson is administrator of General Service Administration and will be making a statement following me.

Dr. George Rutherford, who is not with us but will be speaking with us by phone, is deputy director of preventive services, California Department of Health Services.

And Dr. Louis Cooper, who will be speaking on behalf of the American Academy of Pediatrics. Dr. Cooper is professor of pediatrics at Columbia University and also director of pediatrics residency program at St. Luke's Hospital in New York.

We also have Dr. DeAnn Friedholm from Texas, who is the director of the Texas Medicaid program, who will also be here to respond to questions.

So we're delighted to have this outstanding team of persons with us.

Let me say I appreciate this opportunity to speak briefly about a topic that really takes us to the heart of the mission of both this department, the Department of Health and Human Services, and of the Centers for Disease Control and Prevention. There can be nothing more important to all of us than the health of our children.

The agency which I have the privilege to direct and am representing here today has a long history of experience in directing immunization programs throughout the country and throughout the world. CDC is probably best known for its role in small pox eradication, but also more recently in the virtual eradication of polio in the Western Hemisphere, where we have not had a case of wild virus polio in several years.

The World Health Organization in Geneva looks to the CDC for leadership in developing and directing vaccine prevention programs throughout the world. So we do feel a lot of confidence in the staff that we have at CDC in terms of their training, their experience, and -- just as important -- their commitment

in this very important area.

But I do want to say a word about this program and why it's so important and what kind of program it is.

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We, in this country, are trying to put in place a comprehensive childhood immunization program, not a one-shot program to achieve a certain level of immunizations for one year, but a program that will be in place for years to come in terms of having a strong comprehensive infrastructure.

There are five components to the childhood immunization program. Number one, we would like to improve the quality and the quantity of vaccination delivery services in this country, and that's very important. Two, we would like to reduce vaccine costs as a barrier to immunizations for parents in this country. Three, we would like to enhance community participation of parents and providers, and we're doing that by developing education programs throughout the country and by building partnerships at every level of community. Four, we would like to improve the measurement of immunization coverage, and we'd like to be able to monitor the incidence of these vaccine-preventable diseases throughout the country. And finally, through laboratory research and other means, we'd like to improve the vaccines, and to really simplify the immunization schedules. As you can imagine, the immunization schedules are themselves a problem for many people in this country, so we're trying to simplify that, we're trying to package the vaccines in such a way as to minimize that.

Now, I want one very important point about the Vaccine For Children program, which really aims at reducing the vaccine costs as a barrier. Many pediatricians today must send many of their children to the public health department in order to get vaccines. We're concerned about that, not only because many public health centers or clinics are overwhelmed in terms of their ability to manage these programs and to deal with all of the needs, but also because it interferes with something that we feel is very important, the continuity of relationships between providers and patients. We would like to think that the childhood immunization program is a part of the comprehensive well care of children in this country, and that a pediatrician wouldn't have to send a patient away to get a vaccine away. So the idea of the Vaccine for Children program is that vaccines would be available to children in the offices where they get most of their care.

The other point, of course, is that this is, in fact, a public-private partnership. We're not -- we want to enhance the private sector, just as we would like to see in health care reform a strong public-private partnership where the private sector is strengthened, where parents have choices, and where there is continuity of care between provider and patients. And that's the major point of this Vaccine For Children program.

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Now, there are problems in immunizations in this country, even though we've made a lot of progress. Most people in this audience have never seen a case of polio. Some of you have never seen a case of measles or whooping cough. We've made a lot of progress because of immunizations in this country, but you should also know that there are citizens in this country where far less than 50 percent of children are immunized by the age of two. We have a problem. There are well in excess of a million children under the age of two who have not been immunized, and that means that they're susceptible. Every once in a while we get a reminder; between 1989 and 1991 there were 55,000 cases of measles in this country leading to several -- 11,000 hospitalizations total at a significant cost in terms of suffering, but also financial costs. So every once in a while we get a reminder of the dangers of not having in place a strong system of childhood immunization. So we need to do this and we're determined to do it.

I'm sure that many of you are aware of the GAO report, which has been recently completed, and it was an inquiry into the status of preparation for the VFC, and they concluded that some facets of our efforts are behind schedule, and I want to make it clear that we agree with that analysis. I think GAO did a very thorough job and it's going to be helpful to us. It was a snapshot three months before we are to begin. This program is to begin October 1st, 1994, and we are confident that we will be ready to go. The GAO report will certainly help because it's pointed out some things that are going to be helpful to us in terms of putting the whole system together.

I do want to point out that we have already enrolled many of the public clinics throughout the country in this program. We've enrolled private practitioners. We don't have to enroll all of the private providers by October 1st. We're going to implement this program on October 1st. We will continue to enroll private providers. And every time a private provider is enrolled, we significantly improve the immunization program for children in this country.

So we have a lot of confidence in the ability of our staff and our partners, working together, to implement a very successful program in this country. We're committed to that, and we're primarily committed to it because we're concerned about the children. We don't want children to suffer unnecessarily because they're not vaccinated. So we're concerned about registries and being able to monitor very carefully what's going on at the level of community in this country. So we are very appreciative of those who have joined with us in this regard, and some of them you will be hearing from.

I believe the next person to speak to you will be Mr. Roger Johnson, who is the administrator of the General Services Administration.

Mr. Johnson?

ROGER JOHNSON (Administrator, GSA): Thank you, Dr. Satcher.

It was several months ago that the Centers for Disease Control asked the GSA if they would find a way to adapt a quite extensive physical distribution system and help in this great program providing the actual physical

distribution of the vaccine for our children. I asked our professional staff -- and they are very professional -- who are expert in distribution systems, if they'd take a look at that. These are people who have through the years handled all kinds of products shipped all around the world. we have 165,000 customers who every day receive a variety of materials from us, in fact about \$1 billion worth every year.

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They fill 10-1/2 million orders through the year. These are sound, professional people. They said we could do this in time, and we will do that, and we will do it in time.

I met personally with the GAO staff the other day, after having been involved in encouraging their actions in this program to help us, and I welcomed and applauded their report, as Dr. Satcher said. They made some good, solid recommendations to us. We, of course, are also in a moment in time and in a process and welcome not only their suggestions and thoughts, but any others.

I would like to address some of those particularly here. I think the secretary and Dr. Satcher have addressed the broad issues of the program and others might address some others, but let me deal with some of the particulars having to do with the physical distribution.

The elements of it are quite simple, but we don't underestimate it. We're dealing with vaccines. We're dealing with an extensive program that has a great deal of timing issues with it and tracking issues. The plans break down basically into packaging and shipping containers. It breaks down into the shipping process itself and tracking mechanisms. And it breaks down into physical handling and maintaining of the vaccines.

The distribution system that we have uses specialized containers and packing materials that have been successfully used throughout the industry. The packing materials will be tested on industry standards promulgated by the American Society for Testing Materials, ASTM, and the National Safe Transit Association. So, in addition to our own vast experience moving a variety of goods, we're looking to the professional people for packages and handling in the industry. We will follow their standards. They will check our designs. They will test our processes.

The products -- the vaccines will be eventually physically distributed through the Federal Express system, which is the government's contract carrier, a very effective distribution system, which is also used by most of the drug manufacturers today.

There's a group called Action Pack (sp), which is a full-service professional packaging company that designs and tests packaging. They're members of the National Institute of Packaging, Handling and Logistical Engineering organization. They, too, will be involved in helping assure that our designs and our tests and our process are as safe as can be possibly made.

Shipping of many of these products requires temperature control. We have, and will continue to test, cartons that we're shipping around the country for a variety of issues that may happen in transit. This, in concert with the standards testing bureaus that I've talked about, will assure us that we not only have an intellectual assurance, but that we have physical testing to assure that we've got proper packing.

CDC is providing vaccines for us, and we will actually be shipping and transmitting those around the country in various conditions during the month of August under different packing conditions, those specified, which we could otherwise just proceed with but we're taking what is specified and previously

approved, and we are, in fact, going to physically test those in our own situations.

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The equipment that has arrived in our facilities in New Jersey is in, beginning to be tested. The facilities that will be handling the vaccines will be monitored; there are sensors in them. I think we have about as much control over the actual temperature variations as you could in any situation. The actual freezers that will handle the vaccines before they go into the shipping area are also in a temperature-controlled room, so it's a room within a room. Monitors will constant track the temperatures there. That will be recorded. That, along with bar coding that comes from the manufacturers, which tells us what lot number, when it was manufactured, which manufacturer, that then get packed inside containers that also have bar-coded identification on them, that then goes into a Federal Express system which tracks every movement and maintains that record as it travels around the country, provide us not only with the ability to track any kind of shipment at any movement, but also the ability, of course, if there are any problems or questions, to backtrack and to understand exactly where that vaccine has been, what it has seen, and what it has done.

We have had a great deal of experience, these professionals in GSA, with moving equipment, materials and perishables. You know, it wasn't just too long ago that following Desert Storm, fortunately, I think, our troops had a great deal of food left over. And we were called on fairly short notice to get those perishables distributed not only back in the United States but also throughout our country, the 50 states, to homeless people and other people in need of food. Working in partnership with the Interagency Council for the Homeless, we and they, just as our partnership with CDC is, distributed that food, reached homeless victims in 50 states, Puerto Rico, Virgin Islands, in six weeks. We didn't have any advance notice to do that, we just did it. And to our knowledge, there has been no bad foods or no problems. There will no problems with this program, either.

I think it's unfortunate that federal workers come under attack, almost with a predisposed assumption that they can't do anything right. I've been out of the private sector only a year, I've never been here, and I can tell you that that isn't true. The people I've met, in our agency as well as others, are good people, hard-working people, knowledgeable, and if we just give them a chance and give them some process and procedures, they can operate with the best in the world. And I can tell in this one, we will do that.

Thank you.

DR. SATCHER: Thank you very much, Mr. Johnson.

Our next speaker is coming to us, I think, by phone. Dr. George Rutherford is deputy director of preventive services, California Department of Health Services. Is he already hooked up?

Dr. Rutherford, why don't you go right ahead.

DR. RUTHERFORD: Good afternoon. I'm speaking today on behalf of the Association of State and Territorial -- I'm still --

DR. SATCHER: Yeah, go ahead, you're doing fine.

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DR. RUTHERFORD (sp): (Off mike.)

MODERATOR: Can you speak more closely to the phone, please?

Q (Off mike) -- strongly supports any initiative that effectively strengthens the nation's capacity to improve immunization rates for our children. Vaccines for Children --

MODERATOR: Can you start your statement from the beginning, please?

DR. RUTHERFORD: Surely. I'm speaking today on behalf of the Association of State and Territorial Health Officials, or ASTHO. The organization strongly supports any initiative that effectively strengthens the nation's capacity to improve immunization rates for our children. The Vaccine for Children's program, a key component of the president's childhood immunization initiative, offers the promise of achieving this.

Throughout the past year, states have collaborated closely with CDC and our colleagues in the private sector to anticipate and resolve potential barriers to successful implementation of the Vaccines for Children program. Today, despite a less than optimistic report from the GAO, ASTHO remains committed to assuring successful implementation of the Vaccines for Children program on October 1, 1994, and we're well down the road to getting this done.

I'd also like to echo the sentiments you've heard earlier about how useful we think the GAO report will be in identifying problems so that we can correct them in time.

I want to assure you that states are fully acquainted with the procedures necessary to assure the safety and efficacy of vaccine storage and delivery. Many states have long histories of success in developing and running their own state-wide vaccine storage and distribution facilities. Implementation of this historic national initiative with the potential to improve the health status of so many of our youngest, most vulnerable citizens requires our time, energy and commitment.

On October 1, this investment will only begin to return the dividends of healthier children, a benefit we will enjoy for years to come. The program will not be flawless on this date. Issues will remain that will require the partnership of all of us here today to resolve. We must accept this challenge. We urge Congress to recognize the investments already made in the Vaccines for Children program and to join states in our commitment to implement this important immunization initiative as planned.

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Thank you.

MODERATOR: Will you stay on for questions and answers?

DR. RUTHERFORD: Absolutely.

MODERATOR: Thank you, Dr. Rutherford.

DR. SATCHER: Okay, thank you. Our next speaker is Dr. Lewis Cooper, who is speaking on behalf of the American Academy of Pediatrics, but in his own rights has a long history, an outstanding history of work in this particular field.

Dr. Cooper?

DR. COOPER: Thank you, Dr. Satcher, and I echo the sentiments of the previous speakers.

I've worked on development, distribution of vaccines for over three decades, and there is no era of American medicine that I think we have more right to be proud of, and there is no clearer example of what happens when a team starting with basic researchers, applied scientists, the pharmaceutical industry, the public health endeavor, and private practicing doctors work together.

I remember all too well what it was like to work in a polio ward and what it was like to have wards full of measles and their complications. And there is no question that we have a lot to be thankful for and proud of in terms of the children that we do have immunized. By the same token, we wouldn't be here if the job were done. And the "hard to reach" is the expression we've used for kids who haven't gotten their vaccines and gotten them on time. They get that label for good reason: they are hard to reach. And clearly our job now is to reach the rest of the children.

The American Academy of Pediatrics and its 40 -- almost 50,000 members are fully supportive of the Vaccine for Children program as an important next step. Vaccines are not only important for what they do in terms of preventing disease -- the specific diseases for which they are given, but they are a critical feature in developing a medical home for every child. The child who comes in for immunizations whose mother I can ask about all those poisons that are underneath the sink, and who I can help with all of the other critical preventive health measures that are part of children being in medical homes is frequently there because we can explain the utility of immunization.

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It's been said, of course I've read the papers the last couple of days and I heard some of the comments, though I've not had a chance to read all the GAO audit, that the cost of vaccine is not a barrier to immunization. Very clearly, the cost of vaccine is not the only barrier to immunization, and the Vaccine For Children program in fact concentrates on some of those other features as well. But I can tell you from my own experience and from the experience of our membership, there are lots of families for whom that cost of vaccine is one reason they say, well, we'll hold off this month. And it seems to us inconceivable that we can't address that so that the public education that everyone agrees is necessary is a very simple message: Bring your child in for immunization, and one of the things that people have been concerned about specifically, the issue of cost, is not an issue that you have to worry about.

So I suspect from what I've read that there will be a number of questions about the role of pediatricians and family physicians in the Vaccine For Children program. We don't expect it's going to be glitch-free, but we are absolutely committed to it and we're committed to working with all of those who have to implement it so that as the glitches occur, and I would be shocked if they didn't, you will hear loud and clear from the physicians in this country and we will work with CDC, we will work with this department until we make sure that it's smooth and until ultimately every child in the United States has a medical home, which all of you have heard from us time and time again is what we think every child deserves and what we are committed to working toward. Thank you.

DR. SATCHER: Okay, thank you very much.

We're going to open it up for questions now. And as I pointed out earlier, we also have Dr. David Kessler from the Food and Drug Administration, Dr. Walt Orenstein, who directs this program at CDC, and Dr. DeAnn Friedholm from Texas who is head of the Texas Medicaid program, who will also be prepared to respond to questions.

Yes?

Q At the press conference today, Senator Bumpers indicated that he was going to propose a delay in this program. Could you talk about the implications of that delay and whether a delay, say, till January 1, would be something you couldn't accept?

DR. SATCHER: Well, let me say that we look forward to working with Senator Bumpers. I think he's having a hearing later this week that we will be participating in, so we will have an opportunity to give our response to the GAO report and other concerns.

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We would like to implement this program on October 1st. We think that there are some implications to not doing that, because I think they would require us to find another way to provide vaccine for one thing between October and January.

So I think the issue here is our being able to work Senator Bumpers and others and to try to make sure it's clear where we feel we are and what we can do between now and October 1st and go from there.

Do you want to add anything, Walter? Okay.

Q George Rutherford --

DR. SATCHER: George? Anybody want to add anything to that?

MR. RUTHERFORD: Yeah, this is George Rutherford. I'm sorry that I'm not there. Our feeling is that we're down the road to getting this program in place. And we're trying to line up as much of the physician community as possible and other care providers, like clinics, to participate in this, and then, if we start shifting the goal posts and changing the dates around, that we're going to buy ourselves some headaches, that, you know, we've been using this date in a lot of our promotional literature that we've been sending out to the private physician community. And it's like trying to turn or stop a battleship in the middle of the Potomac River; it's not -- you know, once this gets going, it has its own internal momentum and it's hard to start shifting around or pushing off the dates without, we anticipate, experiencing some dropout of physicians who would otherwise participate.

DR. SATCHER: Thank you very much. That's very helpful.

Yes?

Q Doctor, one of -- some of the main criticisms at the press conference and in the report was that GSA has never had any experience in storing and shipping vaccine and the facility it selected in New Jersey -- the refrigeration space is going to mean extra paint cans and paper clips and regular government supplies, and there isn't apparently any refrigeration in it. There's the space, but not the actual refrigeration. And why was GSA selected for this?

Dr. SATCHER: Well, I think the people at CDC looked at various options for the storing and shipping and looked very critically at what GSA could provide and felt very strongly after that assessment that GSA, in fact, could do the job. Now, you have to understand that this is a partnership. It's a partnership between CDC and GSA, and to a certain extent with the states also. And so we're talking about that partnership. But we have a lot of confidence in it. I'm going to ask Mr. Johnson to respond to your statement, but I do want to let you know that our staff, who've had -- people who've had a lot of experience in storing and shipping and delivering vaccine did, in fact, look very critically at GSA and concluded that they could do the job.

MR. JOHNSON: Well, I always find interesting how people characterize things. At the facility in New Jersey, there is a one million-square-foot facility. We'll be using about 20,000 feet. There are a lot of things stored

in there. Isolating this particular facility, which is already in place, is a 35-foot-high concrete fire-retaining partition and walls. If there were any flammables around there, they will be removed so there won't be any flammables.

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The refrigeration units are the same kind used anywhere -- they are now installed. The room itself is temperature controlled. The GSA was asked if we could do this. I -- because of my own business background -- did not accept that, without personally finding out if we could do it. So this is not a program where a federal agency is looking for work, I can assure you. This is one where my people have tried to prove to me, over and over again, that we can handle this.

These vaccines are packaged inside sub-packages inside other packages -- we don't even break the seals. So, any picture conjured up of federal people wandering around with vials is not accurate. When we moved the perishables from Desert Storm back, they were all frozen foods -- kind of hot over there -- at six weeks notice, didn't lose any. We've had a lot of experience in shipping perishables, and these are good people. We'll continue to learn, and we will not move one package of vaccine unless we're absolutely sure that we can do it safely and effectively. And, a lot less expensively.

DR. SATCHER: I think it's important to get Dr. Kessler to respond because we've also asked FDA to monitor this as an agency that's not involved in this but has a lot of experience in terms of regulation.

DR. KESSLER: As Dr. Satcher has said, he has asked us to hold the CDC and the GSA to the same standards -- to the same regulatory standards -- that we would apply to anyone who is involved in the packaging, distribution, shipment of vaccines. We have already made one visit to the warehouse, in the latter part of June. We found that -- these were FDA inspectors -- we found that it was an excellently run warehouse. The area that the vaccines would be stored would be segregated from any other materials. There was already cold storage that was appropriate, they were awaiting the shipment, the receipt of certain freezer units, and as Mr. Johnson said -- that there were also some testing of shipping and packaging materials and monitoring of temperatures -- and we will be back to make sure that this warehouse and the entire program meets all regulatory requirements.

Those regulatory requirements, I mean normally, are not necessary for, I mean, a federal agency. The law doesn't apply to that. But Dr. Satcher has asked specifically that we hold them to the same standards; and we will regulate this program as we regulate any other program to assure full compliance with all quality control and good manufacturing practices.

DR. SATCHER: Thank you very much, Dr. Kessler.

Yes?

Q Dr. Satcher, another criticism that was levelled today was that immunization rates that were told to members of Congress when this legislation was passed were much lower than current immunization rates recorded today, for 1993 - 1992. Why does the current program emphasize distribution of vaccine, education of members of the community, and getting them into the clinics?

DR. SATCHER: I don't think a that anybody follows this more closely than Dr. Orenstein, so I'm going to ask him to respond.

DR. ORENSTEIN: Let me just say that the current program emphasizes all of

that.

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As initially mentioned, this is a five-part program. The first part is improving the quantity and quality of vaccination delivery services. In FY 1993, we had about \$45 million for this. In FY '94 alone, we have over \$128.5 million for infrastructure, for education, et cetera. In addition, we have over \$33 million in incentive money. This program is just one part of building that system, of assuring vaccines are available and work not only for physicians but for parents, and they're available in the places where parents would like to take their children. And that's why we've looked at ways of making it simple for states, and this is a system which we believe will work and work on time.

The other issue is on the immunization rates. At the time the secretary testified, the latest data that were available were 1991 data. We have since arrived at new data in FY '93 that are the highest immunization levels we've ever achieved. However, even today there are over a million 19-month-old through 35-month-old children who have not received all of the vaccines they should. In fact, for many of our vaccines we are not near 90 percent, and for our basic series, the levels are 72 percent. I want to emphasize that these are children born during the resurgence of measles for the most part or following the resurgence of measles where there was intense publicity, intense efforts to get children immunized. And so we are seeing, in my opinion, the results of those efforts. The purpose of this program is to build a system when we don't have disease so we don't have to be reminded and don't have to make further intensive efforts. And it's the system approach that I think needs to be emphasized here.

DR. SATCHER: Thank you.

Yes?

Q Dr. Orenstein, the fifth element you, I think, discuss here is supporting research for new vaccines and vaccine combinations. At a recent meeting of the HHS Vaccine Advisory Committee, manufacturer after manufacturer complained about the large amount of vaccine you're buying at a low price, and they said that low price would keep them from developing new vaccines and combinations. They called on the secretary to look into it to see if it was keeping -- would keep vaccine initiatives from happening. Do you see this as a problem? Are you concerned?

DR. ORENSTEIN: This is certainly an issue that has been raised which I think will need to be evaluated and will be evaluated.

Certainly the Congress has directed that if in fact research and development for vaccines goes down that the secretary go back to Congress and look at other ways.

I think we need to see what is going to really happen with R&D when we get this program implemented, but it certainly is an issue. No one in this administration wants to see decreased development of high quality vaccines, and there are many agencies within the government, particularly the National Institutes of Health, FDA, as well as CDC, working themselves to help in improving and developing new vaccines.

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x x x vaccines.

So I think it is an issue. I think we will look at it. But there are benefits to this program that we think at this point are worthwhile and need to be pursued.

Q Dr. Satcher, another criticism often heard is that the distribution system is unnecessary and it duplicates what is already done well by the private sector. Can you explain the rationale for the distribution system, whether it will save money, if so, how much, and where those savings will be achieved?

DR. SATCHER: Yes. Costs are definitely a part of the rationale. Dr. Orenstein can give you the specific figures in terms of our projections.

DR. ORENSTEIN: The law requires that vaccines -- costs be covered for those vaccines for which we had contracts in effect in May 1993 at a capped price. We looked to the states as to what would be the simplest distribution system for them, and we developed the GSA option in response to state requests that they did not want to develop distribution systems themselves. What we did is we looked at a variety of things. Number one, as Mr. Johnson has mentioned, the FedEx contract for the government is one of the best, if not the best, contracts. Number two, we had a facility in a sense already in place with refrigeration units waiting to be used, so there needed to be minimal capital improvements. And number three, we had a superb staff to work with that we are continuing to work with. CDC has expertise, FDA has expertise, and so this system we feel will be able to deliver vaccines for about 40 cents a dose.

In contrast, we know with Medicaid replacement programs from private manufacturers that charges have been as high as \$2.00 a dose. This is one-fifth of that cost.

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x x x cost.

We think this is going to be cheap cost savings, and in estimating our prices, we probably overestimated the cost of materials because we think we could get them cheaper than we did, but we wanted to have prices that didn't look like we were trying to push the issue down.

Q If I can follow up with two questions, do you have an aggregate number for your cost savings, and did you allow the pharmaceuticals to bid for the distribution as well?

DR. ORENSTEIN: In looking at this program, as we saw it, there were visits paid to the manufacturers. In visiting those manufacturers, we learned that they were not willing to bid to distribute to -- with full implementation over time up to 79,000 providers within the capped price. Thus, we had to look elsewhere for distribution options, and we looked to the states, and after the states, we came up with the GSA option.

Q Senator Bumpers has used a figure for that. He says the administration has cited over \$30 million savings. Is that -- is that the figure you are using for the total savings?

DR. ORENSTEIN: What we estimate overall is that approximately \$13 million annually will be needed to cover the GSA distribution center. In addition, we are helping states who are enhancing their own delivery systems with about \$18 million.

If you look, then, at \$2 a dose, if in fact that distribution had to take place, you're talking as much as \$65 million, so this could be a savings of as much as \$30 million. I think it's important to point out that the GSA distribution system, again, is not delivering all of the vaccines in the country, it is delivering only the vaccines for which states have asked us. We estimate that roughly 30 percent of the vaccines in the country will go through the GSA distribution center, about 50 percent will go from vaccine manufacturers directly to state health departments who in turn will distribute the vaccine as they have done for years and years and years and years, and about 20 percent of the vaccines will remain in the private sector.

DR. SATCHER: I'm going to ask Dr. Friedholm to respond to that question, too, from the perspective of state Medicaid. Go ahead.

MS. FRIEDHOLM: Just for clarification, I am not a doctor, I am a Medicaid director.

In Texas, our experience is such that we have been in a major initiative to improve our immunization rates for the last couple of years. We are one of the states that experienced a terrible measles outbreak in the early 1990s, and paid a very terrible price for that, so for the last year and a half, we've been working towards trying to improve our immunization rates, and we see the VFC as a very important additional tool that we are going to have to improve our immunization rates. We still have approximately a million children who we need to try to reach out to in our state alone for immunizations, and while we buy and distribute our own immunizations and have for a long time through local health departments, we are very interested in using the GSA system to supplement and help us fill in, so that we can hit

our 100 percent rate.

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x x x rate.

And I think that it's important to understand that every state is at a slightly different place in how they are trying to respond. Each of the programs are different throughout the 50 states, and so you can't just paint with one broad brush. But I think it is fair to say that we see delay as simply delay. If we set a deadline for ourselves, and if we are working very closely with the physician groups, nursing groups -- we have 260 voluntary groups made up of local people interested in improving immunization rates in their communities -- to send a message at which point which says, Oh, wait, we're not going to complete this, we're going to delay it, would be exactly the wrong message at the very time that we're in the midst of trying to get everyone to participate in the program. And I think many states would feel or be able to cite you their specific examples just like that.

MODERATOR: Okay, thank you.

Yes?

Q Dr. Satcher, one of the criticisms of the program is that while the vaccine may be free, private doctors could charge fees for giving the shots. Why is that part of the program? Is that the only way doctors would sign up, and is that going to be a cost barrier?

DR. SATCHER: Well, you know, I think what we're trying to do is to certainly eliminate the cost barrier that's in the vaccine. We are not trying to disrupt the relationship between providers and patients. And we're also not trying in any way to undermine the private sector. We believe that the private sector is important in the success of this program, long-term; we're trying to put in place a system that's going to last.

And you know, there are physicians who charge various rates to see patients. There are physicians who see patients who can't pay. But we don't think that it is our role to undermine the private sector in this effort. But we do believe that if a physician does not want to see a patient and provide the vaccine, that physician still has the option of sending a patient somewhere else. What we're trying to do is protect that relationship among those many physicians who would like to maintain their patients and their practice, and I think that's the overwhelming majority, and to see those patients and provide those vaccines.

Any -- you want to add anything to that, Dr. Cooper?

DR. COOPER: I think the ground rules are fairly simple. Physicians will be allowed to charge an administration fee, an administration fee determined out of a survey of what is currently being charged across the country. And physicians, when patients can't afford those fees, I'm sure will do what they've always done, which is they'll reduce them or eliminate them as necessary.

But this program will do something particularly important: It will stop pediatricians from having to send their patients into public -- already overcrowded public health clinics, and that's a critical issue on the long haul.

DR. SATCHER: Okay, we're going to take a couple more questions, if we

have a couple more questions. One more over here.

Q I'd like to ask Mr. Johnson, as recently as May 18th you sent a letter saying that without the cooperation and support of Congress and the pharmaceutical companies that implementing this distribution could be catastrophic, and you suggested that GSA would not necessarily go ahead. I'd like to ask you, now that you are going ahead, what has changed in terms of those issues? Clearly, there's still concern among some members of Congress and there is opposition among the pharmaceutical manufacturers.

MR. JOHNSON: Well, I think there's a great distinction between opposition and concern. And I think, after I wrote that letter and talked with people and met more with my colleagues here, I think there has been a coming together in terms of people dedicated to get this program done effectively. That's very different from having legitimate concern. The concerns of the GAO report are legitimate concerns. Some of the concerns expressed by Congress, I think, are legitimate concerns. We will address those. But I am fairly confident we are going ahead in a spirit of legitimate concern or we're getting a program done effectively, as opposed to just plain opposing it.

Q Can you say that this program just takes 30 percent of the vaccines being distributed, is that what you're saying --

DR. SATCHER: What percentage --

MR. JOHNSON: I can say that. Yes, the program covers about 30 percent of the vaccines that will be distributed annually.

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x x x annually.

So that at any one time in the distribution center, as I understand it, no more than a two to three-month supply would ever be -- and this is a distribution center, it is not really a warehouse, so we're talking about less than 8 percent roughly of annual need at any one time. So that it is a proportion and it is not the entire distribution center going through. In fact, far more vaccine is going through state health departments that have been distributing vaccines to providers for many, many years.

MR. JOHNSON: Yeah, it's important what words we use. And some folks keep saying warehouse. This is a distribution center, and there's a great difference. Vaccines come in and cannot move instantaneously, so there needs to be a place where they are handled while they're waiting to be boxed. This is not a place where we are bringing things in to store them, and there's a great difference. So it's a process, in and out process. Certainly there are some waiting times in the process. Very different from a warehouse.

DR. SATCHER: I just want to emphasize that the concern which Mr. Johnson expressed is one which we all have in the sense that I think this program in order to be successful requires a level of cooperation among several groups that perhaps we haven't seen before. But, you know, obviously, in addition to those of us in the federal sector -- CDC, FDA, GSA -- the states have such a critical role if this program is to be successful. We have to work very closely with the states. We have to work very closely with the private sector, and we have to be concerned about the needs of the private sector in terms of being able to continue their practice and to have it expedited by this program.

Just as important is the parents and the children. You know, if the parents are aware and they demand that the children be immunized, the chances of it happening are much greater. So we need the support of the parents and the communities throughout the country in order to make this successful. So it's a team effort, and we're confident that we're going to be able to do it, based not only on our history but the high level of commitment to the success of this project.

Thank you very much.

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NEWS CONFERENCE WITH:
SENATOR DALE BUMPERS (D-AR)
SENATOR JOHN DANFORTH (R-MO)

TOPIC: VACCINES FOR THE CHILDREN PROGRAM

U.S. SENATE GALLERY

TUESDAY, JULY 19, 1994

TRANSCRIPT BY: FEDERAL NEWS SERVICE
620 NATIONAL PRESS BUILDING
WASHINGTON, DC 20045

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SEN. BUMPERS: Let me say at the beginning we appreciate your attendance;
number two, that Senator Danforth and I, and our distinguished colleagues on
the House side, are not in a turf fight, or any other kind of fight with
either CDC or HHS. All of us here have been deeply immersed in immunization
-- the immunization program -- as we lawyers say, since the memory of man --
(inaudible) -- not. And we have a deep and abiding interest in reaching the
immunization levels that we talked about last year when we passed fairly
dramatic changes in this program.

I do not personally have anything against a new system of distribution, if
it makes any sense and will save money. But the GAO report, which we are here
today really to release publicly for the first time, the GAO report which we
requested about six weeks ago fortifies the deep concerns we had about the
ability, for example, of the General Services Administration to put together
this mammoth
distribution center in Burlington, New Jersey, have it up and running with
70,000 names of physicians around the country on software; validate the
packaging of vaccines, and validate the addresses of the people who would
receive it.

Now, that sounds like a bureaucratic word, but to reduce it to its
simplest term it means this: GSA has never stored or shipped a dose of
vaccine in its history. It is not an uncomplicated system. On the contrary,
it is a rather sophisticated system. First, you must make sure that unfrozen
vaccine, for example, MMR -- measles-mumps-rubella -- is stored at 34

degrees when it leaves the warehouse and is at 34 degrees when it arrives at its destination. You have to make sure that it will do that for 96 hours, even though the pharmaceutical companies try to get it there within 48 hours. The polio vaccine is a frozen vaccine. You have to make sure it's frozen when it leaves and frozen when it gets there. Otherwise it will be thrown out and definitely not used.

When you look at the packaging that some of the pharmaceutical companies have developed, it isn't all that complicated; and yet it has to be a certain dimension, you have to put things like football players put on a strained muscle -- cellophane or plastic ice bags. Some of them have ice, some of them have water. You have to have exactly the right mix to make sure the vaccine stays at 34 degrees. And you have to make sure that you put just the right amount in a certain sized package to make sure the polio virus is still frozen when it gets there. As I say, this is not an insurmountable chore, but it is not something you can do on the spur of the moment.

Once you validate the packaging, you must then validate the shipping. And that one of the validations you have to do is to make sure that these 70,000 physicians who are going to be receiving the vaccines, that you have their name and their address correct, and preferably their office hours, because if you get the vaccine there on Friday afternoon when they've just shut down for the weekend, you've got a problem.

So all I'm saying is when you start in on a distribution system like this it is not uncomplicated. In my opinion, it would have been utterly impossible for GSA to even come close to validating 70,000 physicians' names, develop the packaging, the thermometers, do the procurement -- everything it was going to take to get this shipped. I'm not telling them not to do it. I'm not saying it's the worst idea in the world -- though I have some questions about it. All I am saying is to presume to embark on a program to raise our immunization levels to 95 percent of all the children of this country -- to presume to do that with this system is foolish in the extreme. I can tell you there isn't one thing about this distribution system that is going to immunize one more child.

And then let me just say that I was concerned about the fact that all of a sudden HHS says doctors will be allowed to charge patients who are uninsured -- let me go back and explain the three categories.

You have youngsters coming in who are insured. There are a few who may not be insured, but whose parents want their children to pay for the vaccine and to pay for the service. That's the first category.

Number two, you have children coming in who are not insured that the private physician will immunize free of charge as far as the vaccine is concerned: he gets the vaccine free -- we will replenish that private physician's stock of vaccine. The physician is entitled to charge what the law says are his costs in this second category. In addition to that, the physician can charge for an office visit. It was estimated at the time we passed this bill that the office cost -- that is, for the syringe, paperwork and so on -- was five to seven dollars per child. But if you do a survey of what the physicians normally charge as their cost, it runs around -- I mean customary charge, rather than cost -- it's about \$15. On top of that, they're entitled to charge that child's parents for an office visit, which can range anywhere from 20 to 50 dollars.

The third category of course is the Medicaid child, virtually all of whom will get their shots at public health clinics, but who are eligible to get their shots in the doctor's office free. Number one, if the doctors are allowed to charge their customary charge, this program is going to cost a lot

more than we thought it was going to cost. Number two, when you have a physician ordering vaccines from the state to cover -- to replenish his Medicaid vaccines, you have him perhaps sending an order to Burlington, New Jersey to replenish his stock of vaccines for uninsured children who were immunized by the private physician. And, thirdly, possibly ordering from the pharmaceutical company to replenish the stock of the vaccine that he gave private patients who were insured.

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BC BUMPERS-DANFORTH
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x x x insured.

All of that vaccine that arrives in the physician's office goes into the refrigerator, and I am quite sure it is commingled there. It's going to be very difficult for that doctor to keep up with the lot number, everything it would take, if we had a batch of vaccine that went bad to know which ones. It's going to be very difficult for him to order knowing which ones are free and which ones he is supposed to pay for. In short, we had one I considered an insurmountable problem, and I value the strong support of my colleagues in making sure that we don't embark on this.

There's one point I want to make in conclusion. That is I've held hearings every year in the Health and Human Services Subcommittee on Appropriations, and every year the proof is conclusive that our immunization levels are not higher not because of the cost -- there is virtually no evidence that the cost is a big impediment. The problem is we don't have clinic hours long enough, we don't have doctors oftentimes who even mention immunization to their own patients. We have public health clinics in Los Angeles where children have gone 10 and 15 times and immunization has never been mentioned to them. We're putting something like 124 or 125 million dollars into outreach programs, clinic hours -- all of those things that have a proven track record of increasing immunizations. This distribution system -- I'll reserve judgment on whatever they finally do until they do it and I hope to be able to maybe sign off on it -- but I can tell you that in itself is not going to immunize one child, in my opinion.

Now let me defer to my distinguished colleague and very good friend, Senator Danforth.

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SEN. DANFORTH: Well, Senator Bumpers, thank you very much. And you have been the leader in this area for a long time. Let me reiterate what Senator Bumpers has said. All of us share the same concern. We would like to immunize every child in the United States far before that child enters first grade where they have to be immunized. The goal is to increase immunization, to make sure that children are immunized. And I commend in a way the concern of the administration and the concern that at HHS. You can just visualize really good hearted souls at HHS trying to say well how do we increase immunization, what can we do about it. And there is something about the mentality of a lot of people who are good hearted people, who say well if we're going to do this, if we are going to immunize people, who is the "we"? Well the "we" has to be those of us who we see around us here in Washington, here at HHS. We have to do the immunization. And so how should we do it?

Well, the first thing we do is just buy a lot of vaccine, we should do the buying. We should buy 80 percent of the vaccine in the United States. We should buy more vaccine than it takes to immunize every child in the country, and then with that vaccine we have to do something, so let's get a warehouse. Well we have one and the warehouse is in New Jersey, but the warehouse unfortunately isn't used for vaccine purposes because we've never been in this business before. But there are some things in the warehouse that we can get rid of, furniture, paper, paint, solvents, adhesives, some 5,000 different products that are located in this warehouse. So let's get rid of those things and spruce up the warehouse and then bring in some refrigeration equipment, then we can store the vaccines and then we can send them out by Federal Express.

But we've never done this before. We don't know whether the containers are adequate, we don't know exactly how the distribution is to function, as Senator Bumpers pointed out. Perhaps the doctor's office is closed when the vaccine arrives. We now have a private distribution system that works, the problem isn't the distribution system. And to replace a private distribution system which works, which is tried and true, with one that is developed on short order from whole cloth, is just a mistake. It's a good hearted mistake, it's a kindly mistake, but it's an impractical mistake.

And the notion of buying up all the vaccine, 80 percent, whatever it is of the vaccine, is a mistake. As Senator Bumpers pointed out, and as the GAO report indicates, cost isn't the problem. People who are in need right now can get free vaccines. The problem is something

other than cost, the problem is something other than the distribution system. The problem is a lack of knowledge on the part of parents, the difficulty of parents of keeping track of multiple shots for their children. The problem is that today sometimes when you go to a doctor's office, when a parent takes a child to a doctor's office for treatment of say a bad ear or whatever, the doctor doesn't immunize the child while the child is there, for economic reasons. These are problems which can be solved, these are problems which can be addressed. And this is the point that Senator Bumpers has been making for some quite time, we should address them, and we should increase immunization.

But this program is one that is absolutely bound to go totally haywire. It's just bound to go haywire. You can't get the government in the business of buying all this vaccine, warehousing all this vaccine, and distributing all

this vaccine, and have it not go haywire. So again, I would say to the people at HHS, you are good people, but this is not a good program.

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Q Jack Luke (ph) from Wisconsin. Let me just make a couple of points because both Dale and Jack have made a good deal outlining some of the central points, but let me start back at the beginning. This entire immunization program was sold for the House and the Senate last year based on statistics that said only 50 or 60 percent of the pre-school age children in this country have been immunized. It turns out those figures actually came from 1985. And if you look at the most recent statistics in 1993, we are already over 90 percent. So even before the warehouse and the government program is off the ground, we've already reached most of the goals that were outlined in the legislation last year.

Which brings us to why do we see a need to change the distribution system, given the fact that, as has already been pointed out, there was no evidence last year that either price or distribution had anything whatsoever to do with low immunization rate. Instead the problems were parental responsibility, an outreach in communities and education.

Now let's take a doctor in California just as an example. Today a physician in Southern California can call a warehouse, in some cases just miles away, and ask them to drop vaccine off the next morning. Now the doctor in California under the new system will have to pick up the phone and call the California Department of Public Health, who will then call the Center for Disease Control in Atlanta, which will then call the General Services Administration in Washington, which will then call the warehouse in New Jersey, which will then finally ship the drug all the way across the country again.

Now we've already tried publicly financed distribution centers in the past. There have been two major studies, one done on the Department of Defense, and one done on the Veterans Administration. And the conclusion was it could be done cheaper in the private sector, in fact generally the operations in the public sector costs 12 times more than already existing distribution systems.

Now also think about this just one final time to kind of make this final point. The General Services Administration, which is in the business of handling paper clips and chairs and paper and copying machines, is now for the first time in its history going to handle a perishable commodity. The General Services Administration warehouse in New Jersey at any given time will have one third of all the vaccines in the country stored in one central facility. And according to the GSA's own map, the cold storage facility for vaccines is located next to the room where flammable products and chemicals are stored.

So this system will work great assuming we can beat the private sector in shipping costs, when every study says it can't, assuming that distribution costs and the distribution itself were originally part of the problem, which they never were, and fingers crossed that there is never an accident at a General Services Administration warehouse where it goes up in flames and one third of the vaccines in this country go up in flames overnight. So I concur with my colleagues from the Senate, and with Ron Wyden from Oregon who you will meet in a minute, that there's a way to solve this problem, and it's putting more money into community outreach and putting more money into vans in order to serve kids in neighborhoods, it's not setting up one more government bureaucracy and one more government warehouse that frankly isn't needed, it's

just expensive.

REP. WYDEN: I'm Ron Wyden of Oregon and I particularly want to commend Senator Bumpers. The fact of the matter is, Senator, there are a lot of kids across this country that are going to get help because you have been at this year after year after year, and I just want the record to show who has been doing all this -- and Jack Danforth and Scott Klug, it's great to team up with them as well.

It seems to me that the American people have made it very clear that they want the youngsters of this country to be immunized. And what we now have is a new report that indicates that some very important problems have to be resolved or we are not going to be able to move further towards the day when all the kids in this country are immunized. I think we ought to note that in about 54 days the first vaccine is to be shipped by the government to 50,000 doctors across the United States, and what the Congressional auditors have raised is some very troublesome issues that have to be resolved first.

For example, my home state of Oregon -- and I spoke yesterday with the Health Department officials that are going to run the program -- they've indicated that the October 1st deadline is, in their words, totally unrealistic. According to the folks in Oregon, they have been unable to even begin to enroll providers for the new program. My state thinks that the October 1st deadline at best, they would be able to sign up about 20 percent of the doctors needed. And in addition, to accomplish even that degree of provider enrollment, the state is very concerned about having to divert resources from proven programs that are getting kids immunized, along the lines of what Scott Klug has mentioned in the area of community education.

So it seems to me that the Department of Health and Human Services ought to look at some key kinds of questions right now. First, they do need to find money to fund the state implementation of the program without diverting resources from proven programs now under way, or they are really going to have to ask Congress for a delay in the implementation date of this program. Public health officials in my state have recommended that January 1st would be a more realistic kind of deadline.

Finally, on the point that Senator Bumpers has mentioned about the fact that the fee schedule might increase the cost for families where they would have to pay for a vaccination, I am very hopeful that the administration will move to ensure that these families would have a right to have their fees waived. I think it is important that they not face additional financial problems.

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Finally, let me close -- it seems to me that what this report really indicates is the very substantial problem you face when you try to go at health care reform piece meal. If our country had real health care reform with universal health care coverage, then we would be in a position to attack this issue in a comprehensive way. Perhaps some of these problems that have been exposed by the General Accounting Office could have been avoided. So, I'm very grateful to you, Senator Bumpers, and look forward to teaming up with you and our colleagues on a bipartisan basis.

SEN. BUMPERS: Thank you very much, Ron. Speaking of refrigeration, we could use a little of that in this air that's in here right now. One announcement before we take your questions, and that is the HHS subcommittee on appropriations will hold a hearing Thursday afternoon at 2:00 PM in their regular meeting room on this subject. You're all cordially invited. Yes?

Q -- (Off mike) --

SEN. BUMPERS: Let me say to you in all fairness, you may get separate answers on that. I have not made up my mind, really, whether or not this is a good idea, because I don't know the numbers. I know that HHS says it would save money; I'm not sure how. I think, as Senator Danforth has said, I'm always reluctant to try something new when an old system seems to be working very well. The distribution system we have now is demonstrated on this chart -- the new one is demonstrated on that chart. It is immensely more complicated. It is my belief -- I'll just blow this out -- it is my belief, we'll start here, in the past the government CDC has purchased 50 percent of all the vaccines in this country. Fifty percent were sold by the pharmaceutical companies in the private sector.

Obviously, the cost to the government on their contracts for that 50 percent was substantially less than private physicians paid. And now, out of this system the government proposes to buy 80 percent. Now what you have to bare in mind is if the government were using the existing distribution system and could buy 80 percent of the vaccine at the same price they've been paying for the 50 percent, there would be a substantial savings for the government. My guess is that perhaps this idea of a big warehouse in Burlington, New Jersey was calculated or conditioned on the proposition that since we were going to be buying roughly 80 percent of the vaccines, whereas incidentally, I think (it actually ?) was intended in the bill that we would buy 60 percent, but now we're headed for 80 percent.

I think this warehouse idea was designed to take care of a significantly bigger federal purchase than they have made in the past. And when they make claims for savings, I've never quite understood that unless they're using that as their savings. Because obviously, this warehouse is going to be an expensive undertaking. It's going to take people to run it; it's going to take a lot of electricity to keep the power, keep the refrigeration at the right temperature and so on. That's one of the reasons that we're going to hold a hearing Thursday afternoon to explore that. Jack, would you like to address that?

SEN. DANFORTH: I can't conceive that we're going to be better off as a country by opening the warehouse in New Jersey, or by creating this new

distribution system. And I think that when you have a system that's working, you don't begin wrecking that system, and there's no way that this amount of dislocation can't have a negative effect on the current distribution system. So, I think that it's a mistake; I really believe that it's a mistake. And I think that if the goal is to increase immunization, and that is everybody's goal, there are ways to accomplish that; there are certainly ways to explore accomplishing that short of buying up huge amounts of vaccines and creating this new governmental distribution system.

SEN. BUMPERS: Ron, I want you and Scott to address this also. But let me just say that CDC or HHS, first of all, they tried to get the VA to do it, then they tried to get the defense department to do it; neither one of them wanted any part of it. But they never one time submitted this to the private sector for bids to see whether or not it could be done cheaper in the private sector than the government's doing it. And I think that was a very bad mistake. -- (Inaudible).

SEN. DANFORTH: Well, in terms of our motives, I think there were kind of two-steps. The first step is to see how the program, as drawn up, is going to work and if it has a chance of working. And I think the evidence, at least in the GAO report, suggests that the program, as on the drawing board, is falling apart even as we speak. They've only signed up four out of 15 pharmaceutical companies; the staff at the GSA warehouse in New Jersey has not been trained at this point; they've not tested, as Senator Bumpers said, any of the packing equipment to see if it will hold up to FDA standards. So even if you assume this is a good idea, I think it's very difficult to believe it will be ready to go up and running in the next 60 days.

Now, as a general statement, last year, there were a number of questions raised in the house side in ways and means, and in energy and commerce on which I said, which essentially looked at this from the beginning to say, wait a minute, there's a very serious problem out there. But how, in God's name, is the government warehouse going to solve any of it. So, I have no objections in spending more money on kids immunization programs; I think it's money well spent. I just don't think the answer's in a warehouse in New Jersey.

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**** printed by:WHPR(BTOI) on 07/19/94 at 14:55EDT ****

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SEN. BUMPERS: Ron, you want to address that?

REP. WYDEN: I think you all have said it very well, and maybe to just highlight Senator Bumpers, here's an example again of what my state has said, or part of the problems that I think have not really been addressed. You know, we're talking, for example, about the impact this is going to have on low-income families, and the question of whether or not they're going to be able to get the doctor's fee waived. Well, my state has said that the Center for Disease Control indicated to them that families have the right to refuse to pay doctors only if it's their regular doctor.

Well, what we know is that a lot of low-income folks in our country don't have regular doctors, so I think what Senator Bumpers and our group is really saying is that we are seeing countless of these kinds of administrative problems that have got to be resolved.

SEN. BUMPERS: Yes.

Q -- (Off mike.) --

REP. WYDEN: No, I've not in the immediate past. I have spoken to him over the last year in regard to the general problem. Wisconsin, several years ago, had a celebrated measles epidemic in the Milwaukee area where we actually had a number of deaths. And it was one, I think, point of controversy that really started this whole debate going again. What public health officials discovered in Wisconsin, I think much to their chagrin, was that 97 or 98 percent of those kids were already eligible for free vaccines because they were Medicaid patients. And so, that really raises the questions again about how do you get that 98 percent of the kids.

It's not going to happen from a warehouse; you reach them by education and making it clear to parents they have a responsibility, and by making sure the clinics are accessible and available and with outreach programs. So I think, you know I can't speak for Wisconsin health officials, but I think given the discussions we've had over the course of the last year, I think we're on the same wavelength.

Q Knowing as much about the government as you do, and I must assume that you -- (inaudible) --

SEN. BUMPERS: Jack?

SEN. DANFORTH: I didn't vote for it.

SEN. BUMPERS: This was a presidential initiative, and with all due respect to the president, who was obviously operating on information handed to him by CDC and HHS, and the information was very badly flawed. Scott has already -- I think it was Scott that pointed this out. They were using information that was old; that showed the immunization levels of children in this country were 50 percent when, in fact, shortly after this bill passed, we learned from CDC that, for example, MMR levels are at 90 percent. DPT, I think, is at 86 percent. Polio is at what, Marianne? Eighty?

So you can see that we did not have the crisis on our hands that was portrayed to us at the time. And so, all of us went to work, and I had heard these figures whispered -- these new figures. But we went to work with this legislation saying, we've got to do something different; we've got to do something dramatic. I voted, unlike Senator Danforth, I voted for it. But it was not my -- the bill I didn't craft. It's not the kind of a bill I would have crafted.

Q Let me just follow up on that.

SEN. BUMPERS: Sure.

Q Is there any possibility that you're -- (inaudible).

SEN. BUMPERS: Well, I don't think you can lose if you can -- for example, if I had my way right now, I'd scrap the money about to spent on the warehouse and add it to the funds for outreach, clinic hours, education awareness, all of those things, Because that has a proven track record. This has no track record, and I'm afraid the one it's about to make could be almost fatal -- it wouldn't be fatal to the program, but it would be very devastating to it.

Q -- (Off mike) --

SEN. BUMPERS: Yes, yes. In my opinion, we will have such legislation.

Q Senator -- (inaudible) -- there are about three million kids born annually in the country, and -- (inaudible).

SEN. BUMPERS: No, the program is designed -- we want to get the 95, somewhere between 95 and 100 percent. And that's always been our goal. When Betty Bumpers got me involved in this in 1972, and I was governor of my state, and she frankly, just at loose ends, she was -- I don't want to get into that Hillary Clinton, she was tired of pouring tea, it wasn't that. She wanted to do something meaningful and take advantage of her position in the state, and so she chose this.

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**** printed by:WHPR(BTOI) on 07/19/94 at 14:55EDT ****

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And the first thing, you know, she was deeply involved, and I remember one Saturday with the help of the National Guard, Nurses Association, about ten different volunteer organizations, we immunized 300,000 children in one day and did not have, incidentally, one single reaction. It was an absolute masterpiece of work, and a stroke of luck not having a reaction. So, I got deeply involved in that, and I've been deeply involved in it ever since. The idea is to eradicate these diseases. We could eradicate measles; polio is about to become extinct on the planet. As you know, Central and South America had the last wild virus polio in the world, and that's about gone. We can eliminate measles, we can eliminate all of these devastating childhood diseases. They sound benign because we say childhood, the truth is they are devastating. When I first got involved in it, eight percent of the people in mental institutions in this country were there because of some syndrome from one of these childhood diseases. So you are talking about cost-benefit ratio that is really staggering.

But let me make one other point. I put a thing in the Congressional Record this morning which I invite you to read. And I'm reluctant to say this, and it's not denigrating of anybody's religion, but it is a fact. We have had over 500 cases of measles this year, due largely to two outbreaks, and both those outbreaks were pools of Christian Scientists where the children were not immunized. Once the outbreak, they were immunized. I mean I don't understand -- I don't choose to talk about what they permit and what they don't permit -- I am just saying that any time you develop a pool that is receptive to one of these diseases, you face a very good chance of getting it. And you will -- if we had 99 percent -- if we had 99 percent of the children in this country immunized against all of these diseases, the chances of a pool that would be receptive to these childhood diseases barely exists. You cannot guarantee that you would always do it, but the higher the level, the less chance of that pool being there. So what we want to do is to eliminate the possibility of the pool and eliminate the disease. And we can do it -- we've done it on polio, we can do it on measles and mumps and rubella.

Q Can I ask one -- just some numbers for you. When this program came up last year there were 13 states -- is that right -- that had universal immunization programs which meant everybody regardless of income or insurance coverage could get free vaccines. And the balance of the states did essentially a public-private split, so private insurance covered, if you had Medicaid you were taken care of. This program was really designed to fill two gaps -- a, kids of families who did not have insurance at all, so essentially too wealthy to be on Medicaid, but still struggling, or secondly, kids who had insurance, but whose insurance did not cover immunization programs. That was the real kind of slice of the pie that this was designed to hit. But obviously, as you've heard, it's a much broader shot than --

Q How much -- (inaudible)

REP. WYDEN: I don't know that.

Q Does anybody know?

SEN. BUMPERS: Nobody can answer that question, but Scott that's an excellent response.

Q (Inaudible)

SEN. BUMPERS: You are trying to create a high class divorce and I don't want to get into that. (Laughter)

Q (Inaudible)

SEN. DANFORTH: I would think we would have to go back to scratch, yes. I mean it just seems to me that this is something that is not just wrong in some specific component, but that it's wrong in design, that it's just a mistake, a mistake in concept. A mistake in concept that if there is a problem, the way to do it is the big government approach, the Washington approach. And I think that that was a bad concept. I think that it was reached for the best reasons, but I think that that is the kind of a mentality that -- there's a problem -- I mean we are the ones who have to fix it and we have to fix it in the most grandiose conceivable way.

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**** printed by:WHPR(BTOI) on 07/19/94 at 14:56EDT ****

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Q (Inaudible)

SEN. DANFORTH: I don't know the answer to that. My impression of the origin of it -- and you know in this bipartisan gathering I don't want to sound partisan -- but my impression of the origin of this was that when the new administration came in it wanted to do something, and that it saw this as something that was very important to do, and that this was going to be one of the new energetic efforts in the early stages of the administration, so that it worked its way into the budget last summer and here we are.

And again I want to say I don't to sound critical of motives because I'm not, I think that the motives in fact are very good. But I think it's just a view of things, it's a way of saying there is a problem, we are the solution, the solution has to be as big and as centralized and as expensive and grandiose as we can possibly make it. And when you do that, first of all you have a negative effect on what is going on right now, which is a good system. You have a negative effect on that good system, have to. I mean you can't come in with this sort of very heavy handed approach without effecting the way things have been done for a period of time, and done well for a period of time. And then secondly you create all of these real problems that would have to be resolved, the problem of the warehouse, the problem of refrigeration, the problem of computerizing the delivery system and actually getting a delivery system. When you look at it, that is Senator Bumpers product, it -- I mean it looks crazy. I mean it just looks crazy. And this is the old system.

SEN. BUMPERS: I don't have -- (laughter) --

SEN. DANFORTH: I don't think you can have both, so yes, I think that you just have to start from scratch. I am not an historian, but I think that it was something that was done by people who are very earnest and very energetic and wanted to do the right thing, and it turned out to be haywire.

Q How much money does Congress appropriate -- I'm having a little trouble here -- (inaudible) --

SEN. BUMPERS: We have obviously failed miserably here this morning. (Laughter.)

Q I mean is there a problem in immunizing our children throughout the country or --

SEN. BUMPERS: There is a problem, and let me reiterate what it is. It is a lack of awareness, it is clinic hours, it is failure to have sufficient outreach programs to reach the low income children who are the ones who are mostly unimmunized. And what we are seeing is this distribution system does not do one thing to solve that basic problem. And what I said was if we were to spend the money that we are spending on this new distribution system, which looks like a possible disaster in the making, if we were to put that money into the proven programs that have brought us to these 90 percent levels, we would be eminently better off.

Let me make one other observation. As you mentioned, Betty Bumpers being on the advisory committee, I remember several months ago she came by, she came home one evening, she had been to the committee meeting, she said "I want you to check something, I just heard the craziest thing today, that the government is talking about storing all this vaccine in New Jersey." So that was really the beginning of my knowledge of this.

And the other thing I want to mention is, you heard me say a moment ago, on that Saturday in Arkansas when we immunized 300,000 children, Betty was admittedly rhapsodic about what had been eminently successful. But then she said that same evening, "This is good for your political career and it's good for the children who are immunized, but it is not a solution. This is a one shot thing that all the cameras covered today, but three years from now we'll be right back where we are right now with the same number of unimmunized children." And she said, "Unless we somehow develop a system in this country to keep up with children from the time they are born until they are six years old, we will never get immunization levels where they ought to be."

Q How much is this program costing -- how much would it cost?

SEN. BUMPERS: Well this is a \$500 million program. Marion, how much was it last year?

Q I'm talking about the difference between that distribution system and the one --

SEN. BUMPERS: I can't answer that precisely. I can tell you that the total program is \$500 million this year and that's roughly \$100 million more than last year, maybe more.

Q You made the statement that if we put the money from what we would spend on this --

SEN. BUMPERS: Whatever amount it is -- I don't know what the amount is -- all I know is it could be better spent, that's the point I was trying to make.

Q Well how are you going to handle that --

SEN. BUMPERS: No, no, no, you are talking about millions. They say they are going to save \$30 million. I don't know how they calculate that. We'll find out Thursday afternoon.

Q Senator Bumpers, what do you intend -- legislation to stop this from being implemented, what do you intend to do about the program?

SEN. BUMPERS: We will use language on the Appropriations Bill to say none of the funds herein may be used until a certain time, namely if they go forward with the distribution system, that they satisfied us. Now Senator Danforth may wish to go further than that and just torpedo the whole idea. That's difficult to do on an Appropriations Bill. John, do you want to say anything about that? (Laughter)

SEN. DANFORTH: Well there will be perhaps other opportunities to deal with health questions on the floor of the Senate -- (laughter) -- between now and October. Actually when the health care bill was marked up in the Finance Committee, I considered offering an amendment to that legislation dealing with this and basically converting it into an average program, but it was impossible under the circumstances because we were -- we limited ourselves to

five minutes per amendment, and this can't -- I mean we can't discuss this in a press conference, much less to try to deliberate in the Finance Committee in five minutes. I think that Senator Bumpers' hearing is going to be a very important hearing because I think it will provide the basis for us devising a constructive approach to it.

Let me just say one thing on the money part, we want to spend money on immunization. When you talk about spending money on health care, that's one of the best ways you can spend money on health care, through immunization. We want to do it, we want to immunize children, we want a program that works. The only question is what is it that works. We believe that what works is education, what works is outreach, what works is some very specific ways of making it more likely that physicians will actually immunize children when the children come into the office. Those are the real issues

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**** filed by:RB--(--) on 07/19/94 at 14:39EDT ****
**** printed by:WHPR(BTOI) on 07/19/94 at 14:56EDT ****

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be addressed. The GAO has said that this scheme isn't going to produce any more immunizations, so it's really much ado about nothing.

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Q (Inaudible)

REP. WYDEN: On the House side, John Porter from Illinois raised similar questions on the appropriations bill, and essentially, we decided not to do anything consciously in the House to force a vote until we got into the conference. And I would suspect you may see an attempt to instruct conferees to essentially agree to the Senate's position on this (thing?).

SEN. BUMPERS: My guess is to conclude that answer to that questions is we will put language on the appropriations bill saying that none of the funds herein may be used at least until something, because I'm not sure we're going to get a health care bill. We could address this in a health care bill, and that would be the best place to do it if I knew that bill was going to pass and be signed by the President. I'm not sure of that right now, and I don't want to take any chances on this, so we probably will put a prohibition. One more question.

Q On that issue, given that the people who designed and -- (inaudible) -- are presumably the ones who are involved in designing and improving the rest of the -- (inaudible) -- on health care, given your low opinion of this system, what gives you greater confidence in the other position -- (inaudible).

SEN. BUMPERS: I would strongly urge you not to draw a parallel between this program and what might happen in national health care. (Ardent?) proponents -- I've read several times -- (ardent?) proponents of a national health care bill of any kind have said this is a typical prelude for people on what will happen if we have national health care; that it will be this compounded on a daily basis. I don't believe that. I happen to very strongly favor a national health insurance bill.

And to say that because this system, because in my opinion poor judgement was used about how to raise immunization levels in this country, doesn't make my national health insurance a bad idea.

SEN. DANFORTH: Well, let me just say that Dale Bumpers is my friend, and he is the host of this news conference, and I wouldn't begin to start a disagreement with him in this particular forum.

-- (Off mike.) --

SEN. DANFORTH: I would just say that among us, there might be some different nuances in answering the question that you ask.

SEN. : But the bottom line is, it seems to me, is the General Accounting Office says that some serious problems need to be fixed. It does not say in this report, throw this entire thing out the window and begin from square one. It says some serious problems need to be fixed. I strongly support what Senator Bumpers has called for which is that we are going to hold off until the problems are fixed. I think among the four of us, you would get wide agreement that the central concern is how you get families educated.

In my state, not a single youngster is going to go without because of cost. But we do know that some youngsters are going to go without because

heir parents don't know about it; maybe they don't have a ride to a public health program. So what we're going to do as we try to fix this program is employ a hands-on public health response, rather than some kind of bureaucratic -- (inaudible) -- program.

SEN. BUMPERS: One final point you should understand, and that is any child who is uninsured, that is if his insurance doesn't cover immunization, that child -- I don't care if he's the bankers son -- can go to the clinic and be immunized free. Is that a correct statement? So you bare in mind, that's another reason cost is not prohibitive. If somebody wants to go to the clinic or their private physician to get -- because they trust him more, for example, and they intend to pay a \$10 to \$15 cost, plus a \$50 office visit, if they don't want to do that, they can go down the block or wherever to a public health clinic, and avoid all of those costs and get a free immunization. That's one thing -- that is the one salient thing that is really new about this kind of a program.

Q Senator Bumpers, -- (inaudible).

SEN. BUMPERS: I didn't intend to sound gloomy, John, I just wanted to say that I know when that thing comes to the floor -- I didn't intend to sound gloomy about the prospects for passage of a national health bill, I simply wanted to say that I think you're talking about apples and oranges when you talk about a program here that we have suggested has gone awry. But there isn't anything about this that can't be corrected in roughly short order. And to suggest that this is typical of the government when they involve themselves in health care, is terribly wrong.

You shouldn't lose sight of the fact that 90 percent of the children in this country are immunized. That says a lot; that says this program has been largely successful. We want it to continue being successful, but to draw a parallel because something has suddenly gone awry in the program to say, this is what we're going to get if we have national health insurance, I think, is an erroneous parallel, an erroneous comparison and just has no foundation.

Thank you.

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**** filed by:RB--(--) on 07/19/94 at 14:43EDT ****
**** printed by:WHPR(BTOI) on 07/19/94 at 14:56EDT ****