# Childhood Immunization Programs: An Analysis of Policy Issues

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HE DEVELOPMENT AND PREVALENT USE OF VACCINES have made a major contribution to the reduction of infectious diseases among children in the United States throughout this century. Beginning with the widespread diphtheria, pertussis, and tetanus immunization programs of the 1940s, vaccinations have captured the attention of the American public and gained the broad acceptance and advocacy of practitioners as have few other preventive medical practices. Immunizations are now available and routinely recommended to protect children against a host of diseases that were, less than a generation ago, significant causes of suffering and death. Improvements in existing vaccines, the development of new ones, and modifications of current recommendations continue. In 1990, the Centers for Disease Control (CDC) amended its recommendation for the Haemophilus influenzae, type b (Hib) vaccine – designed to prevent the leading cause of childhood meningitis in the United States-so that the first dose could be given to all children at two months of age instead of the previously recommended 15 months (Centers for Disease Control 1991a). Recent modifications of this vaccine allowing for its administration at this earlier age could prevent up to 80 percent of all the bacterial meningitis occurring in the pediatric population.

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Current research is also directed toward developing of new immunizations against common causes of other severe childhood illness. Vaccines for rotavirus (the most common cause of infantile diarrhea), respiratory syncytial virus (the cause of bronchiolitis, the most common infantile respiratory disease requiring hospitalization), and varicella (chickenpox) are expected to be licensed within the next five years.

Changes in recommendations for existing vaccines also occur in response to changing social or environmental situations. Most recently, the CDC has recommended universal immunization of infants against the hepatitis B virus (Centers for Disease Control 1991b). Earlier immunization programs targeting only groups at high risk for the virus (e.g., IV drug users) had failed to control the spread of hepatitis B, now responsible for more than 5,000 deaths per year. Therefore, a new strategy was required.

Future efforts in vaccine improvement, new vaccine development, and modification of existing recommendations have the potential further to decrease the burden of suffering from infectious diseases among the children of the United States.

Although immunizations have been among the most successful of preventive interventions, concern exists in the United States that recent epidemics of vaccine-preventable diseases may signal the existence of major underlying problems in immunization policy and in the effectiveness of national, state, and local public health programs to administer these preventive services to children. We will examine the current state of childhood immunizations in this country and offer a broad range of suggestions for policy modification.

# Background

Current Vaccine Rates for Children. In 1991, although national immunization levels for recommended children's vaccines were virtually complete at a level of 97 to 98 percent at the time of school enrollment, up to 40 percent of two-year-old children in the United States did not receive their immunizations at the recommended younger ages. Immunization at school entry does not prevent the life-threatening diseases of infancy for which most of these vaccines exist. Epidemics of vaccine-preventable diseases have recently occurred in many cities throughout the United States, including Houston, Los Angeles, and New York City,

establishing our national problem of poor early childhood immunization rates as a significant public health concern.

In 1983, a record low of 1,497 measles cases was reported in the United States. However, in 1990, over 500 cases per week occurred (a total of 27,672 cases—the largest number reported since 1977). These occurrence rates exceeded the surgeon general's goal of only 500 measles cases nationwide by 50-fold (National Vaccine Advisory Committee 1991). This represented a 52 percent increase over the 18,193 cases reported for 1989. During the 1989–1990 school year alone, five school districts in the United States experienced measles epidemics affecting over 1,200 children each.

By the late 1980s, birth defects from congenital rubella syndrome had almost disappeared in the United States because of the success of rubella immunization. Only two cases of this syndrome were reported in 1989. However, 24 cases were reported in 1991. Concurrently, the incidence of infectious rubella increased 500 percent after 1988 to 1,372 cases (Lee, Ewert, and Frederick 1992).

These epidemics suggest the need for a thorough reexamination of our nation's capacity to deliver vaccines to all children within our current health care system. Such events should serve as a harbinger of the direction of children's immunization status and as a call to action to address deficiencies.

Childhood Vaccination Rates in Other Countries. Immunization rates of school-aged children in the United States are among the world's highest. However, the rates of early childhood immunization in the United States compare poorly with other Western industrialized nations and many developing countries. Dramatic progress has been made worldwide in childhood immunization over the last ten years. The proportion of the world's children under one year of age that has been vaccinated against six potentially lethal childhood diseases has increased from 20 to 80 percent. In 1988-1989, 16 countries had immunization rates higher than those in the United States, including Bulgaria, Hungary, Greece, Brazil, China, Mexico, North Korea, Chile, and Romania (Shea 1991). The World Health Organization reported in 1990 that rates of measles immunization among one-year-olds had reached 87 percent in India and 98 percent in China. Overall, Asia has a higher rate of measles immunization (86 percent) than Europe (80 percent) or the Americas (82 percent). It is remarkable that immunization programs in developing countries have achieved these levels of success in view of the

tremendous barriers and situational difficulties that must be overcome. For example, during the civil war in El Salvador, two- or three-day ceasefires were called to allow childhood immunization teams safe passage in battle zones (Brown 1991).

Rates of vaccine-preventable diseases are traditional measures of the quality and effectiveness of a nation's overall health care delivery system. The recent U.S. domestic trends in immunization rates and vaccine-preventable diseases relative to the rest of the industrialized world may signal that certain aspects of the U.S. health services delivery system are in serious need of reevaluation and reorganization.

Explanations for U.S. Childhood Vaccination Rates. Immunization involves not only vaccines, but also a system for their administration. Many of our nation's immunization problems originate in our current system of vaccine administration, a conglomeration of complex and often uncoordinated efforts in both the public and private sectors. Approximately half of U.S. children receive their immunizations from private physicians; the other half receive vaccines in the public sector (usually from city or county health departments, federally funded community health centers, or public hospital clinics), either in connection with other preventive health services or during provider visits or as an independent categorical service (Hinman 1991).

Federal funds pay for approximately half of vaccines administered via public sector providers through CDC grant programs, Medicaid, Maternal and Child Health Block Grants, and other programs. The remainder is funded by state and local governments. Between 1963 and 1991, federal funds were not used for actual delivery of immunizations at the local level. Rather, these funds were used primarily to purchase vaccines for use in the public sector and to support other immunization-related programs, such as vaccine promotion, periodic surveillance, and assessment of coverage for specific populations. However, in 1992, additional federal funds were made available for immunization delivery. Although the total amount of federal resources allocated for immunization is substantial (\$185 million in 1991), there is limited coordination of the federal role in vaccine programs, and no mechanism exists to coordinate efforts between public and private sector organizations. For example, there is no central record-keeping mechanism either to track a child's immunization status or to monitor immunization rates accurately at either the national or local levels.

Given the huge resources expended in both the public and private sectors for immunizations, the increasing number of children experiencing vaccine-preventable illnesses is alarming. The goal announced by the U.S. Secretary of Health and Human Services for improving this area of preventive services was clearly outlined in the *Healthy People 2000* report: ". . . increase to at least 90 percent the number of children who receive the basic immunization series by age two" (U.S. Department of Health and Human Services 1990). However, a plan for achieving this goal has remained elusive.

Toward a National Immunization Policy for Children. Ideally, immunization policy should be integrated into a comprehensive, national child health care system. Unfortunately, such a system has not been established in the United States and will not exist for the foreseeable future unless one of several dramatic national health reform proposals is enacted, preferably a plan that includes explicit coverage of basic preventive health services such as immunizations. However, this situation must be remedied with or without national health reform. The issues surrounding immunization are very complex; attempts to improve such a massive infrastructure can be overwhelming and frustrating for policy analysts and decision makers. Short-term steps toward the reorganization of national efforts on childhood immunization can best be approached through delineating aspects of the overall problem.

We propose, then, four components of immunization problems in the United States, easily identified as the A,B,C,Ds of immunization:

- A. ACCESS problems for patients, which involve the availability and affordability of adequate health care
- B. BARRIERS in both the public and private sectors, which prevent those who seek care from receiving it
- C. COMPLIANCE with existing vaccine recommendations by physicians and other health care workers caring for children
- D. DEVELOPMENT of new vaccines that are safe, free of serious side effects, and easy to administer

## Problems and Solutions

## Access

Access to health care involves two specific components: (1) the availability of services of acceptable quality to individuals seeking or needing health care, and (2) the affordability of health care services. Many fami-

lies confront problems with both aspects of access. Having a source of health care—ideally, a personal health care provider—as well as the means to pay for these services are the first steps in securing well-child services that include immunizations. The National Vaccine Advisory Committee (NVAC), under the direction of the Assistant Secretary for Health and Human Services, is responsible for advising the National Vaccine Program. NVAC considers inadequate access to care as one of the four principal barriers to immunization (National Vaccine Advisory Committee 1991). Inadequate access can impact on rates of childhood immunization in three critical respects:

- 1. lack of a primary health care provider
- 2. financial constraints to immunizations and other well-child care
- 3. failure of private insurance to cover immunizations

Underserved Children Without a Primary Health Care Provider. Large numbers of preschoolers in this country have no regular primary care physician with whom they have a personal relationship (National Center for Children in Poverty 1990). Many families without a regular source of primary care consider the local emergency department their primary source of care; however, as a rule, emergency departments do not routinely administer immunizations. Without a source of regular care, children have little opportunity to receive the full schedule of vaccines, much less on time. A child stands a far better chance of being fully immunized if he or she has one primary care provider who is likely to monitor the child's immunization status on a regular basis and to provide the required immunizations on site when these needs are identified.

Several measures could result in more children having a primary care provider. Emergency departments should request all pediatric patients to identify a primary health care provider and to make appropriate referrals to community-based care providers when one is not named. For such a program to be effective, participating clinics and local practitioners must make appointment slots readily available to patients identified through this process. Many local medical societies and pediatric societies actually operate physician referral services for families without a regular source of care. Such systems would work optimally if the participating practices and clinics were made aware of the name, address, and phone number of the patients referred to them. This would allow for

follow-up with these families, thereby increasing the probability that a relationship with a primary care provider would be established. Also, increased political and financial support at the national, state, and local levels for the American Academy of Pediatrics' (AAP) Healthy Children and Healthy Tomorrows programs could lead to more children having primary care providers. Both programs support community-based efforts to provide health care access to largely underserved pediatric populations.

Finally, in the hospital following delivery, new mothers usually are asked to identify a primary care provider for their child. If none is identified, a "house" doctor assumes care of the infant during hospitalization, but follow-up well-child care is frequently not arranged. Hospitals should both maintain a list of local public and private providers willing to assume this role for families with no source of care and assist in making appointments with these providers.

Financial Constraints to Well-Child Care and Immunizations. In 1991, 16.6 percent of the nonelderly population—35.7 million people—had no health insurance (Foley 1992). One in six children in the United States lacks health insurance, and one out of four pregnant women is not insured for maternity care. For many children, lacking health insurance is compounded by living in poverty; 35 percent of children living in families whose income is less than the federal poverty level have no insurance. In addition, the number of uninsured children living in nonpoor families is growing steadily. In 1991, 45 percent of uninsured children were in families with incomes at 150 percent or more of the federal government's designated poverty level. The major contributor to the increase in this group is the erosion of employer-subsidized health care insurance for workers and their dependents. In 1990, families headed by low-income workers constituted 85 percent of the uninsured; 60 percent of these were two-parent families (Foley 1992).

Most private insurance coverage is financed, at least partially, by employers. However, large gaps in the willingness of employers to provide coverage exist, especially among small businesses. Whereas approximately 70 percent of the work force receives health insurance via the work place, only 27 percent of firms with fewer than ten employees offer health insurance to their employees (Health Insurance Association of America 1990). The number of Americans who are *underinsured* is an estimated 50 million people. These percentages represent an increase of 24 percent for the general population and of 40 percent for children during the past decade (Friedman 1991).

Medicaid was intended to be the "safety net" designed to cover children in need. However, despite several recent reforms, the program does not adequately serve the increasing numbers of those eligible for assistance. Medicaid is federally mandated, but state managed. Today, the fiscal strains confronting state governments are similar to, or even more severe than, those faced by the federal government (e.g., for the 1991 fiscal year, over half the states posted budget deficits). These constraints combine with other factors to cause a great deal of variation in Medicaid coverage provided by individual states in the following areas:

- 1. funds allocated to the program
- 2. eligibility criteria for enrollment
- 3. administrative complexity for enrollment
- 4. level of payment to providers
- 5. scope of coverage

The federal government recently required states to expand Medicaid eligibility in order to include a significantly larger group of children, yet few federal dollars were provided to assist states in complying with this mandate. States have seen Medicaid expenditures increase dramatically, often well beyond budgeted amounts. As a result, several states are now contemplating ways to decrease Medicaid spending, most often by limiting services. States such as Oregon are experimenting with novel approaches to rationing health care among their Medicaid-eligible population (Hadorn 1991).

Many of the working uninsured are not covered by Medicaid because of complex eligibility policies. Coverage for families earning up to 185 percent of the poverty level is suggested by the federal government as an eligibility threshold, but final determination of this criterion rests with each state. At this time, only 16 states offer coverage at this level. As a result, many children of the working poor are without medical coverage, do not receive Medicaid benefits, and often are not covered by employer-based insurance plans.

States are currently required to cover all children aged six and under and pregnant women from families that earn up to 133 percent of the federal poverty line. Families with children aged six to eight are covered only if their income is at or below 100 percent of the poverty line, and mandatory coverage for children aged eight to eighteen is being gradually phased in, with final implementation due by the year 2002.

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Administrative and bureaucratic difficulties with governmental programs are legend. In some states, the complexities of simply applying for Medicaid greatly impede enrollment. In addition, few states have aggressively recruited the federally mandated newly eligible for obvious financial reasons. In 1989, it was estimated that only 40 percent of families with incomes below the federal poverty line were covered by Medicaid (Friedman 1991).

State-by-state variation in Medicaid benefits prevents all children from having equal access to similar services. A poor child living in Mississippi does not receive the same benefits as his or her counterpart in Massachusetts. Northern and western states, as a rule, offer more generous benefits than southern states, reflecting differences not only in states' wealth, but also in traditions of commitment to public assistance.

Financial constraints to well-child care is a multifaceted topic. Changes in health insurance coverage for children and families involve a complex set of issues related to cost containment, access to care, the role of government, and the importance of prevention and health maintenance. Currently, more than 40 proposals for national health insurance reform are vving for congressional attention. Several are modifications of the current public-private system (e.g., the Pepper Commission recommendations); others suggest expansion of the existing private sector (e.g., the Butler Plan, the Heritage Foundation proposal); and yet others, such as the Physicians for a National Health Program, recommend total government administration (Blendon and Edwards 1991). Also under consideration is a policy designed by the AAP to ensure health insurance coverage for all children and pregnant women. According to NVAC, "Ideally, immunizations should be given as part of a comprehensive child health care program. This is the ultimate goal toward which the nation must strive if all America's children are to benefit from the best our health care system has to offer" (National Vaccine Advisory Committee 1991). Whatever form a revamped insurance system takes, those interested in the welfare of children should support inclusion of a comprehensive children's basic benefits package encompassing routine immunizations, scheduled well-child visits, and prenatal care. Such a package should provide preventive services at little or no cost to beneficiaries.

Private Insurance Immunization Payment Status. Private health insurance historically has looked upon itself primarily as providing protection from the financial consequences of defined medical hazards. Thus,

reimbursement plans in this country have traditionally focused on acute and curative care rather than preventive services, despite data that clearly support their overall cost effectiveness, especially immunizations. In 1989, the Health Insurance Association of America (HIAA) found that only 45 percent of employment-based indemnity plans covered childhood immunizations (Health Insurance Association of America 1988). A study of families in Dallas found that 65 percent of parents in the waiting rooms of public immunization clinics had brought their child to such clinics because they could not afford immunizations at a private practice (Schulte, Brown, and Zelzman 1991).

Solutions to this problem are not complex. Employers should choose health insurance plans for their employees that cover childhood immunizations. Such coverage is affordable, as well as cost effective. Ninety-eight percent of health maintenance organizations (HMOs) cover immunizations, as do 62 percent of preferred provider organizations. However, only 45 percent of traditional indemnity insurance plans cover childhood immunizations (Health Insurance Association of America 1988). Furthermore, an actuarial study contracted by the AAP determined that, if all employment-based insurance plans were mandated to cover childhood immunizations with no deductible or copayment, the costs would be \$10.92 per employee per year; with a 20 percent copayment (and no deductible), the cost would drop to \$7.20 per employee per year. When specifically requested by employers, insurance companies generally are willing to include immunization coverage at increased rates. However, the public health and societal benefit of childhood immunization coverage necessitates that it be a mandated benefit of coverage in all states despite the existence of formidable opposition to mandated benefits throughout the private insurance industry.

#### **Barriers**

Assurances of the availability and affordability of medical care will go a long way toward alleviating the fundamental problem of restricted access to care; however, other roadblocks to complete immunization must be addressed as part of a comprehensive approach to policy and program development. These barriers are described as follows:

- 1. Public clinics are not perceived as "user friendly."
- 2. Resources in the public sector are limited.

- 3. Medicaid participation by providers is incomplete.
- 4. Obtaining parental informed consent is a complex procedure.

Public Clinics Not "User Friendly." To identify barriers to immunization for preschool children, in May 1990 the CDC surveyed program managers from 54 of the 57 largest public immunization projects in the country (Orenstein et al. 1990). Several common policy requirements in public clinics actually served to restrict vaccine administration to eligible children. Most often cited were requirements for

- 1. appointments to receive vaccines
- 2. a physical examination prior to immunization
- 3. physician referrals for vaccination
- 4. enrollment in well-baby clinics
- 5. vaccine administration fees

Surveys of Hispanic families revealed the additional problems of cultural and language barriers at public clinics and culturally inappropriate health education materials.

The route to immunization services must be simplified. Policy-driven barriers to immunization should be abolished. The NVAC recommended developing a set of minimum "standards for immunization practice" to govern immunization practices in the public sector (National Vaccine Advisory Committee 1991). These standards were released in May 1992 at a White House Rose Garden ceremony hosted by President Bush. They represent the collaborative efforts of the Public Health Service, the AAP, the American College of Physicians (ACP), the American Medical Association (AMA), the American Academy of Family Physicians (AAFP), and other concerned health care organizations. In order for these standards to have an impact, dissemination efforts will have to be extensive and well coordinated. NVAC recommendations are published in Morbidity and Mortality Weekly Report (MMWR) and the Journal of the American Medical Association. The importance of these new standards warrants a much wider audience and a more effective, targeted dissemination strategy.

The standards emphasize changes in immunization policies and practices that can immediately improve immunization rates. "The present (immunization delivery) system should be geared to provide 'user-friendly,' family-centered, culturally sensitive comprehensive primary

health care that can provide rapid, efficient, and consumer-oriented services to the users" (Centers for Disease Control 1992). In concrete terms, immunizations should be available upon request with no unnecessary prerequisites; immunizations should be given to all children who have no medical contraindication and who appear to be in good health; no physical examination should be required; any medical visit should be considered an opportunity to screen and immunize a child as needed. To further streamline the process of immunizing children and to eliminate unnecessary waiting, "express lines" should be created in health care facilities for families needing only immunizations. "Immunization only" visits are common practice in many private pediatric practices. Providers should take advantage of "immunization only" visits to refer children for complete well-child care when needed, and to review and address the immunization status of siblings who accompany patients.

For such a program to be safe, effective, and efficient, all providers (e.g., nurses and physicians) should be aware of medically appropriate contraindications. Also, to decrease the need for multiple health care visits, immunizations should not be administered in a piecemeal fashion, even when children have fallen behind schedule. Simultaneous administration of all needed immunizations should be the norm.

Many clinics, especially those in urban and border areas, may serve clients for whom English is not their primary language. In such situations, staff who speak the predominant languages of a clinic's clients should be available. Educational material relating to immunization (e.g., immunization schedules, explanations of common side effects) and other preventive services should also be offered in languages other than English.

Resource Limitations in the Public Sector. Although the responsibility for protecting the health care interests of the population was traditionally left to the states by virtue of U.S. constitutional inference, since World War II the federal government has played an ever-increasing role in the payment for health care services provided to the poor, the elderly, and the disenfranchised. However, recent administrations have shifted additional fiscal responsibility for health care to the states, despite a greater centralization of tax revenue in the federal government. This divergence has led to a growing disparity between available tax bases within the states and both individual and population health care needs.

State governments are experiencing extreme difficulty in maintaining fiscal solvency. Many are required to produce balanced budgets and thus

often are unable to meet the demands of ever-increasing health care costs as their tax bases weaken and federal support for other programs (e.g., aid to cities) is withdrawn. Unfortunately, when faced with pressing health care demands for treatment-oriented services, many states have little option but to curtail the amount of resources expended on preventive care. Provision of preventive care, including immunizations, is often perceived as a luxury when compared with "life-saving" curative care. As fewer resources have been "left over" for preventive services, clinics providing them have received little priority.

The health consequences of the neglect of preventive and immunization programs are substantial. A significant number of immunization projects have reported state and local resource problems as being responsible for: (1) insufficient clinic personnel, (2) inadequate clinic hours, and (3) limited clinic locations (Orenstein et al. 1990). Such problems are frustrating to parents when they try to seek immunizations for their children. Health care is only one of many concerns of parents of low-income children who rely on the services of state, county, or local health departments. Providing their families with food, shelter, transportation, day care, and other essential matters requires the investment of substantial financial resources and occupies a good deal of time. If inefficient and understaffed clinics require inordinate amounts of time to provide simple services, parents understandably may choose to forego certain services for their children, including immunization, in order to meet other daily needs of their families.

All infants and children in the United States should have equal opportunity to receive basic preventive services, regardless of the resources or tax base of the community or state in which they reside. Furthermore, the manner in which these services are provided should not be a barrier to their provision. Public clinics must ensure that convenient hours and adequate staffing are offered in locations where families currently wait a significant amount of time to receive vaccines. States and municipalities must accept the responsibility to assess accurately whether there are adequate numbers of convenient clinic locations to serve clients' needs.

Continued distribution of federal funds could be contingent upon successful compliance by states or localities with federal guidelines for clinic operation. Minimum standards should be set for the staffing and furbishing of clinics giving immunizations to make them more "user-friendly." This may require either that programs be micromanaged from

a federal controlling office, or, preferably, that federal tax money be redistributed, under a system of state accountability, among state and local health agencies on the basis of the needs of the communities they serve. Goals and aims of immunization provision can be set by federal standards and administered on state or local levels. Enforcement could occur by state or by federal "spot" inspection of clinics that receive either total or partial federal funding.

Additional federal support is needed to assure that state and local health departments have adequate supplies of vaccines. To be most effective, these funds should supplement current efforts, rather than substitute for present levels of state or local funding.

Currently, some states are attempting novel approaches to these problems. For example, one innovation is to provide private physicians with vaccines free or at state contract prices so that they can be administered without cost to patients on Medicaid or with no source of coverage for vaccines. Generally, these physicians are entitled to collect a small vaccine administration fee. If adopted in states where the current public vaccine delivery system is inadequate, this approach would increase the number of places children can be immunized free of charge and relieve the current burden on public clinics.

One relatively untapped source of assistance for vaccine programs is the volunteer commitment in the United States. Voluntary organizations, and business and industry, can play a major role in assisting local health departments to improve immunization services through efforts such as fund raising to update clinic facilities and extend outreach, as well as sharing expertise in using the media effectively to promote immunization. Volunteers could aid in the design of computerized tracking and reminder systems and in the production of culturally appropriate educational materials. Finally, the largest impact could be made with the simple donation of time. Clerical and nursing support is always needed for daily operations as well as for special outreach programs based in the community.

Limited Medicaid Participation by Providers. The number of physicians willing to accept Medicaid patients is declining in most states. Although pediatricians traditionally have maintained the highest rates of Medicaid participation among medical specialties, between 1974 and 1989 the percentage of pediatricians refusing to care for Medicaid patients increased from 15 percent to 23 percent (Yudokowsky, Cartland,

and Flint 1990). The percentage of pediatricians that "limited" the number of Medicaid patients under their care increased from 20 to 39 percent. Reasons for refusal include administrative difficulties in obtaining payment and low reimbursement rates. Recent studies have also shown that prevailing attitudes in local medical communities significantly affect physician participation in Medicaid (Margolis et al. 1992). These attitudes appear to be formed by respected physicians in some communities and are promulgated through medical societies and informal networks of local physicians.

To combat the recent trends in provider participation, proposals are being considered in some states to require physicians to accept Medicaid patients as a condition of licensure. Such a bill was recently introduced in the Massachusetts legislature. These laws, if enacted, may antagonize and offend the physician community if concurrent efforts to "fix" the problems viewed by many as obstacles to participation in Medicaid are not also addressed. For example, states must adjust payment levels to approximate market rates so physicians do not "lose money" caring for Medicaid patients.

Realizing the differential response of urban physicians to Medicaid participation, their participation should be especially encouraged. One approach would be for state Medicaid administrators to identify and involve key physician leaders in local efforts to stimulate widespread participation. State and county medical societies, as well as state chapters of physician specialty organizations, could serve as forums for such efforts.

Parent Information. Parents are assured access to the latest information on vaccine-related injuries resulting from immunization by regulations that require providers to review the risks and benefits of immunizations before administering them to the child. Effective April 15, 1992, federal law requires all health care providers to give parents a standardized, eight-page immunization information brochure before administering diphtheria-pertussis-tetanus (DPT), oral polio (OPV), or measles-mumps-rubella (MMR®) vaccines. A separate brochure has been developed for each vaccine. A brochure takes approximately 15 minutes to read (Journal of the American Medical Association 1992). If multiple vaccinations are given at one visit, then the parent must receive each corresponding eight-page brochure. When children receive subsequent doses of the same vaccine, the brochures are again provided to parents. Signed acknowledgment of receipt of these brochures is required from

parents of all children receiving vaccines purchased through the federal contract, which includes most vaccine utilized in the public sector, and a portion of vaccine administered by private physicians.

The development of these documents was mandated by the National Childhood Vaccine Injury Act of 1986 to incorporate important information on the benefits and risks of vaccines in the process of immunization. The brochures were developed by the CDC in conjunction with the AAP, the Public Health Service, NVAC, parent advocacy organizations, and the Food and Drug Administration. Yet, several AAP and government officials have stated publicly that the brochures are too long, too complex, and too frightening to patients to be practical and effective (American Academy of Pediatrics 1992). These brochures give parents mixed messages about the safety of this very necessary preventive service.

Although the intent of the brochures is commendable, there is a more rational approach to transmitting important information about the benefits and potential risks of vaccines. The length of the new pamphlets is the direct result of the National Childhood Vaccine Injury Act. The act stipulates ten information requirements that must be covered in the pamphlets, only one of which is to explain the benefits of vaccines. The other nine describe issues surrounding adverse effects. Because most parents do not have the time or inclination to read and digest the large amount of information involved while sitting in an examination or waiting room with their small children, the brochures must be simplified. While acknowledging that risk (albeit rare) does exist, materials should focus on the benefits of immunizations and on recommended treatments for the more common side effects, such as pain and low-grade fever. The use of media other than print - possibly at a location outside the clinic-to disseminate the information to parents must also be explored.

# Compliance

Even if all access problems and barriers to immunization are overcome, several issues remain in ensuring provider and parent compliance with existing immunization recommendations. Over 90 percent of infants receive at least one immunization, yet many do not complete the primary immunization series prior to the age of two years (Cutts et al. 1992).

Systemic reasons for this failure to comply with the existing recommendations include:

- 1. lack of a comprehensive tracking/reminder system
- 2. missed opportunities for immunization
- 3. variation in parental knowledge and attitudes regarding immunizations
- 4. lack of uniform day care standards
- 5. failure to immunize children enrolled in entitlement programs
- 6. delay in physician adoption of new immunization recommendations
- 7. problems in the dissemination of new immunization recommendations
- 8. continued vaccine-related liability for practitioners

Lack of a Comprehensive Tracking/Reminder System. Currently, no centralized system exists to monitor childhood immunization status, either for individuals or in the general population. States keep records on births, deaths, real estate, criminal and driving records, marriages, and other aspects of our lives. Clearly the technology exists to develop a comparable surveillance system for childhood immunizations.

Unfortunately, major barriers to creating a national tracking system in the United States still exist. An enormous array of providers, both public and private, serve children's health care needs, yet do not share a common record-keeping system. Despite the fact that all births are registered by state vital statistics agencies, the federal government does not maintain a national child identification system. Americans historically have been inherently distrustful of such centralized governmental documentation. The situation is quite different in Europe, where tracking systems are uniformly begun at birth and consistently rooted in the health care system (Williams and Miller 1992).

A comprehensive national tracking system designed to monitor immunizations will be expensive and difficult to implement in this country. It could be argued that the opportunity costs of such a system would be unjustified when compared with other national health priorities such as AIDS prevention, injury surveillance, or reducing infant mortality. This is true only if immunization tracking is viewed as an end in itself. A more compelling argument for a tracking system would be

its potential to serve as the framework of an integrated system of comprehensive childhood preventive health services. Currently, a number of poorly coordinated statewide tracking systems exist, but few have been carefully evaluated.

Recent national attention focused on the problem of infant mortality has resulted in growing numbers of systems of maternity care coordination. Fifteen states, under the direction of the National Center for Clinical Infant Programs, have developed high-risk infant tracking programs to identify infants with special health and/or developmental needs. The Early Periodic Screening and Diagnostic Testing program attempts to monitor the preventive services received by children on Medicaid. These programs are all designed to identify and assist mothers and infants felt to be "at risk."

Two decades ago in Europe, children's risk registries were abandoned in favor of a commitment to monitor the growth and development of all children, regardless of perceived risk or enrollment in programs. The experience of these countries suggests that the best way of tracking high-risk children is through national systems that reach all children with routine screenings and health maintenance activities including immunizations (Williams and Miller 1992).

The Robert Wood Johnson Foundation recently issued a request for proposals (as part of its All Kids Count initiative) to fund demonstration projects in this area. The system under development in North Carolina represents a good example of the possible components of a tracking system. The state already has implemented an electronic birth certificate system. Data from this system will automatically be transferred to the central immunization registry. Date and dose-specific information for every immunization given to a child will be entered by local health departments, the state Medicaid computer system, and private providers. All providers, private and public, will be able to access the registry to obtain data on individual patients via office-based terminals linked to a central data base. Public health officials will be able to obtain community-level, population-based immunization coverage information as well (Meriwether 1992).

A national immunization tracking system is still several years away. Integrating immunization tracking with a more comprehensive child-hood preventive services tracking system is an even more distant goal, although one that should serve as the ultimate outcome of feasibility projects such as those supported by the Robert Wood Johnson Founda-

tion initiative. In the meantime, private practices and public clinics that administer vaccines should develop surveillance/reminder systems for their own patients. Research has shown that office-based systems are effective in raising rates of immunization (McDonald and Barnett 1990).

State and local governments should also begin regular assessment of immunization rates in high-risk urban and rural areas, a process critical in the early recognition and anticipation of outbreaks of vaccine-preventable illnesses. The CDC monitors the immunization status of children under age two nationally through the National Health Interview Survey, an ongoing federal population sample survey that assesses various aspects of the public's health through detailed interviews of random households across the country. However, monitoring the immunization status of the country's children would be substantially more accurate, efficient, and effective with a national surveillance system based on immunization administration records.

Missed Opportunities for Immunization. Investigations of recent measles outbreaks have found that one-third of infected children had experienced at least one previous health care visit at which an opportunity for vaccination was missed (National Vaccine Advisory Committee 1991). Children are inappropriately not immunized during certain visits for several reasons, most commonly for the following reasons:

- 1. Colds or ear infections without fever are incorrectly considered to be contraindications to immunization.
- 2. Providers fail to administer all needed vaccines at one visit and children fail to return for follow-up.
- 3. Providers fail to review immunization status when children are present for acute care (e.g., colds).
- 4. The immunization status of children seen in emergency departments often is not assessed.
- 5. Children admitted to hospitals are often behind in their immunizations, yet are discharged without being vaccinated.

The newly released Standards for Pediatric Immunization Practices includes a simple table of accepted contraindications, as well as information explaining the safety and appropriateness of simultaneous administration of all indicated vaccines at a single visit (U.S. Department of Health and Human Services 1992).

Also, emergency department personnel should routinely screen children's immunization status and, especially in areas of low rates of im-

munization, be willing to administer vaccines. Although this is not a traditional function of emergency departments, the number of children that use these facilities as their only source of care necessitates this change, which could be effected by training emergency department personnel and providing vaccines from public sources.

Moreover, states should require, by law, the vaccination of all hospitalized children who are not adequately immunized, assuming there are no medical contraindications. Such a law already exists in New York.

Parental Knowledge and Attitudes Regarding Immunization. Parents are often unaware of changes in immunization recommendations. In a recent Gallup poll, 47 percent of parents interviewed did not know that children must receive a second measles immunization (Eaton 1991). Many parents were likewise unaware of the change in the vaccine recommendation for Hib. In parents' defense, there has been no systematic plan to inform the public of these changes, so they cannot be faulted for failing to initiate health care visits for immunizations of which they are not aware. Currently, health care providers play a key role in patient education; 75 percent of these parents identified their physician as their primary source of information about vaccines.

The same Gallup poll found that although virtually all parents recognize that immunizations are important to children's health, they are often not a high priority. For poor, single-parent families living in inner-city or remote rural areas, work, food, and shelter are usually of greater concern than getting children immunized.

Unfortunately, programs designed to change health-related behaviors have met with mixed success; however, a few efforts are worth noting. Many more people wear seatbelts today than ten years ago (Baker 1992). Smoking cessation counseling has been documented to be effective in several carefully conducted studies (Green and Kreuter 1991). Both of these efforts included messages that were delivered repeatedly, from multiple sources and over a prolonged period of time (Kottke et al. 1988). Parental knowledge and attitudes toward immunization could be increased by similar programs.

Research in health promotion planning has identified four sets of correlates that predict adherence to recommended behavioral changes or relapse (Green and Kreuter 1991):

- 1. demographic and socioeconomic characteristics
- 2. motivational characteristics

- 3. physical, manual, or economic facilitators and barriers
- 4. circumstantial rewards and penalties associated with the behavior

Demographic and socioeconomic factors are not easily altered, but motivational factors, barriers, and reinforcing factors such as rewards are modifiable. Surveillance data show that children who do not receive their two-month set of immunizations on time are at higher risk for subsequent underimmunization. This suggests that greater emphasis should be placed on motivating parents of infants. Before leaving the hospital with their newborn, parents not only must choose a source of well-child care, but also should be instructed in the importance of immunizations to a child's health. The new practice of initiating the immunization of newborns against hepatitis B in the hospital at the time of delivery adds weight to this message. Parents can be motivated by the fact that their child has already begun an important series of immunizations, an effort that will have been wasted if the child does not receive appropriate follow-up well-child care. In communities where underimmunization is endemic, reward systems should be developed for parents of newborns when they come for their first well-child appointment. For example, a program in Utah awards gift certificates to mothers for participation in well-child care (Williams and Miller 1992). Clinics serving at-risk families should develop and continue the use of reward systems to reinforce the actions of families who adhere to the vaccine schedule.

Multimedia public service announcements (e.g., television, radio, newspapers, general and specialty magazines, billboards) should provide additional reinforcement by informing parents of the importance of immunizations, their time frame, and locations for obtaining them. Publicity campaigns are best orchestrated by local leaders for their own community. Many cities affected by measles outbreaks have conducted effective media campaigns. However, citywide media blitzes using the same message to all economic and social strata may not be as effective in reaching all groups. Community leaders in hard-to-reach, poor neighborhoods are often the best sources of ideas on how to reach, motivate, and reward their neighbors. Thus, a combination of multiple strategies may be most effective.

Parental motivation and reinforcement must continue in the settings where children are immunized. All employees in clinics and physicians' offices (e.g., receptionists, nurses, and physicians) should be involved in

screening children and educating parents. Increasing the attention paid to vaccines will impress upon parents the importance of having their children fully immunized. Further efforts are needed to keep parents aware of the multiple changes that occur in the immunization schedule.

Lack of Uniform Day Care Standards. Upon enrollment in school or licensed day care centers, most obstacles to vaccination are neutralized; as a result, 98 percent of school-aged children in this country are fully immunized. In addition, 94 to 97 percent of children enrolled in Head Start or state-licensed day care centers become fully immunized. However, two-thirds of preschool children and more than 85 percent of those under age two who are cared for outside the home are not enrolled in licensed day care settings. As a result, full immunization rates for young children as a whole are much lower than for school-aged children in the United States (Hinman 1991).

To take advantage of this opportunity for immunization screening, states should require licensed day care centers not only to document complete immunization status prior to a child's enrollment, but also to assess immunization status every six months during the first two years of life and yearly thereafter. Additionally, day care immunization requirements should be updated frequently to reflect new immunization recommendations from the CDC or specialty societies, such as those relating to Hib and hepatitis B. In conjunction, states should attempt to increase the percentage of day care centers requiring licensure.

Failure to Immunize Children Enrolled in Entitlement Programs. A large number of children most at risk for vaccine-preventable diseases are enrolled in some type of public assistance program. In four large inner-city measles outbreaks recently investigated, as many as 86 percent of nonimmunized children with measles were enrolled in the Aid to Families with Dependent Children (AFDC) program and up to 61 percent were enrolled in the Special Supplemental Food Program for Women, Infants, and Children (WIC) (Hinman 1991). These federal programs provide an opportunity, albeit unconventional, to monitor the immunization status of children receiving their benefits. Additionally, recent reforms in Medicaid have greatly increased the number of poor and near-poor children who are eligible for benefits, yet steps have not been implemented to integrate immunization into a comprehensive plan for these children.

To further both the immunization goals of the nation, and the welfare of the children they are designed to serve, appropriate immuniza-

tion should be a condition for continuation—not enrollment—in these programs. WIC provides critical nutritional services to participating families, and compliance with existing regulations for continuation in the program is high. Full immunization as a condition for continuation would have a major beneficial impact on the group of children served by this program. Similar mandatory immunization policies exist in public schools and do not result in children being denied access to public education services. Rather, high immunization rates are achieved. It follows that similar results could be expected with entitlement programs. AFDC recipients also periodically return to the program office, presenting another opportunity to screen and monitor the immunization status of these children.

For such a policy to be effective, immunizations should ideally be offered on site to WIC and AFDC clients who are behind schedule. If this is not possible, a referral system should channel these children to local health departments or physicians where immunizations can be conveniently obtained at little or no cost. The intent should be not to create new barriers to the receipt of AFDC and WIC benefits, but rather to provide incentives to immunization. In addition, AFDC and WIC offices should be familiar with the steps necessary to obtain Medicaid coverage in order to assist clients who do not yet have this coverage in applying.

Physician Adoption of New Immunization Recommendations. The AAP's Committee on Infectious Diseases (the Red Book Committee), as well as committees of the AAP and the ACP, all develop and promulgate vaccine guidelines. In the public sector, the primary body is the Public Health Service's Immunization Practices Advisory Committee (ACIP), but state and local health departments also issue guidelines in times of epidemics. Different entities establishing independent vaccine policies can result in contradictory guidelines, causing confusion to health care providers and parents.

Coordination among the wide spectrum of public and private organizations involved in immunization programs would alleviate current confusion and prevent future problems. These cooperative efforts could provide uniform vaccine recommendations at coordinated times or, alternatively, the constituent parties could combine efforts to create a "national vaccine guideline council" to formulate a single set of recommendations. All relevant groups could have a role in the dissemination of these recommendations.

Problems in Dissemination of New Immunization Recommendations. Current public and private efforts to disseminate and explain new immunization recommendations to practitioners and parents are inadequate. For example, the sole federal effort to disseminate vaccine recommendations nationwide is the publication of new guidelines in MMWR, a periodical neither circulated widely to private practitioners nor read regularly by physicians in the public sector. Although portions of MMWR are reprinted in the Journal of the American Medical Association, only one-half of all physicians are members of the AMA, which limits the number receiving this periodical. Other independent dissemination efforts are initiated by relevant specialty societies, which routinely distribute information about new vaccines to their members only, thereby excluding those physicians and other health care providers who are not members.

Unfortunately, we do not know the most effective method of vaccine recommendation dissemination. However, certain interventions can be helpful at this time. Initially, the federal government should assume responsibility for the widespread dissemination of vaccine guidelines, including information on safety and efficacy of new vaccines, to physicians and other health care workers. Possible methods may include:

- 1. coordinated mailings with the assistance of state medical boards and health departments
- 2. advertisements in medical journals, newspapers, or newsletters
- 3. broader distribution of selected issues of MMWR dealing with vaccine guidelines

Additionally, specialty societies should disseminate new or updated vaccine guidelines to all practitioners in their specialty, not just members of their respective specialty societies. Names of these nonaffiliated practitioners are readily available from master lists kept by the AMA and by state medical licensing boards.

Major public awareness programs utilizing both the public and private sectors would be a useful tool in disseminating immunization information to parents. Examples of public sector initiatives are public service announcements, community-based information sources (e.g., grocery stores, county fairs, sporting events), and mass-mail information campaigns. Possible private sector initiatives include celebrity promotion; incorporating immunization into television programs that feature

children; vaccine information on baby product packaging, milk cartons, or shopping bags; and billboard advertisements.

Finally, research and demonstration projects are needed to find the most effective means of vaccine guideline dissemination to physicians and other health care providers.

Vaccine-related Liability for Practitioners. Despite the unquestioned benefit of childhood immunizations, serious debate in recent years regarding the possibility of severe adverse reactions to certain vaccines has led to a barrage of litigation involving practitioners and vaccine manufacturers. In response to this growing problem, Congress established the National Vaccine Injury Compensation Program (NVICP) in 1986 to limit liability compensation payments and encourage the continued domestic development and manufacture of vaccines. A vaccine injury table (VIT) specifies conditions for allowable compensation. This program was designed to serve as a "no-fault" insurance fund to compensate victims of actual vaccine-related injuries; civil suits were to be permitted only if a claimant rejected the settlement offered by the NVICP.

Unfortunately, the act, as written, has created multiple problems for practitioners (Wilde and Pedroni 1991). Despite the creation of the NVICP, practitioners are still at risk for civil suits over injuries theoretically beyond their control. Additionally, loopholes in the current plan have led to assertions of successful "double-dipping" by some claimants (pursuing claims through the NVICP and through civil courts simultaneously).

Other problems are associated with the concept of injury as outlined in the NVICP. Currently, injuries related to DPT and MMR® vaccines are to be granted compensation under the VIT. However, the Institute of Medicine (IOM) recently completed a comprehensive review of the existing scientific data on 22 adverse events with the DPT and MMR® vaccines. This review found evidence of a causal relation to vaccination for only six of the 22 adverse events examined (Howson, Howe, and Fineberg 1991). Specifically, the report found insufficient evidence to indicate a causal relation between DPT and chronic neurological damage. Accompanying commentary by the author of the IOM report states, "This finding should offer reassurance to health professionals, parents, and other persons concerned with the safety of the pertussis and rubella vaccines" (Howson and Fineberg 1992). However, the VIT includes the clause "may result in various states of permanent impairment . . ." (Fulginiti 1992) as part of the definition of encephalopathy, a condition

for which compensation is provided. The IOM's report does not support this definition. Thus, the VIT has legitimized (in a legal sense) a condition not grounded in accepted scientific data.

Additionally, the wording in the VIT allows for compensation should a covered condition occur without another known cause. Simply by chance, a certain number of children will die from sudden infant death syndrome (SIDS) in the three days following pertussis vaccination. It is of interest to note that no epidemiological data link these two events, but because there is no known cause for SIDS, 90 percent of claimants who filed with the NVICP for this condition were awarded money (Wilde and Pedroni 1991).

To correct these inconsistencies, several modifications in the NVICP are needed. The act should be rewritten to eliminate or limit the ability of claimants to pursue civil claims for cases deemed unrelated to vaccine injury by the NVICP. If such claims have no merit, they should proceed no further in the court system. The current pursuit of such claims, with occasional out-of-court settlement to limit defendant legal fees, thwarts the intent of the program.

Expeditious efforts to revise the VIT in accordance with existing data on adverse vaccine reactions are needed. Epidemiological data now available will help to better define cause-and-effect relationships associated with immunizations and infant injury. As such, it is essential to revise the wording of the VIT specifically to disallow claims that are temporally associated with an adverse event but have no causal link. Definitions used in the VIT should be consistent with the best available scientific data as reviewed by the IOM.

# Development

In the last five years, modifications of the Hib vaccine have allowed for its effective use in younger infants, thereby providing protection during the portion of an infant's life most vulnerable to *H. influenzae* invasive disease. Similarly, recent development and licensing of an acellular pertussis vaccine is expected to lower the incidence of common side effects associated with pertussis immunization. Soon, vaccines to prevent the viruses that cause infectious diarrhea, bronchiolitis, and chickenpox will be available. Thus, the field of vaccine development involves (1) new vaccines, and (2) modification of existing vaccines, both of which play important roles in the future of immunizations in the United States.

New Vaccines. Prior to the liability reforms of the NVICP in October 1988, many manufacturers in the United States had abandoned vaccine production entirely. For example, in 1984, the number of manufacturers of the DPT vaccine dropped from three to one. One discontinued production because of liability concerns, whereas the other left the market temporarily after being unable to obtain needed liability insurance. A true shortage of DPT vaccine occurred nationwide, necessitating the CDC to curtail use of the vaccine for doses 4 and 5 of the five-dose series. Also, several private vaccine manufacturers curtailed research into new vaccines because of the risk of the associated liability; even today, few companies perform this type of research. However, tremendous strides continue to be made by companies that are still in this field. It would benefit all, however, if greater efforts were devoted to vaccine research.

The passage of the NVICP was a strong encouragement to the private sector to reenter the field. However, modification of the NVICP as outlined above, especially in the area of limiting civil claims denied by the program, would encourage wider industry presence and investment of resources into new vaccine development. Also, vaccine pricing contracts should allow a sufficient profit margin to ensure the continued viability of the industry and its research program.

Modification of Existing Vaccines. Although some vaccinations can be combined into a single injection (e.g., measles, mumps, and rubella), many are not. For example, it is currently recommended that a two-month-old infant receive two injections (DPT, Hib) and an oral vaccine (polio). The new universal recommendation for hepatitis B may necessitate a third injection at one or more visits, eliciting a negative reaction from many parents, physicians, and nurses (the so-called "pincushion" effect) (Gorlick 1991). Additional vaccines coming on line in the near future (e.g., rotavirus, varicella) may further exacerbate this problem, resulting in delay, postponement, or total avoidance of valuable preventive measures.

Therefore, development of combination vaccines for those immunizations already recommended should receive a high priority in vaccine research. A combination of these vaccines would permit one injection to be given for all vaccines recommended for a particular visit, thus reducing parental anxiety surrounding multiple injections. Part of this effort will require additional basic immunology research to ensure the safety and efficacy of such preparations.

Development of the "Children's Vaccine" (the "Magic Bullet"). Substantial numbers of children reach the health care delivery system only once in their first year of life; thus, the current need for multiple, scheduled health care visits to receive recommended immunizations sets up the system for failure. The concept of a "children's vaccine," envisioned ideally as a single-dose, multiantigen vaccine, stable at ambient temperature, administered orally, that produces lifelong immunity when administered as a single dose early in infancy, is very attractive. Such a vaccine would simplify our current immunization schedule and reduce significantly the demands placed on the health care system infrastructure by multiple patient visits.

Although the concept appears impossibly complex, such a vaccine is a needed and worthwhile goal. Efforts in the development of recombinant DNA technology and basic science immunology should be channeled toward this effort. Catalyzing and focusing available technology would permit substantial progress even at this time. Full acceptance of the creation of a "children's vaccine" as the ultimate goal of vaccine development by the Department of Health and Human Services would promote new research in this area.

#### **Conclusions**

Recommendations for universal childhood immunizations have been in place since the late 1940s in this country. Over the past 50 years, many advances have been made in vaccine technology and immunization delivery systems; many new vaccines are under active development and will soon be approved for general use. Immunization delivery is a "low tech" intervention by today's standards. Effectively immunizing all children should be a fundamental function of this country's health care system. Nevertheless, decreasing immunization rates and recent outbreaks of vaccine-preventable illnesses serve as a warning to basic scientists, vaccine manufacturers, health care workers, and policy makers alike. If large numbers of children in our country continue to suffer from vaccine-preventable illnesses, the rationale for the development of future vaccines is weakened. New vaccines will only be effective if they reach the children they are designed to protect.

Immunizations are the most basic of all preventive health care strategies. If effective methods to vaccinate our children prove to be elusive.

or the national will does not exist to correct the problems with immunization in our current health care system, there is little hope that other, more complex, preventive strategies (e.g., mammography, colon cancer screening, risk factor counseling, and behavior modification) will be implemented on a population-wide basis.

Changes in the entire child health delivery system will be complex and controversial. Immunizations form a unique component of preventive health services and childhood health needs. Their popularity, ease of administration, and proven cost-effectiveness make them ideal for first-line demonstration changes in childhood health services delivery. If improvements in the immunization programs are successful, they may be used as an example and a challenge to successfully reform the remainder of the system.

We have identified the major causes and key components of the problems related to current deficiencies in childhood immunization coverage in the United States. Dividing the problem into the individual components we have identified, the A-B-C-Ds (Access, Barriers, Compliance, and Development) of immunization, allows for a rational approach to the complexities of this national problem. The solutions we have presented are realistic and, if implemented, would redirect the immunization program of this country toward meeting the needs of all our children.

However, significant reform of even a component of the childhood health care system will face many obstacles. Difficulty in implementing our proposals will be substantial because the inertia of the status quo is powerful. Regardless, we must not shy away from these problems because the task is arduous. As we have noted, the efforts of both the private and public sectors will be essential to effect these plans and to help remedy a pressing national health concern. If we as a nation are serious about achieving the *Healthy People 2000* goals for immunization coverage, the time to address our deficiencies is now. The health of our children depends on it.

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