

populations such as the military. Further, it is important to recognize that industry has historically been the critical player in ensuring that a vaccine becomes available. Typically, one of the large vaccine companies has undertaken pilot manufacturing, efficacy testing, and application for product licensure. Consequently, the private sector plays a key role in vaccine innovation and supply in the United States and hence in the well-being of the American public.

Over the past two decades, there have been several significant shifts in factors that have a major bearing on the private sector's engagement in vaccine development. For example, in 1972, responsibility for the regulation of biologics, including vaccines, was moved from the National Institutes of Health to the FDA. During the mid- 1970's, the FDA established new procedures for the review of safety and efficacy data on vaccine products for which licensure was desired. These changes placed greater demands on vaccine companies that wanted to get new products licensed or to maintain licenses for products approved for marketing before 1972.

In the second half of the 1970's, there was increasing concern over liability for alleged vaccine-related adverse events owing to the outcomes of a small number of jury trials and industry experience with claims (Institute of Medicine, 1986). In 1976, anticipation of a virulent epidemic of influenza, liability concerns, and the emergency timetable necessary for vaccine production led to unique Federal legislation -- creation of the National Influenza Immunization Program, also known as the Swine 'Flu Program -- to provide protection for industry in the case of the "swine 'flu" vaccine. However, the fact that the epidemic did not materialize, that the vaccine had side effects, and that some felt that industry had been bailed out at taxpayer expense cast a shadow over subsequent discussions of immunization, vaccine liability, and pricing. In 1977, the Assistant Secretary of Health appointed the National Immunization Work Groups to study vaccine development and vaccination efforts. However, their recommendations (National Immunization Work Groups, 1977) were not implemented for a variety of reasons, including a change in administration. Public concern over vaccine safety, liability, and compensation, particularly for pertussis vaccine, increased with the airing in 1982 of a television documentary entitled "DTP: Vaccine Roulette" (WRC-TV, 1982) and the 1985 publication of "DTP: A Shot in the Dark" (Coulter and Fisher, 1985).

The combination of these factors and others, such as the need to replace aging production facilities, led to examination by pharmaceutical companies of the attractiveness of involvement in vaccine development and manufacturing. In the late 1970's and early 1980's, vaccine production came to be concentrated in a handful of companies. For some vaccines, the country became -- and has continued to be -- dependent on a single manufacturer. Supply interruptions, arising from production problems, in the early 1980's led to the creation of a Federal vaccine stockpile that has reduced but not eliminated concerns about the security of the national vaccine supply.

After studying the problems outlined above, the Institute of Medicine issued the report "Vaccine Supply and Innovation." This report proposed mechanisms to achieve a more coordinated national approach to vaccine development and identified options for alleviating liability and compensation concerns related to alleged vaccine-related injury (Institute of Medicine, 1985). Through P.L. 99-660, Congress created the National Vaccine Program (NVP) in 1986 as a vehicle for coordinating Federal efforts in vaccine development and immunization. The law also established the National Vaccine Injury Compensation Program (NVICP), as an alternative to the tort system for those seeking compensation for alleged vaccine injury. These measures were designed to facilitate collaboration between the public and private sectors (by improving coordination and making Federal planning more explicit) and to remove the disincentives that uncertainty over liability posed for manufacturers. Although there has been a delay in development of the National Vaccine Plan, coordination between Federal agencies has been improved by the NVP Interagency Group and the Interagency Committee on Immunization (see section X). The NVICP seems to have greatly diminished the disincentive to vaccine companies arising from uncertainty over vaccine liability and compensation. Other factors have also made involvement in vaccine research development and manufacturing more commercially attractive in the 1990's than it was in the early