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Pharmaceuticals Based on Biotechnology

The United States is entering an era when medicines designed to treat hitherto refractory diseases are increasingly available. About 1000 U.S. biotechnology companies are working to develop these new medicines. By early 1996, 16 pharmaceuticals based on biotechnology had been approved by the Food and Drug Administration (FDA) and an additional 150 were in the third and final phase of clinical trials. The major pharmaceutical companies have slowly become convinced that biotechnology can help identify important new drugs. The participation of these companies in research, clinical trials, and marketing will speed the advent of the new era in medicine.

The drug discovery process is being expedited by the use of costly but powerful instruments, expert data processing and analysis, and new fast methods of synthesis and testing of large families of chemicals. These techniques are producing large libraries of chemicals designed to inhibit crucial enzymes, and automated ways of testing the efficacy of these libraries are being developed. Rapid advances are also being made in sequencing the genomes of humans and other creatures, and genes whose mutations give rise to disease states are being identified.

These processes will create a stream of new potential pharmaceuticals. To become commercially available, however, they must first undergo rigorous FDA procedures, including a time-consuming and costly (in the range of \$100 million) series of clinical tests for efficacy and absence of deleterious side effects. Because most biotechnology firms have assets of \$20 million or less and their annual operations are usually conducted at a loss, those that have good candidate pharmaceuticals are finding it desirable to enter into alliances with major pharmaceutical companies. In 1995, 170 collaborative arrangements were made between biotechnology and pharmaceutical companies, in each of which the biotechnology company received \$20 million or more.

The creation of new therapeutic drugs based on biotechnology comes at a critical time for the major pharmaceutical firms. In the early 1990s, their conventional research programs were not producing enough new medicines. As a result, many downsized and reduced their research staffs. In the interval from 1992 to 1994, the large pharmaceutical companies fired more than 40,000 employees. Yet the major U.S. pharmaceutical companies were slow to adopt the new biotechnology. Ronald Cape, the founder of Cetus, one of the early prominent biotechnology companies, has said that the major U.S. pharmaceutical firms greeted the startup biotechnology companies with ridicule and contempt.*

During the past few years, attitudes have changed rapidly. Large pharmaceutical companies have been seeking alliance with or buying control of biotechnology companies with interesting proprietary assets. In 1995, pharmaceutical companies spent \$3.5 billion to acquire biotechnology companies and \$1.6 billion on R&D licensing agreements. The drug companies have also spent more than \$700 million to obtain access to data banks on the human genome that are being developed by nine different biotechnology firms. Five of these firms rely on positional cloning to discover medically relevant genes. One of the five, Myriad Genetics, based in Utah, has a proprietary data bank on the incidence of hereditary diseases that enables it to focus on genes related to a limited number of pathologies, including breast cancer.† Two biotechnology companies are known to have succeeded in rapid large-scale sequencing of cDNA. One, Incyte Pharmaceuticals, processes 30,000 cDNA clones per week and sells its information to clients.† Human Genome Sciences (HGS) has a larger goal; it hopes to become a major pharmaceutical company. HGS has isolated and characterized almost all the human genes. It has also compared cDNA created from mRNA expressed in many diseased tissues with cDNA produced by normal human tissues, as well as with cDNA from other creatures.

Computer-based bioinformation systems are facilitating the exploration of the vast stores of genomic knowledge that are being collected. These data systems have been developed by experts and will help scientists to much better understand disease processes and improve their ability to create better drugs. The new era in medicine will not come immediately, but its foundation is being established now.

Philip H. Abelson

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