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VACCINES FOR CHILDREN

Major Implementation Hurdles Remain

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Mr. Chairman and Members of the Subcommittee:

It is my pleasure to be here today to present information on the implementation plans developed by the Centers for Disease Control (CDC) for the Vaccines for Children (VFC) Program. My statement is based upon our report entitled Vaccines for Children: Critical Issues in Design and Implementation, which we issued on July 18, 1994. In our testimony today, we will describe how CDC plans to implement the VFC Program, and provide information relevant to assessing the likelihood that CDC's proposed system will meet the program's goals as identified by CDC. First, however, I will provide some basic information on the VFC Program and briefly describe the work we conducted in response to your request.

I would like to begin by underscoring the importance of vaccination. Within this century, vaccination has been credited with tremendous reduction in the incidence of some infectious diseases, including the worldwide eradication of smallpox and the elimination of polio from the Americas.

What is commonly referred to as the Vaccines for Children Program is designed to increase vaccine coverage levels nationwide by creating an entitlement to free vaccine and thereby reducing vaccine cost as a barrier to immunization for four groups of children. These four groups are: (1) Medicaid-enrolled children; (2) children without health insurance; (3) underinsured children (that is, children insured under a plan that does not include vaccinations as a benefit), and (4) children covered under the Indian Health Services Act, which applies to American Indians and Alaskan Natives. Other presumed barriers to immunization are addressed in the administration's Children's Immunization Initiative, of which VFC is one part.

CDC, the General Services Administration (GSA), and the states will operate the basic components of the VFC Program: the purchase of vaccine and its distribution to VFC-enrolled providers (that is, physicians in private practice as well as public health clinics) for use in immunizing eligible children. CDC will be responsible for negotiating a price with the vaccine manufacturers and consolidating vaccine orders from the states; GSA will carry out the vaccine distribution function. The states are responsible for enrolling providers, submitting providers' orders to CDC, and ensuring program accountability. CDC's plans for implementing the national VFC Program call for the system to become operational by October 1, 1994, as mandated by the law.

METHODOLOGY

To answer your questions, we conducted four types of activities. First, we reviewed the literature on barriers to childhood immunization and agency documents related to program implementation. Second, we interviewed officials of CDC and GSA, and conducted a telephone survey of immunization projects in 49

states and the District of Columbia to ascertain the status of their implementation efforts. Third, to learn more about existing vaccine distribution arrangements, we interviewed experts and interested parties, including the National Wholesale Druggists Association, the Health Industry Distributors Association, three major vaccine manufacturers, and experts in vaccine research and logistics. Finally, to supplement our conversations with GSA officials, we toured the proposed GSA vaccine distribution facility in Burlington, New Jersey, as well as a nearby vaccine distribution facility operated by Merck. Our work was conducted between June 14, 1994, and July 8, 1994.

STUDY RESULTS

Before discussing our specific findings, we would like to note that the original plan to implement the VFC program by October 1 was very ambitious given the scope, inherent complexity of tasks, and the need for strong leadership to coordinate the efforts of various federal, state, and private sector partners.

By examining the status of several tasks that are integral to program establishment and operation, we found that the current implementation schedule will not allow for delay in any major tasks and that, as of July 6, this already challenging schedule did not incorporate plans for testing vaccine shipping arrangements. Some of the tasks we examined are interdependent and must be performed sequentially, so delays in one task (such as contract negotiation) could have significant impact on others (such as readiness to accept orders and deliver vaccine by October 1) and thereby affect overall implementation. The distribution of responsibilities across CDC, GSA, and states may increase the potential for miscommunication and consequently delay implementation.

First, I will describe the major components of the proposed VFC Program and assess the likelihood that the program will be fully operational on October 1, 1994. Second, I will summarize information relevant to assessing the program's capacity to meet its goals, as articulated by CDC.

Major Program Components

We reviewed seven program components that CDC must put in place for the program to be fully operational by October 1. These seven components are critical to the implementation and effectiveness of the VFC, but are by no means the only components that need to be in place. In this section of my testimony, I will discuss four of these components: (1) vaccine contract negotiations; (2) provider enrollment; (3) order processing; and (4) vaccine distribution plans, including the selection of a distribution facility and the testing of vaccine packaging. The other three components--(5) provider reimbursement, (6)

accountability mechanisms, and (7) evaluation plans--will be discussed in the context of program goals.

Vaccine Contract Negotiations

The program requires that vaccine be purchased in bulk under federal contracts with manufacturers. CDC officials maintain that the current status of contract negotiations is consistent with the agency's time line, which calls for contracts to be awarded by the end of July, with states' orders submitted to CDC in August and vaccine shipped from the distribution facility to states and providers in September. However, when we spoke to CDC officials on July 5, we were told that although bids had been received on each of the 15 vaccine contracts, only 4 of these contracts had been signed, with 11 still under negotiation.

Provider Enrollment

Most state officials told us that they have just begun efforts to recruit providers to participate in the VFC Program. Although CDC has conducted several activities to support state efforts, only five state immunization projects reported to us that they had mailed enrollment forms to potential providers by the end of June. CDC's plans had called for states to begin collecting signed enrollment forms in May. CDC officials told us that, owing to time constraints, the agency is not monitoring the number of providers states have enrolled; they plan to assess this from initial vaccine orders.

Order Processing

States will be responsible for receiving and approving vaccine orders from VFC-enrolled immunization providers. With respect to order processing, CDC's plans appear to be on schedule for training state staff to use CDC's order-processing software; however, some states have not even hired or selected the persons who will use the software. Moreover, the schedule for testing the hardware and software appears to be quite ambitious. CDC's current schedule calls for systems to be delivered to states in late July, at the close of CDC's scheduled training sessions, and tested, through the transmission of mock orders, by the first week of August. Even if CDC meets the demands of this schedule, their tests are only sufficient to demonstrate that the computer systems are functional--not that the order-processing system is capable of accurately and rapidly processing requests from providers in the volume that may be anticipated.

Vaccine Distribution

Based on discussions with vaccine manufacturers, CDC officials concluded that manufacturers were reluctant to deliver vaccine directly to the anticipated 70,000 providers under the

capped price. Therefore, CDC found it necessary to develop an alternative distribution system. However, CDC does not appear to have conducted a systematic review of distribution options before settling on the use of a GSA distribution facility in Burlington, New Jersey. In their deliberations, agency officials appear to have accorded the greatest weight to the October 1 deadline.

While reviewing the plans for distributing vaccine under the VFC Program, we questioned GSA and CDC officials about plans to test the performance of vaccine packaging along various delivery routes to ensure the preservation of a vaccine's potency. GSA officials told us that such arrangements had not been formally initiated or incorporated in their already tight implementation schedule. Moreover, CDC had not instructed GSA to validate shipping processes. This is significant because proper shipment of vaccines requires that the temperatures to which the vaccines are exposed do not fall outside manufacturers' specified limits for periods long enough to damage the vaccine's potency.

Following discussions with us regarding provisions for safeguarding vaccines during transit, GSA officials acknowledged that they would prefer to have an additional 3 to 5 months of time beyond October 1 to implement the program.

In summary, CDC faces many major implementation hurdles if it is to have an operational program by October 1, 1994.

VFC Program Goals

In addition to reviewing the status of VFC implementation plans, we have developed information relevant to assessing the program's capacity to meet its goals, as articulated by CDC--to increase vaccination coverage rates by removing vaccine cost as a barrier to immunization. We found that two of the major implementation decisions made by CDC may be at odds with the program's stated goals and that the agency has not developed an evaluation plan to compare the cost and effectiveness of VFC to the present system.

Provider Reimbursement

While providers may not charge for vaccines under the VFC program per se, the law does authorize them to impose a fee for the administration of the vaccine. According to the Omnibus Budget Reconciliation Act of 1993, a VFC provider may impose such a fee as long as it "does not exceed the costs of such administration (as determined by the Secretary based on actual regional costs for such administration)." As part of its provider enrollment activities, CDC has established administration fee caps for providers based on physicians' prevailing charges as provided by the American Academy of Pediatrics rather than based on actual costs of administration.

However, CDC provided no evidence that it has examined the feasibility of computing the actual cost of vaccine administration. There is no indication that CDC attempted to determine provider willingness to participate at reimbursement levels below what they usually charge for vaccine administration.

Using physicians' prevailing charges rather than cost data may result in vaccine recipients' being asked to pay more for the administration fee than the law stipulates. This would be inconsistent with the primary goal of the VFC Program, which is to remove cost as a barrier to immunization. Using prevailing charge data appears to promote incentives for physician participation at the expense of those children for whom cost is supposed to be a real factor.

There are also unresolved issues as to the importance of cost as a barrier to increasing immunization rates. As we have reported earlier, the savings on vaccine costs that may derive from bulk purchasing programs

> "will do little to improve preschool immunization levels unless funds are provided for educating parents and tracking and following up on the immunization status of children to help ensure that preschool children receive timely immunizations."[1]

The VFC Program aims to increase vaccination coverage rates by reducing vaccine cost as a barrier to vaccination. Yet most recent studies, including those of four inner city areas where the undervaccinated tend to be concentrated, indicate that vaccine cost is not an important barrier. Lower economic status is associated with undervaccination; however, this does not appear to be attributable to cost but rather to other factors associated with poverty. Moreover, most children who are now undervaccinated are eligible for free vaccine under current programs. At your request, we will be providing further information on this issue at a later date.

Accountability Mechanisms

CDC considers it crucial to maintain a balance between accountability and provider participation and believes that accountability mechanisms may impose disincentives for provider participation. Accordingly, the agency's current reporting system does not require providers to report which children receive vaccinations. Further, CDC has specifically discouraged states from requiring specific data elements or information from

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[1]U.S. General Accounting Office, Childhood Immunization: Opportunities to Improve Immunization Rates at Lower Cost (GAO/HRD-93-41, March 24, 1993).

providers, which would enable states to link VFC data to a state registry for tracking children's immunization status. This means that CDC will find it difficult to detect misuse, fraud, or abuse patterns and that the benefits of tracking systems for increasing immunization rates will be lost.

Evaluation Plans

On July 6, CDC officials told us that the agency has not formed plans for evaluating the VFC Program. However, determining the specific impact of the VFC Program will be difficult without collecting baseline information prior to implementation.

Although the goal of the VFC Program is to improve immunization rates for all antigens to 90 percent by 1996, CDC could identify neither the proportion of providers who must enroll nor where recruitment efforts should be concentrated in order to meet the 90-percent goal. It will admittedly be difficult to assess VFC's impact as distinct from the impact of other components of the Children's Immunization Initiative.

In conclusion, our review indicates that it is unlikely that CDC can fully implement the VFC Program by October 1, 1994, and raises questions about whether VFC, when fully implemented, can be expected to substantially raise vaccination rates. Finally, unless plans for an evaluation of the program are included in its design, we may be unable to determine its impact on vaccination rates.

Mr. Chairman, this concludes my opening remarks. I would be happy to answer any questions you or members of the Subcommittee may have.

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