BIOTECHNOLOGY INDUSTRY STUDY REPORT 1996

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ABSTRACT

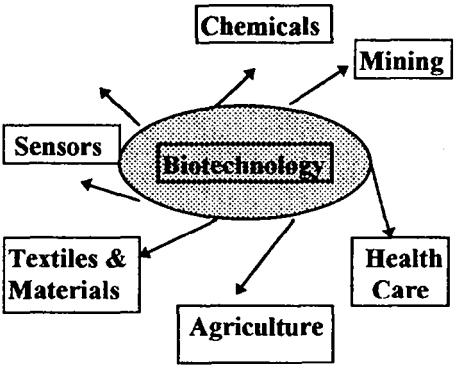
Biotechnology products and processes are revolutionizing the health care, agricultural, industrial chemical, environmental, and other fields. This young, risky, multidisciplinary industry holds endless promise for spin-off products, manufacturing processes in other industries, and sustainability for the future. Biotechnology is niche oriented, geared toward developing high-technology, high-quality, and less expensive products for mankind. Its potential military applications range from biological defenses to new protective materials. The United States leads the world in biotechnology, but the industry is at a critical point in its development cycle and needs continued support for basic research. Just one new discovery can completely change the structure of the industry.

As a result of the biotechnology industry's work, one day in the future a child will receive an AIDS vaccine as a part of her normal pediatric vaccination program, a farmer in Arizona will grow corn in the middle of the desert, and in New Jersey an old industrial site will clean itself for later reuse as a residential area. In the biotechnology industry, the future is limited only by the human mind and financial risk.

INTRODUCTION

The purpose of this report is to describe the applications, condition, and trends of the biotechnology industry against the background of national security requirements and military surge and mobilization needs. To study the industry, we used Caves's (1992) structure, conduct, and performance analysis methodology and Porter's (1990) standards of competitive advantage as appropriate.

THE BIOTECHNOLOGY INDUSTRY DEFINED

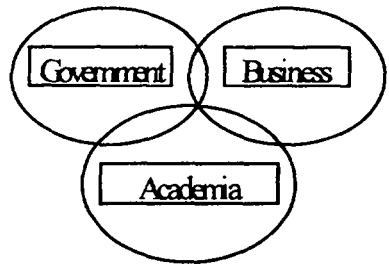


Biotechnology uses living organisms and their products for industrial applications. It combines bioscience principles with multiple current technological disciplines to produce a variety of products and services for society. As the above figure shows, many diverse industries are applying biotechnology as a manufacturing process, and many more will do so as the field gains in experience and knowledge.

Just as the product areas that employ biotechnology are diverse, the industry's structure spans the government, private, and academic sectors. The government has been credited with starting the industry through National Institutes of Health (NIH) grants. Federal and even state government interplay in the industry has been substantial. From funding basic and advanced research to regulating product and process quality standards, the government has a vital role. Universities provide the seeds of new ideas and, through technology transfers, pass innovative projects on to business. Business selects the projects, takes the research through its full development, and finally brings it to the marketplace.

As the figure to the right illustrates, these sectors intertwine because the dynamics of the knowledge base and fluidity of funding sources force close interaction.

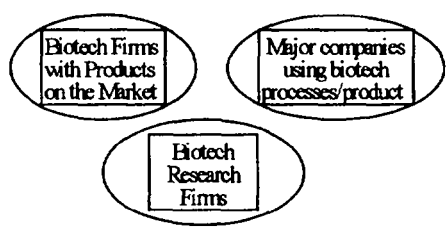
Biotechnology Organizational Interface



Classical biotechnology was first practiced thousands of years ago with the brewing of beer and baking of bread. Yeast acted as the catalyst to alter the organic structure of the compounds into drinkable or edible products. The 1953 discovery of DNA, combined with the recent development of a rapid DNA reproduction process known as a polymerase chain reaction (PCR), changed biotechnology forever. Today, it is a highly sophisticated, collaborative, multidisciplinary scientific field with a fundamental focus similar to that of its ancient predecessor: using living organisms to produce new, enhanced, or less expensive products.

CURRENT CONDITIONS

Biotechnology Industry Structure



Biotechnology formed as an industry in the early 1980s as the growth of small, highly competitive firms drove them to expand their research ideas in focused laboratories. Once its potential captured the interest of financial investors and big business, the industry began to segment into supported product areas. As the above figure indicates, the industry includes biotechnology firms with products on the market (eight companies, such as AmGen, Genentech, Biogen, and Genzyme), biotechnology research firms (such as Advance Tissue, MedImmune, and the Salk Institute), and major corporations in product areas using biotechnology in some portion of their manufacturing processes (for example, Smith Kline Beecham, Novo Nordisk, and Procter and Gamble).

Though a considerable amount of technology is transferred among the segments (since biotechnology processes can be applied to many products), the industry does not lend itself to traditional forms of evaluation. Rather,

the end-product markets greatly dictate the industry's condition. Below we provide an overview of the industry and describe in greater detail the top three market segments, which make up more than 95 percent of today's biotechnology industry.

General

The industry as a whole remains risky as many of the products move from the research into the development phase of their life cycle. Today, more biotechnology products have either reached the market or are quickly approaching it. The all-important survival index of small, medium, and large biotechnology firms has declined. In 1995, these firms had about one-half as many months of operating capital at the average rate of use as they did in 1993, averaging 16 months of operating capital. In addition, as Table 1 shows, the rate at which the industry is obtaining patents remains high but is flattening. Strategic alliance (both national and international) has become a significant form of financing for smaller biotechnology firms. This demonstrates that larger, major firms, which are more risk conscious and business oriented, see great promise for biotechnology in the marketplace.

Table 1. Biotechnology Patent Submissions, 1988-95

Year	Patents	Year	Patents
1988	72	1992	225
1989	115	1993	251
1990	134	1994	250
1991	157	1995	203

Source: Department of Commerce, U.S. Patent Office.

Biotechnology is among the most highly regulated sectors in the U.S. industrial base. The U.S. Food and Drug Administration (FDA), Department of Agriculture (USDA), and Environmental Protection Agency (EPA) multilaterally or unilaterally regulate the quality of products and manufacturing processes. The need for safety and efficacy in its products also places biotechnology among the most research and development (R&D)-intensive industries in the United States. With a $7 billion annual R&D investment that averages $68,000 per employee,

biotechnology's financial payback period must be viewed in terms of many years--possibly two decades. This aspect of the industry makes the role of patents and intellectual property rights protection extremely important in a company's ability to achieve its return on investment (ROI). As noted earlier, the government is an integral player in all facets of the industry.

All segments of the biotechnology industry are sophisticated. Technological processes such as DNA mapping, cell production, protein purification, and gene expression require complicated support equipment and facilities managed and operated by personnel with graduate and postgraduate education. The industry also is linked directly with the information/computer industry, which made possible the complicated algorithms and statistical analyses necessary to identify gene function and location.

The industry's clustering validates Porter's theory of competitive advantage, as a significant number of firms are located in New England, Southern California/San Francisco, and Maryland because the computer industry and major university and government (NIH) centers with biotechnology expertise are located in these areas. The need for close cooperation, information sharing, and virtual integration among biotechnology firms also encourages close proximity. Canada, which has an agricultural cluster in Saskatchewan, further illustrates this logic. All firms gain a competitive advantage from such arrangements.

Overall, the United States clearly leads the world in most statistical indicators for biotechnology (number of firms, dollars invested, value of sales), but other nations have an interest in the industry and possibly advantages in certain niches. Their focus, however, tends to be different. Rather than investing in basic or early applied research, European and Japanese companies have waited until later in the development process to compete, possibly because of more restrictive procedural laws governing biotechnology or government and economic conditions that are not conducive to entrepreneurial firms and venture capital. Nevertheless, foreign companies actively ally with U.S. firms to license technologies or acquire smaller U.S. biotechnology firms. International competition also exists and will likely intensify as new products approach the marketplace.

Finally, the biotechnology industry is not amenable to the use of sales data as a valid measurement of success. To date, only a few biotechnology firms have become profitable, and it is very difficult to obtain sales data on a process industry. Moreover, in many cases, biotechnology serves as a cost-avoidance technique rather than a producer of new-product sales. At this stage, accomplishments with regard to patent and development milestones are better measures of industry status than sales are.

Health Care and Pharmaceuticals

The majority of biotechnology firms and the greatest financial investment occupy the health care and pharmaceuticals segment of the industry. Of the 1,308 U.S. biotechnology firms, about 900, or 70 percent, are in health care-related areas. In addition, 80 percent of federal biotechnology investment goes to health care or related projects. Although sales are not a completely reliable measure of the industry, 1995 sales in this segment were estimated at $8.2 billion. Certain analysts predict 13 percent and 9 percent average annual growth rates over the next 10 years in human therapeutics and diagnostics, respectively.

As shown in Table 2, this segment is characterized by a low seller concentration of many small firms. A few breakthrough firms are market leaders but still do not have sufficient power to affect market dynamics. The soaring growth of biotechnology company start-ups in the 1980s and early 1990s has steeply declined, from 42 in 1994 to only 9 in 1995. The fear of health care reform and price controls may have affected the start-up rate, but the low number of new firms could also be a sign of near seller saturation, investment financiers move away from riskier early research firms and toward applied research companies, or both. Strategic alliances, up 62 percent in 1995, show that the major pharmaceutical firms are now interested in biotechnology companies' products. This interest could significantly affect the structure, conduct, and performance of the industry.

Table 2. Health Care Biotechnology Firms:

Size by Number of Employees and Earnings of Leading Firms, 1995

No. of Employees	Percent of Firms	Firm	Sales (millions of $)
Less than 50	37	AmGen	1,550
51-135	33	Genentech	601
136-299	18	Genzyme	290
More than 299	12	Chiron	276

Source: Ernst & Young, 1995.

Buyer concentration presents a more complicated picture. Many of the smaller biotechnology firms sell intellectual property rights or licenses to produce, and the buyers for such products consist largely of major pharmaceutical firms. The biotechnology firms were able to reap handsome rewards for their intellectual property, but it is unclear whether or not they will be able to continue to do so. Otherwise, the buyers of biotechnology products are either health care professionals or individual patients. In these cases, product differentiation allows the sellers almost to dictate prices.

More than the other segments of the biotechnology industry, the health care segment has focused on new products rather than on improved or less expensive products. To do so, the firms built niches based on staff expertise in immunology, parasitology, virology, and other disciplines. Their focus on niche products, supported by patent protection, gives them a monopolistic capability to set prices for their products. Direct competition among firms exists to a limited degree (being the first to market a product and producing an effective product take precedence)--but it is more the exception than the rule.

At the basic research level, there are almost no barriers to entry, given a highly skilled, technically educated work force. However, carrying a product forward into development calls for significant financial resources. The long FDA approval process requires firms to have substantial staying power (and operating capital) while awaiting their ROI. Also, the need for on-hand manufacturing plant and process prior to FDA approval increases sunk costs. As a result, barriers to entry at the development phase in the product cycle can be extremely high.

Overall, health care and pharmaceuticals remains a risky segment. Only 5 of 4,000 products ever reach the market. The average cost of a new drug exceeds $200 million, and a new vaccine costs over $400 million.

Small firms are reaching a tenuous point in their cash flow: more companies are within one year of exhausting their funds. During 1995, major pharmaceutical companies invested roughly $4.7 billion in smaller biotechnology firms. Without this capital, many companies might not have survived. On the other hand, more biotechnology health care products are in FDA clinical trials than before, with an appropriate growth of products in the later Phase III stage (the top 158 publicly traded health firms have 127 products in this phase, of a total of 450 in trials).

Agriculture

Financially, the agricultural segment of biotechnology is significantly smaller than the health care area. In 1995, approximately 8 percent of biotechnology's $7 billion investment funding went into agriculture. Its projected sales for 1996 were modest at $285 million. At the end of 1995, 10 "agbio" products had received U.S. regulatory approval for commercialization. According to some analysts, this sector has greater potential to expand in terms of product sales than the health care segment does. Robert Fraley, president of Monsanto, believes that the sector will see sales of about $2 billion in five years with another $6 billion by 2005. Other, more conservative analysts predict an average annual growth rate of 20 percent in product sales from $285 million in 1996 to $1.7 billion in 2006. In any case, since agriculture represents 15 percent of U.S. GDP and $40 billion in exports, biotechnology will likely enhance its favorable prospects.

The seller concentration in the agricultural segment began as it did in health care, with numerous small firms. Over time, however, the number of firms declined along with investor enthusiasm. A philosophy of incremental improvement to lower crop production costs and increase yield did not attract investors, so corporate takeovers or affiliations reduced the participants. Today this segment comprises only large chemical and seed companies and a few remaining biotechnology firms. Buyer concentration is also high because farmers, who are not as plentiful as before, are the major customers, not grocery shoppers. This balance between sellers and buyers has made for a relatively even playing field in terms of market and price dynamics.

Definitive economies of scale and high firm concentration preclude the easy entrance of new players. For example, four firms supply more than 60 percent of corn seed. This power gives the firms the ability to set prices below small firms' profit lines or dump for a period to force out the financially weak.

Products are clearly differentiated as traditional and bioengineered crops--the latter carry enhanced survivability while reducing the need for pesticides. These production enhancements, which also lower costs, get farmers' attention, but for the most part they are invisible to the public. Product and process regulation in this segment remains within the purview of the FDA and USDA.

The agricultural segment appears sound and on the brink of profitability. The original biotechnology firms that innovated the ago products, however, will not likely see a return on their investment. Rather, the big seed firms will probably continue their buy-out strategy to ensure that no new competition arises. Because of the continuing population explosion, these firms fully expect a profitable future.

Chemical

The third area of biotechnology that has sufficient maturity to identify a quantifiable production is the chemical community and its product of industrial enzymes. This segment has fewer biotechnology firms and investment--between 4 and 5 percent--but it is the most profitable area today.

The seller concentration for widely used enzymes is high, with two firms dominating over 90 percent of the market. Novo Nordisk, a large chemical-based firm, moved into biotechnology to maintain its leadership role. Genencorp, a start-up biotechnology firm, found the right niche early on. In both instances, these firms acquired others to help them maintain their dominant positions.

Buyers in the chemical segment are highly concentrated because they are also major producers within several industries. Among them are Levi in textiles, Procter and Gamble in soaps, and Kraft in foodstuffs. This concentration makes for a somewhat balanced market arrangement.

Industrial enzymes producers compete against each other because there is only slight product differentiation, mainly in quantity of output. Truer competition occurs in this segment; being the first to patent and market is a key milestone toward success.

Barriers to entry are currently prohibitive to other firms. Novo Nordisk and Genencorp own such a large share of the market and achieve such precise economies of scale that there is no room left for other firms. One $7 billion company abandoned its pilot enzyme program once it realized the size of its competition's share. Until a dramatic breakthrough discovery occurs, this market belongs to the two firms.

Biotechnology within this segment was incorporated as a mainstream process, and it has greater potential in the future as new applications become known. Though the smallest in market size, it is the most stable.

Remaining Segments

The remaining areas that have active biotechnology programs, such as bioremediation of waste products and areas, forensics, biosensors for diagnostic purposes, textile fabric enhancement, and mineral extraction, do not yet approach market scale. They represent the next sectors that should break through and should be closely monitored. Some analysts predict a 19 percent average annual growth in product sales between 1996 and 2006 for the specialty areas of biotechnology, including industrial enzymes.

CHALLENGES

Biotechnology's youth and highly technical nature bring many inherent challenges to its success.

Technical Risk

The industry incurs an extraordinarily high technical risk of failure, particularly within the health care segment, for the following reasons. First, although the knowledge base grows daily, scientists have only begun exploring aspects of the human genome, and many proteins have yet to be discovered. Also, work with living organisms raises legal and ethical complexities. Third, the business must creatively coordinate multiple disciplines to identify, develop, and manufacture a product. .Finally, the government enforces safety and efficacy standards that severely restrict product-to-market ratios. All of these factors make biotechnology heavily R&D oriented, a signal of high technical and financial risk.

Financial Risk

The financial risk for the biotechnology industry is about as high as the technical risk, because very few stand-alone biotechnology firms have made a profit. They still thrive on borrowed money in many different forms. Government grants, venture capital, initial public offerings, and corporate partnerships are all mechanisms for obtaining financial capital, but it can cost hundreds of millions of dollars to bring a product to market in this highly regulated field. The survival index (months of available cash on hand) is low, and smaller firms in the health care segment are at serious financial risk. Many have only one or two products in the pipeline, and if the FDA denies approval of the products, the firms have no reserve. If they survive this stage, they must still survive the possible acquisition plans of major firms trying to consolidate their market position. The small firms thus have a difficult near-term future.

Ethical, Legal, and Social Issues and Public Awareness

Another challenge for both government and industry lies in the ethical, legal, and social implications of certain biotechnology research paths and products. In some areas, the science is outpacing the policymakers' ability

to gauge community standards and ensure the protection of individual rights and privacy. While detection of certain birth defects in unborn children has become widely accepted and commonplace, positive genetic engineering of embryos for certain desired characteristics (e.g., eye color, sex, height, and intelligence levels) has not yet been addressed by policymakers. Issues surrounding insurance companies and employers use of information gleaned from testing for genetically inherited diseases and conditions, such as Huntington's disease and breast and ovarian cancers, are already on U.S. lawmakers' agendas. Procedures developed in the future could cause an upheaval in the U.S. ethical, legal, and social fabric. This problem is compounded by the public's lack of understanding of biotechnology.

The challenge is twofold: industry must act responsibly and cautiously and market itself to gain public trust, and federal policy and legislation need to anticipate issues and appease potential fears. Several European countries have enacted laws, for example, ensuring nondiscrimination by health and life insurance companies on the basis of genetic information.

Regulatory Matters

The FDA has been under constant pressure to reform its procedures and improve the timeliness of the drug approval process. The industry wants greater consistency, consumer advocacy groups want shortened approval times, and the federal government wants reduced health care costs. The FDA's current efforts to reduce the backlog include the critical-product designation, which places a higher priority on certain products, and the pilot test on charging user fees as a way of funding additional staff. While these efforts represent some progress, they will probably not satisfy the interest groups.

Biotechnology lobbyists have a bill in Congress that would (1) contract out product reviews, (2) eliminate the approval process for standard medical devices, (3) allow the export of non-FDA-approved items to foreign countries that accept the products, and (4) harmonize FDA standards with international standards. In the end, the FDA will be forced to further streamline operations without losing its purpose of approving high-quality, safe products. A more "risk-based" model with greater predictability rather than individual evaluator interpretation may grow out

of the effort. In any case, the changes will significantly affect biotechnology.

Continued Supply of Well-Trained Workers

This sophisticated industry requires a highly educated and trained work force. However, educational trends in the United States point toward a decline in students' knowledge of sciences, and an NIH study concluded that only 20 percent of Americans have sufficient knowledge of scientific terms and procedures to understand research vital to their own health. As for knowledge of biotechnology itself, a Minnesota school system poll showed that 78 percent of junior high and 55 percent of high school science courses did not contain a biotechnology module. The FDA's standards for good laboratory and manufacturing practice usually demand a 12- to 18-month apprenticeship.

As biotechnology expands in the future, where will the needed work force, especially at the technician level, come from? The greatest challenge will be in implementing biotechnology education: what should be in the curriculum, how teachers should be trained and retrained, and whether the schools will develop partnerships with industry .

Intellectual Property Rights Protection

Finally, the industry generally relies heavily on the protection of intellectual property rights. Patent acceptance is the first milestone that can lead to financial reward in the form of outside funding and provides the incentive for firms to develop products because they have a better chance of recouping sunk costs with patent protection.

Certain patent issues remain unresolved. For example, serious questions concerning the exhaustion of patent rights and "patent stacking" could compromise aspects of patents' value. Supplemental patent protection may be warranted to offset delays in FDA approval. Implementation of the General Agreement on Tariffs and Trade is critical to the effectiveness of patents and some firms' survival.

OUTLOOK

Because of youth, sophistication, and volatility of the industry and its science, the future characteristics of the biotechnology industry are difficult to predict with confidence. Revolutionary and innovative applications for biotechnology continue to be generated based on a single recent discovery--PCR--and more discoveries are expected in the future.

Near Term (Zero to Five Years)

In the next five years, the biotechnology industry could look much like that of today. Products should continue to move through development and enter the marketing and production phases. Many biotechnology health care firms may still be operating without a profit, but the first profitable year will be just on the horizon. Agricultural firms should realize profits as their newly developed products achieve market acceptance.

The biotechnology industry will also be more prone to employ greater business sense in its practices. New start-ups and older firms will tend to be equipped not just with top-notch scientific staffs, but also with professional business people who can advise firms on better product management and reduction of financial risk. Unrest may grow among market leaders (major pharmaceutical and chemical firms) as the smaller firms start to reach the market. Strategic alliances and buy-outs may increase as a means for the big firms to maintain leadership, which could lead to a reduction in the number of firms doing only biotechnology work. Firms that approach niche markets or outsource into virtually integrated conglomerates will be at lower risk. Efforts to bring about greater public awareness will have begun, with industry and government providing informational references. Public laws addressing biotechnology uses and information could be in place but will not have been fully tested in the court system.

Long Term (to 2020)

We expect that by 2020 biotechnology will be a mainstream element of manufacturing in the world's industrial base. Multiple product lines, including those not yet started, will employ principles of biotechnology. Predicting the conditions of such a young, science-oriented industry,

however, is highly speculative, and analysts disagree in their forecasts. Much of the debate centers on differing assumptions about how mature the industry is today and whether or not it will continue to be highly innovative to 2020.

Analysts who see the industry as maturing today believe that by 2020 a significant reduction of firms will take place--a sign of maturity. Under this scenario, larger but profitable firms will dominate all the traditional biotechnology markets. Universities and small firms will serve R&D roles because their scientific skills and low overhead provide them with a competitive advantage in this area. Major firms will form partnerships with these institutions to keep their competitive edge. Other analysts, however, see the biotechnology industry as still very young, with vast possibilities for breakthroughs and discoveries that could cause numerous new start-ups and product developments. Each new discovery could also generate new stand-alone "survivor" biotechnology companies. These analysts do not see the industry maturing in a classical pattern because of its closeness to its highly scientific roots and the spikes in the industry's development and in the number of firms caused by even small discoveries.

By 2020, public and judicial forums will likely have addressed policy and legislative issues, and biotechnology's role will have been accepted. Health care reform will have occurred, and the FDA will have streamlined its processes. Settling these issues will provide clear signals to the industry and allow firms to make consistent business decisions.

National Security Resource Requirements

Biotechnology undoubtedly will be employed in the production of military hardware. The chemical-biological warfare defense initiative alone has applications in biosensors and vaccine/drug development that use biotechnology. Biotechnology is also used in the military's identification of human remains. General medical, food-processing, textile, and environmental control products are dual-use commodities that have military applications. In addition, energy, advanced materials, and computer technology could easily be using biotechnology processes by 2020. Thus, for the military, biotechnology has strategic importance.

The development of this new industrial base buttresses another pillar in the nation's overall security structure: economic growth. Economic might will be crucial in the next century, so any market segment that enables or substantially contributes to U.S. economic growth must be considered strategic. As a process technology, biotechnology will have a multiplier effect on other industries. A strong biotechnology industry brings growth in financial resources and an elevation of the technology, the quality of employment, and educational bases.

Certainly, the health and quality of life of the U.S. citizen is an important component in the nation's security, and biotechnology shows great promise in this regard. Health care improvements, greater and more secure food production, and less expensive, high-quality products all contribute heavily to the country's welfare.

Finally, biotechnology plays a role in foreign policy that affects the United States' ability to ensure its security. Whether in the form of direct business relations or as a part of foreign aid, the United States can export products and processes from the health care and food production segments of biotechnology that could significantly improve conditions in many troubled nations. In this role, the United States could be seen as a provider of hope and stability.

At the more detailed level of military mobilization and surge, biotechnology does not correct all the problems in the industrial segments it affects, and it may raise new risks in some instances. As a new industry, biotechnology will apply new business management practices that closely size plant capacity, staffing, and inventories to market requirements. As such, the industry is not generally amenable to achieving economies of scale through high-quantity production. Additionally, the FDA approves products to be manufactured only at a certain production rate. Any change requires recertification, which is a lengthy process (possibly over 18 months). As a result, the military cannot expect the industry to carry much excess capacity that could later be filled with mobilization orders. Current technology does not allow for easy switching of products within plants; normally, plants are dedicated to a single product. Over time, greater flexibility is expected, but the current situation limits the ability to surge production when mobilization requires. The industry provides high-quality, high-technology products but does not have the dexterity to

expand quickly. A mobilization deficiency will exist unless the military takes measures to offset purely civilian market factors.

No unusual issues emerge from a review of the military's acquisition system and its interface with biotechnology. As stated, biotechnology heavily emphasizes R&D, and the federal and military laboratory system is currently under close scrutiny. These labs are performing biotechnology research, but the majority is outsourced to businesses and universities.

GOVERNMENT GOALS AND ROLE

The federal government should monitor and, if necessary, assist any industries that are strategic to the nation's welfare. The biotechnology industry falls within this category now and will become even more important in the future. Government actions that will support the long-term health of the industry are described below.

Ethical, Legal, and Social Issues

Federal legislation is required to address biotechnology uses and genetic information. Certain biotechnology research directions, processes, and products could raise explosive issues regarding the nation's social fabric, its values, and even the environment. Such questions include discriminatory use of genetic information by insurance companies and employers, and genetically engineered children. One path is to follow the lead of several European nations, such as Italy, France, and Norway, which have forged national legal positions on the application of biotechnology. The U.S. government should avoid, however, the procedural restrictions in place in many western European nations, especially Germany. These restrictions could cripple the industry and rob the nation of the many benefits of biotechnology.

Targeted Nurturing

As a fledgling strategic industry, direct government funding could greatly help shore up the biotechnology base and foster growth. For example, the government should step in where market forces are not adequate. Venture capitalists have moved into the applied research area, so basic research may be underfunded. The government should maintain a solid stream of

grant funding for basic research through the executive departments. The current tax credits for R&D must continue, but they tend to use sales as a criterion for receipt. Some smaller biotechnology firms may realize that they cannot become producers and therefore revert to pure research concerns, minimizing their sales. The tax credit law could be interpreted or changed to favor these firms.

Sensible Regulatory Reform and International Trade Agreements

The three regulatory agencies that overlap in governing the industry should improve interagency coordination on matters affecting biotechnology companies. At a minimum, a joint committee with members from the FDA, USDA, and EPA could clarify responsibilities and establish consistent guidelines. In addition, trade negotiations and implementation of the resulting agreements are essential for maintaining the integrity of intellectual property rights. Loss of biotechnological property to piracy could devastate the industry. Therefore, the government must remain engaged in protecting intellectual property rights in international trade agreements.

Partnership for an Educated Public and a Well-Trained Work Force

Finally, the government needs to form partnerships with industry to better educate the U.S. public on biotechnology. The effect could be twofold: first, a public that will support biotechnology uses and, second, a technically competent, high-value, basic work force. The state of Wisconsin's model program, which could be emulated on a national basis, includes teacher education workshop programs, hands-on partnerships within science classes, World Wide Web information pages, and a two-year biotechnology associate degree program. A key focus for such programs should be educating future workers at the technician level.

Focused Military Investment and Adjustment to a New Production Process

The growth of biotechnology can significantly benefit the military. If government research grants support the industry's general well-being and state of the art, the military needs to focus on more specific requirements. The military will need to make the cultural adjustment from traditional

R&D and production methods (e.g., for vaccines) to a newer, untested process (e.g., recombinant vaccines). But, on the whole, biotechnology promises better-quality products. At the project or materiel level, biodefense vaccines against biological war agents, human tissue replacement for burn victims, and biosensors for chemical and biological agents are on the brink of development. Military R&D and procurement funding should bring them into the inventory.

Additionally, the military laboratory system needs close scrutiny to validate its usefulness. Its flexibility (that is, whether it has the dexterity to keep up with modern technology) and breadth of focus concern some military customers. We recommend a serious examination of the benefits of having firms compete for or outsourcing some of the research being performed in the military laboratory system.

CONCLUSIONS

Biotechnology is a strategic industry that supports the nation's security and the military's resource mission. This young, process-oriented industry has a multiplier effect because it crosses several traditional product industries in introducing new products, increasing quality, or reducing costs. It provides the nation with economic growth in a new sector while modernizing older industries to give the United States competitive advantages. The industry's economic gains, quality-of-life enhancements, and potential as a foreign policy tool make it a key industry that should receive carefully targeted government support.

Today's industry structure is reaching a crucial point. Smaller firms' financial risk is bringing them to the brink of failure. They are easy targets for cash-rich pharmaceutical, chemical, and seed companies. Larger firms could buy up those firms with "good-potential" products, seriously increasing the seller concentration. On the other hand, new discoveries could cause flurries of start-up companies. Many of the smaller biotechnology firms must decide what their product is: intellectual property rights from R&D or manufactured biotechnology products

The government, in consultation with industry, needs to explore a rational legal framework concerning the uses of biotechnology products and

processes and the information they yield so that privacy and ethical issues do not derail the industry's progress.

The military will benefit from the growth of biotechnology into other disciplines, but the civilian market cannot support all military applications. The military must make wise R&D and procurement decisions to foster those areas most critical to their needs. Most important, biotechnology is not inherently capable of surging for mobilization.

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