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(916) 654-5829 fax

California's Bioscience Industries: Overview and Policy Issues

Executive Summary

By Daniel Pollak

*Prepared at the Request of
Assemblymember Howard Wayne
Chair of the Assembly Select Committee on
Biotechnology*

OCTOBER 2002

CRB-02-015

C A L I F O R N I A

R E S E A R C H B U R E A U

PURPOSE OF THIS REPORT

The bioscience industries use cutting-edge knowledge and techniques from the life sciences to create commercial products and services. Many have predicted that these industries could radically transform virtually every aspect of our lives, from medicine to human reproduction, from industrial manufacturing to the food we eat.

The potential commercial applications are so extensive that state and local governments across the country are eagerly trying to cultivate the bioscience industries as engines of economic prosperity. At the same time, the advance of the biosciences causes concern, even fear, in some quarters, leading to controversies and calls for caution. The goal of this report is to provide an overview of California's bioscience industries, and to outline the actual and potential role of state policy with respect to these industries.

THE PROMISE OF THE BIOSCIENCE INDUSTRIES

The biosciences have delivered many important innovations, but these may be only a foreshadowing of things to come:

- *New kinds of medicine.* Genetic engineering has provided new ways to manufacture valuable medicines such as insulin and human antibodies. Hundreds of new biotechnology drugs are under development, targeted at a wide range of illnesses such as cancer, heart disease, and multiple sclerosis. Research into cloning and human stem cells could someday lead to advances in organ transplantation and the treatment of degenerative diseases such as Alzheimer's.
- *Medical devices.* Advances in materials science, engineering, computer science, and biology are coming together to bring us a host of sophisticated medical devices that are transforming the diagnosis and treatment of disease.
- *New kinds of food.* Genetically engineered varieties of corn, soy and cotton that resist pests or herbicides are already an important part of U.S. agriculture. These crops represent only a small fraction of the agricultural products that could be produced through biotechnology.
- *Industrial innovations.* Advances in biotechnology could transform industries such as chemical manufacturing and environmental cleanup.

PERILS OF THE BIOSCIENCE INDUSTRIES

If the bioscience industries arouse great hopes, they also arouse fears and controversy. These include concerns that genetically modified foods might be unsafe, and that genetically modified organisms could harm the environment. At the same time, a wide variety of critics worry that the biosciences could enable us to do things that are immoral, unethical, or could change our society in undesirable ways. For example, there are critics who worry about the ethics of using human embryos for research; or who question our growing ability to alter human biology (and perhaps human nature) through drugs and other medical innovations.

ECONOMICS AND GEOGRAPHIC DISTRIBUTION OF THE BIOSCIENCE INDUSTRIES

The bioscience industries are an important sector of the economies of the U.S. and California. However, the intense interest in them is due at least as much to their potential for growth as it is to their current stature.

California is the nation's leader in the biosciences, with more firms and employment in these industries than any other state. California is also the nation's leader in the private and academic research and development that drives these industries. In California, as elsewhere, the bioscience industries tend to form regional concentrations or "industry clusters." The San Francisco Bay Area and the San Diego region contain the largest concentrations in California. There are also large numbers of bioscience companies in other parts of California, such as the Los Angeles region, but they are more widely dispersed.

The advanced medical device field is the largest industry addressed in this report. However, pharmaceutical biotechnology has firmly established itself and is poised for rapid growth. The techniques of agricultural biotechnology are equally advanced and promise many new products, but that industry has been slower to grow, particularly in California. Among the chief obstacles faced by agricultural biotechnology are the controversies here and abroad over its alleged environmental and health risks, and resulting caution among food producers and marketers.

FUTURE PROSPECTS AND CHALLENGES TO GROWTH

There are a number of factors and challenges that bioscience companies typically confront. Such companies expend a great amount of capital on research and development. It takes a long time to develop new bioscience products and bring them to market, meaning that young companies often must operate for many years without revenues.

As a result, bioscience companies are heavily dependent on venture capital and other forms of investment to achieve commercial success. These financing sources often display a volatile "boom and bust" cycle, creating a climate of both opportunity and high risks.

There are strong reasons for optimism about the long-term growth of these industries. Particularly in its medical sectors, the bioscience industries are maturing rapidly with many promising new products in the development or regulatory pipelines. Basic scientific advances, such as the mapping of the human genome, have been arriving with startling rapidity.

PROBLEMS IN CALIFORNIA'S BUSINESS CLIMATE

Bioscience companies in California enjoy significant advantages that attract them to this state and keep them here. Chief among them are proximity to world-class universities and the critical mass of talent and support industries that characterize California's bioscience industry clusters. However, a number of issues are becoming a growing concern for their potential to inhibit future growth. These include deteriorating infrastructure, traffic, the cost of land and housing, costs imposed by regulation, and uncertainties about the cost and reliability of water and electricity.

In addition, California's educational system may be unable to meet the growing demand for a scientifically and technologically adept workforce. There are already indications that our K-12 system is not preparing enough students for scientific careers, a trend that is expected to deepen as the ethnic composition of the state changes and groups that have traditionally been under-represented in the sciences form a growing share of the population.

While California is likely to remain a leader in the biosciences for many years to come, the problems it faces could inhibit the growth of these industries in the state. For example, as biotechnology companies produce a growing array of pharmaceuticals, there is already a shortage of manufacturing capacity. Given the challenges of high land costs and other business climate issues, it is an open question whether the next generation of high-tech biopharmaceutical plants will be built in California or elsewhere.

THE ROLES OF GOVERNMENT

State and federal government influence the bioscience industries in many ways. The federal government provides billions of dollars for life science research and development (R&D) in the state, and California's government provides hundreds of millions of dollars for such R&D.

The state of California funds a variety of programs and policies that support the biosciences and other high-tech industries. Among these are economic development programs such as the state's six Regional Technology Alliances. The state and federal government provide a wide variety of tax incentives such as R&D tax credits that can be used by these industries.

By far the state government's most vital contribution to the bioscience industries is the support of the University of California system. University research is the wellspring of innovation that nourishes these industries. A great many California companies are commercializing inventions discovered by UC scientists. Furthermore, the entrepreneurs, managers and workers at these companies are very often UC graduates or current or former UC faculty.

The state of California has so far largely deferred to the federal government in regulating the biosciences with regard to the environmental and human health impacts of its

products. Such federal regulations can add significantly to the costs and time required to bring new products to market. While the federal regulatory process has been criticized for being slow and cumbersome to industry, some critics of biotechnology claim the system does not adequately protect human health and the environment. While the risks of biotechnology appear to be largely hypothetical at this point, many respected scientists have called for improvements in the federal regulatory system.

A MENU OF POLICY OPTIONS

If California's policy-makers decide to develop a strategy for dealing with the biosciences, they will be faced with a wide array of policy options. The range of options includes a number put forward to help the industries grow, such as:

- Creating or restructuring tax incentives to help the bioscience industries to grow;
- Addressing the infrastructure, land, and affordable housing issues that are hindering the bioscience industries in some regions;
- Providing grants, loans or other assistance to young companies to help them get through the lengthy and expensive product development process;
- Addressing problems in the process of licensing technologies from the UC system for commercial use ("technology transfer"); and
- Increasing support for basic K-12 science education; and increasing support for applied, vocational bioscience certificates and degree programs at the college and post-graduate level.

At the same time, some are less concerned with promoting these industries than in addressing perceived risks. For example, there are calls to require labeling of genetically modified foods, tighten regulation of the release of genetically modified organisms into the environment, or further restrict stem cell research and human cloning.

TOWARD A BIOSCIENCE STRATEGY

California's government is actively engaged with the biosciences on several fronts, but there are clearly many important unresolved issues. Policy-makers have the choice of maintaining the status quo, or of adopting some of the aforementioned policy options in an incremental fashion. A third alternative would be to follow several other states in developing a broad strategic plan for the biosciences. Any ambitious new plan for changing the state's role would require broad-based support. This would in turn likely require a systematic effort to assess the state's needs and goals, weighing the views of a variety of stakeholders in the process.