

- Consideration of HIV vaccine development has further renewed concerns over liability and compensation for vaccine injury, including the possible consequences of stigma or discrimination associated with seropositivity. (Two states -- California and Connecticut -- have passed liability legislation to encourage commercial involvement in HIV vaccine development).
- Other possibilities in HIV vaccine development -- such as the need for behavioral counseling in trials, early testing in women and children, overseas trials, and testing of live, attenuated approaches -- have highlighted other complicated ethical, legal, and scientific questions, in some cases pertinent to testing vaccines for other diseases, that may influence commercial involvement.
- Changing arrangements for Federal vaccine purchases, and the evolution of health care reform in general, are likely to contribute in some degree to a reexamination of long-term commercial investment decisions, such as those for product development.
- Consumer pressure for vaccine combinations may further generate research, manufacturing, or marketing alliances.
- The number of U.S.-based vaccine companies with sufficient in-house resources for taking vaccine candidates through the process of product development, licensure, and marketing is still very small.
- Many vaccine companies based outside the United States cite U.S. licensure requirements and the liability environment as major factors in decisions regarding entry into the U.S. market, although acquiring FDA approval for a product is widely viewed as an asset internationally, and some major companies have started to market vaccines in the United States in the last few years.
- Historically, vaccines whose major use would be in developing countries are not regarded by vaccine companies in industrialized countries as attractive or even justifiable development investments; however, many economists believe that the growing economic strength of transitional developing countries in Asia and Latin America, and the numerically large affluent classes in some very large developing countries, offer potentially large markets for certain vaccines or opportunities for joint ventures, as in product finishing.

On the international side, a systematic survey of vaccine supply systems by WHO's Expanded Programme on Immunization and the CVI revealed that less than 50 percent of the vaccines used in developing countries were actually supplied by private-sector producers through the UNICEF procurement mechanism. The proportion estimated to be manufactured in the country of use, mostly by public-sector manufacturers, was highest for DTP (60 percent), which entails relatively old production technology.

Because of the extent of local manufacturing, international attention and U.S. assistance have been increasingly focused on helping to ensure the quality of locally produced vaccines through provision of technical assistance by quality-control experts or through strengthening regulatory capability in developing countries and elsewhere. USAID is currently working with U.S. vaccine companies, the FDA, and Russian vaccine manufacturers to improve the quality of local produced vaccines. In other countries, USAID and other donors are working to catalyze government steps to allow greater autonomy or even privatization of public-sector vaccine producers.

Given the changing environment in which vaccine companies make decisions, as well as the specific concerns cited above, it is evident that it is necessary to continuously monitor private-sector involvement in, and attitudes toward, vaccine development. There may be situations in which public health priorities and commercial interest do not coincide, with consequent delays in or the complete absence of development of priority vaccines. There could be many more vaccine candidates requiring efficacy testing in the coming decade than there have been historically, and special efforts may be needed to accommodate such testing. Some candidates of low