From Laboratory to Market:

The Biotechnology Industry in the Third District

BY TIMOTHY SCHILLER

Basic biotechnology has been around a long time. Bakers have used yeast for centuries, and smallpox vaccination was introduced in the 18th century, long before the details of cell structure were known. However, recent events, such as the human genome project, have firmly anchored biotechnology and its applications in the public's mind and imagination. Here, Tim Schiller briefly describes major biotechnology products, reviews estimates of the industry's size and scope, and outlines where the industry is most active in the United States, especially in the Third District states of Pennsylvania, New Jersey, and Delaware.

Biotechnology uses living organisms at the cellular or molecular level for medical, agricultural, or industrial purposes. The publication of the human genome sequence in 2001 brought biotechnology dramatically before the public as a leading-edge scientific endeavor. Although biotechnology has only relatively recently gained widespread public interest, basic biotechnology is thousands of years old.

This article briefly describes major biotechnology products currently in use or under development and their applications; it reviews estimates of the biotechnology industry's size and scope; and it gives some details on where biotechnology companies are active in the U.S., with emphasis on the industry's presence in the states of the Third Federal Reserve District: Pennsylvania, New Jersey, and Delaware.

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THE RISE OF BIOTECHNOLOGY

Yeast has been a component of baking and fermenting throughout recorded history, and its use is probably older than the written record. Vaccination against the smallpox virus was introduced in the 18th century, long before the details of cell structure and action were known. But it was James Watson and Francis Crick's discovery of the structure of DNA, the molecule that carries genetic information, in 1953 that ushered in the modern era of biotechnology. Since then, the science of genetics and its technological applications have advanced rapidly. In 1961, the first biopesticide was developed to protect important agricultural crops. In 1973, came the first alteration of a DNA molecule, the biotech process now referred to as recombinant DNA technology. (See the *Glossary of Biotechnology Terms*.) In 1982, the U.S. Food and Drug Administration approved the first drug developed by biotechnology: human insulin produced in genetically modified bacteria. In 1989, cotton was genetically modified to protect it against insects, and corn followed the next year. The first animal cloned from an adult cell, Dolly the sheep, arrived in 1997. Advances in biotechnology are accelerating, and the scope of biotechnology's applications is widening. More than 100 biotechnology drugs and vaccines are used today in the United States; agricultural applications of biotechnology are extensive; and industrial uses are growing.

MAJOR BIOTECHNOLOGY PRODUCTS

Recent advances in understanding the chemistry of cells and biological molecules, such as DNA and proteins, have been extensive. This growing knowledge has led to a variety of technologies and products that have provided benefits to human health and

Glossary of Biotechnology Terms

Antibody – a protein produced in the body in response to foreign proteins entering the body, as in infections. Antibodies chemically deactivate the foreign protein to protect the body.

Antigen – a substance that induces the body's immune response system to produce an antibody.

Assay – a scientific test for measuring biological response to a drug or other treatments.

Autoimmune disease – a disease in which the body produces antibodies that attack its own tissues.

Biocatalyst – an enzyme that causes or facilitates a biochemical reaction.

Biochemical – a chemical resulting from a chemical reaction in a living organism.

Bioinformatics – the collection and analysis of data by computers for use in biological research; often used in genomic research.

Biologicals – medicines made from living organisms or their products; also known as biological drugs. Examples include vaccines and serums.

Chromosome – components of a cell nucleus that carry genes, made up of DNA and protein.

Clone – genes, cells, or organisms that are derived from a single common gene, cell, or organism and that are genetically identical.

DNA (Deoxyribonucleic acid) – the molecule that carries genetic information.

DNA probe – a piece of nucleic acid that has been labeled with a radioactive isotope and used to locate a particular gene on a DNA molecule.

Diagnostic – a product used for the diagnosis of a medical condition. Monoclonal antibodies and DNA probes are biotechnological diagnostics.

Enzyme – a protein that controls chemical reactions in living organisms.

Expression – manifestation of a characteristic that is based on a gene. Also used to refer to the production of a protein by a gene.

Gene – a segment of a chromosome that has a specific hereditary function. Genes control the production of proteins and regulate other molecular functions in living organisms.

Gene mapping – determining the location of genes on a chromosome.

Gene sequencing – determining the specific order of the nucleotide bases (constituent parts of the DNA molecule) in a strand of DNA.

Gene therapy – the replacement of a defective gene.

Genetic modification – altering the genetic material of living cells to make them capable of producing new substances or performing new functions.

Genome – the complete chromosome set in the cell nucleus.

Genomics – the study of gene function.

Monoclonal antibody – an antibody derived from one clone of cells that reacts to only one antigen.

Protein – a molecule made up of amino acids (acids containing one nitrogen and two hydrogen atoms in combination). Proteins carry out the chemical processes involved in genetic activity and other cell functions.

Proteome – the total collection of proteins in a cell, different for different types of cells.

Proteomics – the study of a proteome and the functioning of proteins.

Recombinant DNA – the process of making new DNA by combining DNA components from different organisms; used in genetic modification and gene therapy.

Stem cell – a cell that can grow into any specific type of cell in a living organism. Embryos develop from stem cells.

applications of economic significance to agriculture and other industries. (For a brief description of major biotechnologies, see *Biotechnologies and Their Applications*.)

Biotech Drugs. There were over 100 biotech drug products and vaccines available in 2000.[1] Current biotech medicines include important treatments for anemia, cystic fibrosis, growth deficiency, hemophilia, hepatitis, transplant rejection, and leukemia and other cancers. Biotech products are also used for several diagnostic procedures. Biotech drugs have been introduced at an increasing rate, especially since the mid-1990s. Approvals of new biotech drugs and new uses for existing biotech

[1] See Biotechnology Industry Organization, 2001.

drugs generally increased from 1993 to 2001.[2] In that same period — mid-1990s to the present — the number of new drug and new use approvals annually for nonbiotech drugs rose, but not by as much as biotech drugs. Thus, in the past several years, biotech drugs have become a larger percentage of the annual number of total new drug and new use approvals, increasing from 6 percent in 1993 to 15 percent in 2001 (Figure 1).

In 2000, the latest year for which data are available, 369 biotech medicines were undergoing clinical trials.[3] Clinical trials usually come at around the mid-point in the drug development process, about eight years after research to discover a specific new drug begins and about seven years before FDA approval. Most new biotech drugs currently being tested are intended for cancer treatment (175 drugs). Other therapeutic categories with a large number of biotech drugs in the clinical trial phase are infectious diseases (39), neurological disorders (28), heart disease (26), and respiratory diseases (22).

Agricultural Uses. Biotechnology has become an important aspect of plant agriculture in a short time. The most important use of genetic modification in plant agriculture is herbicide tolerance. In this process, the genetic composition of plants is altered to make them resistant to damage from the chemical herbicides used to kill weeds in the fields where they are grown. In this way, crop losses from herbicides are reduced and yields are increased. When plants are made resistant to more lethal herbicides, fewer applications of herbicide can be used, reducing both farmers' production costs and environmental damage.

The second major use of genetically modified crops is insect resistance. This process involves taking genetic material from naturally occurring organisms that are lethal to insects and inserting it into plants. When the genetic insecticide from a naturally occurring bacterium is inserted in the genetic makeup of plants, the insects that feed on them are killed before they destroy the plant.[4] This obviates the need for chemical insecticides, thereby protecting crops more efficiently and reducing the threat of poisoning animals and humans.

Biotechnologies and Their Applications

Cell culture technology is the growing of cells outside the living organism in which they develop naturally. Applications of this technology include growing cells on which to test new medicines, growing cells to replace dead or malfunctioning cells in human organs, and mass producing natural substances of medicinal value.

Cloning is the reproduction of molecules, cells, plants, or animals that are genetically identical to their source. Cloning gained notoriety in 1997 when scientists cloned a sheep from an adult sheep cell. Before that, animal cloning had been done with embryo cells. Monoclonal antibody production and much of cell culture technology are based on cloning. Cloning is used in livestock breeding, pharmaceutical manufacturing, and modification of agriculturally important plants. In addition, cloning is a basic part of other biotechnologies.

Genetic modification technology, sometimes called ***genetic engineering*** or ***recombinant DNA technology***, is the insertion of genetic material from one organism into the genetic material of another organism. In a sense, this technology is a more specific and direct approach to the same ends as selective breeding in that desirable traits, coded in genetic material, are transferred from one organism to another. Subsequent generations of this organism will have these traits. Genetic modification technology is already widely used in agriculture. Other uses of this technology include production of medicines and vaccines, treatment of genetic diseases, and nutritional enhancement of foods.

Monoclonal antibody technology develops antibodies from cloned cells that can be used to identify and treat antigens that infect humans, animals, and plants. Because antibodies are very specific in their action, monoclonal antibody technology encompasses an extensive field of research. One of the more important applications of this technology is cancer treatment and vaccines, such as the biotech vaccine against hepatitis B. Another important use is the diagnosis of infectious diseases in humans, animals, and plants. Monoclonal antibody technology is also used to locate environmental pollutants and to detect harmful microorganisms in food.

Protein engineering technology is used to modify proteins, which are constituents of genes and enzymes. Proteins are the chemical substances through which much genetic and cellular activity occurs, so there is a growing research effort to understand and manipulate proteins. Currently there are several biotech drugs based on protein chemistry for treatment of anemia, cystic fibrosis, hemophilia, leukemia, and some cancers. Besides their functions in living organisms, enzymes are also used as biocatalysts to improve the efficiency of production processes for chemicals, textiles, pharmaceuticals, pulp and paper, food, and animal feeds.

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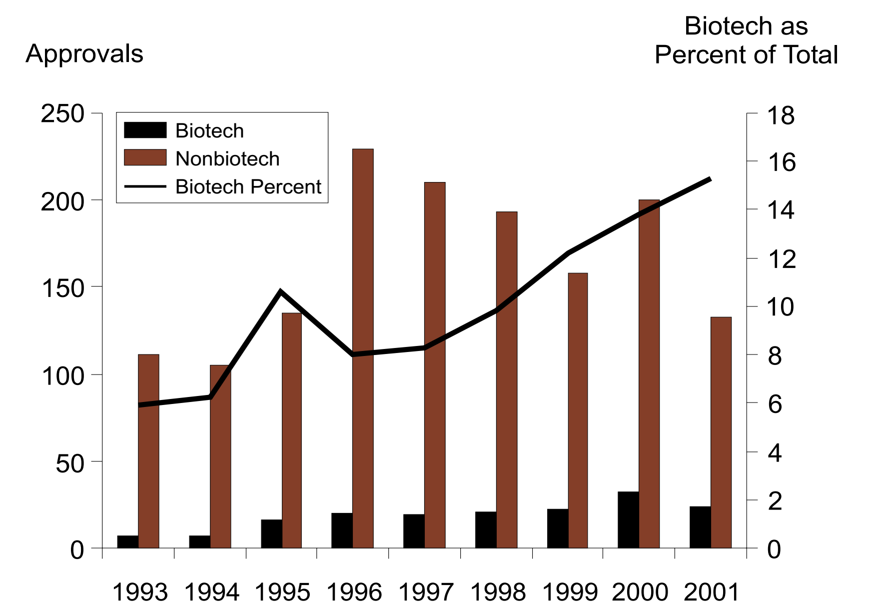
[2] Since 1993 the Food and Drug Administration has counted new use approvals (formally called "efficacy supplements") separately from new drug approvals.

[3] See Pharmaceutical Research and Manufacturers of America, 2000.

[4] The most common source in this application is genetic material from *Bacillus thuringiensis* (Bt), a naturally occurring bacterium lethal to insects.

FIGURE 1

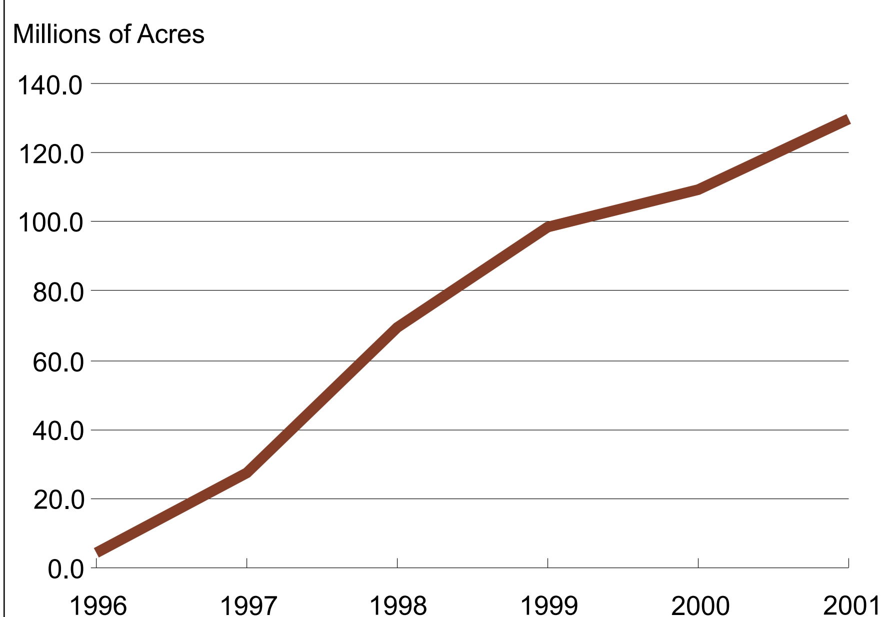
New Drug and New Use Approvals



Source: FDA Center for Drug Evaluation and Research; Biotechnology Industry Association

FIGURE 2

Global Area of Transgenic Crops



Source: International Service for the Acquisition of Agri-Biotech Applications

Agriculture has also made use of genetically modified seeds, which first became commercially available in 1996. Between 1996 and 2001, the area planted with genetically modified crops worldwide increased 30 times (Figure 2). Although the share of the world's total cropland planted with genetically modified seeds is small — approximately 3 percent — genetically modified seeds are a large share of the acreage of some important food crops. Of the four main crops — soybean, cotton, canola, and maize (corn) — for which genetically modified seeds are used, the portion planted with genetically modified seeds comprises 19 percent of the world's total acreage planted with those crops (Figure 3).

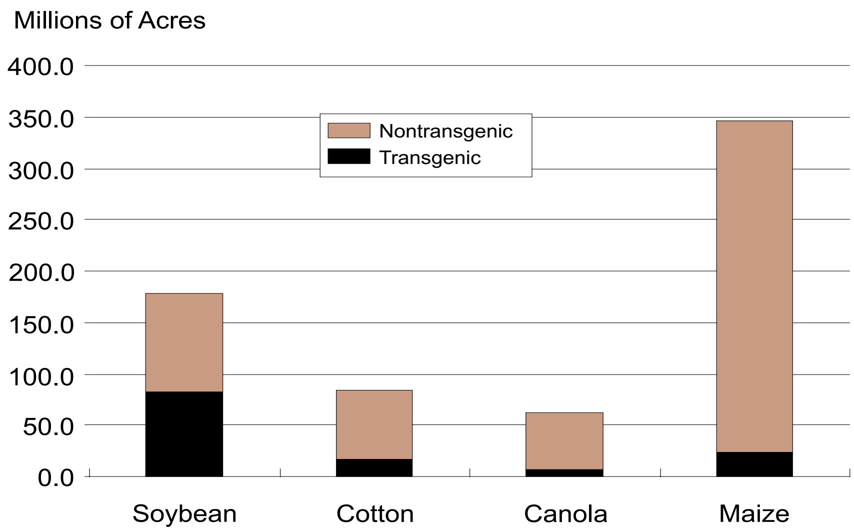
The use of transgenic crops continues to grow, and American farmers have been the world leaders in adopting their use.[5] Recently, the U.S. Department of Agriculture estimated that American farmers will increase their plantings of genetically modified corn, soybeans, and cotton this year to 32 percent, 74 percent, and 71 percent, respectively, of the total acreage for these crops. Although farmers' interest in using transgenic crops appears to be increasing, there is growing public concern about possible harm to human health and unintended effects on naturally occurring plants through uncontrolled dissemination of transgenic agricultural products. Many national governments have begun to regulate transgenic food products, and an effort is under way through the United Nations to establish international rules for identifying, packaging, and handling genetically modified living organisms.[6]

[5] "Transgenic" means carrying genes transferred from another species or breed. Data on U.S. farmers' use of transgenic seeds are from the U.S. Department of Agriculture crop and planting reports (U.S. Department of Agriculture, 2001a, 2002).

[6] See United Nations, 2000.

FIGURE 3

Transgenic Crops vs. Total (2001)



Source: International Service for the Acquisition of Agri-Biotech Applications

Industrial Applications. In industry, the most prevalent biotech products are enzymes used in chemical processes. There is a wide variety of enzymes, each acting on different compounds. The most commonly used enzymes in industry break down protein, cellulose, fats, and starches. These enzymes are used in detergents and industrial cleaners, in baking and brewing, and in the production of cheese and other dairy products.

BIOTECHNOLOGY AS AN INDUSTRY

Specialized medical biotech firms fall mainly within the pharmaceutical and the physical and biological research industries. There is no industrial classification for biotechnology, as such. Furthermore, educational institutions and hospitals conduct biotech research, and chemical firms carry out research as well, especially for agriculture. Consequently, data on the economic scale of biotechnology are difficult to obtain. Information on revenue, employment, and other aspects of the biotechnology industry must be obtained primarily from industry sources, such as the Biotechnology Industry Association, and individual companies.

Biotechnology companies had sales of $18 billion in 2001, according to the Biotechnology Industry Association.[7] The industry's revenues are still small compared with the overall U.S. pharmaceutical industry, which had estimated worldwide sales of around $180 billion in 2001, but they have been growing rapidly.[8] Aggregate sales revenue of biotechnology companies has increased more than 200 percent since 1993, compared with an increase of 137 percent since then in sales of the overall U.S. pharmaceutical industry. Moreover, sales figures of biotech firms do not represent the true importance of biotechnology. Biotechnology research and development (R&D) is an important and growing part of larger, more diversified firms in the medical, pharmaceutical, agricultural, and industrial sectors.

According to the Biotechnology Industry Association, there are about 1400 biotechnology companies in the U.S., of which approximately 340 are publicly held. Many, but not all, of the companies are classified in the pharmaceuticals industry. Employment in the biotech industry is estimated at 174,000 jobs. Total employment in the pharmaceutical manufacturing industry is 214,000.[9] These numbers are not strictly comparable because biotech firms and employment in those firms encompass not just biotech-based drug companies but also other nondrug companies related to biotech, such as research firms, universities, and firms providing services to the biotech industry. Outside of specialized biotech firms, many people are employed in biotechnology research and the production of biotechnology products in large firms, primarily major pharmaceutical companies, and in chemical companies that produce agricultural products, such as seeds and pesticides.

Capital invested in biotechnology firms can also give us a measure of the industry's size. This measure is especially relevant for this industry because the industry is new and many firms are spending on R&D, without significant sales. Estimates of the funds raised by biotech firms approached $40

[7] Data on biotech sales, revenue, and employment are from the Biotechnology Industry Association, 2002a.

[8] Data on the overall pharmaceutical industry are from Pharmaceutical Research and Manufacturers of America, 2001.

[9] U.S. Bureau of the Census, 2002.

billion in 2000, the recent peak year, with approximately $25 billion of that coming from public stock and debt offerings, such as bonds.[10] In comparison, total funds raised via stock and debt offerings by all U.S. public corporations in that year were $944 billion.[11] As the stock market weakened subsequently, biotech financing shrank along with the overall decline — to about $11 billion in 2001.[12]

Biotechnology firms rely on a variety of financing methods (Figure 4). Public financing comes primarily from initial public offerings (IPOs) of stock and follow-on stock offerings. Publicly held biotech firms also use loans, warrants, debt offerings, and private placements to finance their work.[13] Lesser amounts are raised by companies that have not yet tapped the public market. Financing for these companies comes primarily in the form of venture capital and equity buys from partners, often large pharmaceutical companies. Although the amount of money raised in this way is lower than publicly raised funds, it is critical for biotech firms in the early stages of R&D, when the need for financing is great but the ability to attract investment in the market is slight.

Venture capital was around 10 percent of total biotech industry funding in 2000, according to industry sources. Although venture capital accounts for a small portion of the industry's funding, venture capitalists serve important functions for young biotech companies by providing management expertise and preparing the firms for their initial public offerings.[14] Nationally, venture capital invested in biotechnology companies was 6 percent of total venture capital investments in 2001.

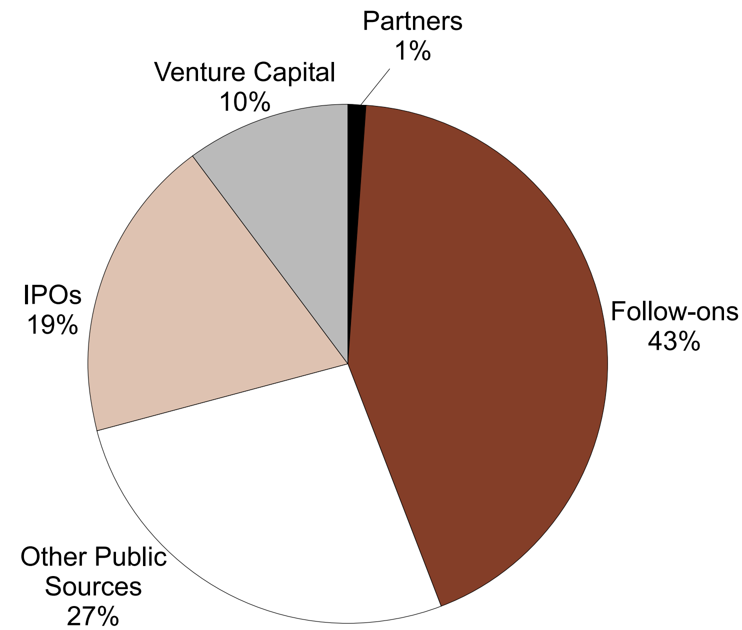
In our tri-state region, the proportion of venture capital going to biotechnology has been greater than in the nation as a whole. In New Jersey, biotechnology venture capital was 19 percent of the state total; in Pennsylvania, it was 15 percent (see the Table).[15]

Another common feature of early-stage biotech financing is collaboration with a major pharmaceutical company. The larger firm in a collaborative agreement often provides R&D support, production facilities, and marketing arrangements for the biotech firm. The larger firm recoups its investment through marketing rights under a license agreement. Although funds provided through collaborative agreements are not a large portion of the biotech industry's total capitalization, the money is an early source of much needed capital, and the interest of a large pharmaceutical firm can be an important signal to the markets about the biotech startup's prospects.

Once beyond the early financing stage, biotech firms rely on initial public offerings of stock, loans, private placements, and other forms of capital. These more traditional forms of corporate financing have recently become more available to biotech firms than they were in the past. According to industry analysts, by the end of the 1990s, a number of large, well-capital-

FIGURE 4

Biotech Industry Funding (2000)



Source: BioWorld Financial Watch

[10] See Biotechnology Industry Association, 2001.

[11] See Board of Governors, 2001.

[12] See Burrill and Company.

[13] A warrant is a company-issued certificate that represents an option to buy a certain number of stock shares at a specific price before a predetermined date. A private placement is a large block of securities offered for sale to an institutional investor or a financial institution through private negotiations.

[14] See the article by Mitchell Berlin.

[15] No amounts of venture capital for biotech firms were reported for Delaware.

TABLE

Biotech Venture Capital Invested (2001)

State	$Million	Percent of State Total Venture Capital
California	845	5.4
Massachusetts	310	6.6
New Jersey	268	18.9
New York	150	7.2
Maryland	149	14.6
Colorado	131	9.9
Pennsylvania	123	14.5
Connecticut	110	18.9
North Carolina	60	12.8
Washington	57	5.5
Virginia	50	7.6
Texas	44	1.6
Illinois	21	3.4
Michigan	21	13.0
Utah	18	9.2
Rhode Island	13	29.8
Wisconsin	10	2.1
Georgia	9	1.1
Indiana	8	15.8
Arizona	7	4.5
Minnesota	7	1.3
Nebraska	6	66.7
Maine	3	36.8
New Mexico	2	9.0
Alabama	1	1.4

Source: PricewaterhouseCoopers/Venture Economics/National Venture Capital Association Money Tree Survey

ized biotech firms had emerged, and these firms now have the financial resources to fund their development efforts for several years.

GEOGRAPHIC DISTRIBUTION OF BIOTECHNOLOGY

Biotechnology firms are concentrated in places that are popularly considered high-tech areas. According to Ernst & Young, there are approximately 1460 major biotech firms in the country, concentrated in a few states. A little over 400 are in California, just over 200 in Massachusetts, nearly 100 in Maryland, about 90 in North Carolina, and approximately 70 each in Pennsylvania, New Jersey, and New York. Other leading states are Washington, Georgia, and Texas (around 40 companies each) and Florida and Colorado (approximately 30 companies each). These 12 make up the top biotech states in Ernst & Young's tally (Figure 5).

The geographic distribution of research efforts shows a cluster pattern as well. A few biotech centers dominate the rankings of metropolitan areas in terms of number of biotech patents granted between 1975 and 1999. The New York consolidated metropolitan area is first with nearly 12,000 patents, followed by San Francisco and Philadelphia with over 5000 each. Next comes Boston with over 3000, and Washington, D.C. and Chicago with over 2000 each. Only six other metropolitan areas have more than 1000 biotech patents each.[16] The data for the New York area reflect much of the biotech activity that takes place among the many pharmaceutical firms located in the New Jersey portion of New York's metropolitan area. Likewise, a substantial share of biotech activity in the Philadelphia area takes place among the chemical firms located in the Delaware portion of the metropolitan area as well as among biotech and pharmaceutical firms in the Pennsylvania portion.

Because the biotechnology industry is growing rapidly and because many biotech firms are small, any count of their numbers is likely to be an underestimate. Furthermore, universities and other nonprofit organizations as

[16] Data on patents issued 1975-99 are from the paper by Joseph Cortright and Heike Mayer. The patent data used include patent classes for drugs, molecular biology, and multicellular living organisms. The patent class for drugs includes biotech and nonbiotech drugs. When only data from the patent classes for molecular biology and multicellular living organisms are used, as a more restricted classification of biotech, the geographic distribution of patents is substantially similar among the top six metropolitan areas, but there is some reordering within the group and two areas are displaced by others not in the first grouping. Using the restricted classification the order is Boston, San Francisco, San Diego, Raleigh, New York, and Philadelphia. The areas moving down, including Philadelphia, have proportionately more of their biotech research devoted to discovering new drugs compared with the areas moving up or retaining their original ranking.

well as large pharmaceutical firms undertake biotech research. These factors should be taken into account to accurately assess the biotechnology industry nationally and in the region.

BIOTECHNOLOGY IN THE REGION

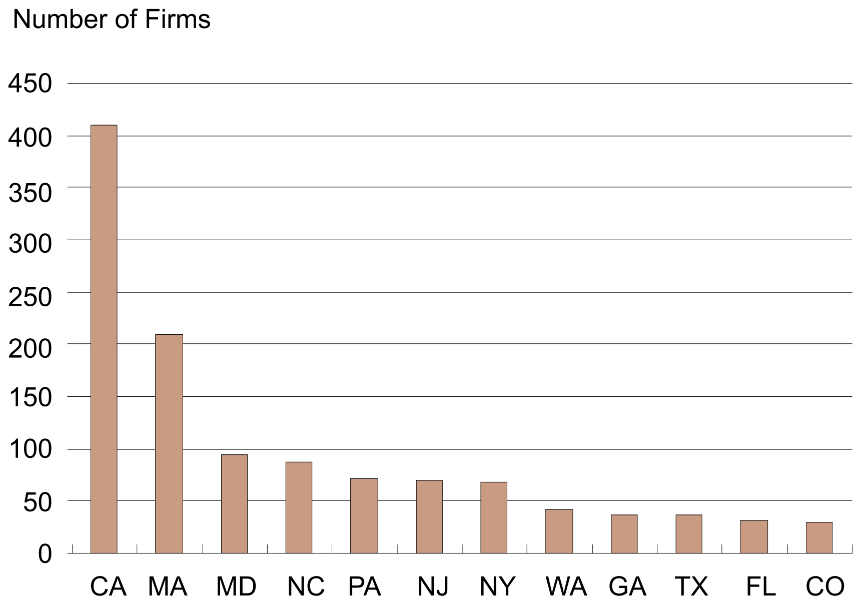
Biotechnology is well represented in the three states of the Third District. As noted above, data from Ernst & Young place New Jersey and Pennsylvania among the top biotech states in terms of the number of major biotech firms located in the two states. Both states, as well as Delaware, figure prominently in biotech patenting. State biotechnology associations are active in Pennsylvania and New Jersey, and membership in these associations takes in more firms and institutions than are included in Ernst & Young's count. Within the region, biotech firms tend to cluster in locations that have established bases of pharmaceutical firms and life sciences facilities, such as research universities and medical centers (see the map).

In New Jersey, biotechnology firms have sprouted in an area where many of the world's largest pharmaceutical firms have been well established. Universities in the state are also engaged in biotech research. Biotech and other life sciences firms are concentrated in the middle and northern parts of the state.

In Pennsylvania, the Philadelphia metropolitan area is a biotech hub, but there are also biotech clusters in central Pennsylvania, centered on Pennsylvania State University, and in the Pittsburgh area, the location of Carnegie Mellon University and the University of Pittsburgh, which have active biotech research programs. In the Philadelphia area, the life sciences are represented by major pharmaceutical firms as well as educational institutions with health and medicine programs,

FIGURE 5

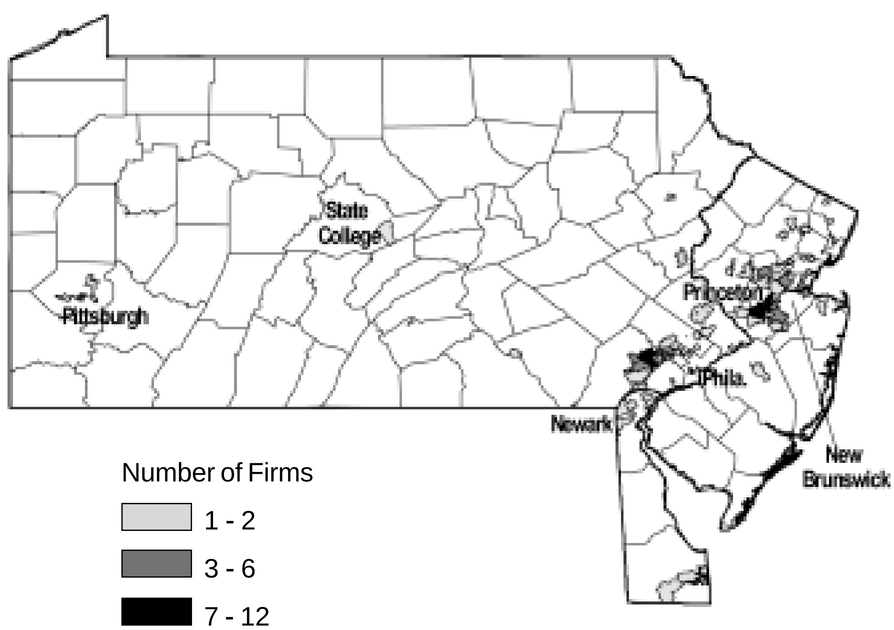
Leading Biotech States (2001)



Source: *Beyond Borders*, Ernst & Young's 2002 Global Biotechnology Report. Used with permission.

MAP

Biotech Firms
Pennsylvania, New Jersey, and Delaware



such as the University of Pennsylvania, Thomas Jefferson University, University of the Sciences, and Drexel University/ MCP Hahnemann University.

Delaware should not go unmentioned; the state's traditional chemical industry is evolving from producing basic chemicals to more specialized products, including pharmaceuticals. Besides Wilmington, where chemical and pharmaceutical companies have a well-established presence, the New Castle area is developing as a center for biotech firms.

Biotechnology firms and other establishments engaged in biotech research in the region are using all the major technologies outlined earlier. They are applying these technologies in human health, agriculture, and environmental protection. The region's firms and other institutions have developed expertise in several major technologies. A partial list includes genomics, proteomics (the study of the functioning of genes and proteins, respectively), monoclonal antibody production, implants and tissue substitutes, combinatorial chemistry, gene therapy, genetic modification of plants, and DNA sequencing.

In addition to these relatively more established technologies, firms and institutions in the region are taking the lead in newer biotechnologies.[17] One of these is bioinformatics, the use of computer database management and computer simulation to model cells and biological molecules. A broader use of bioinformatics is to analyze data from different research and testing sources in an integrated way. Another new biotechnology in which the region's institutions are at the forefront is biosensor and bio-nanotechnolgy, which combine information about cellular activity gained by biotechnolgy with nano-scale electronics. Some applications of this technology are monitoring single-cell activity electronically, analyzing blood components in real time, and testing food products for safety and nutritional value.

Recognizing the economic potential of biotechnology, educational institutions and state and local governments have joined with biotechnology companies and industry groups to promote the industry in their areas. Sixteen states are using funds from the tobacco industry case to support bioscience research and development, and 10 states have formulated biotechnology or life sciences strategic plans.[18] Important aspects of joint public and private efforts to facilitate the development of biotech firms will be early-stage funding, academic and industry cooperation, and alliances between established large firms and startups, all of which have been key elements in the early growth of the biotech industry.[19]

Pennsylvania has sketched out an ambitious program to support the biotechnology industry in the state, using funds from the tobacco settlement. The state is establishing a life sciences venture fund and creating three "biotech greenhouses." One will be located in Philadelphia and one in Pittsburgh; the third, in central Pennsylvania, will coordinate the biotechnology efforts of Pennsylvania State University, Penn State Milton S. Hershey Medical Center, Penn State College of Medicine, and Lehigh University. The greenhouses will be consortiums of educational institutions, medical research establishments, private companies, and industry groups. They will provide venture capital, promote commercialization of technology developed at universities, operate business incubators for biotechnology startups, and market their areas' biotechnology resources. The goal of the greenhouses is to commercialize the biotech expertise of the educational institutions and start-up companies in their areas.[20]

In New Jersey, state government agencies, universities, and the Biotechnology Council of New Jersey, an industry association, have formed the New Jersey Coalition for Biotechnology to promote the state's biotechnology industry and facilitate pharmaceutical research. In recent years, the state's Commission on Science and Technology has provided start-up funds for several biotechnology research facilities, including the Biotechnology Center for Agriculture and the Environment and the Center for Advanced Food Technology at Rutgers University/Cook College, the Center for Advanced Biotechnology and Medicine at the University of Medicine and Dentistry of

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[17] See the reports of the three Pennsylvania biotech greenhouses (Biotechnology Greenhouse Corporation of Southeastern Pennsylvania, 2001; Pittsburgh Life Sciences Greenhouse, 2002; Life Sciences Greenhouse of Central Pennsylvania, 2002); Biotechnology Council of New Jersey, 2001; Delaware Biotechnology Institute, 2002.

[18] See the paper from Battelle Memorial Institute.

[19] See the article by Martha Prevezer.

[20] The Philadelphia greenhouse will focus on research in genomics, proteomics, monoclonal antibodies, diagnostics, implants, and bioinformatics. The Pittsburgh greenhouse will conduct research on proteomics, bioinformatics, gene therapy, diagnostics, and bio-nanotechnology. The central Pennsylvania greenhouse will focus on biotech drug design and delivery techniques, implants, and bio-nanofabrication.

New Jersey and Rutgers University, and the Lewis Thomas Molecular Biology Laboratory at Princeton University. In other forms of state support, the New Jersey state pension fund has begun making investments in biotechnology firms, and the state has enacted several tax credits that benefit biotech and other high-tech companies.

In Delaware, a consortium of state government, higher education institutions, and biotech companies was formed in 1999. This Delaware Biotechnology Institute opened a research facility in 2001 in the Delaware Technology Park, adjacent to the University of Delaware's campus in Newark. The institute provides research facilities and offers educational programs in the sciences and in the business aspects of biotechnology. The institute focuses on biotech applications in agriculture, biomaterials, human health, and marine ecosystems. In addition to funding the institute, the state of Delaware invests in biotech firms through several venture capital funds. Delaware also offers tax credits to businesses that engage in R&D in certain fields, including biological sciences, beyond the credits available for other types of industrial research and development.

OUTLOOK FOR THE BIOTECHNOLOGY INDUSTRY

Most industry analysts expect strong growth in the biotechnology industry in terms of both number of new products and revenue. Cancer has emerged as a major target of biotechnological research. Around half of the 500 drugs expected to be in development during 2002 will be aimed at treating a range of cancers.[21] Developments in proteomics are stimulating much of this work.

Another stimulus is the national effort to develop and stockpile vaccines and medicines to cope with biological terrorism. Short-term efforts to defend against bioterrorism are focused on developing vaccines and antibiotics to treat such diseases as anthrax, plague, and smallpox.[22] But longer term, there will be an increased effort to develop means of detecting and responding to bioterror attacks based on DNA testing and bio-nanotechnology. In an effort to speed up the testing process, biotech firms will develop genetically appropriate organisms for drug trials. In addition, decoding the genomes of disease-causing bacteria and viruses will receive greater emphasis.

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Some public policy issues might affect biotech R&D in medicine, chiefly stem cell cloning and patent protection for biotechnology products. The biotechnology industry generally supports the current voluntary moratorium on attempts to clone a complete human being, but it opposes total restriction on cloning human stem cells.[23] With respect to patenting, Congress is considering changes to U.S. patent law that will promote biotech research on a wide scale while providing effective patent protection to developers of new biotech products. The biotechnology industry favors maintaining and strengthening patent protection of modified genes and other biotechnological products. Areas where biotech patent protection might be vulnerable, according to industry organizations, are generic biotech products and the timing of patent protection during the drug approval process.[24] Specifically, the industry argues that the long lapse between the application for a drug approval and commercial introduction of a drug reduces the amount of time the patent protects the product once it is on the market.

In agricultural biotechnology, consumers' attitudes toward genetically modified foods might hinder further development. To date, genetically modified foods have gained acceptance among U.S. consumers, but they have been less well received in Europe. Surveys indicate that when consumers are aware of the desirable characteristics possible through genetic modification, they are more likely to have positive attitudes toward genetically modified foods.[25] Some agriculture industry analysts speculate that a dual market for foods may develop, in which consumers will tend to choose either genetically modified foods or nonmodified foods.[26] Such a development might ensure a continuing market for genetically modified foods, but the costs of segregating modified and nonmodified foods from farm to table is currently estimated to be almost prohibitively high. Working in the opposite direction, however, is the increasing effectiveness of genetic modification in reducing food-production costs.

With respect to the industry's structure, some maturing is in prospect.

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[21] See Frank DiLorenzo's *Industry Surveys*.

[22] See Pharmaceutical Research and Manufacturers of America, 2002.

[23] See Biotechnology Industry Association, 2001.

[24] See Biotechnology Industry Association, 2002b.

[25] See U.S. Department of Agriculture, 2001b.

[26] See the article by Nicholas Kalaitzandonakes.

Interest in the industry is growing among venture capitalists, institutional investors, and large pharmaceutical firms. Although early-stage investments will still be important to young biotech firms, more and more biotechnology companies have amassed sufficient capital and personnel to bring new drugs to market without the need for alliances with major pharmaceutical firms. Thus, an increasing number of biotech firms will remain independent of pharmaceutical companies as they expand from research into manufacturing and marketing. At the same time, mergers and alliances between biotech firms, rather than between biotech and pharmaceutical firms, are likely to become more common. Nonetheless, major pharmaceutical firms are expected to retain an interest in alliances with biotech companies in order to ensure themselves of a continuing stream of new products and to complement their own biotechnology research.

In agricultural biotechnology there has been an increase in vertical combinations of firms. For example, chemical companies and other biotech firms have merged with or acquired seed companies to obtain sources of seeds for modification and sales channels for modified seeds. In addition, high levels of research expenditure, the need to protect intellectual property rights, and increasing globalization of the agriculture industry in general have fostered increases in joint ventures, licensing agreements, and strategic alliances among biotech and traditional agricultural firms. These trends are expected to continue.

SUMMARY

The biotechnology industry is advancing rapidly in its ability to develop new medicines, diagnostic methods, and agricultural products. It is also growing as an industry. Capital investment in the industry is forecast to increase sharply, and as more new products are brought to market over the next several years, the industry is expected to experience strong revenue growth. More companies as they grow will add production and marketing to their research and development efforts. Nevertheless, rapid advances in the life sciences that support commercial applications of biotechnology will mean that research remains a large and vital activity for successful biotech firms.

In the region, the well-established biotech presence should continue to grow. Public and private efforts in the region to further stimulate the industry are expanding. Particularly important, according to industry analysts, is a strategy for taking research discoveries on to successful product launches. This process of commercialization is a focus of state government and other efforts to encourage the industry here. The region is a biotechnology wellspring, and private and public interest in biotechnology in the region should ensure its continued success.

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