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ABSTRACT

Since the discovery of recombinant DNA in the early 1970s, biotechnology has become an essential tool for many industries. The potential of biotechnology to improve the Nation's health, food supply, and the quality of the environment leads logically to questions of whether current levels of investment in research and development, human resources, and policy formulation are adequate to meet these expectations. This executive summary discusses policy issues regarding biotechnology including training and employment; business-education collaboration; development opportunities; barriers to development; and areas for application such as plant agriculture, human therapeutics, and hazardous waste disposal. Ten policy issues for congressional action are highlighted. Appendices list biotechnology companies, corporate investors, and educational programs. (CW)

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New Developments in Biotechnology









U.S. Investment in Biotechnology

Summary

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New Developments in Biotechnology







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Foreword

Since the discovery of recombinant DNA in the early 1970s, biotechnology has become an essential tool for many industries. The potential of biotechnology to improve the Nation's health, food supply, and the quality of the environment leads logically to questions of whether current levels of investment in research and development, human resources, and policy formulation are adequate to meet these expectations.

This special report is the fourth in a series of OTA studies being carried out under an assessment of "New Developments in Biotechnology," requested by the House Committee on Energy and Commerce and the House Committee on Science, Space, and Technology. This fourth report in the series describes the levels and types of investment currently being made by the Federal, State, and private sectors. Ten major issues that affect investment were identified. They concern levels of R&D funding, research priorities, interagency coordination, information requirements, training and education needs, monitoring of university-industry research, State efforts to promote biotechnology, the effects of tax law on commercial biotechnology, the adequacy of Federal assistance for biotechnology start-ups, and the effects of export control on biotechnology commerce. The first publication in the series was Ownership of Human Tissues and Cells, the second was Public Perceptions of Biotechnology, and the third was Field-Testing Engineered Organisms. A subsequent study will examine issues relevant to patenting plants, animals, and micro-organisms.

OTA was assisted in preparing this study by a panel of advisors, four workshop groups, and reviewers selected for their expertise and diverse points of view on the issues covered in the report. OTA gratefully acknowledges the contribution of each of these individuals. As with all OTA reports, responsibility for the content of the special report is OTA's alone. The special report does not necessarily constitute the consensus or endorsement of the advisory panel, the workshop groups, or the Technology Assessment Board.

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NOTE: OTA is grateful for the valuable assistance and thoughtful critiques provided by the Advisory Panel members. The views expressed in this OTA report, however, are the sole responsibility of the Office of Technology Assessment.

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V

Summary, Policy Issues, and Options for Congressional Action

SUMMARY

Biotechnology can change the way we live. It has already provided, and promises to provide, many products never before available, as well as greater quantities of products now in short supply. Some products produced by biotechnology will be less expensive and safer to use than those now produced by other means. The potential of biotechnology to improve the Nation's health, food supply, and the quality of the environment leads logically to questions about the adequacy of current funding levels.

This report, the fourth in a series on new developments in biotechnology, analyzes the current level of support for biotechnology by the Federal Government, by State and local governments, and by the private sector. The report is titled "U.S. Investment in Biotechnology;" investment indicates expectation that the expenditures will result in significant benefits to society. Investment is treated broadly in this report to encompass financial resources, human resources, and industrial policies.

Any analysis, however, is confounded by wide variation in the definitions used by various sectors to describe biotechnology, and in the methods used to account for that investment. As a consequence, figures on expenditures are approximate, and the scope of investment cannot be determined precisely. It is important to look beyond the numbers to the scale and diversity of efforts underway within the United States to support research in biotechnology and its various applications. In this report, biotechnology is broadly defined to include any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific use. This report focuses on "new biotechnology" (e.g., recombinant DNA techniques, cell fusion, and novel bioprocessing techniques) rather than "old biotechnology" (e.g., use of micro-organisms for brewing and baking or selective breeding in agriculture and animal husbandry).

Several conclusions are apparent about the nature of U.S. investment in biotechnology.

First, in some areas, the investment level is insufficient to meet the promise suggested by current work in the area. In particular, progress in such areas as agricultural biotechnology and biological approaches to waste disposal is hindered by inadequate investment by the public and private sectors. In both fields, technical barriers exist because of incomplete knowledge of basic processes involving plants, micro-organisms, and microbial ecology.

Second, the regulatory process is often perceived to be a significant obstacle to commercial development of some biotechnology-related products. Whether the perceptions are due to ambiguity, unresponsiveness, extreme caution, or outright bias, confusing regulatory mechanisms are seen by industry officials as a major impediment to the acquisition of knowledge and an obstacle to the economic success of future products. On the other hand, industry officials agree that reasonable and well designed regulations are necessary to ensure the public health and safety to the environment.

Third, the rate of biotechnology commercialization and the factors affecting that rate vary among industrial sectors. Policy issues relevant to the application of biotechnology to human therapeutics, for example, differ from those relevant to plant agriculture or chemicals.

How Much Does the United States Spend on Biotechnology?

Twelve Federal agencies and one cross agency program spent roughly \$2.7 billion in fiscal year 1987 to support research and development in biotechnology-related areas (see table 1-1). The National Institutes of Health (NIH) contribute by far the largest share of that support, approximately \$2.3 billion. Significant investment



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Table 1-1.—Federal Support for Biotechnology Research, 1985-87 (current dollars in thousands)

Agency	FY 1985	FY 1986	FY 1987
National Institutes of Health:			
Basic	1,208,229	1,202,094	1,388,337
Applied	638,916	678,003	887,614
Total	1,847,145	1,880,097	2,275,951
Department of Defense [.]			
Basic	44,100	51,600	60,800
Applied	48,500	49,000	58,000
Total	92,600	100,600	118,800
National Science Foundation	81,570	84,072	93,800
Department of Energy:			
Basic	45,500	45,000	50,100
Applied	9,600	10,900	11,300
Total	55,100	55,900	61,400
JSDA Cooperative State Research Service	48.000	46.000	49,000
JSDA Agricultural Research Service	24,500	27,000	35,000
Agency for International Development:	,	•	,
Broad definition	NA*	46,854	43,756
Narrow definition	N A	14,332	6,082
National Aeronautics and Space Administration	N A	6,400	7,200
Veterans Administration	5,400	6, 36 5	9,400
Environmental Protection Agency	3,000	3,400	5,666
National Bureau of Standards	850	3,300	3,300
Food and Drug Administration	3,000	4,700	5,800
National Oceanic and Atmospheric Administration	2,144	2,215	2,680
Small Business Innovation Research**	12,033	12,000	NA

[&]quot;NA Not available

is also being made by the Department of Defense, \$119 million; the National Science Foundation, \$93.8 million; and by the Department of Energy, \$61.4 million. The Department of Agriculture expects to fund some \$84 million in biotechnology research, divided between the Cooperative State Research Service and the Agricultural Research Service.

Federal support of biotechnology research and development has increased minimally every year since 1984. Although one reason for these increases may be its political attractiveness to agency officials, a more likely explanation is that biotechnology comprises a set of tools that have become fully integrated into the life sciences.

Some 33 States are actively engaged in some form of promotion of biotechnology research and development. These efforts are seen as a means to achieve academic excellence in their colleges and universities or as a path to economic development, or both. State investment totaled \$147 million in fiscal year 1987 (1/16th the Federal investment), with three States—New Jersey,

New York, and Pennsylvania—making up more than half of that amount. The States employ various funding mechanisms to reach their goals, including issuance of bonds, direct legislatice appropriations, allocation of State lottery funds to biotechnology, and mandatory industry and government matching funds.

With the oldest State program, that of North Carolina, only in its sixth year, it is too early to judge the success of State efforts. The only available measures of success are indirect ones, namely, the size of the budget, the number of biotechnology companies within a State's borders, and the extent of involvement by universities and private industry. Although long-term, stable funding runs counter to the pattern of State investment, it is vital in the area of biotechnology. State programs with strong support from their governors appear to hold an advantage, as do those that can manage to avoid fiscal duress, severe unemployment, and educational insufficiencies. States that have an existing base of strong research universities hold the greatest advantage.



^{**}SBIR dollars are a part of the total spending reported by the above agencies. They should not be added on to total spending

SOURCE Office of Technology Assessment, 1988

The commercialization of biotechnology by U.S. industry remains healthy and competitive. OTA identified 403 American companies dedicated to biotechnology, and 70 established corporations with significant investments in biotechnology. Combined, U.S. industry is spending an estimated \$1.5 billion to \$2.0 billion annually in biotechnology research and development (see appendixes A an.\(^1\) B).

Because biotechnology has become an essential tool for many industries, there is no such entity as "the biotechnology industry." Rather, it is a tool employed by several industrial sectors, each with its own advantages and obstacles in the race to market. Human health care, primarily therapeutics and diagnostics, continues to be the focus of most R&D investments, with chemicals ranking second and agriculture third as fields of application for industrial biotechnology.

Strategic alliances between large corporations and smaller, dedicated biotechnology companies are increasing and are seen as a sign of financial strength by investors. Instability in the financial markets may accentuate the dependence of many smaller firms on large, established corporations. Most large corporations continue to rely on outside sources of innovation, either a smaller firm or a university scientist, with these collaborations benefiting both parties. However, the development of in-house expertise in biotechnology is occurring rapidly in major U.S. corporations.

Training and Employment

The number of jobs in biotechnology has grown rapidly in the past decade. A 1987 OTA survey of both dedicated biotechnology companies and large established corporations in the United States yielded an estimate of 35,900 jobs in the field, of which 18,600 are for scientists and engineers. Nevertheless, despite employment growth in recent years, biotechnology is not expected to become a major industrial employer.

Although the supply of specialists in biotechnology appears adequate to meet current demand, shortages in particular areas will occur from time to time. Shortages in such emerging areas as protein engineering have occurred but were largely unavoidable. Anticipated shortages of bioprocess engineers have not yet developed, although the problem could worsen as more biotechnology products reach the later stages of commercialization. Demand for expertise in plant and animal tissue culture and protein chemistry may be outstripping supply, and a growing need for persons to assess the risks of engineered organisms released into the environment has led to a shortage of microbial ecologists.

The mix of personnel at biotechnology companies is changing as production and quality control become more important. The 1987 OTA survey of biotechnology companies found that Ph.D. scientists represent 20 percent of total personnel and 28 percent of scientific personnel. A 1983 survey had found that 43 percent of R&D personnel possessed Ph.D.s. This shift has created more opportunities for biologists and biochemists at the master's and bachelor's degree levels, and will be providing room for those with 2-year associate of applied science degrees.

Molecular biologists and immunologists constitute about a third of the research workers in biotechnology. For the most part, companies see an



Photo credit: University of California, San Francisco

Molecular biologist preparing for DNA cloning and in vitro mutagenesis experiments.



ample supply of scientists trained in molecular biology, biochemistry, cell biology, and immunology as a result of the traditionally strong support for those fields by the National Institutes of Health.

The NIH, by far the largest Federal source of fellowships and training grants, is also the largest supporter of such training for biotechnology. NIH estimates that \$70 to \$80 million of its training funds support graduate students working in areas either directly or indirectly related to biotechnology, approximately 6,000 students. At the same time, the share of NIH's research budget devoted to training has shrunk from 18 percent in 1971 to a low of less than 4 percent in 1987.

The National Science Foundation spensors roughly 150 predoctoral fellowships, totaling about \$8 million, in the biological and biomedical sciences. Only 20 fellows are funded at the post-doctoral level; these are all in plant biology and environmental sciences, at a total cost of \$2.2 million. Other Federal agencies, notably the Department of Agriculture and the National Oceanic and Atmospheric Administration, support varying smaller numbers of students in areas related to biotechnology.

Based on a 1984 survey, biotechnology companies provide between \$8 million and \$24 million for training grants and scholarships. Industry funding is estimated to account for about 10 to 20 percent of all money for biotechnology training programs. Combined with the contributions made by industry to the research and salaries of trainees at research universities, industry provides financial assistance to about 20 percent of biotechnology trainees.

Colleges and universities have responded fairly rapidly to advances in biotechnology, by creating a range of new programs in biotechnology training and education. OTA has identified 60 such programs at 49 different U.S. colleges and universities. About three-fourths of these programs are based at State institutions (see appendix C).

Seventeen States reported funding university and college training programs in biotechnology. But complexities in accounting procedures and disbursement of such funds mean that few can provide exact dollar figures. For those that did report spending on specific programs, the figures for fiscal year 1987 ranged from a high of \$1.3 million in Georgia to a low of \$40,000 in Pennsylvania.

Campus-Industry Collaboration

Collaboration between industry and academia has always played an important role in biotechnology research. The industrial contribution to academic research is approximately four to five times greater in biotechnology than in other fields; per dollar invested, industrially supported university research in biotechnology generates four times as many patent applications as does company sponsorship of other research on campus. Nearly half of biotechnology companies support university-based research. Although small compared to the contribution made by the Federal Government, that support has grown by an average of 8.5 percent annually in the first half of the decade.

The nature of this commitment appears to be changing. Few biotechnology companies are planning to invest large sums over long periods for undirected research, as was done in the early 1980s by Monsanto at Washington University. An increasing number of cooperative arrangements represent consulting and contract research rather than long-term partnerships.

The debate over the impact of such collaboration on academic science remains unresolved. With the exception of isolated studies, little evidence exists to either substantiate or refute the claims that such cooperative efforts are undermining the university's mission and independence. As this debate continues, two tradeoffs bear watching:

- whether losses to science or to university values that result from increases in the level of secrecy in universities are offset by net additions to knowledge that result from infusion of industry funds into university laboratories; and
- whether shifts in the direction of the university research agenda toward more applied and commercially relevant projects have benefits for human health and economic growth that far outweigh the risks to basic research.



Collaborative efforts in biotechnology pose specific problems for each group of participants. A recent survey found that faculty receiving industry funds are much more likely than other biotechnology faculty to report that their research has resulted in trade secrets and that commercial considerations have influenced the choice of research projects. In another study, 40 percent of faculty with industrial support reported that their collaboration resulted in unreasonable delays in publication.

For industry, the major issue is whether such collaboration will prove fruitful and hasten the development of new products and processes. The nature of the agreement—specifically, who negotiates the contract and how property rights are assigned—plays an important role in the process and is, therefore, a major concern for companies entering into such agreements.

Added to those uncertainties is the great variation among collaborative agreements. Despite those variations, universities can take several steps when negotiating collaborative agreements to maximize the benefits to all parties and minimize pot' atial risks. Those steps include specifying the scope of the agreement (the research area to be supported and the commitment expected from faculty); maintaining control over the selection, methodology, and review of the research to be undertaken; detailing the sponsor's responsibilities; and spelling out in advance guidelines on proprietary information, publication requiren ents, patent rights, and income. Apart from continued funding of the academic research that often sets the stage for such collaboration, the mechanics of Federal monitoring of such relationships are not without problems.

Any funding source has the potential to shape the research agenda and influence those who carry out the work. A history of Federal programs, dating from the Morrill Act of 1862 that established the land grant colleges, indicates how universities can be shaped by outside forces. While many early fears about the influence of industrial sponsorship of biotechnology research in university laboratories have not been borne out, the situation warrants monitoring. There remains sufficient concern about the long-term effects of such

funds on research agendas, secrecy, conflict of interest, and student education.

Opportunities for Development

There is tremendous variation in the way that States and the Federal Government define and account for bic ... nology spending. Also, there is no single model by which industry funds research in the field, nor is there a common approach to the carrying out of commercial developments of biotechnology products. At the same time, each sector affords significant opportunities to foster growth in the field.

At the Federal Level

The activities of the NIH determine to a large extent the nature of Federal support for biotechnology. In recent years the White House and others have increasingly pressured NIH to expand its mission and provide support for more applied research.

In 1986, an NIH committee began to draft guidelines that would permit companies unprecedented cocess to NIH resources. The guidelines, written in response to the Technology Transfer Act of 1986 (Public Law 99-502), give companies exclusive licensing rights to the fruits of governmentsponsored research and encourage scientists to seek commercial applications for their work. This opening of the laboratory doors to commercial application offers great promise to the biotechnology industry, which has long relied on work conducted by NIH scientists.

Although the NIH investment in biotechnology dwarfs that of other agencies, opportunities to foster growth abound throughout the Federal Government. Other agencies, such as the Nacional Science Foundation, the National Aeronautics and Space Administration, the Department of Energy, and the National Oceanic and Atmospheric Administration, fund basic and applied research in biotechnology. Agencies with diverse missions, such as the Departments of Defense and Agriculture, and those with regulatory missions, such as the Food and Drug Administration and the Environmental Protection Agency, fund biotechnology research relevant to their mandate.



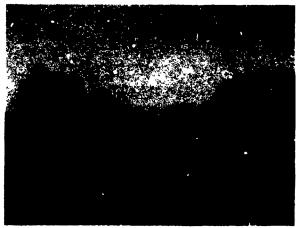


Photo credit: Michigan Biotechnology Institute

The Michigan Biotechnology Institute, a 120,000square-foot business and research center funded by an industrial revenue bond issue, a low-interest State loan, and Institute funds.

Finally, agencies traditionally viewed as service oriented, such as the Veterans Administration, the Agency for International Development, and the National Bureau of Standards, fund biotechnology research relevant to their service roles. The National Bureau of Standards is a partner in a joint venture with the University of Maryland and Montgomery County, MD, to develop a national resource for biotechnology-related measurement research. A plan developed at the direction of the Senate Commerce, Science, and Transportation Committee estimated that measurement needs will add as much as 25 percent to the costs of biotechnology products, and the Bureau is devoting more than 2 percent of its budget to generic applied and basic research in this area.

The Small Business Innovation Research (SBIR) program has invested more than \$36 million in various bio chnology companies since it first awarded grants in 1983. In fact, biotechnology is the leading recipient of SBIR funds, which are derived from a percentage of the budget of every Federal agency that spends at least \$100 million on extramural research. SBIR invests more in biotechnology than in information processing and medical instrumentation.

Federal agencies report higher levels of support for applied work in biotechnology in fiscal years 1985, 1986, and 1987, than in 1984. Yet applied research support as a percentage of total R&D support has declined (in constant dollars) across the Federal research budget in the past 5 years. It is not clear, therefore, whether an actual increase in support for applied biotechnology has occurred or whether agencies have become more proficient at describing work as applied and accounting for expenditures in those areas.

By itself, greater support does not translate directly into successful ventures. NSF's Engineering Research Centers program expects to devote a growing share of a budget, which could reach \$50 million in fiscal year 1988, to biotechnology-related work. Yet the effectiveness of the program has not been proven, and several factors could impede its progress. These factors include the reliance in funding decisions on scientific merit over other relevant criteria, inadequate coordination by Federal officials with State programs and the possibility of competing initiatives, and the lack of clearly defined evaluation and monitoring criteria.

Because Federal agencies seek an array of applications from biotechnology research, a certain amount of redundancy among supported programs is inevitable and probably healthy. At the same time, the goals of various agencies might at times be better met by increased cooperation among agencies wishing to pool their resources on common projects.

At the State Level

States have different expectations about their return on biotechnology investments. Some spend money to strengthen faculties so that universities can better attract private business to the State. Others offer direct incentives, including facilities and tax advantages, to attract small firms. Regardless of approach, successful programs rely on a strong academic and research base, sufficient local venture capital, and an unusually vigorous interaction among researchers, manufacturers and users, and State authorities.

Successful State programs in biotechnology build on previous efforts to attract high technology industries. Thus, it is not surprising that California and Massachusetts lead the nation in the share of biotechnology companies within their



Table 1-2.—State Allocations for Biotechnology R&D, Training, and Facilities

State	FY 86	FY 87
Arizona	\$1,170,0C0	\$1,540,000
Arkansas	757,173	800,000
California	2,500,000	2,500,000
Colorado	500,000	500,000
Connecticut	665,000	1,100,000
Fiorida		7,050,000
Georgia	2,600,000	3,000,000
Idaho	438,800	450,000
Illinois	4,500,000	5,000,000
Indiana	4,000,000	1,029,904
lowa	500,000	3,750,000
Kansas	162,000	172,000
Kentucky	908,500	896,600
Louisiana	670,000	NA
Maryland		3,900,000
Massachusetts	485,000	935,000
Michigan	6,000,000	4,000,000
Minnesota	1,032,000	1,100,000
Missouri	1,500,000	3,700,000
New Hampshire		450,000
New Jersey	10,000,000	35,690,0001
New York	34,300,000*	•
North Carolina		6,900,000
North Dakota		1,601,783
Ohio	2,194,787	50,000
Oklahoma	1,584,000	1,542,000
Oregon	350,000	360,000
Pennsylvania	2,848,824	18,035,4941
Tennessee	NA	800,000
Utah	110,000	500,000
Vermont	NA	300,000
Virginia		1,750,000
Wisconsin	. 190,000	418,000

NA Not available

"Indicates multi-year appropriation

SOURCE Office of Technology Assessment, 1988

boundaries, with 27 percent and 13 percent, respectively. (See table 1-2 for levels of investment in all States.)

An NSF program begun in 1978 to ensure greater geographical distribution of research awards has proven to be a springboard for biotechnology efforts in Vermont, North Dakota, Montana, Kentucky, and Oklahoma. While it is too early to assess the extent to which NSF's EPSCoR (Experimental Program to Stimulate Competitive Research) funds will help other States gain a foothold in the field, it is clear that several States had such a purpose in mind when they entered the program.

Most States are not aiming only to woo existing firms from other States. Instead, they have turned to nurturing in-State start-up companies in the hope that they will benefit from the industrial growth of those companies. And, as more companies seek sites for manufacturing facilities, States that could not provide an attractive environment for R&D facilities may be able to compete for the manufacturing facility. Regardless of the approach taken, States will remain dependent on Federal research support to universities to achieve their goals in biotechnology. Those contributions must be tied to the existing economic and academic base within each State.

Although some States may not be able to maintain current high levels of support for biotechnology, sustained commitments are vital for long-term success. Unlike the changes that have come about from growth in other high-tech areas, strategic investments in biotechnology promise to transform a State's entire economy, not just increase its work force temporarily or add to its industrial base.

At the Commercial Level

The boom in biotechnology company formation occurred from 1980 to 1984. During those years, approximately 60 percent of current companies were created, with nearly 70 new firms begun in 1981 alone. Consolidation within the industry and the predominance of a few firms have slowed the formation of new firms; nevertheless, the amount of money invested by larger, more diversified corporations continues to grow.

The range of companies commercializing biotechnology encompasses many traditional industrial sectors. They include pharmaceuticals, plant and animal agriculture, chemicals, energy, and waste management. Table 1-3 lists the primary emphases of biotechnology R&D of dedicated biotechnology companies and large, diversified corporations. Human therapeutics is the primary focus of both groups.

Each sector commercializing biotechnology faces different financial markets, public markets, regulatory requirements, patent issues, personnel needs, and problems in attaining product commercialization. As the tools of biotechnology become integrated into each sector, the paths to commercialization more closely resemble those historically taken for more conventional products.



Table 1-3.—Areas of Primary R&D Focus by Biotechnology Companies

Research area	Oedicated biotech companies #(%)	Large, established companies #(%)
Human therapeutics	63 (21%)	14 (26%)
Oragnostics	52 (18%)	6 (11%)
Chemicals	20 (7%)	11 (21%)
Plant agriculture	24 (8%)	7 (13%)
Animal agriculture	19 (6%)	4 (8%)
Reagents	34 (12%)	2 (4%)
Waste disposal/treatment	3 (1%)	1 (2%)
Equipment	12 (4%)	1 (2%)
Cell culture	5 (2%)	1 (2%)
Oiversified	13 (4%)	6 (11%)
Other	31 (18%)	0 (0%)
Total	296 (100%)	53 (100%)

SOURCE Office of Technology Assessment 1988

More than in any other high-technology industry, commercial biotechnology expects R&D to generate revenues. The R&D budget for dedicated biotechnology companies surveyed by OTA averages \$4 million per firm, or more than 40 percent of anticipated revenues. For large, established companies investing in biotechnology, the annual R&D budget for biotechnology averages \$11 million, a figure that represents one-fifth of their total R&D expenditures. Although nearly every major corporation investing in biotechnology spends some of its R&D budget in house, 83 percent also spend some of their budgets on research conducted by outside firms or by universities.

To date, U.S. dedicated biotechnology companies have raised over \$4 billion from private investors, according to one estimate. Yet 80 percent of that investment has been made in 10 companies. Investment in health care applications accounts for 75 percent of all investment. Agricultural applications have received only 16 percent of the total investment.

Dedicated biotechnology companies finance their research in two ways—through equity investments and collaborative ventures. If uncertain financial markets prevail, flexibility in access to equity may become restricted, resulting in an increase in joint ventures with larger more established firms. Venture capital and private equity have been the mainstay of support for start-up companies through 1987. As companies mature, however, they turn to public offerings. OTA found a decreased dependence on private investments, a doubling of U.S. equity holders, and a 10-fold

increase in public stock offerings in maturing companies over a typical 5-year period. Dedicated biotechnology firms focusing on therapeutics are more likely to be publicly held than those in other fields, although several agricultural biotechnology firms issued an initial public offering in 1987 as they sought cash to bring their products to market.

Although equity investments also may come from individuals or financial institutions, corporate financing is the fastest-growing type of support. Historically, equity investments by large firms tend to be passive, giving the larger firm the chance to keep abreast of new developments. When these investments do lead to research contracts and product licensing agreements, the larger firm often handles final development, licensing approval, manufacturing and marketing, while the dedicated firm retains patent rights and receives royalties for the sale of the product.

Most incustrial alliances occur between U.S. companies rather than between U.S. and foreign firms. Although collaborations with foreign companies may provide dedicated biotechnology firms with better access to international markets, there is a legitimate concern that such alliances could reduce future revenues and growth for U.S. firms. The most common foreign collaboration, when it does occur, is with Japanese firms, overwhelmingly in the application of biotechnology to human health care.

Barriers to Development

The growing concern that U.S. trade policy toward high-technology goods may be compromising national security poses a potential threat to the growth of biotechnology exports. Proponents of tighter controls argue that easing restrictions would give the Soviet Union easier access to Western technology. In the case of biotechnology, some fear that unrestrained exports would enhance the ability of other nations to produce biological warfare agents. On the other hand, opponents argue that strict controls will hamper economic competitiveness. A technical advisory committee within the Department of Commerce was formed in 1985 to address the question of biotechnology exports, but committee efforts to date have been marginal.





Photo credit Monsanto

Genetically engineered tomato plants are shown being planted by researchers at a Monsanto-leased farm in Jersey County, IL.

The second major factor that could hamper commercialization of biotechnology is regulatory uncertainty. Biotechnology faces a much different and more stringent regulatory environment than do many other high technology industries because, among other factors, it is used by highly regulated industries, such as food and drugs. This environment promises to raise the cost of R&D and, thus, the amount of investment needed to market a product. One issue is whether a product produced using biotechnology will result in higher costs for regulatory review than similar products made using traditional methods. This issue will be resolved differently depending on whether the product is a pharmaceutical, an engineered organism, or a plant.

Other potential barriers to commercialization will also affect investment. With patent protection of biotechnology products a major unresolved issue, many companies have pursued trade secrecy as a short term and more certain strat-

egy to assure protection of their technology. This strategy is not their optimal choice. With respect to antitrust issues, OTA was unable to find any aspect of the problem that could be considered unique to biotechnology companies. The impact on biotechnology of the Tax Reform Act of 1986 (Public Law 99-514) is not clear. Although some tax specialists believe that the revised incentives may affect the distribution of investment, they do not expect them to shrink the total amount of money available. At the same time, the repeal of the investment tax credit is expected to increase dramatically the tax rates in research-related areas. That rise is likely to have a long-term negative impact on biotechnology companies.

A Closer Look at Three Sectors

This report examines three areas of research and development in biotechnology; plant agriculture, human therapeutics, and hazardous waste



management. Each is of legislative and regulatory interest to the Federal Government, and each presents a different set of issues for debate. Differences in the state-of-the-art, levels and proportions of public and private support, the effects of regulation, and the degree of commercialization in each area illustrate the necessity of viewing biotechnology as a diversified set of tools affecting a variety of sectors.

Biotechnology as applied to the development of human therapeutics represents an area where there has been substantial Federal support of basic research. As a result, the knowledge base is vast and growing, the commercial aspects enticing, and the regulatory regime similar to that applied to more traditional approaches of drug design and manufacturing. In contrast, plant biotechnology faces a smaller knowledge base due to lower levels of Federal support for basic research in the plant sciences. The commercial applications in the field are less developed, although potentially highly profitable, and the regulatory framework new and evolving. The third case study, biotechnology as applied to hazardous waste management, represents an area of minimum R&D investment by both the public and private sectors. As a result, the knowledge base is small and large scale application nearly nonexistent. Applications of biotechnology in this field tend to be driven by regulation.

Human Therapeutics

Biotechnology has become an integral part of research in the pharmaceutical industry, where the emphasis has already begun to move away from technology development and toward clinical applications. Applications of biotechnology to the development of human therap rutics enjoys a level of public and private funding for R&D that greatly exceeds that in any other sector. Such high levels of support stem from expectations that recombinant DNA and hybridoma technologies will bring about the development of products never before available in the quantities necessary for therapeutic applications. Contributions thus far include the production of naturally occurring human proteins through the use of recombinant DNA technology and the production of monoclonal antibodies from rodent and human hybridoma cell lines; others are expected from the available tech-



Photo credit Centocor

Industry scientists sterilize vials for monoclonal antibodies.

nologies for making proteins function more efficiently and for creating proteins that do not exist in nature.

In the face of such promise, it is noteworthy that only seven human therapeutics using biotechnology have been approved for marketing in the United States. There are more than 400 biotechnology-based human therapeutics in some stage of clinical trials, comprising less than 2 percent of the 25,000 active applications for investigational new drugs. Nevertheless, of the 20 FDA approvals of new human therapeutics in 1986, four were products of recombinant DNA or hybridoma technology. This high approval rate of biotechnology products is one reason why industry analysts project billions of dollars in worldwide sales of therapeutics made from the new technologies, and should help to sustain or increase the level of public and private investment.

Six major factors will influence the rate of progress in the development of human therapeutics:

- availability of funds for research;
- support of personnel;
- regulation of products made using biotechnology;
- protection of intellectual property;
- access to information generated by research; and
- gaps in basic research.



Plant Agriculture

A critical industry in the United States, agriculture forms a large portion of this country's economy. Research contributes significantly to its success, with an annual rate of return on investment estimated at between 30 and 50 percent. Biotechnology is expected to play a major role in strengthening this important part of the nation's economy. Its tools have the potential to modify plants to resist insects and disease, grow in harsh environments, provide their own nitrogen fertilizer, or be more nutritious. The newer technologies can potentially lower costs and accelerate the rate, precision, reliability, and scope of improvements beyond that possible by traditional plant breeding. But success in this field is by no means assured. Many barriers must be overcome for U.S. agricultural products to remain competitive in world markets.

Of all the problems facing agricultural research, the most pressing is the need for increased Federal support. Only 1.4 percent of the Department of Agriculture's budget is devoted to research. In part, the advent of genetic engineering and related biotechniques has, itself, altered the shape and scope of U.S. agricultural research investment decisions. In particular, the emerging technologies present fundamental challenges and opportunities for the public component of U.S. agricultural research. Widespread commercialization of plant biotechnology depends on breakthroughs in many technical areas that can come only through cooperation with public universities, economic incentives from government, and a favorable regulatory environment. The Federal Government also plays a major role in ensuring an adequate supply of trained personnel.

Basic science advocates charge that the USDA-led system has not been on the cutting edge of science, and has focused research primarily on methods for increasing yield. Other critics have argued that the advent of the biotechnologies has led to private sector, proprietary-dominated research efforts. Others point out that increased private sector research investments have uniquely contributed to the fundamental knowledge base and resulted in a positive economic impact.



Photo credit Calgene

Cell and tissue culture methods are used to regenerate plant cells containing foreign genes into whole plants.

Biotechnology's impact on the direction of agricultural research has also raised issues about proprietary interests, such as the exchange of plant breeding materials.

Hazardous Waste Management

Waste cleanup is a substantial and growing industry. But the application of biotechnology to waste disposal is still largely experimental, and the investment is small compared with efforts in pharmaceuticals and agriculture. Its potential remains undeveloped due to a variety of technical, institutional, economic, and perceptual barriers. And, more so than in any other industry studied by OTA, the research agenda for waste disposal and management is driven by regulation. The influence of the regulatory regime affects, to a large degree, the extent to which biotechnological applications have been studied. Regulation shapes the field of waste disposal and, thus, provides the impetus for efforts to develop new methods of pollution control. Yet fears of regulatory barriers are discouraging researchers from investigating genetic engineering as a way to discover potentially beneficial organisms.

The Environmental Protection Agency is the lead agency in conducting research and development in waste disposal. But EPA's current investment in R&D in biotechnology is not sufficient to overcome a number of technical barriers in the near



future. There is also a widespread feeling that EPA is biased against biological approaches to waste disposal and unwilling to support approaches involving biotechnology. The field lacks credibility because biological techniques were oversold during the 1970s. In addition, many biological approaches take longer than incineration or excavation and are avoided because of a desire to address the problem quickly.

Funding appears to be insufficient and comparatively unstable. The in-house research EPA funds is of high quality, but it is at a relatively low level. At the same time, reports from individual companies lack credibility due to the potential conflict of interest inherent in any company-sponsored research. The Federal Government must take the lead in addressing critical research areas and establishing clearly defined cleanup standards.

Because of these factors, small start-up biotechnology firms usually cannot afford the high financial risk required to achieve progress in the field. The large initial investment needed to develop the appropriate technology, as well as the necessary knowledge base, is another obstacle.



Photo credit: Ecova Corp.

Daily tilling of soil provides oxygen to naturally occurring microbes, enabling them to remediate hydrocarbon-contaminated soil in an enclosed, solid-phase soil treatment facility. Current applications of biotechnology to waste management rely on naturally occurring microbes; the application of genetic engineering to this field remains some years away.

Finally, public acceptance is required to implement biotechnological approaches to waste disposal. The generic fear of genetically engineered organisms may be compounded by the difficulty of containing the waste to be disposed.

POLICY ISSUES AND OPTIONS FOR CONGRESSIONAL ACTION

Ten policy issues relevant to U.S. investment in biotechnology were identified during the course of this study. They are:

- Federal funding for biotechnology research;
- balancing support for basic and applied research and development;
- interagency cooperation in support of biotechnology;
- information needs and reporting requirements;
- training biotechnology personnel;
- monitoring university-industry relationships in biotechnology;
- Federal support of State programs in biotechnology;
- providing financial incentives for private investment in commercial biotechnology;
- providing direct support for start-up and scale-up in commercial biotechnology; and
- Federal controls on the export of biotechnology products and processes.

Associated with each policy area are several issues that Congress might consider, ranging from taking no action to making major changes. Some of the options involve direct legislative action. Others are oriented to the actions of the executive branch but involve congressional oversight or direction. The order in which the issues and options are presented should not imply their priority. The options provided for each issue are not, for the most part, mutually exclusive: adopting one does not necessarily disqualify others in the same category or within another category; however, changes in one area could have repercussions in others. Finally, and of critical importance, many of the issues are more germane to certain sectors, such as human therapeutics, plant biotechnology, or hazardous waste management.



ISSUE 1: Should current levels of Federal funding for biotechnology research and development be altered?

An issue central to the findings of this report pertains to the adequacy of Federal support for R&D relevant to biotechnology. There are no objective and reliable measures for determining whether current Federal support for biotechnology R&D is sufficient. Clearly, intensive and sustained Federal investment in applications of biotechnology to the life sciences has been transformed into commercial products in some industries much faster than in others. Commercial applications are more advanced in areas such as human therapeutics, diagnostics, and chemicals than in plant and animal agriculture, or bioengineering for waste degradation. In some cases, the slow progress is due to insufficient funds for basic research; in other cases, potential products are simply not being developed because industry does not consider the biotechnology product or process sufficiently better (either functionally or economically) than those that already exist. Furthermore, excessive regulatory burdens or public perceptions associated with applications of recombinant DNA research can be more important factors than underfunding in some biotechnology applications, most notably in plant agriculture.

Option 1.1: Take no action.

Congress may conclude that Federal levels of investment in R&D over recent years have adequately supported the forward integration of biotechnology into many sectors, suggesting steady levels of support as the best approach. The continuance of existing funding patterns, however, will perpetuate current disparities in research emphases.

The current focus of biotechnology application on human health care products is due, in part, to the steady and high levels of funding for biomedical research. However, research applicable to medical biotechnology has moved only recently from technology development into new clinical applications; without Federal funding increases, this transition could be more difficult.

Maintaining the existing funding level for biotechnology research targeted to agriculture could result in a static agricultural sector that is unable to respond to future economic, technological, and scientific needs—both domestically and internationally. Basic knowledge in the plant sciences, for example, would continue to remain in short supply. The barrier to commercialization created by this lack of knowledge would increase. Inadequate funding could also slow some areas of research to help alleviate surpluses, provide new options for the small farmer, result in better products, and make farm practices more environmentally sound.

Biotechnology for waste management has suffered in recent years from a variety of funding and institutional barriers. Its development is in a relative state of infancy compared with that of biotechnology in pharmaceuticals and agriculture. Without sufficient funds, adequate efficacy and efficiency demonstrations will not be carried out, and EPA is not likely to develop sufficient in house professional expertise for the assessment and regulation of bioremediation techniques.

Particularly underdeveloped areas of biotechnology research could remain stagnant in the absence of additional funds. These areas include: the exploitation of marine organisms to obtain new sources of potential pharmaceuticals, industrial chemicals, and materials; and the development of new biotechnological applications, such as conversion of biomass to fuel and biological sensors for use in measurement devices and bioreactors.

Option 1.2: Decrease existing budgets.

Due to current fiscal constraints, Congress may conclude that it is necessary to cut Federal funding of biotechnology research. Such a decision is more likely to be a consequence of overall reductions in R&D budgets, of which biotechnology would be a part. Reductions in Federal support for biotechnology could slow the transfer of basic research results to applied areas and would require greater private investments in basic research.

Congress could determine that funding of health-related applications of biotechnology is disproportionately high, and reduce funds in these areas. A targeted reduction of research funds for biotechnology applications to human health could have undesirable consequences for non-medical



sectors, however, because advances in biotechnology continue to emerge from NIH-funded research that have immediate applications to agriculture, marine biology, the use of micro-organisms in waste management, and many other fields.

Some areas of research, currently underfunded, would suffer disproportionately. For example, Federal support for biotechnology R&D in waste treatment is so minimal now that decreases will further retard new developments. If Congress determines that Federal investment in plant biotechnology is excessive, it could decrease allocations for this sector. However, decreased funding for agricultural research and training would result.

Option 1.3: Increase existing budgets.

Congress could conclude that because of its social, economic, and strategic importance, the rapid development of biotechnology and its transfer into many sectors warrants increased Federal R&D support. Increases could expand the knowledge base necessary for applied research and development and could result in more rapid commercialization of biotechnology in some fields.

Funding increases in the application of biotechnology to basic and applied research relevant to human health might be aimed at some of the important bottlenecks, including research in protein structure and function, protein engineering, the role of natural chemical modifications of proteins in protein stability and function, and development of novel delivery systems for protein drugs. Additional support in many of these areas should continue to yield generic applications—contributing to uses in the pharmaceutical industry as well as chemical, agricultural, and other diversified industries.

Congress could determine that present spending for agricultural research is insufficient. If Congress increases agricultural research funding, plant biotechnology is likely to benefit. The basic science base in the plant sciences is seriously deficient.

Congress could provide additional funds for EPA to develop innovative waste cleanup technologies, particularly those derived from biotechnology. Without increased funds, EPA will continue to emphasize funding of risk assessment studies on micro-organisms containing recombinant DNA,

while other high priority projects continue to be supported at relatively low levels.

Increased funds for the application of biotechnology to renewable biomass resources, and for the exploitation of marine biotechnology, currently funded primarily by DOE and NOAA, respectively, should enhance the United States' role in developing these novel uses.

Option 1.4: Reallocate existing funds.

Should Congress conclude that present funding levels are adequate or, because of fiscal constraints, must remain the same, then it could direct that Federal resources be reallocated. Although the budgetary process works against centralized research planning, Congress could decide that pressing needs for advanced R&D in specific industrial sectors warrants a shift of emphasis in research support. This option, however, promotes a degree of instability in patterns of research support in that political and temporal influences could overly bias the National research agenda.

ISSUE 2: Are current emphases on basic v. applied and multidisciplinary research appropriate?

Anecdotal evidence suggests that the current system of research support in the U.S. sometimes fails to till critical gaps in basic research related to biotechnology and development. Gaps could be filled through additional financial support for applied research, technology transfer, and increased Federal support for multidisciplinary research programs.

Option 2.1: Direct Federal agencies to dedicate more of their budgets to applied and multidisciplinary research in biotechnology.

This option would not necessarily require new funds but would direct agencies to identify areas of applied research in biotechnology in which awards could be made. Applied areas deserving increased funding could be identified by committees of peers comprised of government, academic, and industrial scientists. In addition, areas of research that require multidisciplinary involvement could receive higher levels of support.

For example, at the NIH, support for individual investigator-directed, basic research projects in



disciplines underlying medical biotechnology-such as cell biology, immunology, virology, neurobiology, structural biology, and genetics-could be redistributed to multidisciplinary programs involving researchers from several of these disciplines. Possible mechanisms for implementing this approach might involve Congressional reallocation of single investigator awards to center grants (center grants are common in the categorical institutes but not in National Institute for General Medical Sciences). An alternate approach would require that NIH contribute to healthrelated multidisciplinary projects funded by other agencies, such as the NSF-administered Engineering Research Centers and Biological Centers Programs. Congress might also reallocate NIH funds to create centers and programs that have not moved as rapidly as desired with funds from individual agencies. Such a program is already in place, for example, to apply new methods in structural biology to AIDS vaccine development.

Historically, agricultural research has been applied. The applied nature of the land grant system, combined with a decentralize 1 structure that includes local agricultural experiment stations and extension services, provides a unique national capacity to identify and solve local or regional problems. Reallocating resources away from formulabased funding would diminish the role that even the smallest, poorest funded land-grant universities play. Congress could protect the applied orientation of agricultural research by maintaining strong formula-based funding at the expense of competitive research funding, which is directed towards basic research. Because the database for plant sciences is sparse, however, decreasing awards that foster excellence in basic research could hinder rapid progress in plant biotechnology.

To support more applied work applicable to hazardous waste management, Congress could direct EPA to devote more funds to applications research in demonstration and evaluation. Comparative data on the efficacy, economics, and environmental safety of biotechnical versus other methods is lacking. Additional efforts in testing and evaluation would significantly assist industry development, resolve issues relating to efficacy of specific techniques, and, along with regulatory changes, promote private sector investment.

Any effort to increase emphases on applied research carries the risk of harming the support base for basic science, the source of new ideas. Each agency needs to consider the balance of support between basic and applied work within its mission. Service-oriented agencies, such as the Agency for International Development and the Veterans Administration, report that they emphasize applied research, which best supports their mission. Recent efforts to support more applied and multidisciplinary research at the National Science Foundation indicate a shift in the historical mission of that agency. Such shifts are viewed with skepticism and encouragement, depending on the observer's outlook.

Option 2.2: Require agencies to report on the extent to which the goals of the Federal Technology Transfer Act of 1986 (Public Law 99-502) have been met.

Under The Federal Technology Transfer Act of 1986, directors of government operated Federal laboratories may enter into collaborative R&D agreements with other Federal agencies, State and local governments, industrial organizations, and nonprofit organizations. Biotechnology is an area of research currently pursued in many Federal laboratories that could be more effectively shared with industry and universities through active compliance with Public Law 99-502. As one means of encouraging compliance with the intent of the law, Congress could request that agencies document the extent to which this has occurred within their laboratories.

ISSUE 3: Should there be more interagency cooperation in funding biotechnology R&D?

Some redundancy and duplication of effort is essential to a healthy research enterprise. However, more formal cooperation between agencies in areas of shared interest could facilitate more rapid advances in some areas of biotechnology lacking sufficient or focused support.

Option 3.1: Establish an interagency coordinating body to identify areas of research that could be co-funded across agencies, address solutions to filling research needs, and develop strategies to promote technology transfer.

Congress could conclude that this option would reduce some redundancy in Federal research ef-



forts in biotechnology and promote cost savings. This type of cooperation might best be implemented through a cross agency coordinating body that meets regularly to discuss shared areas of research interest in biotechnology. At present, such coordination is rare and informal.

Applications of biotechnology to human health enjoy the highest levels of Federal funding. The overall medical biotechnology research agenda is evolving from research funded almost exclusively by the National Institutes of Health, with additional contributions from the National Science Foundation, the Department of Defense, and the Department of Energy. A coordinated effort by these agencies is essential if unnecessary duplication is to be avoided and the technological gaps impeding medical applications of biotechnology are to be removed.

A recently formed cooperative effort in plant sciences was initiated by the Office of Science and Technology Policy. The Plant Science Initiative, to be co-funded by the National Science Foundation, the Environmental Protection Agency, and the Department of Agriculture, aims to address gaps in research areas of common interest to each agency.

Advances in the use of bioengineering in waste clean-up could benefit from this type of coordinated approach. For example, EPA, NIH, NSF, the Department of the Interior, the Department of Energy, and the Department of Defense have significant programs related to bioengineered waste cleanup technologies. An interagency coordinating group could identify major gaps in the research and work to prevent unnecessary duplication of efforts by Federal agencies.

ISSUE 4: Are information requirements for informed decisionmaking about Federal support of biotechnology R&D and training being met?

Currently, information about Federal support for biotechnology research and training is scattered and inconsistent. Systematic evaluation of total Federal spending and a direct comparison of spending in specific areas across multiple agencies are complicated by the definition of biotechnology each agency employs and by the method of accounting for expenditures.

Option 4.1 Direct Secretaries and Administrators to report regularly on biotechnology activities.

The Congress could conclude that strategically important areas, such as biotechnology, are important enough to the Nation's economic growth that a more systematic accounting of Federal investment in supportive research is warranted. Authorization Committees could direct individual agencies to develop more routine systems of accounting for spending in specific areas, such as biotechnology, so that overall trends and possible necessary actions can be identified. Some agencies, such as the National Science Foundation and the National Institutes of Health have already adopted such mechanisms. Regular and institutionalized reporting on levels of funding for research and training could promote a more coordinated approach to setting strategies for biotechnology development.

Option 4.2: Direct Secretaries and Administrators to agree upon a uniform definition of biotechnology.

The adoption of a uniform definition could resolve vagueness in future policy development and would allow for more direct comparisons of research support across agencies.

However, Congress could decide that in the absence of any comprehensive mechanism for affecting total Federal spending in biotechnology, there is no sound reason to request that all agencies funding and conducting biotechnology R&D adopt a uniform definition of biotechnology. Given the various and diverse missions of the agencies, flexibility in definition may be desirable. This argument might not apply to reasons to adopt uniform terminology for the purpose of regulation. Also, given the rapid advances in research, any definition would have to be flexible enough to accommodate new technologies or would soon be obsolete.

ISSUE 5: Are Federal efforts in training and education for biotechnology sufficient?

Federal funds, directly and indirectly, support a significant amount of training and education for biotechnology. Most of these funds are directed at research rather than training, but contribute to training nonetheless.



Option 5.1: Take no action.

Training and education for biotechnology in the United States is strong, successful, and well supported. For the most part, personnel needs for the industry are being met. While shortages have been difficult to predict in advance, they have been short lasting when they have occurred. By and large, the current system is working well, though additional support in specific areas could pay off significantly. If Congress takes no action, the United States can expect to continue to enjoy high quality personnel in the biological sciences, but certain needs may not be met and the fit between personnel needs and availability may not be optimal.

Option 5.2: Require Federal agencies to direct more funds for training.

While NIH, USDA, NSF, and other Federal agencies provide substantial research funds, which contribute indirectly to training, training grants and fellowships are less well funded and have declined in recent years. In molecular biology, competitive training grants have effectively encouraged university departments to establish coherent training programs and enable money from faculty research grants to be used for research rather than salaries. Training grants in particular areas of possible need, such as bioprocess engineering, plant molecular biology, microbial ecology, and protein crystallography, could be given special consideration.

Option 5.3: Increase funds for the National Science Foundation or other Federal agencies to provide equipment for biotechnology education and training programs.

Equipment and instrumentation for biotechnology training and research is expensive. Almost every program contacted by OTA reported unmet needs for equipment and facilities. Direct Federal support for R&D equipment and physical plant has been declining, leaving many universities with outmoded equipment. Direct support for instrumentation in biotechnology could provide many programs with much needed equipment, enabling them to train students on state-of-theart equipment used by industry. Such funds may also encourage researchers from related areas, such as chemistry and engineering, to collaborate in biotechnology research.

Option 5.4: Establish programs to foster the interdisciplinary education needed for most applications of biotechnology.

Peer-reviewed, individual investigator initiated grants provide the bulk of funding for basic research but may be biased against the interdisciplinary nature of many research projects in biotechnology. Interdisciplinary programs could foster the interaction among various fields needed to improve research and training for biotechnology and promote technology transfer across fields and industrial sectors. Congress could encourage agencies to more actively support programs that foster multidisciplinary training in areas related to biotechnology.

Option 5.5: Request the National Academy of Sciences to assess comprehensively future personnel needs in biotechnology.

Given the long time needed to prepare individuals for careers in biotechnology, it is important at both the national and the individual level to be able to anticipate personnel needs several years into the future. The Committee on National Needs for Biomedical and Behavioral Research Personnel of the Institute of Medicine has twice systematically investigated personnel needs in biotechnology by surveying U.S. biotechnology companies These surveys provide important information on recruitment difficulties faced by biotechnology companies, assist policymakers in setting appropriate funding levels, and enable students to make more informed career choices. Though the Committee was able to make these studies in 1983 and 1985, funds were not available for a similar study in 1987. The National Academy of Sciences could update and expand this work by seeking additional information from the U.S. Department of Agriculture, the Environmental Protection Agency, and the National Institutes of Health on medical, agricultural, environmental, and other personnel needs in biotechnology and the role of predoctoral versus postdoctoral support as it affects the pool of available biotechnology personnel.

Such personnel forecasts, however, depend on assumptions about gross national product, demographic trends, government policy decisions, technological innovation, foreign activities in the field, and other factors that cannot be known with certainty. Given the uncertainty of many of the



assumptions that must be considered in making forecasts about labor demand, making such forecasts may be futile. OTA has concluded in previous reports that predictions of shortages should be treated with skepticism. Market forces often significantly alleviate any shortages that do develop. It may be that accurate forecasts of future needs are neither possible nor necessary.

ISSUE 6: Should Congress set guidelines for university policies on industry-sponsored research?

Industrial sponsorship of university-based biotechnology research has become a widespread and generally accepted phenomenon over the past five years. These relationships have provided additional resources for R&D and training in university laboratories, and appear to have facilitated technology transfer into industry. Some of the early fears concerning the potential for skewing the research agenda toward more applied work, increased secrecy among scientists, and negative influences on the educational process have not been realized. Yet there remains concern that if public funds for basic research decline, universities may become more reliant on private funds, possibly allowing some of these fears to be realized.

Option 6.1: Take no action.

Because there is little empirical evidence that university-industry relationships in biotechnology have had significant adverse effects, Congress may conclude that no action is necessary. Most universities whose faculty have entered into contractual agreements with industry have aiready developed institutional guidelines regulating such agreements. These agreements appear to be satisfactory to participating parties. In addition, most parties continue to be optimistic about the goals of these relationships and are more comfortable with them than they were 10 years ago. Congressional action might stifle interchange between academe and industry.

On the other hand, most Federal research dollars are spent on university campuses. Allowing individual institutions to self-police these relationships while continuing to receive Federal funds could diminish public account whity.

Option 6.2: Require Federal granting agencies to request that universities receiving Federal research money file guidelines for faculty-industry contracts as a condition of receipt of funds.

To ensure that Federal funds are not being used to support research that becomes overly secret or proprietary, Congress could direct agencies to require universities to submit guidelines regarding faculty consulting and contractual agreements. Most research universities have already developed such guidelines. Under this option, those that have not would be forced to do so. While this option would not guarantee that undue secrecy or conflict of interest would not occur, it would encourage universities to set clear policies regarding limits of acceptability for faculty-industry interactions. In addition, this option is consistent with requirements that universities file statements of assurance that other areas—such as protection of human and animal research subjects-are being monitored.

On the other hand, while this approach could raise the accountability level of universities and scientists receiving Federal funds, it could add a layer of bureaucracy to an already burdensome grants process.

Option 6.3: Ensure that a minimal level of facility and equipment needs are being met by public funds to decrease the potential for disproportionate university reliance on private funds.

Industrial sponsorship of research augments public funding, but contributes only partially to the unmet capital needs of universities. Congress could decide that in order to avoid the consequences of some universities relying disproportionately on industry for research funding, adequate levels of construction and equipment grants should be available through granting agencies. This option would not prohibit or discourage universities from seeking industrial funds but would free them from undue reliance on the private sector.

Some would argue, however, that the private sector should make a **larger** contribution to university research if it wants to reap its benefits. Increased public subsidies for university research will allow industry to make even less of a contribution than it already does.



ISSUE 7: Do State efforts in biotechnology need Federal assistance?

There are few mechanisms by which the Federal Government can properly assist State programs in biotechnology. Historically, those States receiving large percentages of Federal research dollars through their universities have held an advantage over those that have received less. In an effort to address distribution inequities, the National Science Foundation initiated the Experimental Program to Stimulate Competitive Research (EPSCoR) to assist States in the development of science and technology programs. The EPSCoR program has helped some States gain a foothold in biotechnology.

Option 7.1: Take no action.

Congress could conclude that Federal assistance for State efforts in biotechnology is unwarranted. The EPSCoR program has assisted those States with historically lower levels of Federal research support in developing new programs in biotechnology, as well as many other fields.

Option 7.2: Direct the NSF to consider an extension of the time frame for EPSCoR grants.

Under the provisions of the current EPSCoR program, qualifying States receive 5-year continuing grants for program development. At the end of the 5-year period, funding ends. Under other programs at NSF, such as the Engineering Research Centers and the Science and Technology Centers, grant recipients demonstrating outstanding achievements are eligible for a new 5-year grant at the end of the first five years. This is not the case in the EPSCoR program. Because it is likely to take longer than five years to establish a new program at the State level, EPSCoR recipients that can demonstrate progress should also be eligible for continued funding after five years. This would allow the stability necessary for States to build the support and infrastructure required for a successful program.

ISSUE 8: Should the Tax Reform Act of 1986 (Public Law 99-514) be amended to provide greater incentives and assistance for firms commercializing biotechnology?

Option 8.1: Take no action.

The tax measures of the Tax Reform Act could remain as they are. These provisions include: extension and reduction from 25 to 20 percent of the R&D tax credit; repeal of the investment tax credit for equipment investment; and abolition of the preferential treatment for capital gains. Due to current fiscal stress, Congress may determine that the provisions of the Tax Reform Act of 1986 are equitable. However, if as a result of some of these measures, the level of private investment in biotechnology is reduced, there will be a negative effect on the level of innovatior. This will manifest itself in decreased equipment and capital investment.

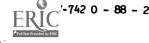
Option 8.2: Make the R&D tax credit a permanent part of the U.S. Tax Code and increase it from 20 percent to its original 25 percent incremental rate.

The purpose of the tax credit is to provide an incentive to companies to increase their commitment to industrial R&D. The R&D tax credit was renewed when it expired in 1985. The credit will again expire at the end of 1988. At this time, Congress could grant the R&D tax credit permanent status. A permanent credit would reduce the uncertainty that exists for industrial R&D planners concerning the credit's future existence. In addition to permanent status, Congress could restore the credit to its original level of 25 percent. This was the level adopted in the 1981 Economic Recovery Tax Act (Public Law 97-34).

Option 8.3: Offer the R&D credit to start-up dedicated biotechnology companies.

The structure of the R&D credit currently provides a 20 percent credit for expenditures in excess of the average amount of R&D expenditures for the previous three years. The purpose of the incremental credit is to provide incentives to companies to increase research expenditures. Companies that do not have a 3-year expenditure base are not eligible for the R&D credit as it is currently structured.

Congress could offer a refundable credit to startup companies in the year earned. A refundable tax credit would be more valuable to biotechnology start-ups in the year earned than a tax credit



carried forward to the years in which enough taxable income would be earned to take advantage of the credit

Option 8.4: Make the basic research tax credit a permanent part of the U.S. tax code.

The basic research tax credit, an incentive included in the 1986 Tax Reform Act, encourages companies to increase spending on basic research at universities and other non profit research institutions. It is seen as a mechanism to encourage cooperative relationships between industry and universities. On contractual research, the credit equals 20 percent of the company's total contract research payments over a fixed base. A permanent credit of this sort would reduce future uncertainties associated with this tax incentive.

Option 8.5: Restore the preferential treatment of capital gains incurred under Research and Development Limited Partnerships (RDLPs).

Under the new tax law, capital gains are treated as ordinary income. The former treatment of capital gains attracted investors to RDLPs because the gains from the sale of a limited partnership were treated better than the dividends themselves. Because RDLPs represent a large portion of the investment in biotechnology, Congress could reinstate the preferential treatment of capital gains for investors in RDLPs. This would restore incentive for investors to pursue this investment option, thereby increasing private investment in the biotechnology industries.

ISSUE 9: Are Federal mechanisms for assisting biotechnology firms in obtaining the financing necessary for start-up and scale-up adequate?

To date, venture capital and private equity placement have been the mainstay of biotechnology start-ups. Nearly all dedicated biotechnology companies in existence have received venture capital. As firms mature, they turn to public offerings and corporate equity investment as sources of funding. There are inherent risks to overdependence on any of these sources. Venture capital sources may become restricted because of fluctuations in the economy. The risks of reliance on the public markets to finance scale-up and production may be too great for firms caught in a

downturn in the market. To ensure the continued growth and maturation of biotechnology companies, Congress could decide that more aggressive action is needed to assist biotechnology companies in two critical stages—start-up and scale-up. Support of industrial innovation could, in part, finance areas of applied research and development not already supported through the Federal research agencies.

Option 9.1: Take no action.

Congress could decide that the growth of biotechnology companies has been a result of creative financing through available sources of capital. Congress could conclude that sufficient investment capital is available to commercialize biotechnology and the Federal Government need not intervene at this time.

Some have argued that traditional policy discouraging government subsidies for industrial innovation places the United States at a disadvantage compared to other industrial nations, which have targeted funds to support industrial biotechnology. Allowing the marketplace to remain the sole influence over the health of these industries may be detrimental in the long run.

Option 9.2: Direct the Small Business Administration to evaluate programs under existing authority that could provide a source of venture capital funding for small businesses, biotechnology included.

The Small Business Investment Act of 1958 authorized the Small Business Investment Company, or SBIC Program. SBICs are privately capitalized, owned, and managed investment firms that provide equity capital, long-term financing, and management counsel to new and expanding small business concerns. They are licensed and regulated by the Small Business Administration and can borrow funds from the Government on a long-term basis for reinvestment in small business. SBICs, however, have faced uncertain congressional funding and restricted access to capital markets. To insure continued availability of venture capital for biotechnology, the Small Business Administration, with proper authority, could form a quasi-governmental corporation that would raise money in the private sector to be used as a venture capital fund for start-ups. The SBA could



evaluate the success of the SBIC program and make recommendations for its improvement.

ISSUE 10: Is the current export control system as dictated by the Export Arministration Regulations working efficiently in the approval of biotechnology products for export?

The Departments of Commerce and Defense each play important roles in the export control process. The DOC monitors the Commodities Control List (CCL) and the DoD monitors the Militarily Critical Technologies List. Each agency brings to the process a different philosophy on what export controls should accomplish. As more and more biotechnology products become available for export, there is some concern on the part of industry that these products will become caught between the interests of Commerce and Defense, or will become delayed due to administrative confusion about the required approval process for biotechnology products.

Option 10.1: Take no action.

Congress could determine that the current export control system as dictated by the Export Administration Regulations is working efficiently, and has achieved a sufficient balance between economic and national security interests. The 1985 amendments to the Export Administration Act (EAA) addressed several issues that were not covered in the original EAA. For example, foreign availability and decontrol were two items that were to be emphasized by the agencies. However, little progress in the reduction of the CCL has been made.

Maintaining the current CCL could adversely affect the U.S. position overseas because it is often viewed by U.S. and foreign industry as encompassing too many products and technologies, making it difficult to manage. Continued operations under the present system could hamper efforts to promote U.S. products abroad and penetrate valuable foreign markets. The final outcome could be migration of U.S. industries abroad to avoid U.S. export regulations.

Option 10.2: Congress could decide that the present export control system is adequate and could request that even greater controls be enacted.

Those in favor of greater controls are concerned that our national security would be compromised by reduction of the CCL and decontrol of goods even when foreign availability is documented. Once foreign availability is documented, decontrol can be withheld while negotiations are pursued with supplier countries. The result has been that few items have completed the procedures necessary for decontrol and removal from the CCL.

Congress could request that the agencies involved in the export control process maintain stricter control over exports. For the biotechnology and other high-technology industries, this could result in the loss of valuable overseas markets to foreign competitors in Western Europe and Japan. This may also provoke overseas migration of companies who do not want to be burdened with U.S. unilateral export controls.

Option 10.3: Direct the Secretary of Commerce to evaluate the efforts of the Biotechnology Technical Advisory Committee (TAC).

The Biotechnology TAC began in early 1985 to advise agencies involved in export control on technical matters and new developments in the biotechnology industries. The TAC can make recommendations to the Department of Commerce on items to be removed from the CCL. This mechanism of communication between the biotechnology industries and those in charge of export control policies is valuable to both parties. The TAC can give important technical information to the actors involved in controlling biotechnology exports. Thus far, however, the TAC has submitted recommendations of items to be decontrolled and has seen no results. Because the decontrol process is often held up for national security reasons, few items have been removed because of foreign availability. Congress could request the Department of Commerce to review the TAC, with the intent to develop recommendations for improved use of the TAC mechanism.



Appendixes



Dedicated Biotechnology Companies (DBCs) by State

Alabama

Southern Biotech Associates P.O. Box 26221 Birmingham, AL 35226

Arizona

Bio Huma Netics 201 Roosevelt Ave. Chandler, AZ 85226

Vega Biotechnologies, Inc. P.O. Box 11648 Tucson, AZ 85734

Arkansas

Pel-Freeze Biologicals, Inc. P.O. Box 68 Rogers, AR 72757

California

Advanced Genetic Sciences 6701 San Pablo Ave. Oakland, CA 94608

Advanced Genetics Research Institute 2220 Livingston St. Oakland, CA 94606

Agouron Institute 505 Coast Blvd., South La Jolla, CA 92037

American Biogenetics Corp. 19732 Macarthur Blvd. Irvine, CA 92715

American Bionetics, Inc. 4560 Horton St. Emeryville, CA 94608

American Qualex Int'l., Inc. 14620 E. Firestone Blvd. La Mirada, CA 90638

Amgen 1900 Oak Terrace Lane Thousand Oaks, CA 91320 Antibodies, Inc. P.O. Box 1560 Davis, CA 95617

Applied Biosystems 850 Lincoln Center Dr. Foster City, CA 94404

Automedix Sciences, Inc. 9401 S. Vermont Ave., Suite B100 Torrance, CA 90502

Behring Diagnostics 10933 N. Torrey Pines Rd. La Jolla, CA 92037

Berkeley Antibody 4131 Lakeside Dr., Suite B Richmond, CA 94806

Biogenex Laboratories 6549 Sierra Lane Dublin, CA 94568

Bio-Rad Laboratories, Inc. 1414 Harbour Way South Richmond, CA 94804

Bio Research, Inc. 11189 Sorrento Valley Rd. San Diego, CA 92121

Bio-Response, Inc. 1978 W. Winton Ave. Hayward, CA 94545

Biogrowth 3065 Atlas Rd., Suite 117 Richmond, CA 94806

Bioprobe International, Inc. 2842 Walnut Ave., Suite C Tustin, CA 92680

Biosearch, Inc. 2980 Kerner Blvd. San Rafael, CA 94901

BioSym Technologies 10065 Barnes Canyon Rd., Suite A San Diego, CA 92121 Biotherapy Systems, Inc. 291 N. Bernardo Ave. Mountain View, CA 94043

Biotrack 430 Oakmead Parkway Sunnyvale, CA 94806

Breit Laboratories 2510 Boatman Ave. W. Sacramento, CA 95691

Brunswick/Technetics 4116 Sorrento Valley Rd. San Diego, CA 92121

BTX 3742 Jewell St. San Diego, CA 92109

Calgene, Inc. 1920 5th St. Davis, CA 95616

California Biotechnology, Inc. 2450 Bayshore Frontage Rd. Mountain View, CA 94043

California Integrated Diagnostics 1440 Fourth St. Berkeley, CA 94710

California Biotherapeutics 10901 N. Torrey Pines Rd. La Jolla, CA 92037

Calzyme Laboratories, Inc. 3443 Miguelito Ct. San Luis, CA 93401

Cetus Corp. 1400 Fifty Third St. Emeryville, CA 94608

Chemicon International, Inc. 100 Lomita St. El Segundo, CA 90245

Chiron Corp. 4560 Horton St. Emeryville, CA 94608



Clontech Laboratories, Inc. 4055 Fabian Way Palo Alto, CA 94303

Codon 430 Valley Dr. Brisbane, CA 94005

Collagen Corp. 2500 Faber Pl. Palo Alto, CA 94303

Cooper Development Co. 3145 Porter Dr. Palo Alto, CA 94304

Cryschem, Inc. 5005 LaMart Dr., Suite 204 Riverside, CA 92507

Cygnus Research Corp. 701 Galveston Dr. Redwood, CA 94063

Cytotech, Inc. 11045 Roselle St. San Diego, CA 92121

Dako Corp. 22 North Milpas St. Santa Barbara, CA 93103

Diagnostic Products Corp 5700 W. 96 St. Los Angeles, CA 90045

Dnax 901 California Ave. Palo Alto, CA 94304

E-Y Laboratories, Inc. 107 N. Amphlett Blvd. San Mateo, CA 94401

Engenics, Inc. 3760 Haven Ave. Menlo Park, CA 94025

Enzon 518 Logue Ave. Mountain View, CA 94043

Fermentec Corp. 101 First St., Suite 490 Los Altos, CA 94022

Gen-Probe, Inc. 9880 Campus Point Dr. San Diego, CA 92121 Genenchem 460 Point San Bruno Blvd. S. San Francisco, CA 94080

Genencor, Inc 180 Kimball Way S. San Francisco, CA 94080

Genentech 460 Point San Bruno Blvd. S. San Francisco, CA 94080

Gensia Pharmaceuticals, Inc. 11180 Roselle St., Suite A San Diego, CA 92121-1207

Hana Biologics, Inc. 805° Marina Village Parkway Alameda, CA 94501-1034

Hybritech, Inc. 11095 Torreyana Rd San Diego, CA 92121

Idec, Inc. 11211 Sorrento Valley Rd., Suite H San Diego, CA 92121

Idetek, Inc. 1057 Sneath Lane San Bruno, CA 94066

The Immune Response Corp. 8950 Villa La Jolla Dr., Suite 1200 La Jolla, CA 92037

Immunetech Pharmaceuticals 11045 Roselle St. San Diego, CA 92121

Infergene Co. 433 Industrial Way Benicia, CA 94510

Ingene, Inc. 1545 17th St. Santa Monica, CA 90404

Intek Diagnostics, Inc. 1450 Rollins Rd. Burlingame, CA 94010

Intelli-Genetics 700 East El Camino Mountain View, CA 94040

International Enzymes, Inc. 1667 S. Mission Rd. Fallbrook, CA 92028 International Plant Research Institute 830 Bransten Rd San Carlos, CA 94070

Kirin-Amgen Amgen, 1900 Oak Terrace Lane Thousand Oaks, CA 91320

Lee Biomolecular Research Labs 11211 Sorrento Valley Rd. San Diego, CA 92121

Liposome Technology 1050 Hamilton Ct. Menlo Park, CA 94025

Lucky Biotech Corp. 4560 Horton St Emeryville, CA 94608

Microbio Resources 6150 Lusk Blvd., Suite B105 San Diego, CA 92121

Microgenics 2341 Stanwell Dr Concord, CA 94520

Molecular Biosystems, Inc. 11180 Roselle St., Suite A San Diego, CA 92121

Molecular Devices 3180 Porter Dr. Palo Alto, CA 94034

Monoclonal Antibodies, Inc. 2319 Charleston Rd. Mountain View, CA 94043

Moor Associates 2190 Crestmoor Dr. San Bruno, CA 94066

Multiple Peptide Systems, Inc. 558 Ford Ave., P.O. Box 5000 Solana Beach, CA 92705

Mycogen 5451 Oberlin Dr San Diego, CA 92121

NeuroScience Inc. 1520 McCandless Dr. Milpitas, CA 95035

Neushul Mariculture 475 Kellogg Way Goleta, CA 93117



NMS Pharmaceuticals 1533 Monrovia Ave. Newport Beach, CA 92663

Ocean Genetics 140 Dubois St. Santa Cruz. CA 95060

Omni Biochem, Inc. 2215 Cleveland Ave. National City, CA 92050

Organon Diagnostics 316 Prospect St. La Jolla, CA 92037

Pacific Biotech Inc. 8535 Commerce Ave. San Diego, CA 92121

Penninsula Laboratories, Inc. 611 Taylor Way Belmont, CA 94002

Pharmatec, Inc. 9401 S. Vermont Ave , Suite B100 Torrance, CA 90502

Phytogen 101 Waverly Ave. Pasadena, CA 91105

Plant Genetics, Inc. 1930 Fifth St. Davis, CA 95616

Protein Design Labs 3181 Porter Dr. Palo Alto, CA 94304

Quidel 11077 N. Torrey Pines Rd. La Jolla, CA 92037

Research and Diagnostic Antibodies P.O. Box 7653 Berkeley, CA 94707

Salutar, Inc. 428 Oakmead Parkway Sunnyvale, CA 94806

Scripps Laboratories 9950 Scripps Lake Dr. San Diego, CA 92131

Sepragen 2126 Edison Ave. San Leandro, CA 94577 Sibia P.O. Box 85200 San Diego, CA 92138

Stratagene Cloning Systems 3770 Tansy St San Diego, CA 92121

Sungene Technologies Corp. 3330 Hillview Ave. Palo Alto, CA 94304

Synbiotics Corp 11011 Via Frontera San Diego, CA 92129

Synthetic Genetics 10457 Roselle St., Suite E San Diego, CA 92121

Syntro Corp. 10655 Sorrento Valley Rd. San Diego, CA 92121

Syva Co. 900 Arastradero Rd. Palo Alto, CA 94304

Techniclone International, Inc. 3301 South Harbor Blvd. Suite 101 Santa Ana, CA 92704

Telios Pharmaceuticals 2909 Science Park Rd. San Diego, CA 92121

Three-M (3M) Diagnostic Systems 1500 Salado Dr. Mountain View, CA 94043

Triton Biosciences, Inc. 1501 Harbor Bay Parkway Alameda, CA 94501

Vector Laboratories, Inc 30 Ingold Rd. Burlingame, CA 94010

Viagene, Inc. 11180 Roselle St., Suite A San Diego, CA 92121

Westbridge Research Group 9920 Scripps Lake Dr. San Diego, CA 92131

Xoma Corp. 2910 Seventh St. Berkeley, CA 94710 Xytronyx, Inc. 6555 Nancy Ridge Dr. San Diego, CA 92121

Zoecon Corp. 975 California Ave. Palo Alto, CA 94304

Zymed Laboratories, Inc. 52 S. Linden Ave., Suite 4 S. San Francisco, CA 94080

Colorado

Advanced Mineral Technologies 5920 McIntyre Golden, CO 80403

Agrigenetics 3375 Mitchell Lane Boulder, CO 80301

Amgen Development Corp. 2045 32nd St. Boulder, CO 80301

Biostar Medical Products, Inc. 5766 Central Ave. Boulder, CO 80301

Coors Biotech Products Co. (subsidiary of Coors Brewing Co.) Mail #CC150 Golden, CO 80401

Genetic Engineering, Inc. 136 Avenue and North Washington St. PO-33554 Denver, CO 80233

Synergen, Inc. 1885 33rd St. Boulder, CO 80301

Synthetech 5547 Central Ave. Boulder, CO 80301

Techometrics, Inc. 1960 Sherrelwood Circle Denver, CO 80221

Connecticut

Agotek 1465 Post Rd. East, PO-5117 Westport, CT 06881

American Diagnostica, Inc. 111 North St. Greenwich, CT 06830



Biopolymers, Inc. 309 Farmington Ave. Farmington, CT 06032

John Brown E&C Inc. P.O. Box 1432, 17 Amelia Pl. Stamford, CT 06904

Chimerix P.O. Box 976, 55 Nye Rd. Glastonbury, CT 06033

Deltown Chemurgic Corp. 191 Mason St. Greenwich, CT 06830

Intl. Biotechnologies, Inc.275 Winchester Ave.P.O. Box 9598New Haven, CT 06511

Microgene Systems 400 Frontage Rd. West Haven, CT 06516

Molecular Diagnostics, Inc. 400 Morgan Lane West Haven, CT 06516

Novo Labs, Inc. 59 Danbury Rd. Wilton, CT 06897

Technology Management Group 25 Science Park New Haven, CT 06511

University Genetics Co. 1465 Post Road East Westport, CT 06881

Xenogen 1734 Storrs Rd. Mansfield, CT 06268

Delaware

Triad Technologies, Inc. 308 W. Basin Rd. New Castle, DE 19720

District of Columbia

Alpha I Biomedicals 777 14th St., N.W., Suite 747 Washington, DC 20005

Florida

Applied Genetics Labs., Inc. 3150 S. Babcock St. Melbourne, FL 32901 Diamedix, Inc. 2140 N. Miami Ave. Miami, FL 33127

Immunomed 5910-G Breckenridge Parkway Tampa, FL 33610

Innovet 3401 N. Federal Highway Boca Raton, FL 33431

Life Sciences 2900 72nd St., North St. Petersburg, FL 33710

Molecular Genetic Resources 6201 Johns Rd., Suite 8 Tampa, FL 33634

Petroferm USA 5400 First Coast Highway, Suite 200 Ferandina Beach, FL 32034

Viragen 2201 W. 36th St. Hialeah, FL 33016

Georgia

Biosystems, Inc. 762 U.S. Highway 78 Loganville, GA 30249

Murex Corp. P.O. Box 2003 Norcross, GA 30071

Hawaii

Hawaii Biotechnology Group, Inc. 99-193 Aiea Heights Dr. Aiea, HI 96701

Illinois

Ball Biotech Co. 250 Town Rd. W. Chicago, IL 60185

Dekalb-Pfizer Genetics 3100 Sycamore Rd De Kalb, IL 60115

Petrogen, Inc. 2452 East Oakton Arlington Heights, IL 60005

United Agriseeds, Inc. P.O. Box 4011 Champaign, IL 61820

Indiana

Agdia, Inc. 1901 N. Cedar St Mishawaka, IN 46545

BioProducts for Science, Inc. P.O. Box 29176 Indianapolis, IN 46229

Consolidated Biotechnology, Inc. 1413 W. Indiana Ave. Elkhart, IN 46515

Iowa

Ambico, Inc. P.O. Box 522, Route 2 Dallas Center, IA 50063

Kansas

Clinical Biotechnologies, Inc. 11844 W. 85th St. Lenexa, KS 66214

Hazelton Research Products P.O. Box 14848 Lenexa, KS 66215

Monoclonal Production Int'l. Twentieth and Sydney Sts. Fort Scott, KS 66701

Syngene Products 15 and Oak, P.O. Box 338 Elwood, KS 66024

Louisiana

Helix Corp. 635 Louisiana Ave. Baton Rouge, LA 70802

Imreg, Inc. 144 Elk Pl., Suite 1400 New Orleans, I.A 70112

Microbe Masters 11814 Corsey Blvd., Suite 285 Baton Rouge, LA 70802

Maine

Agritech Systems, Inc. 104 Fore St. Portland, ME 04101

Atlantic Antibodies 10 Nonesuch Rd. Scarborough, ME 04704



Binax, Inc. 95 Darling Ave. S. Portland, ME 04106

Immucell Corp. 966 Riverside St. Portland, ME 04103

Ventrex Laboratories 217 Read St. Portland, ME 01403

Maryland

Advanced Biotechnology, Inc. 12150 Tech Rd. Silver Spring, MD 20904

American Biotechnology Co. 7658 Standish Pl., Suite 107 Rockville, MD 20855

Andrulis Research Corp. 7315 Wisconsin Ave., Suite 650N Bethesda, MD 20814

BBL Microbiology Systems
(Division of Becton-Dickinson & Co.)
Box 243, 250 Schilling Circle
Cockeysville, MD 21030

Bionetics Research, Inc. 1330 Piccard Dr. Rockville, MD 20850

Biospherics 4928 Wyaconda Rd. Rockville, MD 20852

Biotech Research Labs, Inc. 1600 E. Gude Dr. Rockville, MD 20850

Biotronic Systems Corp. 1522. Shady Grove Rd., Suite 306 Rockville, MD 20850

Braton Biotech, Inc. 1 Taft Ct. Rockville, MD 20850

Cellmark Diagnostics 20271 Goldenrod Lane Germantown, MD 20874

ChemGen Corp. 2501 Research Blvd. Rockville, MD 20850 Crop Genetics International . 170 Standard Dr. Hanover, MD 21706

Design Engineering and Manufacturing Co., Inc. 4906 46th Ave. Hyattsville, MD 20781

Diagnon Corp. 11 Taft Ct. Rockville, MD 20850

Digene Bldg. 334 University of Maryland College Park, MD 20742

Electro-Nucleonics, Inc. Cell Science Institute 12050 Tech Rd. Silver Spring, MD 20904

Genex, Inc. 16020 Industrial Dr. Gaithersburg, MD 20877

Gentronix, Inc. 12150 Tech Rd. Silver Spring, MD 20904

Igen 1530 E. Jefferson St. Rockville, MD 20852

Igene Biotechnology, Inc. 9110 Red Branch Rd. Columbia, MD 21405

ImmuQuest Laboratories, Inc. 2 Taft Ct., Suite 101
Rockville, MD 20850

In Vitro International, Inc 611P Hammonds Ferry Rd. Linthicum, MD 21090

Inter-American Research Association 1160 Taft St. Rockville, MD 20850

Keystone Diagnostics, Inc 9062 Route 108 Columbia, MD 21405

Life Technologies, Inc. 8717 Grovemont Circle Gaithersburg, MD 20877 Loftstrand Laboratories 8042 Cessna Ave. Gaithersburg, MD 20879

Microbiological Associates 5221 River Rd. Bethesda, MD 20816

Molecular Diagnostic Systems, Inc. 3100 Wyman Park Dr. Baltimore, MD 21211

Molecular Toxicology 335 Paint Branch Rd. College Park, MD 20742

Nordisk-U.S.A. 3202 Monroe St., Suite 100 Rockville, MD 20852

Oncor, Inc. 209 Perry Parkway, Suite 7 Gaithersburg, MD 20877

Pharma-Tech Research Corp. 6807 York Rd. Baltimore, MD 21212

P & S Biochemicals, Inc. 7879 Cessna Ave. Gaithersburg, MD 20879

Survival Technology, Inc. 8101 Glenbrook Rd. Bethesda, MD 20814

Synax, Inc. One Kendall Sq., Bldg. 700 Cambridge, MA 02139

University Micro Reference Lab 611P Hammonds Ferry Rd. Linthicum, MD 21090

Westinghouse Bioanalytic Systems 2096 Gaither Rd. Rockville, MD 20850

Whittaker M.A. Bioproducts, Inc. Biggs Ford Rd. Walkersville, MD 21793

Massachusetts

A/G Technology Corp. 34 Wexford St. Needham, MA 02194

Advanced Magnetics, Inc. 45 Spenelli Pl. Cambridge, MA 02138



Amicon Corp. 24 Terry Hill Dr. Danvers, MA 01923

Angenics 100 Inman St. Cambridge, MA 02139

Applied Biotechnology 80 Rogers St. Cambridge, MA 02142

Applied Protein Technologies, Inc 103 Brookline St. Cambridge, MA 02139

Bioassay Systems Corp 225 Wildwood Ave. Woburn, MA 01801

Biogen 14 Cambridge Center Cambridge, MA 12142

Biomedical Technologies 378 Page St. Stoughton, MA 02072

BioPURE 136 Harrison Ave. Boston, MA 02111

Biotechnica International 85 Bolton St. Cambridge, MA 02140

Biotechnology Development Corp. 44 Mechanic St. Newton, MA 02164

Cambridge Bioscience Corp. 35 South St. Hopkinton, MA 01748

Cambridge Medical Diagnostics 575 Middlesex Turnpike Billerica, MA 01865

Cambridge Neuroscience Research 1 Kendall Square, Bldg. 700 Cambridge, MA 01730

Cambridge Research Laboratory 195 Albany St. Cambridge, MA 02139

Charles River Biotechnology Services 251 Ballardvale St. Wilmington, MA 01887 Chemgenes 925 Webster St. Needham, MA 02192

Ciba Corning Diagnostics Corp. One Kendall Square Bldg., Rm. 200 Cambridge, MA 02139

Collaborative Research, Inc. 2 Oak Park Bedford, MA 01730

Corning Biomedical Research 1 Kendall Square, Bldg. 200 Cambridge, MA 02139

Creative Biomolecules 35 South St. Hopkinton, MA 01748

Damon Biotech, Inc. 119 Fourth Ave. Needham Heights, MA 02194

E. I. du Pont Products 331 Treble Cove Rd. N. Billerica, MA 01862

Endogen 451 D St., 8th Floor Boston, MA 02210

The Enzyme Certer, Inc. 36 Franklin St. Malden, MA 02148

Genetics Institute, Inc. 87 Cambridge Park Dr. Cambridge, MA 02140

Genetics International, Inc. 50 Milk St. Boston, MA 02109

Genzyme Corp. 75 Kneeland St. Boston, MA 02111

Hygeia Sciences 330 Nevada St. Newton, MA 02160

Immunogene, Inc. 124 Mount Auburn St., Suite 200 Cambridge, MA 02138

Immunotech Corp. P.O. Box 860 Boston, MA 02134 Instrumentation Laboratories 113 Hartwell Ave. Lexington, MA 02164

Integrated Chemical Sensors 44 Mechanic St Newton, MA 02164

Integrated Genetics, Inc. 31 New York Ave. Framingham, MA 01701

Karyon Technology, Ltd. 333 Providence Highway Norwood, MA 52062

Milligen 75 Wiggins Ave. Bedford, MA 01370

Millipore Corp. 80 Ashby Rd. Bedford, MA 01730

Moleculon Biotech 230 Albany St. Cambridge, MA 02139

New England Biolabs, Inc. 32 Tozer Rd. Beverly, MA 0915

Nova Biomedical Corp. 200 Prospect St. Waltham, MA 02254

Parexel International Corp. 55 Wheeler St. Cambridge, MA 02138

Penicillin Assays, Inc. 36 Franklin St. Malden, MA 02148

Repligen Corp.
One Kendall Square, Bldg 700
Cambridge, MA 02139

Schering Corp 333 Providence Highway Norwood, MA 02602

Sepracor, Inc 33 Locke Dr Marlborough, MA 01752

Seragen, Inc 54 Clayton St. Boston, MA 02122



Serono Diagnostics, Inc. 100 Longwater Circle Norwell, MA 02601

Serono Labs 280 Pond St. Randolph, MA 02368

Swartz Associates 15 Manchester Rd. Winchester, MA 01890

T-Cell Sciences 840 Memorial Dr. Cambridge, MA 02139

Toxicon 125 Lenox St. Norwood, MA 02062

Transformation Research, Inc. P.O. Box 2411 Framington, MA 01791

Travenol-Genetech Diagnostics 600 Memorial Dr. Cambridge, MA 02139

Michigan

Covalent Technology Corp. P.O. Box 1868 Ann Arbor, MI 48106

National Geno Sciences 22150 W. Nine Mile Rd Southfield, MI 48034

Neogen Corp. 620 Lesher Pl. Lansing, MI 48912

Recomtex Corp. 4700 S. Hagadorn, Suite 290 East Lansing, MI 48823

Minnesota

Biotrol, Inc. 11 Peavy Rd. Chaska, MN 55318

Endotronics, Inc. 8500 Evergreen Blvd. Coon Rapids, MN 55433

Genesis Labs, Inc. 5182 West 76th St. Minneapolis, MN 55435 Lifecore, Inc. 315 27th St., S.E Minneapolis, MN 55414

Molecular Genetics, Inc. 10320 Bren Road East Minnetonka, MN 55343

Protatek International, Inc 1491 Energy Park Dr. St. Paul, MN 55108

Missouri

Bioclinical Systems, Inc. 5977 S.W. Ave St. Louis, MO 63139

Invitron Corp. 4349 Le Bourquet Dr St. Louis, MO 63134

Montana

Gametrics, Ltd.
Colony (Wyoming) Route
Alz la. MT 59311

RIBI Immunochem Research, Inc. P.O. Box 1409 Hamilton, MT 59840

Nebraska

American Laboratories, Inc. 4410 S. 102 St. Omaha, NE 63127

Biologics Corp. 2720 N. 84th St. Omaha, NE 68134

New Hampshire

Verax Corp. HC61 Box 6, Etna Rd Lebanon, NH 03766

New Jersey

Agri-Diagnostics Associates 2611 Branch Pike Cinnaminson, NJ 08077

Alfacell Corp. 225 Belleville Ave. Bloomfield, NJ 07003

Bio-Recovery, Inc. P.O. Box 38, 193 Paris Ave. Northyale, NJ 07647 Bioconsep, Inc. RD 3, Homestead Rd Bldg 5, Unit 9 Belle Mead, NJ 08502

Biomatrix, Inc. 488 Hobart Rd. North Brunswick, NJ 08902

Biotest Diagnostics Corp. 6 Daniel Rd., East Fairfield, NJ 07006

Chemical Dynamics Corp P.O Box 395 South Plainfield, NJ 07080

Cistron Biotechnology, Inc. 10 Bloomfield Ave., Box 2004 Pine Brook, NJ 07058

Clinical Sciences, Inc. 30 Troy Rd. Whippany, NJ 07981

Cytogen Corp. 201 College Rd., East Princeton, NJ 08540

DNA Plant Technology Corp. 2611 Branch Pike Cinnaminson, NJ 98077

Electro-Nucleonics, Inc. 350 Passaic Ave. Fairfield, NJ 07006

Emtech Research 15 W. Park Dr. Mount Laurel, NJ 08054

Enzon, Inc. 300-C Corporate Ct. S. Plainfield, NJ 07080

Glen Mills, Inc. 203 Brookdale St. Maywood, NJ 07607

Immunomedics, Inc. 5 Bruce St. Newark, NJ 07103

Inter-Cell Technologies, Inc. 422 Route 206, Suite 143 Somerville, NJ 08876



Interferon Sciences, Inc. 783 Jersey Ave. New Brunswick, NJ 08901

Liposome Company, Inc. One Research Way Princeton, NJ 08540

Marcor Development Corp. 206 Park St. Hackensack, NJ 07601

Pharmacia Biotechnology Group 800 Centennial Ave. Piscataway, NJ 08854

Queue Systems, Inc. P.O. Box 5366 North Branch, NJ 08876

Seapharm, Inc. 791 Alexander Rd. Princeton, NJ 08540

Unigene Laboratories, Inc. 110 Little Falls Rd. Fairfield, NJ 07006

New Mexico

Summa Medical Corp. 4272 Balloon Park Rd., NE. Albuquerque, NM 87109

New York

An-Con Genetics 1 Huntington Quadrangle Melville, NY 11747

Applied Microbiology Brooklyn Navy Yards Bldg. 5 Brooklyn, NY 11205

Bionique Labs, Inc.
Bloomingdale Rd., Route 3
Saranac Lake, NY 12983

Biotechnology General Corp. 375 Park Ave. New York, NY 10152

Brain Research, Inc. 46 E. 91 St. New York, NY 10028

Cellular Products 688 Main St. Buffalo, NY 14202 Charles 688 Main St. Buffalo, NY 14202

Diagnostic Technology, Inc 240 Vanderbilt Motor Parkway Hauppauge, NY 11788

Enzo Biochem, Inc. 325 Hudson St. New York, NY 10013

Exovir, Inc. 111 Great Neck Rd., Suite 607 Great Neck, NY 11021

Genetic Diagnostics Corp. 160 Community Dr. Great Neck, NY 11021

Imclone Systems, Inc. 180 Varick St. New York, NY 10014

Intra Gene International, Inc. 987 Elliott Dr. Lewiston, NY 14092

Lifecodes Corp. 4 Westchester Plaza Elmsford, NY 10523

Nuclear and Genetic Technology 172 Brook Ave. Deer Park, NY 11729

Nygene Corp. One Odell Plaza Yonkers, NY 10701

Oncogene Science, Inc. 222 Station Place N , Room 301 Mineola, NY 11501

Praxis Biologics 30 Corporate Woods, Suite 300 Rochester, NY 14623

Sulzer Biotech Systems 230 Crossways Park Dr. Woodbury, NY 11797

United Biomedical, Inc 2 Nevada Dr. Lake Success, NY 11042

North Carolina

Biotherm P. O. Box 1409 Research Triangle Park, NC 27709 Embrex, Inc. 401 Oberlin Rd. Raleigh, NC 27605

Environmental Diagnostics, Inc. P. O. Box 908, 2990 Anthony Rd. Burlington, NC 27215

Maricultura, Inc P.O. Drawer 565 Wrightsville, NC 28480

Mycosearch, Inc P.O. Box 941 Chapel Hill, NC 27514

Organon Teknika 800 Capitol Dr. Durham, NC 27713

Ohio

Agrigenetics Corp. 29400 Lakeland Blvd. Wickliffe, OH 44092

Enzyme Technology Corp. 783 U.S. 250 E., Route 2 Ashland, OH 44805

North Coast Biotechnology, Inc. 19701 S. Miles Rd. Warrensville Heights, OH 44128

Ricerca, Inc. 7528 Auburn Rd., Box 100 Painesville, OH 44077

United States Biochemical Corp. 26111 Miles Rd. Cleveland, OH 44128

Oregon

American Bioclinical 4432 S.E. 16th Ave. Portland, OR 97202

Antivirals, Inc. 249 S.W. Avery Corvallis, OR 97333

Bend Research, Incorp. t 4550 Research Rd. Bend, OR 97701

Bentech Laboratories 635 Water Ave. East Albany, OR 97321



Epitope, Inc. 15425-E Southwest Koll Parkway Beaverton, OR 97006

Pennsylvania

Biochem Technology, Inc. 66 Great Valley Parkway Malvern, PA 19355

Biological Energy Corp. P.O. Box 766, 2650 Eisenhower Ave. Valley Forge, PA 19482

Bioscience Management, Inc. BFTC-South Mountain Dr. Bethlehem, PA 18015

Centocor 244 Great Valley Parkway Malvern, PA 19355

Cytox Corp. 954 Marcon Blvd. Allentown, PA 18103

Du Pont Biosystems 368 Turner Way Aston, PA 19014

Ecogen Inc. 2005 Cabot Blvd. West Langhorne, PA 19047-1810

Jackson Immunoresearch Lab 872 Baltimore Pike West Grove, PA 19390

Polybac Corp. 954 Marcon Blvd. Allentown, PA 18103

Rhode Island

Scott Laboratories 771 Main St. Fiskville, RI 40182

South Carolina

Fluor Daniel Daniel Bldg. Greenville, SC 29602-2170

Tennessee

Biotherapeutics, Inc. 357 Riverside Dr. Franklin, TN 37064

Texas

Bethyl Labs, Inc. P.O. Box 850 Montgomery, TX 77356

Biotics Research Corp. 4850 Wright Rd., Suite 150 Stafford, TX 77047

Brown and Root, Inc P.O. Box 3 Houston, TX 77001

Detox Industries 12919 Dairy Ashford Sugar Land, TX 77478

Gamma Biologicals, Inc. 3700 Mangum Rd. Houston, TX 77092

Granada Genetics Corp. 10900 Richmond Ave. Houston, TX 77242

Houston Biotech 3606 Research Forest Dr. The Woodlands, TX 77380

Hyclone, Inc. P.O. Box 3190 Conroe, TX 77305

Immuno Modulators Labs, Inc 10521 Corporate Dr. Stafford, TX 77477

Inland Laboratories P.O. Box 180456 Austin, TX 78716

Kallestad Laboratories 1120 Capital of Texas Highway, So. Austin, TX 78746

Monoclonetics International, Inc. 18333 Egret Ray Blvd , Suite 270 Houston, TX 77058

O C.S. Labs Box 2868 Denton, TX 76202

Utah

Biomaterials International, Inc P.O. Box 8852, 420 Chipeta Way Suite 160 Salt Lake City, UT 84108 Hyclone Laboratories 1725 S. State Highway 8991 Logan, UT 84321

NPI 417 Wakara Way Salt Lake City, UT 84108

Virginia

Flow Laboratories, Inc. 7655 Old Spring House Rd. McLean, VA 22102

Glen Resarch Corp. P.O. Box 1047 487 Carlisle Dr., Suite A Herndon, VA 22070

Hazelton Biotechnologies 9200 Leesburg Turnpike Vienna, VA 22180

Interleukin-2 413 N. Washington St. Alexandria, VA 22313

Meloy Laboratories, Inc. 6715 Electronic Dr. Springfield, VA 22151

Washington

Bio Techniques Labs, Inc. 15555 NE. 33rd St., Biotech Rd. Redmond, WA 98052

Biocontrol Systems 21414 68th Ave., South Kent, WA 98032

Biomed Research Labs, Inc. 1115 E. Pike St. Seattle, WA 98122

Cyanotech Corp. 18748 142nd Ave., NE. Woodinville, WA 98072

Ecova Corp. 3820 159th Ave., N.E. Redmond, WA 98052

Genetic Systems Corp. 3005 First Ave. Seattle, WA 98121

Immunex Corp. 51 University St. Seattle, WA 98101



IMRE Corp. 130 5th Ave., North Seattle, WA 98109

NEORX Corp. 410 W. Harrison St. Seattle, WA 98119

Oncogen 3005 First Ave. Seattle, WA 98121

R & A Plant/Soil, Inc. 24 Pasco Kahlotus Rd. Pasco, WA 99301

Solomon Park Research Laboratories 12815 N. E. 124th St., Suite I Kirkland, WA 98034

Zymogenetics, Inc. 2121 N. 35th St. Seattle, WA 98103

West Virginia

Allelic Biosystems Rt. 1, Box 230 Kearneysville, WV 25430

Wisconsin

Agracetus 8520 University Ave. Middleton, WI 53562 Agreco Route 4 Viroqua, WI 54665

Agrigenetics Advanced Science Co. 5649 East Buckeye Rd. Madison, WI 53716

American Breeders Service P.O. Box 459, Route 1 DeForest, WI 53532

American Genetics Inc. 7685 Mineral Point Rd. Verona, WI 53593

Anaquest 2005 W. Beltline Highway Madison, WI 53718

Bio-Technical Resources, Inc. 1035 S. 7th St. Manitowoc, WI 54220

Epicenter 2131 Kendall Ave Madison, WI 53705

Genetic Designs, Inc 5146 Anton Dr. Madison, WI 53719 Hazelton Biotechnologies Corp 3301 Kinsman Blvd Madison, WI 53704

Incell Corp. 1600 W. Cornell Milwaukee, WI 53209

Knight Hollow Nursery, Inc. 2433 University Ave. Madison, WI 53705

Molecular Biology Resources, Inc. 5520 W. Burleigh St. Milwaukee, WI 53210

Pharmacia P·L Biochemicals Inc. 2202 N. Bartlett Ave. Milwaukee, WI 53202

Promega Biotech 2800 South Fish Hatchery Rd. Madison, WI 53711

Universal Bioventures Corp. 6143 North 60th St. Milwaukee, WI 53218



Major Corporations Investing in Biotechnology

Abbott Laboratories Abbott Park N. Chicago, IL 60064

Allied Chemical Corp.
Columbia Rd. & Park Ave.
P.O. Box 2245R
Morristown, NJ 07960

Allied-Sigr al, Inc Columbia Rd. & Park Ave. P.O. 1021R Morristown, NJ 07960

American Cyanamid Co P.O. Box 400 Princeton, NJ 08540

American Home Products 685 Third Ave. New York, NY 10017

American Hospital Supply Corp. One American Plaza Evanston, IL 60201

Amoco Corp. P.O. Box 400, MS B-1 Naperville, IL 60566

Ares-Serono Laboratories 280 Pond St. Randolph, MA 02368

Baxter Travenol Labs, Inc. One Baxter Parkway Deerfield, IL 60015

Becton Dickinson & Co. 1 Becton Dr. Franklin Lake, NJ 07417

Bio-Rad Laboratories 2200 Wright Ave. Richmond, CA 94804

Boehringer Ingleheim Corp 90 E. Ridge P.O. Box 368 Ridgefield, CT 06877 (Overseas Only) Boehringer-Mannheim Corp 9115 Hagu€ Rd. Indianapolis, IN 46250

Bristol-Meyers 100 Forest Ave. Buffalo, NY 14213

Burroughs Wellcome Co. 3030 Cornwallis Rd. Research Triangle Park, NC 27709

Campbell Institute for Research & Technology
Campbell Soup Co.
Campbell Rd.
Camden, NJ 08101

CIBA GEIGY Corp. 556 Morris Ave. Summit, NJ 07901 (Overseas only)

Celanese Research Co. 86 Morris Ave., Box 1000 Summit, NJ 07901

Corning Glasswor! 3 Houghton Park Corning, NY 14831

Del Monte USA Agricultural Biotechnology Program P.O. Box 36 San Leandro, CA 94577

Diamond Shamrock Biotechnology Research SDS Biotech Corp P.O. Box 348 Painsville, OH 44077

The Dow Chemical Co. 1701 Building Midland, MI 48674

E. I. du Pont de Nemours Co. Barley Mill Plaza Wilmington, DE 19898 Eastman Kodak Co. Bio-Products Division Rochester NY 14650

Ecogen Inc. 2005 Cabot Blvd. West Langhorne, PA 1: 047-1810

Eli Lilly & Co Lilly Corporate Center Indianapolis, IN 46285

Exxon 180 Park Ave. Florham Pk, NJ 07932

FMC Corp. 2000 Market St. Philadelphia, PA 19103

General Electric R&D Laboratories, 1 River Rd. Schenectady, NY 12345

General Foods Corp. 250 North St White Plains, NY 10625

Gist-Brocades USA, Inc. 5550 77 Center Rd P O Box 241068 Charlotte, NC 28224 (Overseas only)

Glaxo Inc.
5 Moore Dr, Box 13398
Research Triangle Park, NC 27709

W. R Grace & Co. 7379 Route 32 Columbia, MD 21044

Hercules R&D Hercules Plaza Wilmington, DE 19894

Hoffman-La Rouche Inc. 340 Kingsland St Nutley, NJ 07110



Intl. Mineral & Chemical Corp. 2315 Sanders Rd. Northbrook, IL 60062

Johnson & Johnson 501 George St. New Brunswick, NJ 08903

Key Pharmaceuticals 18425 N.W. 2nd Ave. Box 694307 Miami, FL 33269 (subsidiary of Schering-Plough)

Kimberly-Clarke 1400 Holcomb Bridge Rd. Roswell, GA 30076

Life Technologies Inc. 8717 Grovemount Circle Gaithersburg, MD 20877

Litton Bionetics, Inc. 1330 A. Piccard Dr. Rockville, MD 20850

Lubrizol Enterprises 29400 Lakeland Blvd. Wickliffe, OH 44092

Merck and Company, Inc. 126 East Lincoln Ave. Rahway, NJ 07065

Miles Laboratories, Inc. 1127 Myrtle St. P.O. Box 10 Elkhart, IN 46515

Miller Brewing Co. 3939 W. Highland Blvd. Milwaukee, WI 53201

Monsanto Agricultural Co 800 N. Lindbergh Blvd. St. Louis, MO 63166

Natl. Distillers & Chemical Corp. 11500 Northlake Dr. P.O. Box 429550 Cincinatti, OH 45249

New England Nuclear Corp. 549 Alban; St. Boston, MA 02118

Norwich Eaton Pharmaceuticals, Inc. Procter & Gamble Co Cincinnati, OH 45201 (subsidiary of Procter & Gamble

Olin Corp. 275 S. Winchester Ave New Haven, CT 06511

Ortho Pharmaceutical Corp. Rt. 202 Raritan, NJ 08869 (division of Johnson & Johnson)

Pennwalt Corp. P.O. Box 1710 Kochester, NY 14603

Pfizer Inc. Eastern Point Rd. Groton, CT 06340

Phillips Petroleum Co. 15C4 Phillips Bldg. Bartlesville, OK 74004

Pioneer Hi-Bred Intl., Inc. Plant Breeding Division Box 85 Johnston, IA 50131-0085

RJR Nabisco, Inc 1100 Reynolds Blvd. Winston-Salem, NC 27102

Rohm & Haas Co. Independence Mall West Philadelphia, PA 19105

Rorer Group Inc 500 Virginia Dr. Ft Washington, PA 19034

Sandoz, Inc. 59 Route 10 East Hanover, NJ 07936

Schering-Plough Corp. One Giralda Farms Madison, NJ 07940-1000 Smith Kline & French Labs. 1500 Spring Garden St. PO. Box 7929 Philadelphia, PA 19101 (division of Smith Kline Beckman)

Squibb Corp. P.O. Box 4000 Princeton, NJ 08543-4000

The Standard Oil Co. 200 Public Square Cleveland, OH 44115-2375

Syntex Corp. 3401 Hillview Ave. P.O. Box 10850 Palo Alto, CA 94304

Texaco Research Center
Texaco Inc
Research & Environmental Studies
Div.
P.O. Box 509
Beacon, NY 12508

3M 3M Center Building 220-4NE-01 St. Paul, MN 55144

Universal Foods Corp. 433 East Michigan St Milwaukee, WI 53202

The Upjohn Co. 7000 Portage Rd. Kalamazoo, MI 49001

Weyerhauser Co. Tacoma, WA 98477

Wyeth Laboratories P.O. Box 8299 Philadelphia, PA 19101 (division of American Home Products)



Training and Education Initiatives in Biotechnology

Note: The programs and degrees listed here do not include the more traditional disciplines that contribute to biotechnology, such as genetics, molecular biology, microbiology, and chemical engineering, though most of the universities listed here offer those degrees as well. Listing here does not constitute any endorsement or certification by OTA.

California

*California Polytechnic State University **Biochemical Engineering**

San Louis Obispo, CA 93407 Degrees Offered: B.S./M.S. Year of Initiation: 1986

California State University, Hayward Certificate Program in Biotechnology

Department of Biological Sciences

Hayward, CA 94542

Degrees Offered: M.S. with certificate in

Biotechnology

Year of Initiation: 1986

California State University, Los Angeles Certificate Program in Biotechnology

Department of Biology 5151 State University Dr. Los Angeles, CA 90032

Degrees Offered: Graduate Certificate in

Biotechnology

Year of Initiation: 1987

San Diego State University

Program for Biotechnology Education and Research

Molecular Biology Institute San Diego, CA 92182

Degrees Offered: Certificate in Recombinant DNA (1983); Certificate in Protein Engineering (1988),

M.A. in Biotechi ology and Certificate in Agricultural Biotechnology (pending approval).

Year of Initiation: 1980

San Diege State University California State University System Program for

Biotechnology Education and Research

Molecular Biology Institute San Diego, CA 92182-0328 Degrees Offered: None Year of Initiation: 1987

San Francisco State University Genetic Engineering Certificate

Department of Biology San Francisco, CA 94132 Degrees Offered: Certificate

Year of Initiation: 1983

University of California, Davis **Biotechnology Program**

College of Agriculture and Environmental Science

Davis, CA 95616

Degrees Offered: B.S., M.S., Ph.D. in various

disciplines

Year of Initiation: Not Applicable

District of Columbia

Catholic University of America

Center for Advanced Training in Cell and Molecular Biology

Room 103 McCort-Ward Building

Washington, DC 20064 Degrees Offered: None Year of Initiation: 1982

Florida

*University of Florida

Florida Biotechnology R & D Institute

1 Progress Blvd. P.O Box 26 Alachua, FL 32615 Degrees Offered: None Year of Initiation: 1987

*University of Florida

Interdisciplinary Center for Biotechnology

Research

1301 Fifield Hall

Gainesville, Florida 32611 Degrees Offered: None Year of Initiation: 1987

^{*}Survey information not provided by program to OTA



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*University of South Florida

Biotechnology Tracks

Tampa, FL 33620

Degrees Offered: Biotechnology Tracks in Chemical Engineering and Biology: Combined

B.S./M.S. in Biotechnology is planned

Year of Initiation: 1985

Georgia

*University of Georgia Biotechnology Center

Athens, GA 30602 Degrees Offered: None Year of Initiation: 1982

Illinois

University of Illinois-Uı bana/Champaign

Biological Engineering Program and Bioprocess Engineering Research Laboratory

Bioprocess Engineering Laboratory Committee 208 North Romine

Urbana, IL 61801

Degrees Offered: M.S. and Ph.D. in Biological

Engineering (planned)

Years of Initiation: Research (1986), Engineering

Program (1988)

Iowa

*Iowa State University

Biotechnology Program

Office of Biotechnology

1301 Agronomy

Iowa State University of Science and Technology

Ames, IA 50011 Degrees Offered: none

Year of Initiation: 1984

University of Iowa

Biocatalysis: A Graduate Program in Biotechnology

College of Pharmacy Iowa City, IA 52242

Degrees Offered: No specific biotechnology degree

Year of Initiation: 1983

University of Iowa

Biochemical Engineering/Biotechnology

Department of Chemical & Materials Engineering

Iowa City, IA 52242

Degrees Offered: M.S., Ph.D. in Chemical and Materials Engineering with emphasis in

Piochemistry/Biotechnology Year of Initiation: 1985

*Survey information not provided by program to OTA

^aThe Department of Applied Biological Sciences at the Massachusetts Institute of Technology is being phased out

University of Iowa Medical School

Iowa Biotechnology Training Program

Department of Microbiology

Iowa City, IA 52242

Degrees Offered: No specific biotechnology degree

Year of Initiation: 1984

Kentucky

University of Kentucky

Biotechnology Undergraduate Degree

Department of Biochemistry

800 Rose St

Lexington, KY 40536

Degrees Offered: B.S. in Biosciences/Biotechnology

Year of Initiation: 1987

Maryland

University of Maryland, Baltimore County

Master of Science in Applied Molecular Biology

Applied Molecular Biology

Department of Biological Sciences

Catonsville, MD 21228

Degrees Offered: M.S., 5-year BS./MS

Year of Initiation: 1981

Massachusetts

*Becker Junior College

Biotechnician Program

3 Paxton St.

Leicester, MA 01524 Degrees Offered: A.A.S Year of Initiation: 1988

Massachusetts Institute of Technology^a

Biochemical Engineering

Department of Applied Biological Sciences

MIT Room 20A-207 Cambridge, MA 02139

Degrees Offered: M.S. and Ph D. in Biochemical

Engineering

Year of Initiation: 1955

Massachusetts Institute of Technology

Biotechnology Process Engineering Center

Biotechnology Process Engineering Center

Room 20A-207

Cambridge, MA 02139 Degrees Offered: None Year of Initiation: 1985



*Metropolitan College

Boston University

Biotechnology Program

755 Commonwealth Ave.

Boston, MA 02215

Degrees Offered: A.A.S.

Year of Initiation: 1987

Tufts University

Biotechnology Engineering Center

Pearson Building P-103 Medford, MA 02155

Degrees Offered: B.S./M.S., M.S., Ph.D. in

Biochemical/Chemical Engineering; Certificate

program in biotechnology processing

Year of Initiation: 1986

Worcester Polytechnic Institute

Biotechnology

Department of Biology and Biotechnology

Worcester, MA 01609

Degrees Offered: B.S. and M.S. in biotechnology

Year of Initiation: 1982

Michigan

Ferris State College

Biotechnology Emphasis, B.S., Applied Biology

Department of Biological Sciences

Big Rapids, MI 49307

Degrees Offered: B.S., Applied Biology

Year of Initiation: 1988

Minnesota

University of Minnesota

Program in Microbial Engineering

Box 196

School of Medicine

420 Delaware St., S.E.

Minneapolis, MN 55455

Degrees Offered: M.S. in Microbial Engineering

Year of Initiation: 1984

University of Minnesota

Institute for Advanced Studies in Biological **Process Technology**

240 Gortner Laboratory

1479 Gortner Ave.

St. Paul, MN 55108

Degrees Offered: Ph.D. minor in Biological Process

Engineering is under development

Year of Initiation: 1985

Montana

Montana State University

Institute for Biological and Chemical Process

Analysis

Bozeman, Montana 59717 Degrees Offered None

Year of Initiation: 1983

Nebraska

Central Community College

Biotechnology Program

PO Box 1024

Hastings, NE 68901

Degrees Offered: A.A.S

Year of Initiation: 1986

New Jersey

*Rutgers University

Biochemical Engineering

Department of Chemical and Biochemical

Engineering

P.O. Box 909

Piscataway, NJ 08854

Degrees Offered: B.S., M.S., and Ph.D. in

Biochemical Engineering

Year of Initiation: 1970 *Rutgers University

Certificate in Biotechnology

Department of Chemical and Biochemical

Engineering

PO. Box 909

Piscataway, NJ 08855

Degrees Offered: Certificate in Biotechnology

Year of Initiation: 1982

*Rutgers University

Center for Advanced Biotechnology and Medicine

P.O Box 759

Piscataway, NJ 08854

Degrees Offered: None

Year of Initiation: 1986

Rutgers University

Short Courses in Biotechnology

Cook College

Office of Continuing Professional Education

P.O Box 231

New Brunswick, NJ 08903

Degrees Offered: None

Year of Initiation: 1984

^{*}Survey information not provided by program to OTA



Rutgers University **Biotechnology**

Cook College

Department of Biochemistry and Microbiology

Lipman Hall

New Brunswick, NJ 08903

Degrees Offered: B.S. in Biotechnology (pending

approval)

Year of Initiation: 1986

New York

Cornell University

Cornell Biotechnology Program

Baker Laboratory Ithaca, NY 14853 Degrees Offered: None Year of Initiation: 1983

*Monroe Community College

Biotechnology Program

1000 E. Henrietta Rd. Rochester, NY 14623 Degrees Offered: A.A.S. Year of Initiation: 1983

Rochester Institute of Technology

Biotechnology

Department of Biology One Lomb Memorial Dr. Rochester, NY 14623

Degrees Offered: B.S. in Biotechnology

Year of Initiation: 1983

*State University of New York, Alfred

Biotechnology Program

Alfred, NY 14802 Degrees Offered: A.A.S.

Year of Initiation: 1986

*State University of New York, Buffalo

Center for Biotechnology

School of Medicine 462 Grieder St. Buffalo, NY 14215 Degrees Offered: None Year of Initiation: 1984 State University of New York, Fredonia

Bachelor of Science Major, Recombinant Gene Technology

Department of Biology Fredonia, NY 14063

Degrees Offered: B.S., Recombinant Gene

Technology

Year of Initiation: 1983

State University of New York, Plattsburgh/Miner

Institute

In Vitro Cell Biology and Biotechnology

Miner Center Chazy, NY 12921

Degrees Offered: B.S. and M.A.

Year of Initiation: 1980

State University of New York, Stony Brook

Center for Biotechnology

130 Life Sciences Bldg. Stony Brook, NY 11794 Degrees Offered: None Year of Initiation: 1983

North Carolina

*North Carolina State University

Biotechnology Program

Raleigh, NC 27695

Degrees Offered: Ph.D. minor in Biotechnology

Year of Initiation: 1982

Technical College of Alamance

Biotechnology

P.O. Box 623

Haw River, NC 27258 Degrees Offered: A A.S. Year of Initiation: 1986

University of North Carolina

Program in Molecular Biology and Biotechnology

Room 402 Swing Bldg. Chapel Hill, NC 27514 Degrees Offered: None Year of Initiation: 1981

North Dakota

North Dakota State University

Biotechnology Academic Program

Box 5516

Fargo, ND 58105

Degrees Offered: B.S. in Biotechnology

Year of Initiation: 1986

^{*}Survey information not provided by program to OIA



Ohio

Case Western Reserve University

Concentration in Biotechnology and Genetic Engineering

Department of Biology Cleveland, OH 44106

Degrees Offered: B.A./B.S, M.S., Ph.D.

Year of Initiation: 1984

*Ohio State University

Ohio State Biotechnology Center

Rightmire Hall 1060 Carmack Rd. Columbus, OH 43210

Degrees Offered: Not yet formulated

Year of Initiation: 1987

Pennsylvania

Cedar Crest College

Genetic Engineering Technology Program

Allentown, PA 18104

Degrees Offered: B.S. major in Genetic Engineering

Year of Initiation: 1983

Lehigh University

Applied Biological Science (M.S.)

Center for Molecular Bioscience & Biotechnology

570 A Whitaker Labs Bethlehem, PA 18015

Degrees Offered: Ph.D. & M.S. Biochemical

Engineering

Year of Initiation: 1987

Pennsylvania State University

Penn State Biotechnology Institute

532 Biotechnology Headquarters Bldg.

University Park, PA 16802

Degrees Offered: None specifically in

biotechnology

Year of Initiation: 1985

*University of Pittsburgh

Center for Biotechnology and Bioprocess

Engineering

911 William Pitt Union Pittsburgh, PA 15260 Degrees Offered: None Year of Initiation: 1987

Tennessee

University of Tennessee

Biotechnology

M303 Walters Life Sciences Bldg.

Knoxville, TN 37996

Degrees Offered: M.S. in Life Sciences

Biotechnology

Year of Initiation: 1985

Texas

Texas A & M University

Agricultural Biotechnology

Department of Biochemistry & Biophysics

College Station, TX 77843

Degrees Offered: None specifically in

biotechnology

Year of Initiation: 1984

Utah

Utah State University

Center of Excellence in Biotechnology

Logan, UT 84322-4430

Degrees Offered: None specifically in

hiotechnology

Year of Initiation: 1987

Virginia

Old Dominion University

Biotechnology

Center for Biotechnology

Norfolk, VA 23508

Degrees Offered: M.S. in Biotechology

Year of Initiation: 1987

Wisconsin

Madision Area Technical College

Biotechnology Laboratory Technician Program

3550 Anderson St. Madision, WI 53704 Degrees Offered: A.A.S. Year of Initiation: 1987

^{*}Survey information not provided by program to OTA



University of Wisconsin Biotechnology Center

1710 University Ave Madison, WI 53705 Degrees Offered: None Year of Initiation: 1984

*University of Wisconsin

University of Wisconsin Bioprocess and Metabolic Engineering Program

Department of Chemical Engineering

Madison, WI 53706 Degrees Offered: None Year of Initiation: 1987

*Survey information not provided by program to OTA

NOTE: Copies of the report "New Developments in Biotechnology: U.S. Investment in Biotechnology—Special Report" can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325, GPO stock No. 052-003-01115-8.



General Information

Contacts Within OTA

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Energy, Materials, and International Security Division228-6750
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To obtain information on availability of published reports, studies, and summaries, call the OTA Publication Request Line (202) 224-8996.

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Congressional and Public Affairs Office Office of Technology Assessment U.S. Congress Washington, DC 20510-8025 (202) 224-9241

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List of Publications.—Catalogs by subject area all of OTA's published reports with instructions on how to order them.

Assessment Activities.—Contains brief descriptions of recent publications and assessments under way, with estimated dates of completion.

Press Releases.—Announces publication of reports, staff appointments, and other newsworthy activities.

OTA Annual Report.—Details OTA's activities and summarizes reports published during the preceding year.

OTA Brochure.—"What OTA Is, What OTA Does, How OTA Works."



Related OTA Reports

The following OTA reports are available from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (202) 783-3238.

- New Developments in Biotechnology, 1: Ownership of Human Tissues and Cells—Special Report, OTA-BA-337 (Washington, DC: U.S. Government Printing Office, March 1987). The GPO stock number is 052-003-01060-7; the price is \$7.50.
- New Developments in Biotechnology, 2: Public Perceptions of Biotechnology—Background Paper, OTA-BP-BA-45 (Washington, DC: U.S. Government Printing Office, May 1987). Out of print at the GPO. Now available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, (703)487-4650. The NTIS stock number is PB 87-207 544 A/S; the price is \$6.95 for microfiche copy, \$19.95 for paper copy.
- New Developments in Biotechnology, 3: Field-Testing Engineered Organisms: Genetic and Ecological Issues, OTA-BA-350 (Washington, DC: U.S. Government Printing Office, May 1988). The GPO stock number is 052-003-01104-2; the price is \$7.50.
- Mapping Our Genes—The Genome Projects: How Big, How Fast? OTA-BA-373 (Washington, DC: U.S. Government Printing Office, April 1988). The GPO stock number is 052-003-01106-C; the price is \$10.



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