

cough) vaccine, for example, has led to a sharp decline in its use in England.^b

Second, in this era of mounting malpractice liability problems, some physicians may be hesitant to administer vaccines that are known to be more dangerous than others, especially when vaccination is perceived to be of marginal benefit to a particular patient. Physicians' liability for vaccine-related injury rests on at least two responsibilities:

1. To warn the vaccinee about potential adverse reactions⁷
 2. To administer the vaccine without negligence.
- Increased public awareness of vaccine-related injury could increase physicians' vulnerability to legal action. An increased risk of being sued could impede physicians' use of vaccines in general.

^aUnfortunately, the decline in pertussis vaccine use has led to a substantial increase in the incidence of whooping cough. Some authorities believe the dangers of this disease are more worrisome than the side effects of the vaccine.

⁷In three major court cases, *Davis v. Wyeth*, *Reyes v. Wyeth*, and *Givens v. Lederle*, however, the duty to warn obligation has been assigned to the vaccine manufacturer. In the swine flu program, the duty to warn obligation was assumed by the Federal Government. Topics related to vaccine liability issues are discussed in chs. 5, 6, and 7 of this report.

Appendix 4.2

THE IMPACT OF FEDERALLY FINANCED STATE AND LOCAL IMMUNIZATION PROGRAMS ON THE INCIDENCE OF MEASLES (1962-78)

Federal Support of State and Local Measles Immunization Programs

By 1962, licensed vaccines in the United States included vaccines to prevent four major childhood diseases—polio, diphtheria, whooping cough (pertussis), and tetanus. Probably as a result of vaccine use, the incidence of these diseases had been decreasing. Some authorities, however, believed that national levels of protection against these diseases were too low; levels of protection were especially low among lower income groups not reached by the private sector fee-for-service health care delivery system (Lemke, 1977). Responding to these concerns, in 1962, Congress passed the Vaccination Assistance Act, which authorized the Federal Government to provide financial assistance to States for the specific purpose of implementing vaccination programs to help prevent these four diseases.

Children at the time remained unprotected against one prevalent childhood disease for which no vaccine had yet been licensed—measles. About 3.5 million cases of measles occurred annually (Sencer, 1973). This disease is often mild and usually not fatal, but sometimes causes deafness and other neurological disorders. When not prevented, measles results in substantial loss of school days and significant use of medical resources (Sencer, 1973).

In 1963, the Federal Government licensed an American pharmaceutical company, Merck Sharp and Dohme, to produce and sell a measles vaccine in the United States. Two years later, Congress passed the Community Health Services Extension Amend-

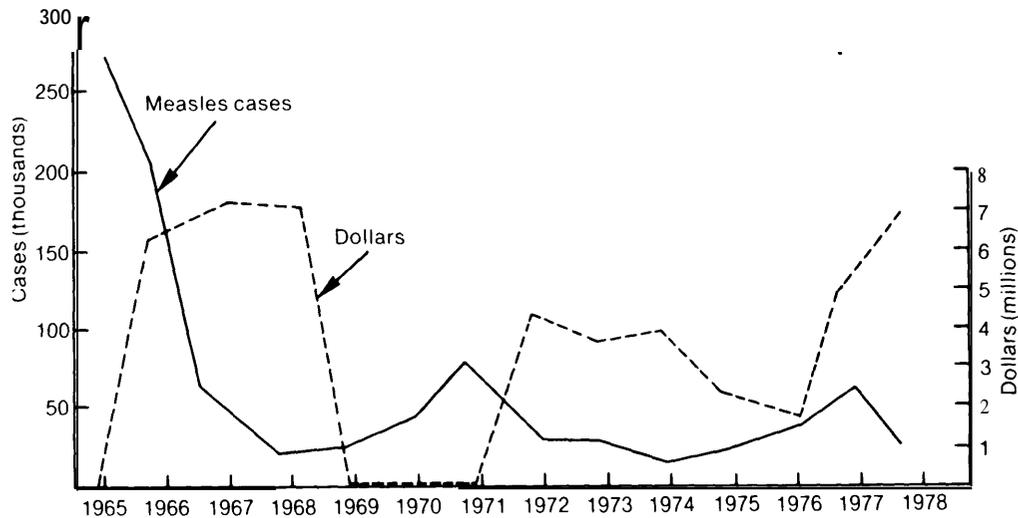
ments of 1965, which added measles to the list of diseases which the Federal Government was seeking to prevent through the provision of Federal funds for State vaccination programs. Between early 1963 and the middle of 1966, approximately 15 million children were vaccinated with the new measles vaccine, and the incidence of reported cases of measles dropped by about 50 percent (Sencer, 1973). (See figure 4.2A.)

Based on this success, in 1966, the Public Health Service (PHS) launched a national campaign to eliminate measles from the United States. This campaign, which was coordinated by the Center for Disease Control (CDC) with the support of professional and voluntary health organizations, emphasized community immunization programs. In 1967 and 1968, the Federal Government spent about \$14.5 million to control measles in the United States. (See figure 4.2A.) Approximately 11.7 million doses of measles vaccine were distributed, and the incidence of measles dropped from an estimated 900,000 cases in 1967 to 250,000 cases in 1968 (Sencer, 1973).

For fiscal years 1969 and 1970, Congress authorized no Federal funds for community immunization programs. Apparently, the lack of Federal funds for such programs substantially curtailed the distribution of measles vaccine. During these 2 years, only 9.4 million doses of measles vaccine were distributed, and the number of measles cases rose from 290,000 cases in 1969, to 533,000 in 1970, to 847,000 in 1971 (Sencer, 1973).

Because of the rising incidence of measles, and possibly, because proportionately fewer children in poverty areas than children in nonpoverty areas were

Figure 4.2A—Measles Cases^a and Federal Grant Funds^b Obligated for Measles Control Programs in the United States by Year (1965-78)^c



^aCalendar year

^bFiscal year

^c1978 data provisional

SOURCE Center for Disease Control, Bureau of Immunization 1978

being vaccinated, Congress passed the Communicable Disease Control Amendments of 1970. Under this legislation, Federal appropriations for State and local immunization programs targeted against the five diseases mentioned above and rubella (German measles) were authorized for fiscal years 1971 and 1972. Apparently, Congress believed that when Federal assistance for community immunization programs was cut back, the levels of national protection against targeted communicable diseases decreased, and that a resumption of Federal assistance might improve national levels of protection. This perception, at least in the case of measles, proved to be accurate. In 1971 and 1972, the Federal Government provided about \$8 million to the States to enable them to re-establish their immunization programs. (See table 4.2A.) During this period, 16.5 million doses of measles vaccine were distributed (Sencer, 1973), and the estimated incidence of measles dropped from **847,000** cases in 1971 to about 400,000 cases in **1972**. (See figure 4.2A.)

Based on the success of this 1971-72 program, Congress passed the Communicable Disease Control Amendments Act of 1972, which detailed the State assistance program for immunizations. Under this legislation, Federal funds for grants to States, including separate amounts for measles programs, were authorized through fiscal year **1975** (Lemke, **1977**). Congress continued to authorize Federal funding for immunization programs by enacting the National

Consumer Health Information and Health Promotion Act of 1976, under Title 11, Disease Control Amendments of 1976. This act extended and expanded the Federal Government's program of grants to States for disease control. Current immunization programs operate under its provisions and authorizations.

Since 1972, the inversely proportional relationship between the amount of Federal grant funds obligated for measles control programs and the incidence of measles has continued. Federal spending for measles control declined from about \$4 million in 1972 to slightly less than \$2 million in **1976**; correspondingly, the number of reported cases of measles rose from about **31,000** in **1972**, to **39,000** in **1976**, to **60,000** in **1977**. (See figure 4.2A.) Federal spending for measles control rose continually throughout 1977 and nearly reached \$7 million in **1978**; the incidence of measles began to drop substantially during the last 3 months of 1977, and reported measles activity (number of cases) during the first 26 weeks of 1978 was approximately 40 percent of that reported for the corresponding time period in 1977 (U.S. Ex. Br., CDC, MMWR, 1978).

Three factors probably contributed to this most recent decline in the incidence of measles. First, because measles activity rose during the period 1974-77, fewer children were left susceptible to the disease. Second, the total number of doses of measles vaccines administered in public clinics during 1977 in-