

1980's. Vaccine pricing is more favorable to industry, providing higher revenues from which to support research on future products, and there are more scientific opportunities to pursue.

The Institute of Medicine (1993b) and Sisk (1993) have noted that there seems to be greater activity by the private sector in vaccine research and development in the early 1990's, as compared to the late 1970's and early 1980's. In addition, Mowery and Mitchell (1993) have noted considerable activity in the last few years in acquisitions, joint ventures, and licensing agreements among companies undertaking vaccine development, suggesting that the private sector is reacquiring a significant interest in the commercial potential of vaccines.

A portion of the apparent increase in private-sector vaccine research and early development is being conducted by smaller, recently founded biotechnology companies. The increasing involvement of such companies in early product development, which predates the creation of the NVICP (Sisk, 1993), is probably attributable, at least in part, to the existence of scientific opportunities and the availability of venture capital to fund exploratory endeavors in the field.

Thus, private-sector involvement in vaccine development superficially appears to be much healthier now than it was in the late 1970's and early 1980's. However there are some compelling reasons for carefully examining vaccine development prospects and long-term policy setting:

- Much of the present private-sector activity, particularly that of smaller biotechnology companies, is in early vaccine research and development, which is less demanding of human and financial resources than efficacy trials.
- Many smaller biotechnology companies do not have the resources or experience for pilot manufacturing of candidate vaccines to standards required by the FDA for efficacy trials or for the conduct of the trials themselves.
- There is a possibility that investors in newly founded biotechnology companies are looking for a return on investment more from an increase in company value than from an increase in revenue from products, and are thus not necessarily committed to long-term vaccine development through licensure.
- There is a possibility that those companies with more experience in the final stages of vaccine development and marketing may not be interested in taking through to licensure those vaccine candidates with which they have little technical experience and in which they have limited proprietary claims.

These concerns raise questions as to whether smaller biotechnology companies can consistently obtain sufficient capital and routinely guide prototype products through full testing and licensure, as do the larger vaccine companies, and whether the current level of biotechnology company activity will be sustained if profitable products are not rapidly forthcoming and investors look elsewhere for more attractive opportunities. The only experience to date on the potential of smaller biotechnology companies to contribute to vaccine availability is with glycoconjugate vaccines for *Haemophilus influenzae* type b (Hib), in which a small company did successfully develop and license a product; the company was Praxis, which was later acquired by Lederle.

There are additional points to consider that are not specifically related to the involvement of smaller biotechnology companies:

- The reduced uncertainty on injury liability provided by the NVICP pertains only to routinely used childhood vaccines; hence, vaccine companies are still apprehensive over liability concerns for other vaccines.