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Biotechnology in a Global Economy

"Will the United States retain its preeminence in biotechnology, or will products and services created by biotechnology be more successfully commercialized in other nations?"

That question is posed and addressed in a document recently issued by the Office of Technology Assessment (OTA).* A definitive answer is not forthcoming, but a wealth of relevant information is provided. Topics considered include the status of the innovative, dedicated biotechnology companies and their newly created pharmaceutical products, of agricultural research, and of use of the new technologies in the chemical industry and bioremediation. The report also deals with matters affecting competition such as patents, fair trade practices, protection of intellectual property, regulatory climate, and tax policies.

For many scientists the most interesting portions of the document will be those dealing with the experience of the many biotechnology companies that were established to exploit opportunities created by recombinant DNA techniques and development of monoclonal antibodies. These new companies were essentially a phenomenon of the United States. Their genesis sprang from the enormous pool of talent and research results fostered by the federal grant system, and they were financed by venture capitalists and stock offerings. The great era for founding biotechnology companies was 1980 to 1984, when hundreds were formed. Most targeted development of human health care products as their goals. Many of these companies hoped to grow into large-scale pharmaceutical houses, but that goal has proved elusive.

Although the biotechnology companies were founded with great resources of human capital, they had limited numbers of dollars. Only a small fraction of the companies obtained funds from stock offerings. The OTA report names 46 companies listed on the various securities exchanges. All of the companies have experienced a big drain of funds as they worked to develop new products. As a result, the companies have been forced to scramble for funds to stay alive. A noteworthy mechanism has been to enter into alliances with major pharmaceutical companies located in the United States and abroad. The 46 companies are listed as having 160 foreign arrangements. In addition, alliances were made by some of the other hundreds of U.S. biotechnology companies.

In attempting to become major factors in pharmaceuticals, the biotechnology companies were seeking riches in a high-risk, high-reward game. Total global sales are $150 billion, of which about one-third are in the United States. However, the major global companies are well entrenched. They have capital, regulatory experience, and marketing capabilities. In the United States the major companies spend 24% of sales dollars on marketing. Each year their sales representatives make 30 million visits to U.S. physicians' offices.

The biotechnology companies have been relatively effective in developing new drugs, but not in bringing them to markets. As of May 1991, 15 biotechnology-based drugs had been approved by the Food and Drug Administration (FDA). About 100 are in the approval pipeline. Most of the new biotechnology-related drugs and vaccines are designed to treat some form of cancer or to be helpful in combating AIDS. Had they been approved quickly they might have saved a significant amount of human suffering.

However, the public seems to demand risk-free pharmaceuticals. In an effort to avoid censure, the FDA has been extremely cautious and has established testing procedures that often consume 10 to 12 years after the development of a pharmaceutical. These include extensive tests for toxicity and three levels of clinical trials. As a result of the caution of the FDA, most new pharmaceuticals for human use are approved in other countries before they can be sold here. Of the 135 new drugs approved by the FDA between 1984 and 1989, 106 were first approved abroad. Lately, the FDA has attempted to expedite some of its processes.

In its discussion of the U.S. climate for innovation in biotechnology, the OTA report lists a number of other impediments. These include delays in the issuance of patents and interagency ideological disputes over the scope of proposed regulations. The OTA report states, "Scrutiny and improvement of regulatory policies, especially the length of time required to obtain FDA approval, will contribute to U.S. competitiveness in the commercialization of biotechnology." A reading of the report leaves one with the impression that the United States will remain a substantial factor in the commercialization of biotechnology. However, a dominant role is being frittered away.—PHILIP H. ABELSON

*Office of Technology Assessment, *Biotechnology in a Global Economy* (OTA-BA-494, U.S. Government Printing Office, Washington, DC, October 1991).