thereby creating a noninfectious, immunogenic agent. The antigenic proteins also can be cloned into bioreactors which will produce large quantities of the protein. These proteins are termed subunit vaccines. The hepatitis B vaccine, Recombivax®, is a subunit vaccine that is produced by genetically engineered yeast. There are over 40 biotech vaccines in clinical trials in the U.S. (*Genetic Engineering News*, Vol. 15, 1995).

Gene Therapy. Today, most therapies for genetic disorders involve medications, diets and blood transfusions. Individuals with Gaucher diseases can receive the missing protein through injections, while other individuals with sickle cell anemia may receive blood transfusions or bone marrow transplants. An alternative approach would be to provide the afflicted patient with "corrected" somatic cells which contain a normal, functioning copy of the defective gene. With these normal cells, the patient would be able to produce the missing protein or enzyme, or possibly produce a new therapeutic protein or enzyme. This strategy is termed somatic cell gene therapy and it is in a preliminary stage of development.

Various strategies for implementing gene therapy are under study. Ex vivo gene therapy involves collecting cells from the infected individual, transferring a functional gene into these cells, growing these transgenic cells, and infusing or transplanting the transgenic cells back into the patient. In vivo gene therapy entails the direct delivery of a remedial gene into cells of the prospective patient via a benign vector, typically a virus. By contrast to ex vivo and in vivo therapies, antisense therapy is designed to prevent or lower the expression of a specific gene. In some types of human genetic diseases and cancers, genes are overexpressed. Antisense genes produce RNA that bind to the RNA of the overexpressed gene, thereby effectively "shutting down" the overexpressed gene. Today, there are over 40 diseases being considered for treatment with somatic cell gene therapy (Culver, 1994).

Diagnostics Modern medicine depends on the rapid detection and correct diagnosis of a disease. Molecular diagnostic procedures using either immunologic or DNA detection methods have revolutionized clinical diagnosis. Diagnostic monoclonal antibodies have been commercially developed for polypeptide hormones, tumor markers, cytokines, drugs, infectious disease, and a host of other targets. Immunologic detection systems are sensitive, specific, rapid, and simple. They are used for a wide variety of applications on a daily basis.

Nucleic acid based diagnostics also are powerful tools. DNA probes have been developed for most human, animal and plant pathogens. The PCR procedure allows for the amplification of target DNA sequences which are present in minute amounts. DNA analysis procedures also are routinely used for diagnosing genetic disorders. They can be used for early diagnosis before the onset of symptoms, for prenatal diagnosis, or for identifying carriers of rare genetic diseases. DNA typing methods are also employed by law enforcement agencies to "DNA fingerprint" biological samples (hair, blood, skin, etc.) left at crime scenes; by agricultural companies to patent their proprietary germplasm (seeds, animals, etc); and by naturalists to determine the genetic relatedness of individuals in endangered species populations.