# THE U.S. POLICY CONTEXT AND BIOTECHNOLOGY: An Exploration of Two Current Issues

A Report to JETRO-New York

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March 15, 2003

**_Technology Policy International_**
*www.technopoli.net*
*An International Consultancy with Representatives in Boston, Washington, Silicon Valley and Tokyo*

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## Preface

This report was commissioned by JETRO-New York in 2002 to examine two important influences on the development of biotechnology: public research funding in the area of biodefense, and the pattern of human resource mobility in American high technology sectors. Undertaken by the authors as independent consultants in the firm of Technology Policy International*, the work and its findings derive in significant part from their experience in government, the private sector and academic life. The opinions herein do not necessarily reflect the views of JETRO-New York or the institutions with which the authors are affiliated.


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## 1. INTRODUCTION: THE SOCIETAL AND POLICY CONTEXT FOR TECHNOLOGY DEVELOPMENT

The process of technology development is as much a societal phenomenon as a technical one. In the U.S., the institutions that pursue scientific inquiry and technology commercialization – universities and private firms overwhelmingly -- have become highly attuned to societal needs, particularly as expressed in public policy. A clear pattern of demand and response can thus be seen throughout the post-World War II period, in which American academe and industry have provided human resources, scientific research and technology development for large-scale public policy initiatives in areas as diverse as defense, space, health, the environment or biotechnology. The current imperative of homeland security – particularly biodefense – will undoubtedly call forth the same kind of response, assuming public policy provides the appropriate resources and direction.

The ways and formats in which science, engineering and technological innovation unfold are also highly conditioned by social structures, which are in turn deeply rooted in history and culture. While the U.S. has traditionally been a flexible, mobile and entrepreneurial society, the last 25 years have witnessed the unfolding of a number of new social patterns that are particularly important for technology development. A tendency toward technical cooperation – across universities, industry and government, and among firms – has become strongly apparent. New talent – to a significant extent female and foreign-born – contributes new perspectives and dynamism to the science, engineering and business community. And the creation of new technology-based firms, coupled with the challenges to established institutions, has created a milieu of both entrepreneurship and change.

The U.S. biotechnology sector – the subject of this report – clearly exhibits these general trends. It is hard, if not impossible to envision U.S. biotechnology absent a base of public research funding – either historically or today. Or without other public policies – regulation, intellectual property, technology transfer, and investment incentives – that have played an equally vital role. It is just as hard to imagine the industry outside of the context of start-up firms, spin-offs from universities, corporate acquisitions, venture capital, and the constant entry of new personnel, often from abroad.[1]

The purpose of this report is to address – in the particular context of biotechnology – how two factors affect the process and context for technology development: public policy, notably current policies and proposals directed at "biodefense;" and the human resource situation in the biotechnology sector. In the Chapter 2, federal government support for biodefense research is discussed. Although this is very much still an "emerging picture," the general shape of federal policy in this area, along with how it is likely to affect biotechnology can be ascertained to some degree. In Chapter 3, patterns of professional education, employment and mobility relevant to the U.S. biotechnology industry are surveyed and/or discussed. The numbers of technically skilled people available to the industry, the openness of the social and human resources system, and a case study of the San Diego biotech complex are all discussed as explanatory factors in the biotechnology industry situation today. Chapter 4 offers conclusions from the preceding analysis.

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[1] The development of the U.S. biotechnology sector and the influence of public policy throughout its history are discussed in detail in Policy Innovation: The Initiation and Formulation of New Science and Technology Policies in the U.S. During the 1980s, A Report to JETRO-New York and NEDO-Washington by Technology Policy International, March 2000. (Available at www.technopoli.net)

# 2. FEDERAL SUPPORT FOR BIODEFENSE RESEARCH: AN EMERGING PICTURE

## 2.1 Introduction

Since the attacks of September 11, 2001, and the attack on leading American institutions by the still-unknown person or persons who mailed anthrax spores, the U.S. government has substantially increased its interest in and commitment to research in various fields related to biodefense. National interest in biodefense has been reinforced by concerns that the Iraq government might have developed bioweapons that it might use in the event of an external invasion or internal upheaval, by indications that the Al Qaeda network might have bioweapons, and by a variety of smaller scale bioweapons attacks known to have been attempted over the years by non-governmental groups.

This section offers an overview of the state of federal biodefense research funding, the current debates about future funding, and the nature of the responsible federal institutions. It begins with a description of the kinds of research that might be considered as within the domain of "biodefense" research. It then turns to a discussion of the recent politics of biodefense research in the context of the larger political debates over homeland security and the federal budget. Next, we provide information about biodefense research funding programs that are now in place and those that are expected to emerge over the next few months. We end with a few observations on the impacts that biodefense initiatives might have on the biotechnology industry in the United States.

## 2.2 The Scope of Biodefense Research

Research related to biodefense might address a wide variety of topics, including but not limited to the fundamental molecular biology of pathogens and disease processes, biosensors and other methods of detection of pathogens in the environment, development of vaccines or of treatments for diseases, mechanisms of disease transmission, the epidemiology of infectious diseases, and improved strategies for evacuation of areas that have come under attack. If one takes a systems approach to biodefense, it is clear that there are important uncertainties at many points of the system that research could help address. It is also clear that many fields and disciplines can contribute to biodefense issues that are not strictly-speaking "biodefense" or infectious-disease related. For example, the development of new sensors for detecting the presence of pathogens in the environment is a top priority that may involve materials science, electronics, and computational methods in addition to microbiology. Similarly, modeling the transmission and spread of pathogens may involve computational modeling of the movement of air masses, social models of the interaction of people, transportation modeling of how infected people may move in space and time, etc.

Biodefense has a closely related "dual," or complementary domain; namely, biowarfare research. The United States ended its program of research on methods of waging biowarfare in 1969. Such work had been carried out in the US Army Medical Research Institute for Infectious Diseases (USAMRIID) at Fort Detrick, Maryland. After 1969, however, the scope of work at USAMRIID was limited to understanding how to defend against biological attack.

Because biowarfare and biodefense had not been high priority topics prior to the anthrax attacks in October 2001, the capacity of the country to conduct research in such fields was limited. Very few specialized facilities appropriate for the conduct of research on the kinds of pathogens that might be weaponized exist in the nation. Such work should be conducted in highly secure environments (e.g., so-called Biosafety Level III or even IV laboratories.) Few such labs exist in the United States. Even fewer exist with the capability to do experiments with such diseases on large live animals that can serve as surrogates for humans, such as other primate species.

Likewise, few scientists in the United States are expert on the set of pathogens most likely to be used in bioattacks, and the experience of the American medical communities in dealing with outbreaks of such highly contagious diseases as smallpox, ebola and Marburg disease is very limited.

Furthermore, since smallpox was "eradicated" in the 1970s and since most of the other dread diseases that might be used as bioweapons rarely occur naturally, there has been very little commercial demand for products and protocols that could be used to treat such diseases. In fact, in the absence of an actual bioweapons attack, it is clear to many observers that the private sector has almost no incentive to invest in biodefense research or in developing and producing products useful in coping with dreaded diseases, such as vaccines or antibacterials. The administration's "Bioshield" initiative (see Section 2.4) addresses the lack of commercial incentives by offering guaranteed markets for biodefense products under certain conditions.

In light of the paucity of experience, expertise, and facilities to do biodefense research in federal laboratories, academia, and the private sector, a key focus of the President's proposed research agenda for biodefense has been to construct new facilities in which such research can be performed and to extend the breadth of bidefense-related expertise (see section 2.4).

A key aspect of biodefense research is that modern methods of genetic engineering now make it possible for a determined adversary to modify the genetic make up of existing pathogens in such a way as to enable those pathogens to infect people who have previously been immunized against their natural forms. Such genetically modified pathogens may also be resistant to standard treatment methods, where such methods even exist, and they may make it difficult to use established means to sense their presence in the human environment. This aspect of molecular biology means that research in biodefense may need to address an ever-evolving range of threats--the problem of biodefense will not be "solved" any time soon. Furthermore, it has been claimed by Ken Alibek, for example, that genetic engineering now makes it possible to engineer new pathogens resistant to vaccines or antibiotics much more quickly than medical researchers can discover and develop new treatments or new vaccines. This suggests that the traditional strategies for coping with infectious diseases; namely, vaccines and antibiotics, may not be sufficient to defend against a determined and sophisticated adversary.

Finally, it should be noted that testing the safety and effectiveness of vaccines against, or treatments for, weaponized biological products and diseases poses a special challenge for researchers. Ordinarily, new medical treatments, such as drugs and vaccines, are subjected to rigorous development and testing, first in animals and then in human volunteers. Testing proceeds carefully and sequentially through a series of tests that are designed to maximize learning while minimizing the risks of harm to human subjects. Developers must demonstrate both safety and efficacy before commercial production and distribution can begin. This is ordinarily a process that takes years to complete and costs hundreds of millions of dollars to conduct. In the case of defense against bioweapons, however, a key obstacle exists to the standard model of development and testing. It is highly unlikely that American society would wish to expose human volunteers to diseases that have a high fatality rate, such as ebola or tularemia, or that can kill or leave victims disfigured or diseased for life, such as smallpox. Thus, in the absence of a clear national threat, such as a direct bioweapons attack, there is no way to test such substances according to traditional protocols. This has led to a growing recognition that testing such substances on non-human primates may be the principal gatekeeper over which substances are developed, produced and stockpiled for use in case of attack.[2]

2.3 The Politics of Biodefense Research Funding

Biodefense is part of a larger domain of public policy that is highly unsettled and in which progress has been much less rapid than the national concern over the potential of a biologically based attack might suggest. The national determination to give new emphasis to defense against biologically based weapons and to the field of "homeland security" more generally has encountered two major obstacles that have slowed progress and left many issues unresolved.

The first obstacle is the general debate over federal spending that has dominated the first two years of the Bush administration. The second is the politicization of the proposal to establish a new cabinet level Department of Homeland Security that became the central focus of the 2002 congressional election campaigns. These two issues combined to forestall congressional agreement on the Homeland Security bill until near the end of calendar year 2002, and to delay action on most federal FY2003 appropriations acts until after the new Congress convened in early January 2003. Because only one of the traditional thirteen appropriations acts--the act to fund the Department of Defense--was completed before the end of the congressional session in December 2002, most programs proposed for FY2003, including those in biodefense, were

[2]See Jennifer Couzin, "New Rule Triggers Debate Over Best Way to Test Drugs, " *Science*, Vol. 299, 14 March 2003, pp. 1651, 1653.

not funded until the passage of the Omnibus Appropriations Act in late February 2003, nearly five months into the fiscal year.

The high visibility and considerable importance of the Bush administration's war on terrorism at home and abroad might suggest that the Administration would aggressively encourage Congress to provide generous funding for the agencies whose programs are relevant to that war effort at home. This has not, however, been the Administration's stance, especially regarding homeland security. Instead, the Administration, in concert with the conservative leadership in the House of Representatives has been focused at least as much on holding down the growth in "domestic discretionary spending" and on providing a large, new cut in taxes as it has on providing new funds for biodefense. "Domestic discretionary spending" includes funds for most programs related to biodefense other than those in the Department of Defense. In the 106$^{th}$ Congress, which adjourned in late November 2002, the Senate, which was then controlled by the Democrats as the majority party, had generally adopted appropriations bills to fund the government in FY2003 that would spend about $13 billion more than the Republican-controlled House was prepared to spend. The President supported the House Republican position.

Ordinarily, it would be expected that the House and Senate would come to compromise positions on the appropriations bills and pass them into law prior to the beginning of the fiscal year on October 1. However, owing to the anticipated closeness of the congressional elections of November 2002, neither side had an incentive to arrive at such agreement before the elections. In the campaign, the Democrats tried to use the failure to agree on spending as an indication that the Republicans were unsuccessful in "running the Congress" in a business-like fashion, while they hoped as well to enhance their strength in Congress so as to force their spending priorities through after the election. The

Republicans hoped, on the other hand, for a stronger congressional position to force their (lower) spending priorities through in the same way. Gridlock resulted. (It is important to point out that the federal government continued to spend money in the new fiscal year in general under the provisions of several so-called "continuing resolutions." This mechanism held all agencies to spending levels no greater than that of FY2002 until new appropriations acts were passed into law. Because spending for biodefense was budgeted for considerable growth in FY2003 over 2002, the continuing resolution meant that such growth was postponed.)

As it turned out, of course, as a result of the November 2002 elections the Republican position was enhanced in the House, and they also assumed control, although by a narrow margin, in the Senate. Soon after the election, the House leadership stated its very strong determination not to increase spending for FY2003 above the President's requested levels. This statement exposed a rift among the House Republicans: the leadership favored tight limits on spending whereas the chairs of the appropriations subcommittees typically favored more generous spending, even among Republicans.

Even when the appropriations bills for FY2003 finally became law, they provided funding increases only for the seven months remaining in the fiscal year. Thus, biodefense-related programs will receive their anticipated growth in spending authority very late in the fiscal year, at least a half year later than could reasonably be expected.

The debate over the establishment of the Department of Homeland Security (DHS) also took a very long time to resolve as a result of the proposal having been tied up in an election year political battle over what many observers believe was a relatively peripheral issue. When it was first proposed by Senator

Lieberman, Democrat of Connecticut, in the spring of 2002, the Department of Homeland Security idea was opposed by the Bush Administration. In ensuing months, however, the Administration had a change of heart, or at least of political strategy. It turned around sharply and endorsed the concept of the Department, at least in part owing to the political firestorm that erupted over the apparent incompetence of the early federal responses to the challenge of improving airline security after September 11. As it endorsed the DHS, the Administration added a subtle but politically important proviso regarding the authority of the President to reorganize the new Department, to reassign its personnel, and to waive various civil service protections enjoyed by those employees in the interests of national security.

The President's position on managing the personnel of the proposed new DHS drew fierce opposition from labor unions representing federal government workers, from other elements of organized labor in their support, and from their Democratic friends in Congress. Labor's position was that the reorganization powers sought by the President, along with powers he sought to reassign staff in the interests of national security, amounted to a major assault on the job protections of the federal work force in general and on the unions of federal employees in particular. Democrats in Congress took the position that they would support and vote for all other aspects of the President's Homeland Security bill but would not vote for it so long as it included the reorganization and reassignment powers he demanded. Owing to this sharp difference of view, the narrow majorities of each party in the House and Senate, and election year politics, an impasse was reached. As a result, the Homeland Security act did not pass the Congress until after the election in early December.

The Homeland Security act as passed is only an authorization act--without a companion appropriations act, none of the new programs included in it or funding it authorizes can be put in place. As of this writing (March 2003), no new appropriations for homeland security have been passed. It is expected that a "supplemental" appropriations act will be sought by the President in the next few weeks, both to fund the war in Iraq and to fund some of the new programs in Homeland Security.

It is reasonable to ask why, if the challenge of homeland security and the threat of terrorist attack are as great as some say they are, did Congress and the President not set aside relatively petty differences of view over personnel management in the new department so they could act to put in place the essential new Department to manage the national response? There are several possible explanations. Perhaps the most likely explanation is that the formation of the Department of Homeland Security is largely a symbolic response to these national threats. It is largely a plan to reorganize existing agencies and programs of government, augmented by the new Transportation Security Agency, which has already been put in place using other authorities. The real addition to the ability of the federal government to enhance homeland security by forming the Department is marginal, relative to the ability of the government to mobilize already existing agencies, including those that will join the new department, in pursuit of this objective. Thus, more important than the delay in forming the new department was the delay in appropriating funds to pay for new domestic preparedness activities already conceived of and ready for implementation in the existing agencies and departments.

Soon after the new Congress convened in January 2003, it was widely reported that the first item of business would be to act on the twelve domestic appropriations bills that had not yet been decided on for FY2003. Action before January 20 was promised at one point. However, that was before the presumed incoming Republican Senate Majority Leader, Trent Lott, got in political difficulty over his remarks at the Strom Thurmond retirement party. Several weeks of organizing and decision-making were lost in his unsuccessful struggle to survive as leader, and more time was lost as Senator Frist, the new Majority Leader, assembled a new team before being able to assert control.[3] There were also disputes in the Senate concerning the allocation of memberships to committees and the hiring of staff, because the Republican majority was so slim (51-48 with one Independent who votes with the Democrats making the margin 51-49). Resolving these differences delayed the appropriations even further. The Omnibus Appropriations Act for FY2003 did not pass and become law until the end of February 2003.

As soon as the FY2003 appropriations process was completed, both houses of Congress reorganized their appropriations committees and both created new subcommittees on homeland security to provide for coherent consideration of the budget of the new Department of Homeland Security, which was made up from a number of agencies that reported to a number of different appropriations subcommittees. This action should enable relatively effective consideration of budgets for DHS in FY2004 and beyond.

2.4 Current Biodefense Research Programs

Like so much of Federal R&D funding, support for research in biodefense is scattered through several Federal agencies, including the National Institutes of Health, The Centers for Disease Control, the Department of Defense, the Department of Homeland Security, the Department of Energy, the National

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[3]Important to biodefense, Senator Frist is a physician who, as a US Senator, has spoken out strongly on the challenge of biodefense to the nation. Following the anthrax attacks in October 2001, he published a popular book on bioterrorism, *When Every Moment Counts*, Rowman and Littlefield Publishers, 2002.

Science Foundation, the Environmental Protection Agency, and so on. However, NIH and DOD have the bulk of this responsibility at the moment.

One of the compromises made in setting up the new Department of Homeland Security was that the biodefense research programs of NIH were not transferred to the new DHS.[4] This represented a major decision in financial terms, because NIH is currently in the midst of conducting a major competition to fund construction and/or operation of several new centers for advanced biodefense research at universities, consortia of universities, and other entities. This program was intended to address the problem of insufficient and inadequate facilities for biodefense research as well as to jump start new research activities. Approximately $1.7 billion was set aside in the NIH FY2003 budget for the National Institute for Allergy and Infectious Diseases to fund these centers. At this writing, the competition for these funds has closed, but awards have not yet been made.

The rationale for not transferring the NIAID program to DHS seems clear enough--major progress in research on bioweapons will require deep engagement of all of the scientific capabilities of NIH and its many grantees in universities and elsewhere. Splitting this activity off and transferring it to DHS would have enforced an undesirable separation from the rest of NIH.

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[4]DHS is organized into five major administrative units, each reporting to an under secretary. From the perspective of research, the most important is the Directorate for Science and Technology. According to the DHS web site, "under the direction of Under Secretary Designate Dr. Charles McQueary, this Directorate will coordinate the Department's efforts in research and development, including preparing for and responding to the full range of terrorist threats involving weapons of mass destruction." See http://www.dhs.gov/dhspublic/display?theme=9. Accessed March 23, 2003.

At the same time, the new DHS will pay significant attention to biodefense. The official position of the S&T Directorate of DHS is that, "One priority of the Directorate will be to sponsor research, development, and testing to invent new vaccines, antidotes, diagnostics, and therapies against biological and chemical warfare agents."[5] The specifics of the research programs of the new DHS have not yet been announced. In its FY2004 budget request, DHS asks for "$365 million for the development of biological countermeasures to reduce the probability and impacts of a biological terrorist attack."[6] Furthermore, one of the features of DHS is that it has taken over control from the Department of Agriculture of the Plum Island Animal Disease Center,[7] which has the responsibility to ensure that animals used in agriculture are free from infectious disease. Some months are likely to pass before the S&T Directorate is sufficiently staffed and organized to develop and promote a new research agenda in detail.

DOD conducts research in biodefense through a DARPA program in biodefense as well as through the US Army Medical Research Institute for Infectious Diseases (USAMRIID) at Fort Detrick, Maryland. The DARPA program funds research conducted at universities, federal laboratories and industry, whereas USAMRIID conducts research in its own facilities. The Defense Threat Reduction Agency, DTRA, also has responsibilities in the field of biodefense, as it does for all weapons of mass destruction.

Two important sources of up to date information on federal biodefense R&D programs are the National Institutes of Health (NIH) and the American

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[5] See: http://www.dhs.gov/dhspublic/interapp/editorial/editorial_0095.xml. Accessed March 23, 2003.

[6] AAAS R&D Funding Update, "Department of Homeland Security Opens Doors, Proposes $1.0 Billion for R&D," March 4, 2003.

[7] See: http://www.ars.usda.gov/plum/. Accessed March 23, 2003.

Society for Microbiology (ASM). Within NIH, responsibility for most programs explicitly named as biodefense programs lies in the National Institute of Allergy and Infectious Diseases (NIAID).

NIAID offers a comprehensive overview of its own programs on a web site at: http://www.niaid.nih.gov/dmid/biodefense/.

ASM has prepared a comprehensive summary of such funding proposals for FY2003 on the Web at: http://www.asmusa.org/pasrc/biofunding11602.pdf. ASM also maintains a useful Web site featuring the most recent announcements of new programs at: http://www.asmusa.org/pasrc/biofundopp.htm.

In early February 2003, President Bush announced Project "BioShield,"[8] a comprehensive effort to develop and make available modern, effective drugs and vaccines to protect against attack by biological and chemical weapons or other dangerous pathogens. Among other activities, BioShield will provide authority to agencies to purchase improved vaccines and drugs for dread diseases likely to be used in biowarfare, and it emphasizes expanded programs of research support on biodefense in the NIAID.

2.5 Impacts of Biodefense Initiatives on the Biotechnology Industry

The history of breakthroughs underlying the biotechnology industry in the United States is one in which fundamental research carried out largely in response to challenges in human health has proven after the fact to yield important new capabilities that can be exploited in the biotechnology industry

[8]See: http://www.whitehouse.gov/news/releases/2003/02/20030203.html

for applications not only to human health but to agriculture, industrial processes, and a range of other industries. To the extent that research to combat bioterrorism yields another stream of new fundamental understanding it will undoubtedly prove useful to the biotechnology industry more generally.

As noted earlier and in other reports by Technology Policy International for NEDO and JETRO, the American research system is exquisitely responsive to changing national needs and priorities, motivated heavily by new money and by new opportunities to work on challenging problems whose solutions "matter" to society. Biodefense now takes its place as a focus for the very best scientists to explore an entirely new area of concern. Money is likely to flow from the federal government relatively generously into this field, which is almost certain to produce both new practical treatments and preventatives, and also to produce unanticipated new understanding that can be exploited for commercial purposes.

There is, of course, the possibility that research in biodefense, or, what's much worse, an actual biological warfare attack on the United States, could sour the public's enthusiasm for biotechnology in general. Biotechnology promises great benefit but also contains the chance for great harm. Dr. Frankenstein is never far from the public mind when biotechnology is concerned, and the kinds of research done in the name of biodefense can raise the specter of great unanticipated negative consequences. In this sense, the biotechnology industry is put at some risk by a focus on bioterrorism and biodefense, although most would agree that such a risk simply must be assumed in the interests of national defense.

# 3. HUMAN RESOURCES AND BIOTECHNOLOGY IN THE U.S.

## 3.1. Section Introduction

The U.S. biotechnology industry has grown rapidly in recent years. Yet it has not encountered significant shortages of trained people – either scientists with Ph.D. degrees or other skilled professionals with masters and bachelors degrees. Why does the United States have adequate numbers of professional workers for this rapidly growing industry? And what have been the consequences of this situation for individuals, universities, companies, and the U.S. economy in general?

This section of the report addresses these two questions, and it is organized as follows:

- This section first presents data on employment and employment growth in the U.S. biotechnology industry. Employment in the U.S. industry has grown rapidly.
- Next, what basic conditions – that is, what key features of U.S. economics, society, culture, and policy – have led to the presence of large numbers of skilled biomedical professionals in the United States? Important factors include generous U.S. funding for biomedical research, a world-class university system, and the ability to recruit increasing numbers of American women and foreign students.
- What additional set of conditions in the U.S. enables the biotechnology industry to recruit and effectively use large numbers of these biomedical professionals? Key factors here include both policies and a culture that encourage entrepreneurship.
- We then present a brief case study to illustrate how these various basic conditions contribute to a vibrant U.S. biotechnology industry. The case study is San Diego, California, now home to one of the country's largest clusters of biotechnology companies.
- We next offer some conclusions about human resources in the U.S. biomedical field and the biotechnology industry.

- And, finally, this section discusses some of the consequences of this situation in U.S. biotechnology human resources for individuals, for universities, for the national economy, and for U.S. regional economies.

## 3.2 Employment and Employment Growth in the U.S. Biotechnology Industry

The biotechnology workforce in the United States has grown rapidly in recent years. And since biotechnology is a "knowledge-based" industry – crucially dependent on having adequate numbers of highly skilled people – then the availability of these people is undoubtedly a key factor in the industry's growth and success.

### *3.2.1. The Biotechnology Workforce*

There has been relatively little analytic work done on the U.S. biotechnology work force. There is also no clear definition of what constitutes either biotechnology or the biotechnology workforce. New biotechnology (as opposed to old biotechnology like fermentation) has usually meant technologies based on genetic engineering. Now however, a large range of technologies is included under biotechnology. The Biotechnology Industry Organization defines new biotechnology as the use of cellular and molecular processes to solve problems or make products.[9] Examples include:

- Monoclonal Antibodies
- Cell Culture
- Cloning
- Recombinant DNA
- Protein Engineering
- Biosensors
- Tissue Engineering

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[9] Biotechnology Industry Organization, *BIO's Editors' and Reporters' Guide to Biotechnology 2002-2003,* Washington, http://www.bio.org.

- Nanobiotechnology
- Microarrays

Biotechnology tools such as genomics, proteomics, stem cell culture, and bioinformatics can also be considered part of biotechnology.

Biotechnology workforce data is limited by several factors. First, government data related to the science and engineering workforce (such as the National Science Foundation's SESTAT statistics) are generally collected by disciplines (e.g. biological sciences) rather than by industry or technology. Second, as discussed above, the scope of the biotechnology industry is difficult to define precisely and is constantly changing as new technology are developed and as "old" industries, such as pharmaceuticals, chemicals, and agriculture increasingly use biotechnology tools. Third, the workforce needs change rapidly as companies shift from primarily research companies to product development companies. As a result, this analysis is based both on industry data from non-governmental sources (Biotechnology Industry Organization, Ernst& Young), as well as some government data on the most closely related academic disciplines (e.g., biological sciences).

#### *3.2.2. Biotechnology Industry Workforce Data*

The U.S. biotechnology industry has grown quite rapidly. Table 1 and Figure 1 show that the number of employees has grown from 79,000 in 1992 to 191,000 in 2001. Sevier and Dahms project that the biotechnology industry workforce will grow to 500,000 by 2012.[10]

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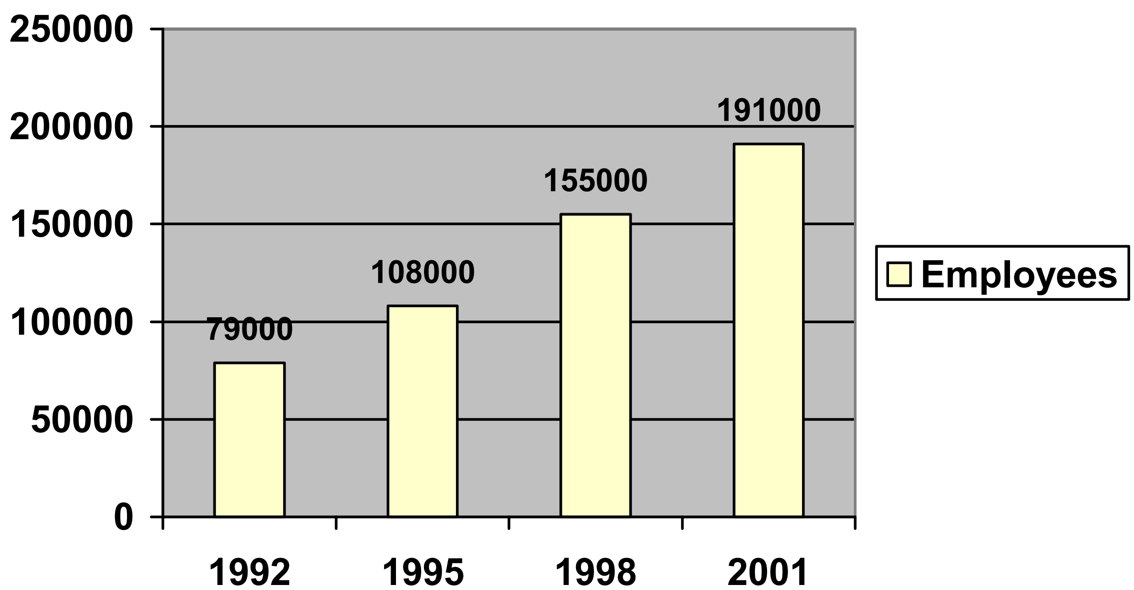
[10] Seveier, E. Dale, and A. Stephen Dahms, "The Role of Foreign Worker Scientists in the US Biotechnology Industry," *Nature Biotechnology 20*, 9 (September 2002), 955-956, http://www.nature.com/cgi-taf/DynaPage.taf?file=/nbt/journal/v20/n9/full/nbt0902-955.html.

**Table 1. Biotechnology Industry Statistics: 1992–2001***

| Year | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 | 2001 |
|---|---|---|---|---|---|---|---|---|---|---|
| Sales* | 5.9 | 7.0 | 7.7 | 9.3 | 10.8 | 13 | 14.5 | 16.1 | 19.3 | 20.7 |
| Revenues* | 8.1 | 10 | 11.2 | 12.7 | 14.6 | 17.4 | 20.2 | 22.3 | 26.7 | 28.5 |
| R&D Expense* | 4.9 | 5.7 | 7.0 | 7.7 | 7.9 | 9.0 | 10.6 | 10.7 | 14.2 | 15.7 |
| No. of Public Companies | 225 | 235 | 265 | 260 | 294 | 317 | 316 | 300 | 339 | 342 |
| No. of Companies | 1,231 | 1,272 | 1,311 | 1,308 | 1,287 | 1,274 | 1,311 | 1,273 | 1,379 | 1,457 |
| Employees | 79,000 | 97,000 | 103,000 | 108,000 | 118,000 | 141,000 | 155,000 | 162,000 | 174,000 | 191,000 |

*Amounts are U.S. dollars in billions.
*Source*: Ernst & Young LLP, annual biotechnology industry reports, 1993–2002.
Financial data based primarily on fiscal-year financial statements of publicly traded companies.
http://www.bio.org/er/statistics.asp

**Figure 1. Number of Employees in the U.S. Biotechnology Industry**

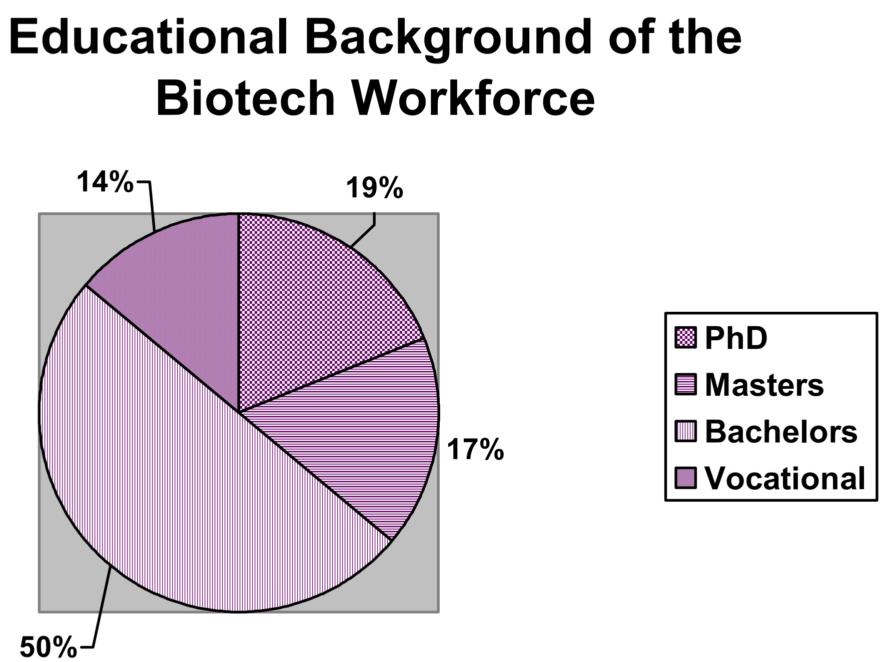



*Source*: Ernst & Young LLP, annual biotechnology industry reports, 1993–2002.
http://www.bio.org/er/statistics.asp

#### *3.2.3. Educational Background of the U.S. Biotechnology Industry Workforce*

As one might expect, the biotechnology industry workforce is highly trained. The workforce is estimated to be 19 percent Ph.D., 17 percent masters, 50 percent bachelors, and 14 percent vocationally educated or community college trained.[11] Figure 2 summarizes these data.

**Figure 2.**




*Source:* Dahms, Stephen A, "Workforce Development: A Key to Biotech Regional Competitive Advantage," *Bio/Medical Synergies,* Summer 2000, 10-11.

### 3.3. Basic Conditions Affecting Numbers and Skills of Biomedical Professionals

Three basic conditions have led the United States to produce a large number of highly skilled biomedical professionals. One important point is that

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[11] Dahms, A. Stephen, "Workforce Development: A Key to Biotech Regional Competitive Advantage," *Bio/Medical Synergies,* Summer 2000, 10-11, and Seveier, E. Dale, and A. Stephen Dahms, "The Role of Foreign Worker Scientists in the US Biotechnology Industry," *Nature Biotechnology 20,* 9 (September 2002), 955-956.

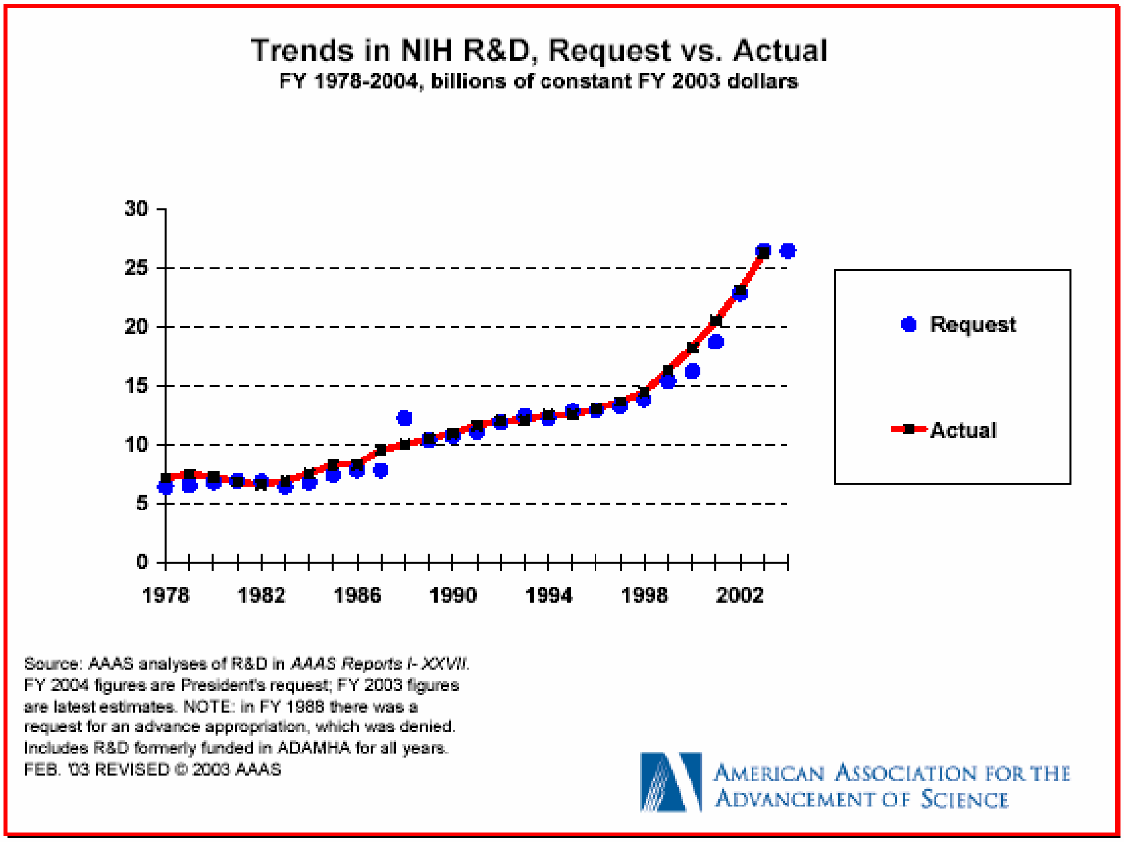
not all of these biomedical professionals want to work in the biotechnology industry. However, in a later part of this section we will see that another set of conditions has made it possible for the industry to attract the numbers and types of skilled people that it needs.

### *3.3.1. Large Amounts of Funding for Biomedical Research and Training*

In the United States, graduate students preparing for Ph.D. degrees receive much of their training in laboratories run by research professors. The more funding that is available for university biomedical research, the more graduate students and post-doctoral fellows that the universities can train. And in recent years the amount of funding available in the U.S. for biomedical research has skyrocketed.

While private foundations fund some biomedical research in the U.S., most university biomedical research funding comes from the federal government, particularly the National Institutes of Health (NIH). For fiscal year 2003 – the current federal fiscal year – Congress provided $27.2 billion to NIH. Figure 3 shows how much the NIH budget has increased in recent years. In approximate terms, the NIH budget has doubled over the past five years. Most of this growth occurred before the recent increase in NIH's biodefense budget. Both Figure 3 and Figure 4 come from the American Association for the Advancement of Science (AAAS).

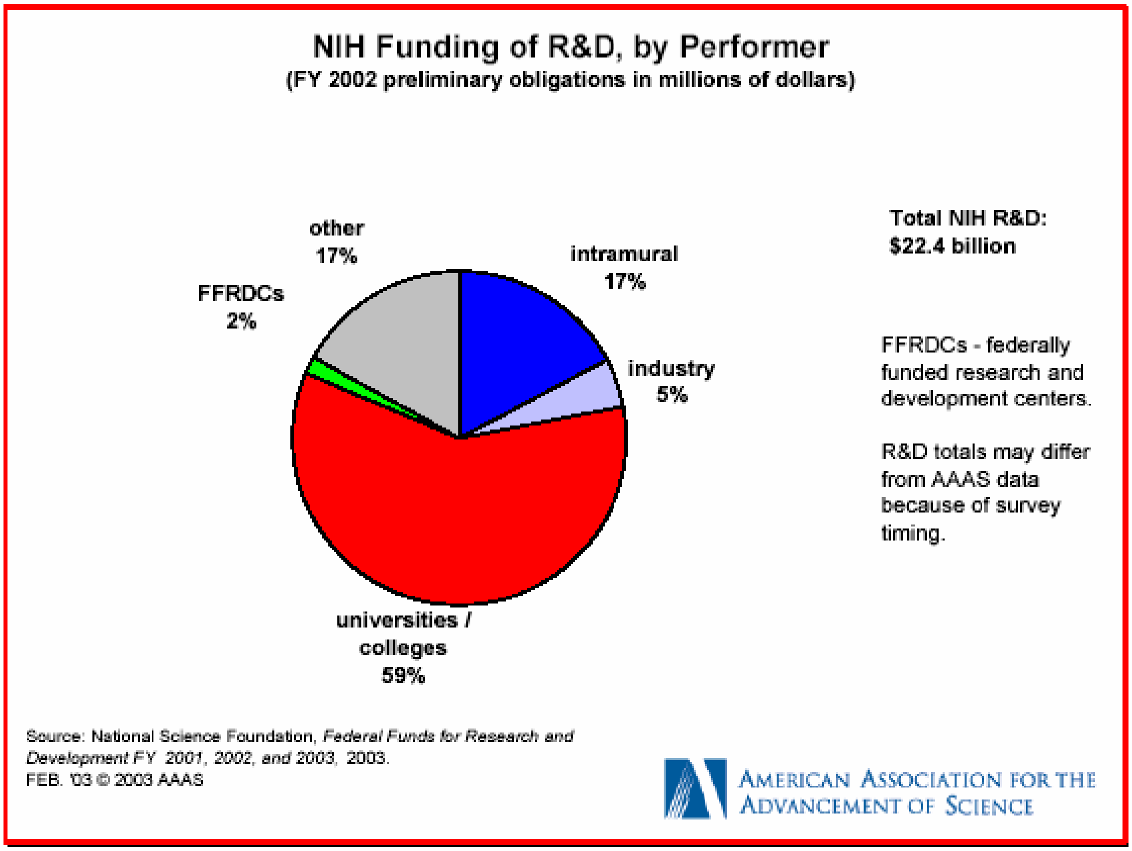
**Figure 3. Trends in NIH R&D Funding**




*Source:* AAAS, http://www.aaas.org/spp/rd/nih03f.pdf

As shown in Figure 4, nearly 60 percent of NIH's funds for fiscal year 2002 went to universities and colleges, and much of the funding in the category called "other" went to non-profit institutions that conduct research similar to that performed within universities. In short, in recent years a great deal of NIH money has gone to support biomedical research and the associated training of graduate students and post-doctoral fellows who work in university research laboratories.

**Figure 4. NIH Funding of R&D, by Performer – Fiscal Year 2002**




*Source:* AAAS, http://www.aaas.org/spp/rd/nih03f.pdf

### 3.3.2. *A World-Class University System*

The American university system that NIH and private foundations support is world-class at both research and training. As a result, it attracts bright and highly motivated faculty and students, and it produces skilled and professionally flexible graduates. This is important to the U.S. biotechnology industry because that industry draws heavily on university research and university-trained researchers.

The U.S. university system in biomedicine is strong for several reasons:

- As discussed earlier, the university system is well-funded. That funding supports many research professors, provides for state-of-the-art laboratories, and helps train many graduate students and post-doctoral fellows. (In the U.S., professors want to have graduate students and post-doctoral fellows in their laboratories because these young people help carry out the professors' research.)

- Money is allocated in a highly competitive manner, through a merit-based review process. While this system is not perfect, money tends to go to high-quality researchers.

- By training graduate students through research apprenticeships under faculty mentors, the U.S. system creates young Ph.D.-degree holders who can conduct their own cutting-edge research. This leads to graduates who are skilled and who can take the initiative in research.

- U.S. procedures for funding and performing university research are highly flexible. NIH, for example, can move quickly into new research areas, such as biodefense, and universities and their entrepreneurial faculty can move quickly to apply for new funds and create university laboratories and centers in new areas of research.

- The high mobility of research faculty in America leads to even more flexibility in the U.S. university research system. In the U.S., professors and other researchers often move within the university world – sometimes because they are forced to, sometimes because they choose to. This mobility allows universities to pick and choose the people they consider best, and gives the overall university research system enhanced flexibility and strength.

This mobility of research faculty results from several factors. In some cases, moving is not voluntary. To begin with, moving away from one's graduate school is generally mandatory. Very few academic departments offer regular faculty positions to their own Ph.D. students. Post-doctoral fellows also experience very high mobility. In addition, faculty members are also usually forced to move if they are denied tenure.

Tenured faculty and even untenured faculty, if they are good researchers, often have optional mobility. Universities compete for the best researchers, and it is not unusual for even a senior professor in biology or medicine to move to another institution. Also, in America professors can stay at one institution but still temporarily reside at other institutions through sabbaticals and visiting professorships.

The skill and flexibility of these individuals – when combined with the ability of funding agencies to support new promising areas of research – leads to an overall U.S. academic research system that is often is both highly productive and highly flexible.

#### 3.3.3. *The Ability to Recruit Students and Faculty Nationally and Worldwide*

U.S. universities are very open to bright people. In recent decades, for example, women students have found it easier to gain acceptance to good graduate schools. And U.S. immigration law – through the J-1 visa process – makes it legally possible for universities to recruit foreign as well as domestic students. This ability to recruit and then train bright students from around the world contributes greatly to both the quality and quantity of skilled university graduates available in the U.S. (Whether U.S. companies can then legally hire foreign nationals who have trained in American universities is a separate issue, one discussed later in this section of the report.) American universities also recruit post-doctoral fellows and faculty from all over the world.

#### *3.3.4. The Resulting Pool of Professionals Trained by U.S. Universities*

The combination of high federal funding, a world-class university system, and a willingness and ability to recruit good students from all over America and the world has in fact led to a significant increase in the number of biomedical professionals trained in American universities. The data we can cite here focus primarily on students who receive Ph.D. degrees.

Over the past 25 years the characteristics of Ph.D. recipients in the biomedical sciences have changed dramatically. From 1977 to 1997, the total number of Ph.D. degrees awarded has increased by 78 percent, the percentage of Ph.D. degrees awarded to women has increased from 22.9 to 42.8 percent, and the percentage of degrees awarded to U.S. citizens has decreased from 82.8 to 63.0 percent. Table 2 summarizes this situation.

**Table 2. Demographic Characteristics of Ph.D. Recipients in Basic Biomedical Sciences**

| | 1977 | 1982 | 1988 | 1992 | 1997 |
|---|---|---|---|---|---|
| Total Number | 3050 | 3444 | 3465 | 4456 | 5420 |
| Percent Women | 22.9 | 29.8 | 36.9 | 38.2 | 42.8 |
| Percent U.S. Citizens | 82.8 | 84.8 | 77.1 | 68.9 | 63.0 |

*Source:* Committee on National Needs for Biomedical and Behavioral Scientists and the Education and Career Studies Unit, National Research Council, *Addressing the Nation's Changing Needs for Biomedical and Behavioral Scientists* (Washington: National Academy Press, 2000).

The growth in the number of Ph.D. degrees awarded in biomedicine is not without controversy. The National Research Council (NRC) found that the number of new Ph.D.s awarded annually in the basic biomedical sciences is well above that needed to keep pace with growth in the U.S. economy. The U.S. biomedical research system generates a large number of Ph.D. scientists who are trained for and aspire to academic positions. Many of these new Ph.D. scientists are unable to find regular academic positions and work for extended periods of time in postdoctoral or other temporary positions. The NRC concluded that research training and overall Ph.D. production in these fields should not be increased. The NRC found, however, that there are enormous opportunities for more broadly trained investigators.[12]

Of course, the biotechnology industry likes having such a large labor pool. It gives them an opportunity to pick and choose among the best students, and the large supply helps keep down average salaries.

### 3.4. Another Set of Basic Conditions: Factors That Enable the Biotechnology Industry to Attract Professionals

As we have seen, the United States trains a large number of highly skilled biomedical professionals. However, how many of these professionals are willing and able to work for biotechnology companies? A second set of basic conditions in the United States has led many skilled biomedical professionals to work in or with biotechnology firms – a fact that has greatly contributed to the growth, flexibility, quality, and success of the U.S. industry.

Here we will look at two ways in which biomedical professionals can contribute to biotechnology companies – as founders and advisors and as employees. We start with the founders and advisors.

#### *3.4.1. Factors That Make Top University Scientists Willing and Able to Help Start New Companies and Work with Established Firms*

Over the past 25 years, the very best biomedical research professors in American universities, themselves an important part of U.S. human resources in this field, have become increasingly willing and able to work with industry. In some cases, they work with established biotechnology and pharmaceutical firms, including by accepting long-term corporate funds to support research in campus

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[12] Committee on National Needs for Biomedical and Behavioral Scientists and the Education and Career Studies Unit, National Research Council, *Addressing the Nation's Changing Needs for Biomedical and Behavioral Scientists* (Washington: National Academy Press, 2000).

laboratories. But the most dramatic and important change is their ability and their growing willingness to work part-time, or a temporary basis, or even permanently to help start or nurture new biotechnology companies. Their increasing job mobility and the associated willingness to play multiple roles are enormous assets to an industry that depends so much on the insights and talents of the country's top biomedical researchers.

American professors, even those working for universities sponsored by state governments, have long had the ability – the freedom – to work with outside organizations. Most U.S. universities allow professors to spend up to 20 percent of their time on outside activities – activities such as consulting, advisory work, and, more recently, start-up companies. Universities also generally allow professors to take temporary leaves of absence, meaning that they can leave the university for one to three years and still keep their jobs. Universities do issue regulations to limit conflicts of interest and conflicts of commitment, but rarely block professors from working with companies. The American system of tenure also plays a role. Once a professor receives tenure – a permanent job – she or he has increased freedom to engage in activities other than writing traditional publications.

But why would a professor want to start a new biotechnology company or help a start-up by serving as a senior advisor? Twenty-five years ago few biomedical professors in the United States wanted to work with start-ups. To work with companies was to leave the path of pure basic research. What incentives led research professors to work with business executives to start companies? Several seem important:

- New pharmaceutical companies can succeed in the marketplace. Drug prices in the United States traditionally have been relatively high. While high prices cause problems for patients, they provide an incentive for both large pharmaceutical companies and biotechnology start-ups to offer new products. Companies with good products can make considerable money. This promise of large profits is a particularly important incentive for the biotechnology industry, because government approval of new drugs can take many years and great investment.

- Individuals who start biotechnology companies in the U.S. can reap great rewards if their companies flourish. First, they can become wealthy: stock options and relatively low U.S. taxes on capital gains offer the opportunity to make money. But for biotechnology professionals, there is also a second important incentive: they can create new products that truly help people.

- Public policies encourage and support entrepreneurship. Along with tax policies, U.S. laws allow people to start companies easily, obtain intellectual property protection for their ideas, and hire employees easily. The Bayh-Dole Act played a major role, by providing universities with an incentive to license promising new biomedical patents.

It is fortunate for the U.S. biotechnology industry that top professors in genetic engineering and other biomedical fields began to respond to these incentives. In fact, the biotechnology industry in America was initially based on a few key research professors.

In the field's early days, in the 1970s and 1980s, very few scientists understood the new technologies of genetic engineering, PCR, and so forth. Lynn Zucker and Michael Darby, social scientists at the University of California, Los Angeles, have documented the important role that academic "star scientists" played in the early years of the industry. When these "stars" decided to start or cooperate with new companies, their contribution was enormous. In one of their papers, Zucker and Darby begin with a quote from Donald Kennedy of Stanford University – "technology transfer is the movement of ideas in people" – and then go on to provide this summary:

> The most productive ("star") bioscientists had intellectual capital of extraordinary scientific and pecuniary value for some 10-15 years after Cohen and Boyer's 1973 founding discovery for biotechnology…. This

> extraordinary value was due to the union of still scarce knowledge of the new research techniques and genius and vision to apply them in novel, valuable ways…. Close, bench-level working ties between stars and firm scientists were needed to accomplish commercialization of the breakthroughs.[13]

Zucker and Darby also note that the early U.S. biotechnology industry grew up around the universities and other non-profit research organizations in which these star researchers worked – locations such as San Francisco, Boston, San Diego, and Washington, D.C. The willingness and ability of these stars to become involved in companies was thus a key factor in the establishment of the U.S. biotechnology industry.

As mentioned earlier, in the 1970s and into the 1980s, the professional culture of U.S. academic scientists favored staying in university research, not helping to start companies. But this culture slowly changed. One of the most famous stories concerns Dr. Herbert Boyer of the University of California, San Francisco, co-developer of the famous Cohen-Boyer technique for genetic engineering. A young business executive named Bob Swanson called Boyer in the early 1970s and persisted in trying to interest the scientist in forming something new, a biotechnology company. In 1976 Swanson and Boyer put together a business plan. The resulting company was Genentech.

The success of Genentech helped changed attitudes within university biomedical departments. By the mid-1990s, the culture had changed from distain for researchers who worked with companies to a new era in which one seemed strange if she or he were not involved with companies.

In these early days of the U.S. industry, professors began either to take leaves of absence to start companies or else to stay in academia but devote that

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[13] Lynne G. Zucker and Michael R. Darby, "Star scientists and institutional transformation: Patterns of invention and innovation in the formation of the biotechnology industry," *Proceedings of the National Academy of Sciences, USA*, volume 93, November 1996, page 12709.

20 percent of their time to serve as company founders or members of scientific advisory boards.

Some professors who left their universities to work full-time in the new companies later returned. One example is Dr. Edward Penhoet, who left the University of California, Berkeley, to help start the successful biotechnology company Chiron and then later returned to Berkeley as Dean of the School of Public Health. After retiring from that position, he moved to a senior position in the new Gordon and Betty Moore Foundation, which supports innovative research. He is an example of a top researcher who moved in ways that contributed to both industry and academia. He is also an example of a new type of American scientist – the person with deep experience in both academia and industry and able to help bridge the two worlds. That kind of expertise and flexibility is another positive result of job mobility.

This mobility by star scientists, and later by university biomedical scientists in general, has played a very important role in the U.S. biotechnology industry. Because people are willing and able to switch jobs or to assume multiple roles – such as professor and company founder at the same time – the industry obtained the expertise and dynamic scientific leadership it needed.

Finally, one other type of labor mobility has become important in the biotechnology industry: employees of early biotechnology companies have gained experience and confidence and gone on to start other firms. Entrepreneurship has bred more entrepreneurship. Genentech's Web site, for example, says with pride: "Genentech has been a breeding ground for many biotech startups. More than 30 biotech companies have come to fruition through the direct efforts of an ex-Genentech employee or currently have high-ranking ex-Genentech people in senior level positions."[14]

#### 3.4.2. *Supportive Policies and Institutions That Help Company Founders*

Of course, just because professors and their business colleagues want to start companies does not, by itself, guarantee that they will succeed or even know much about how to build a company. In the United States, biotechnology entrepreneurs often succeed in part because of the help they received from supportive policies and from specialized experts and institutions. Among the policies and institutions are the following:

- Patent and licensing laws, particularly the Bayh-Dole Act, provide an orderly way to protect intellectual property in biotechnology and other fields and make it available to interested companies. In addition, university technology licensing offices have gradually developed effective ways to license that technology.
- The modern venture capital industry is of course one of the important institutions in today's American economy. Besides providing money, venture capitalists also mentor new entrepreneurs and help recruit experienced managers. Despite the economic troubles of the past three years, the venture capital industry remains a crucial part of the U.S. entrepreneurial world.
- Social networks and business support services have also become very valuable. Entrepreneurs need assistance, particularly new entrepreneurs such as university professors who have never before started a company. The most successful high-technology regions in the United States have developed social networks that can refer new entrepreneurs to mentors, angel investors, venture capitalists, and business support services. Those support services include law firms, accountants, specialized real-estate firms, and public relations firms that can help a new entrepreneur quickly and successfully start a

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[14] http://www.genentech.com/gene/features/25years/biotech-factsheet/index.jsp

company. Several regions in the United States have deliberately tried to develop these social networks and business support services.

#### *3.4.3. Recruiting Biotechnology Employees: For American-born Scientists, Opportunities and Constraints*

We now turn to the question of what conditions enable U.S. biotechnology companies to recruit high-quality professional employees, especially staff scientists with Ph.D. degrees. As noted earlier, many of the students who graduate with Ph.D. degrees would prefer to work in academia. So why have biotechnology companies been so successful in recruiting many of them to work in industry?

First, let us consider U.S. citizens and permanent residents – scientists for whom immigration law is not an issue. Two factors seem particularly important here:

- In the United States, no one who graduates with a Ph.D. degree or who serves as a post-doctoral fellow is guaranteed a professional job within academia. In fact, as discussed earlier, American universities produce far more biomedical Ph.D.s than can find permanent work as professors. Young people compete intensely for the relatively low number of tenure-track university jobs that become available each year. This leaves many young people looking for other employment, and for some biotechnology companies are an important alternative.
- Some young Ph.D.s, including some of the very best, find the corporate world attractive. Salaries are higher than in academia, facilities are often better, the research problems are compelling (such as trying to find cures or better treatments for major diseases), one does not have to apply constantly for research grants, and some people like the opportunity to work full-time on research rather than dividing their time between the laboratory and teaching. Biotechnology companies can be exciting and rewarding places to work.

#### *3.4.4. Recruiting Biotechnology Employees: Immigration Laws Allow Companies to Hire Foreign Professionals*

One of the most important forms of labor mobility in the United States is the ability of companies to hire foreign-born scientists and engineers who do not yet have permanent U.S. residency. In particular, U.S. immigration law provides for a special type of temporary work permit – called an H-1b visa – that enables companies to hire non-residents for up to six years. Through the H-1b process and other immigration paths (such as getting residency because of relatives in the United States), the total number of foreign-born scientists and engineers working in the United States is large and of great benefit to the U.S. economy. In effect, the United States gets many of the world's smartest, best-trained, and most ambitious scientists and engineers.

Some of these foreign-born scientists and engineers working in the United States received their education in America, while others received their educations in their native countries. Whether they are mostly American-educated or overseas-educated varies from industry to industry.

Sevier and Dahms estimate that six to 10 percent of current U.S. biotechnology employees hold H-1b visas. About 80 percent of these biotechnology professionals holding H-1b visas are products of U.S. colleges and universities. This is in contrast to the information technology (IT) industry, where a much higher percentage of H-1b recipients have received the degrees at universities outside of the United States. This difference is consistent with the fact that the biotechnology industry requires longer and more specialized scientific training (reflected in the high employment of Ph.D. recipients) than the IT industry. Sevier and Dahms estimate that 85 percent of biotechnology H-1b holders eventually acquire permanent residency in the United States.[15]

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[15] Seveier, E. Dale, and A. Stephen Dahms, "The Role of Foreign Worker Scientists in the US Biotechnology Industry," *Nature Biotechnology 20*, 9 (September 2002), 955-956

Medical and life sciences, however, account for a relatively small percentage of total H-1b visas, and not all of the medical professionals work in research or biotechnology. The holders of H-1b visas are dominated by computer-related fields, as shown in Table 3.

**Table 3. October 1999 to February 2000 S&E-Related Occupations on Approved H-1b Petitions**

| Occupation | Number | Percent of Total |
|---|---|---|
| Total | 81,262 | 100.0 |
| Computer related | 42,563 | 53.5 |
| Engineering and architecture | 10,385 | 13.1 |
| Education | 4,419 | 5.3 |
| **Medical** | **3,246** | **4.1** |
| Social sciences | 1,963 | 2.5 |
| **Life sciences** | **1,843** | **2.3** |
| Mathematical and physical sciences | 1,453 | 1.8 |
| Non–S&E-related occupations | 15,390 | 18.9 |

*Source:* National Science Board, *Science & Engineering Indicators – 2002* (Arlington, VA: National Science Foundation, 2000). Based on Immigration and Naturalization Service data.

Analysts writing from the biotechnology industry perspective point to the high growth rates of the biotechnology industry, and argue that employment of foreign scientists is essential to meet the skill needs of the industry to maintain this growth. However, as mentioned earlier, the National Research Council has concluded that there are not enough good jobs for all of the American biomedical scientists holding Ph.D. degrees

The number of foreign-born degree holders now working in the United States in biological sciences is similar to the numbers for science and engineering as a whole (see Table 4). Agricultural sciences, which may include some biotechnology, has a lower percentage of foreign-born degree holders than science and engineering as a whole. Twenty-seven percent of doctorate-holders in biological sciences in the United States and 14 percent of master's degrees holders were foreign born.

**Table 4. Foreign-born scientists and engineers working in the United States, by field of highest degree and highest degree level: 1999**
(Percentages)

| Field of highest degree | Total labor force | Bachelor's | Master's | Doctorate |
|---|---|---|---|---|
| All S&E | 12.2 | 9.9 | 19.9 | 27.0 |
| Engineering | 19.8 | 14.6 | 31.1 | 44.6 |
| **Life sciences** | **11.7** | **8.8** | **13.7** | **26.1** |
| **(Agriculture)** | **7.9** | **5.4** | **14.9** | **22.7** |
| **(Biological sciences)** | **13.3** | **10.4** | **14.0** | **27.0** |
| Computer and mathematical sciences | 17.1 | 12.8 | 26.4 | 35.4 |
| (Computer sciences) | 21.1 | 15.2 | 34.3 | 46.4 |
| (Mathematical sciences) | 12.5 | 10.2 | 15.4 | 31.1 |
| Physical sciences | 15.8 | 11.2 | 17.2 | 29.3 |
| Social sciences | 7.5 | 6.7 | 10.0 | 12.9 |

*Source:* National Science Foundation, Division of Science Resources Statistics (NSF/SRS), Scientists and Engineers Statistical Data System (SESTAT), 1999 and *Science & Engineering Indicators – 2002*

### 3.5. A Biotechnology Case Study: San Diego

Much of America's economic growth during the past 25 years has occurred in specific regions of the country, in which "clusters" of research capbilities and high-technology companies have formed.[16] San Diego is one region that has created a major cluster of companies in biotechnology.[17] San

[16] For a good introduction to "cluster theory," see Michael E. Porter, "Clusters and Competition: New Agendas for Companies, Governments, and Institutions," in his book, *On Competition* (Cambridge: Harvard Business School Press, 1998).
[17] The following discussion draws on two reports: (a) Edward Furtek, Mary Lindenstein Walshok, Patrick Windham, Carolyn Lee, Mark Jones, and Sara Burke, "Networks of Innovation:

Diego did not originally have a pharmaceutical industry. It grew one, based on biotechnology. The following factors played a major role:

- In the 1960s, several organizations established biomedical research units on the Torrey Pines Mesa, above the La Jolla section of San Diego: The Scripps Research Institute, the Salk Institute, and the University of California, San Diego. Later, additional groups appeared, such as the Burnham Institute and the Neurosciences Institute.

- Federal funding, especially from NIH, played a major role in building biomedical research in San Diego.

- The region drew heavily – and continues to draw heavily – on talented researchers from around the United States and the world. For example, today many of the graduate students at UCSD and The Scripps Research Institute come from China and other foreign countries and then stay in the United States. And the director of the highly respected Burnham Institute comes from Finland. (He is now a member of the U.S. National Academy of Sciences.)

- In the early1980s, Dr. Ivor Royston, a physician and medical researcher trained at Stanford, and one of his colleagues established San Diego's first biotechnology company, Hybritech. At the time, San Diego had no local venture capital industry, but they drew upon funding from a Silicon Valley venture capitalist. Hybritech became a great success, and Dr. Royston's example inspired other biomedical researchers in the region.

- By the mid-1980s, San Diego's traditional economy of defense, tourism, and banks was suffering. Local leaders saw high-technology industries, including biotechnology, as a possible area of growth. So they created an organization, based at the University of California, San Diego, to provide advice and help for new entrepreneurs. Called UCSD CONNECT, it became a social network that helped many new entrepreneurs.

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San Diego's Telecommunications and Biotechnology Clusters, " a report to the Office of the President, University of California, April 2000, unpublished, and (b) Mary L. Walshok, Edward Furtek, Carolyn W.B. Lee, and Patrick Windham, "Building Regional Innovation Capacity: The San Diego Experience," *Industry & Higher Education*, February 2002, pages 27-42.

- With the help of UCSD CONNECT, other professors became entrepreneurs and began to attract venture capital. Some of these professors were native-born Americans and others were born in other countries. At the same time, Hybritech, like Genentech before it, became a source of entrepreneurs. Former executives of Hybritech started some 50 biotechnology companies in San Diego.

Today, San Diego is one of the four leading biotechnology regions in the United States – along with San Francisco, Boston, and Washington, D.C. Even with the problems now confronting the U.S. biotechnology industry, San Diego remains a major leader in the field.

### 3.6. Some Observations About Human Resources, Mobility, and the Quality and Flexibility Professionals in the U.S. Biotechnology Industry

The data and analysis presented above support the following observations about the U.S. biotechnology industry and its workforce:

- There is a substantial pool of Ph.D. scientists available to the biotechnology industry. The U.S. system of biomedical research generates a large number of Ph.D. scientists. The availability of Ph.D. scientists does not appear to be limiting the growth of the U.S. biotechnology industry.

- The Ph.D.-degreed U.S. biology-related workforce has expanded both due to the use of foreign workers and increasing numbers of women graduate students.

- The U.S. university system is a magnet for attracting foreign talent. Most Ph.D.-level H-1b visa holders in biotechnology received their degrees from U.S. universities.

- The use of H-1b visas appears to be different in the biotechnology industry than in the information technology industry. In particular, there does not appear to be the widespread use of firms that specialize in hiring and contracting out H-1b visa holders to industry, as is the case in the IT industry.

- U.S. employers (both in industry and universities) have access to a large pool of international workers with skills relevant to biotechnology.

- As in other industries, the biotechnology industry generally wants a larger pool of scientists and engineers. A larger supply tends to reduce wages and allows industry to be more selective in its hires.

- The availability of foreign workers may decrease wages in scientific and engineering fields, and thus may in time decrease the attractiveness of these fields for U.S. citizens.

- The main weakness in the U.S. system is not in assuring a sufficient supply of Ph.D. scientists but rather in having Ph.D. scientists who are broadly trained. Another weakness is assuring adequate numbers of workers trained at the baccalaureate and master's degree levels. There also may be insufficient numbers of people who are trained with a focus on biotechnology processing.

## 3.7. Some Consequences

The analysis above shows that the United States has a large, skilled, and highly mobile population of biomedical professionals – a pool of people from which the biotechnology industry draws both founders and professional employees. What are some of the important consequences of this situation?

### *3.7.1. Consequences for Individuals*

The consequences of individual biomedical professionals are mixed. The main negative consequence is that many young people who train as Ph.D. scientists and aspire to become professors find that there are not enough academic jobs for all them. Many individuals become deeply frustrated. Some stay in academia as long-term post-doctoral fellows, but they aspire to something more. Another negative is that at any given time many biotechnology companies are small start-ups, and many start-up companies fail. Some people like the excitement and challenge of start-up firms, while others do not.

Positive aspects also exist, however. Top research professors and the business executives who work with them benefit greatly from the freedom to start companies. If their companies succeed, these professors become rich, their academic work actually tends to improve as a result of working on tough practical problems, and they have the satisfaction of seeing their basic research lead to valuable therapies and diagnostic tools.

The biomedical professionals who become employees of biotechnology companies also benefit. They get good jobs in their fields, good salaries, access to interesting research problems, and a chance to develop valuable products. Some of these professionals learn valuable business skills and gain enough confidence to become entrepreneurs themselves.

#### *3.7.2. Consequences for Universities*

As discussed above, in the early days of the U.S. biotechnology industry many professors and some university administrators frowned upon their colleagues who became pioneering founders or advisors to biotechnology companies. Working with industry compromised a total focus on basic science, they said. And working with industry could lead to conflicts of interest.

Today, those concerns are largely – but not completely – gone. When some early pioneers became rich and saw their discoveries turned into valuable therapies, other professors decided that working with industry was not so bad. The academic culture in biomedical departments changed dramatically. For their part, university administrators found they needed to revise their policies regarding interactions between professors and companies, a complex process. But administrators reveled in the positive publicity and occasional money they received from licensing university-owned biomedical patents to both start-ups and established pharmaceutical firms. And top faculty and students from all over the world flocked to those universities that seemed most active and exciting in the world of academic-industry interaction.

Some real concerns remain, however. Potential conflicts of interest are real and need to be managed. Graduate students need protection, especially from situations in which professors might push students to work on projects that will benefit the professors' companies but not necessarily the students. In a few cases, very large collaborations involving companies and multiple professors have provoked intense controversy; one example was the debate at the University of California, Berkeley, in the late 1990s over a collaboration between that school's plant and microbial biology department and what was then a division of the Novartis Corporation.

#### *3.7.3. Consequences for Industry and the Overall U.S. Economy*

The analysis presented above discusses the benefits that biotechnology companies receive from America's large pool of skilled, flexible biomedical professionals. But the country as a whole benefits, as well, in at least two ways.

First, of course, the nation benefits from the new medical therapies and diagnostic tools that these biotechnology companies develop.

Second, the economy benefits from the jobs and economic growth that the biotechnology sector provides. In an era when "knowledge-based" (or "innovation-based") activities provide many of America's new jobs and growth, biotechnology is the classic example of a knowledge-based industry. It is true that many biotechnology companies fail, and that it may be many years before many companies make large amounts of money. It is also true that many biotechnology companies employ relatively few people, and thus are unlikely to create large numbers of manufacturing or production jobs to offset the millions of traditional manufacturing jobs that the United States has lost in recent years.

Still, biotechnology has become a vibrant, growing, and important part of the U.S. economy, with the promise of even greater economic benefits in the future.

#### *3.7.4. Consequences for U.S. Regional Economies*

Finally, the growth in biotechnology has proven particularly beneficial for a few regions of the United States. The combination of top biomedical researchers, usually funded by the federal government; entrepreneurial spirit; and supportive policies and institutions has created major biotechnology centers in San Francisco, Boston, San Diego, and Washington, D.C. Other regions of the United States hope to create similar "clusters" of research institutions and biotechnology companies. While the number of new jobs created is sometimes small, the economic benefits in revenues and taxes can be substantial for these regions. America's skilled, flexible, and mobile human resources help make these clusters – and the overall U.S. biotechnology industry – possible.

## 4. CONCLUSIONS

Technology development is a process that remains highly responsive to its societal context. In the U.S., universities and private firms have traditionally responded with alacrity to the needs of the nation as expressed in public policy. The technical activities in public and private institutions are similarly conditioned by social structures and practices. The U.S. biotechnology sector offers a clear example of this dynamic: built on a base of public research funding and sustained by a climate of socially dynamic entrepreneurship.

The policy context facing the U.S. biotechnology sector today continues to be of high importance. Two current issues have been explored in this report: federal government support for biodefense research, and a dynamic and technically rich human resource context for the industry.

The following main conclusions emerge from the analysis of federal biodefense policies:

- Biodefense research will address a wide variety of topics, including relevant science that is not directly concerned with defending against biological agents

- Given the low priority of biowarfare and biodefense before 9/11 and the subsequent anthrax attacks, a prime U.S. objective has been to build up scientific capability and facilities

- The politics of the war on terror have conditioned the funding for biodefense research. In spite of the visibility of the issue, generous funding has not been requested, and the Department of Homeland Security's budget has not been clarified. Effective consideration of budgets should occur in FY 2004 and beyond.

- Biodefense research is currently spread across several agencies, with the largest components currently in the NIH and DOD.

Approximately $1.7 billion in NIH is set aside in FY 2003 for the establishment of biodefense research centers. DHS is requesting $365 million for FY 2004 for the development of biodefense countermeasures.

- The ASM and the NIAID offer comprehensive views of biodefense work on their web sites.

- The impact of biodefense on the biotechnology sector is likely to present new challenges to the best scientists to explore new areas of concern. It is, however, not without the possibility of souring public enthusiasm for biotechnology if risks or harm materialize.

The following main conclusions emerge from the analysis of the human resource situation in the biotechnology sector:

- While little analytical work has been done on the biotechnology workforce, it is clear that employment in the industry has grown approximately three-fold over the last decade, reaching approximately 191,000 employees in 2001.

- The education background of the workforce is very high, with 19% holding PhDs

- Generous amounts of funding from NIH to U.S. universities have produced both a world-class university system and a large pool – which some analysis suggests is more than necessary – of well-trained scientists. The ability of U.S. universities to attract the best students from around the world intensifies this situation.

- Over the past 25 years the demographic characteristics of PhD recipients has changed dramatically, with the percentage of women doubling (now approximately 43%) and the proportion of U.S. citizens declining by about a quarter (now 63%)

- A number of social, economic and legal factors have combined to create a dramatic change in the biotechnology employment situation: university personnel are now eager to work with or for industry in any number of capacities, from consultant to company founder.

- Star scientists who found companies have become legendary in the industry.

- The support systems for company founders include favorable intellectual property laws and licensing practices, the venture capital system, and social networks

- The H-1b visa category has brought a large number of foreign scientists into the biotechnology (and other high-tech sector) workforce. Not only are these individuals especially valuable to companies, but a very large percentage eventually become permanent residents and U.S. citizens

- The San Diego area offers a particularly telling example of the creation of a leading biotechnology region, based on NIH funding, the attraction of external talent, and a strong entrepreneurship network

- The large pool of skilled and mobile professionals in the biotechnology area has led to diverse consequences. Individuals have great freedom but are often frustrated in their career aspirations. Universities have experienced a revolution in attitudes toward work with industry, which continues to create sensitive circumstances of conflicts of interest. Biotechnology has proven extremely beneficial for a few regions in terms of economic growth, taxes and employment. For the national economy, biotechnology has also contributed importantly, although it is a relatively small employment generator.