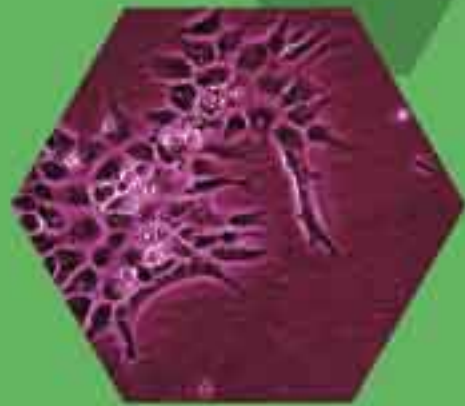


BAYBIO



Innovative
SCIENCE

Delivering
GLOBAL CURES

MPA
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2007



Congresswoman Nancy Pelosi

Democratic Leader, US House of Representatives

The continued development of Northern California's biotechnology and life sciences sector represents a tremendous opportunity for California and our nation. Not only is this industry driving economic growth and fueling the development of new jobs in our region, but it is also providing new health care technologies, applications, and innovations that will lead to a better life for countless Americans.

The talent, intellect, and entrepreneurial spirit of the American people have made this nation a leader in biotechnology and life sciences advancements. As this sector continues to grow, we must educate a new generation of innovators and ensure that today's students get the job skills they need at all levels of learning. America's greatest resource for innovation resides within classrooms across the country, but we must give our students more opportunities to be highly-trained in math, science, and technology so that they can turn new ideas into innovations.



Public Policy: Trends, Challenges, and Solutions

Northern California is the birthplace of biotechnology. Cetus, the world's first biotechnology company was founded in 1971 in Emeryville; Genentech opened its doors in South San Francisco 30 years ago, in 1976. Since those early days of discovery and scientific exploration, biotechnology and the life sciences have grown to become one of the most vibrant and dynamic industries in California. Innovation has been the key driver of growth, with hundreds of new discoveries and treatments being developed each year.

In order to continue the growth and success of this industry, it is paramount that a supportive regulatory environment is fostered. Facing numerous hurdles to innovation, companies have a difficult time researching and developing the myriad of amazing products to mitigate the burden of life-threatening diseases. California needs to remain a place where biotechnological development and innovation can flourish, right in the place where it all began.

- **Innovation:** New ideas and research fuel the search for cures and the growth of the industry
- **Access to Capital:** Turning research into a successful product is expensive and requires a tax environment that recognizes the high costs and long development times of treatments and cures.
- **Demographic Changes and Personalized Medicine:** Changing trends in population and technology are creating new challenges and opportunities for future innovations.
- **Intellectual Property and Regulatory Environment:** The protection of scientific ideas and clear and consistent regulations are essential to the growth of the industry.
- **State by State Comparison:** Other states are developing incentives to lure away life sciences companies, what is California doing to keep its leadership? And what can it do better?

INNOVATION DRIVES CURES

Innovation is the driving force of the life sciences industry. Innovation drives the search for cures down to the molecular and DNA code level. Life sciences companies can only grow and thrive as long as they continue to produce dynamic products that make the most of these scientific advances. Without these advances, new treatments and cures can't be developed.

Research into new ideas and techniques has always been the intellectual focal point of the life sciences industry. All of the products, treatments and tests the life sciences industry develops are the results of basic scientific research and experimental projects. These early-stage projects allow scientists to test theories and gain new knowledge and insights about the human body and the causes of various diseases and disorders. These ideas and innovations will continue to form industry research and development pipelines, which turn concepts and theories into treatments and cures.



Senator Bill Frist, M.D.

Majority Leader, United States Senate

Undoubtedly, biomedical research is linked to both public health and national prosperity. As a physician, I understand the deep-seeded desire to pursue excellence when treating a patient. Encouraging innovation and diminishing the roadblocks to success in biomedical research are necessary steps to ensure the overall improvement in quality patient care.

Throughout my tenure in the Senate, I have actively supported increasing government-funded research and development in hopes of building a lasting relationship between government and the life sciences industry. It is this relationship that is, in part, responsible for many of the innovations the life sciences industry has developed to date.

Continued research and innovation is essential to the development of the life sciences industry. Current and future research will lead to new treatments that will improve the quality of life for Americans here at home and people around the world. The research we do here today can lead to cures for the world's most devastating diseases and disorders. While I am a strong advocate of biomedical research and believe in its potential, we must not diminish the deep, ethical concerns involved in this research.

Inevitably, the more we learn about human development, the more we will continue to face ethical and moral policy decisions. For this reason, I have continued and will continue to support government investment in biomedical research within a strict ethical construct. I am confident that a measured partnership between government and the scientific community will build on past successes, spur progress, and pave the way for future medical breakthroughs.

Basic scientific research requires a large financial investment and carries with it enormous uncertainties about the success and direction of the resulting efforts. Because it is tremendously difficult to develop a product from very early stage research, private markets are not the major source of funding for basic research. Private companies are successful because of their abilities to build upon new and existing scientific knowledge to create new, innovative and marketable products and treatments. The development of future treatments and cures however, depends on having access to continually developing basic research.

The bulk of basic scientific research is funded via governmental institutions and begins as study by academia. Limited funding is provided by grants from private foundations. Government supported basic research, though, is critical to the future development of the life sciences industry and has significant economic benefits. There is a direct relationship between government investment in scientific research and future economic growth. Advancements in basic research and science result in new technologies and commercial applications. In addition to their health applications, new technologies stimulate the creation of new companies and industries that create high paying jobs, increase industrial output and contribute to overall national economic growth. In fact, this model has been so successful that economists estimate that approximately 50 percent of U.S. economic growth since the end of World War II can be attributed to new technologies.

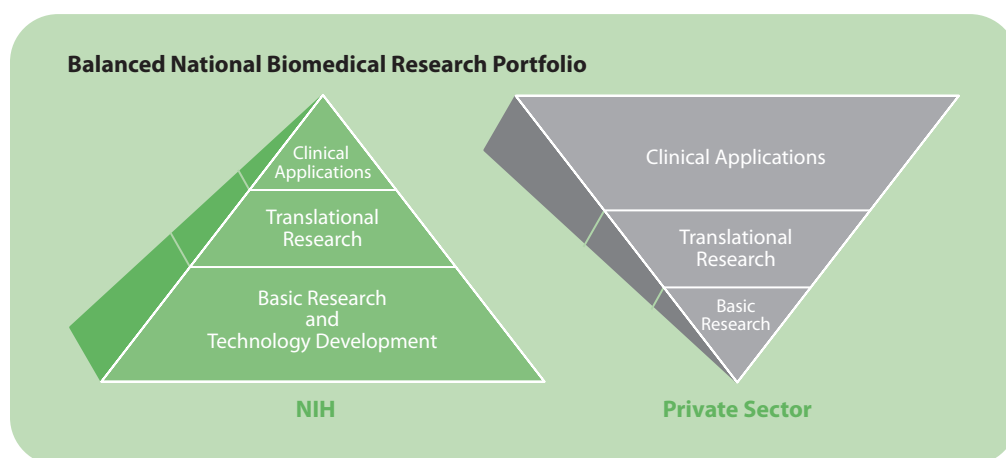


Figure 1.

Source: National Institutes of Health (NIH)

The primary mechanism for biomedical research funding has been grants from government entities such as the National Institutes of Health (NIH). NIH funding levels have seen a total nominal increase of approximately 5.5 percent between FY 2003 and FY 2007. When adjusted for inflation and corrected for purchasing power, NIH funding has seen a 7.3 percent drop since 2003.

An increase in NIH funding that accounts for the increased costs of research is an essential part of a successful biomedical research investment portfolio. While private industry is focused on clinical applications, government funded basic research is still needed to support future innovations.

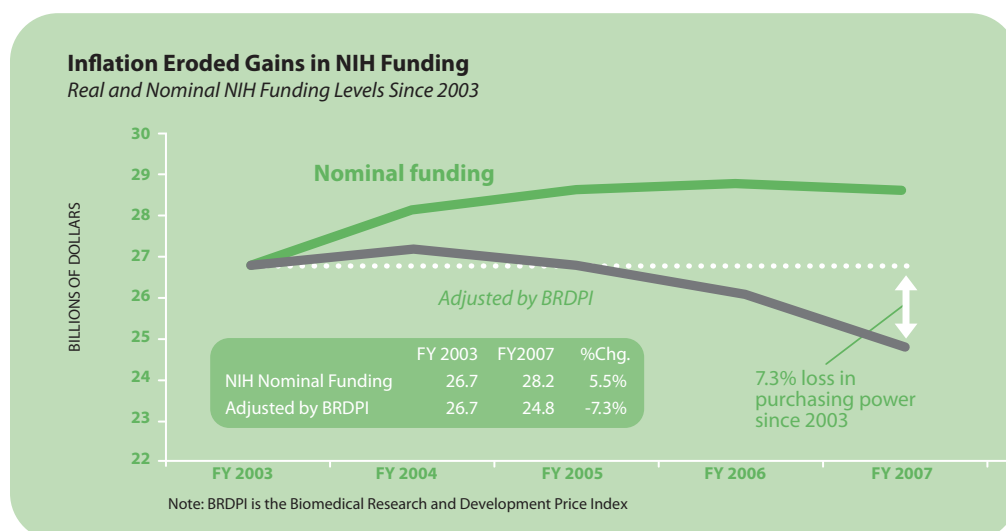


Figure 2.

Source: National Institutes of Health (NIH)

Most of the basic research funding from government sources is directed toward universities. These public and private institutions play a critical role in developing the future innovations that the life sciences industry is based upon. Northern California's success in developing a productive life sciences sector is a direct result of the high concentrations of universities in the area. According to the National Science Foundation (NSF), four of the top twenty U.S. institutions receiving research and development funds are universities located in Northern California.

Between Stanford, UC Berkeley, UC Davis and UC San Francisco, Northern California received a record \$2.8 billion in R&D funding this year. It is this high concentration of research and development dollars that has allowed the successful development of the sector. The private sector has been tremendously successful because it has been able to develop and commercialize research carried out by Northern California universities. This dynamic partnership has already produced incredible results. The University of California system is the single largest biotechnology patent holder in the United States receiving 1,585 patents between 1977 and 2003. Through relationships with universities, life sciences companies are able to take this strong scientific research and turn it into a marketable product. Given this strong and dynamic relationship, it is no surprise that the areas with the largest life sciences and biotechnology sectors are those with a high concentration of government-funded research institutions.



Senator Don Perata

President pro Tem, California State Senate

In 2006 Biotech continued its impressive advance as one of California's signature industries. The biotech industry has great potential to make a difference for this state -- not just in terms of contributions to our overall economic health, but through improvements to our individual health as well. As the author of legislation to help Californians find out about the chemicals and toxins present in their bodies, I know the biotech industry has a crucial role to play in public health.

On a personal level, as someone who is astounded by the number of people I know who are fighting cancer and other serious conditions, and who has watched autism reach epidemic proportions here, I am hopeful the biotech industry will be the source of sorely needed breakthroughs. As President pro Tem of the California State Senate, I am strongly committed to some of the issues the industry is most concerned with, including ensuring that we have a strong pool of qualified workers and helping provide a safe and sufficient supply of water for all the state's needs. My colleagues and I look forward to working with the industry as we move to protect and strengthen California's health, environment and economy.

The basis of future success in the life sciences industry will continue to come from commercialization and development of basic research. Future innovations have the potential to radically redefine the healthcare industry. The advances in science and technology that will drive these innovations are not strictly limited to therapeutics. Rather, future innovations will combine techniques and technologies from a variety of scientific disciplines and fields. A confluence of scientific advances in areas as disparate as nanotechnology, computer science and chemistry will make fundamental changes in how we define healthcare. This will not just be limited to new healthcare products; instead these future innovations will change how future patients are treated, diagnosed and even administrated in the healthcare system.

To see these and other innovations become reality, future funding in NIH and other forms of government-sponsored biomedical research must be sustained and increased.

Northern California's life sciences sector is a tribute to the benefits of successful government investment in basic research. Yesterday's research and ideas are creating today's products and cures. New innovations (and investments) are needed today to ensure that future cures can be developed.



Speaker Fabian Nunez
Speaker, California State Assembly

With more than \$62 billion in revenues, California biotechnology firms represent the very best of California's unrelenting drive to solve our greatest healthcare challenges – cancer, diabetes, infectious disease – while simultaneously representing the future of the state's economic growth. From California's historic public investment in stem cell research and technology to the leading role played by the University of California scientists in founding 25% of all the state's biotech firms, California remains committed to the unique public/private partnerships that will foster this industry.

Four hundred California life sciences and biotech companies account for 68.5% of the market value of all NASDAQ-listed life sciences companies. They currently provide an estimated 100,000 jobs and it is predicted that they will employ more than 250,000 by 2015. One in four of California's biotech firms were founded by University of California scientists. More than 50% of all companies spun out from universities in California have come from Bay Area institutions.

The UCs have teamed up with hundreds of companies to help in the research and development of nanosystems and biomedical solutions to 21st Century problems. There are over 800 new medicines in California's research and development pipeline, many of which may never make it to the marketplace but may lead to other innovations to fight cardiovascular or infectious diseases, cancer, diabetes, and respiratory disorders. Our investments in stem cell research will likely pay dividends for generations to come. Biotechnology will fuel the economy and lifestyle of California's future.

ACCESS TO CAPITAL: FINANCING INNOVATION

The transition from basic scientific research to marketable product is arduous. There is a world of difference between the development of lab based scientific knowledge and the practical application of that knowledge. Companies often require several rounds and sources of capital in order to translate innovation into cures. Many companies end up in the so-called "valley of death" where innovations from the lab have commercial promise but are unable to get capital funding to continue their development. Furthermore, all life sciences products are subject to strict regulations that require a demonstration of safety and efficacy before they can be sold to the public. As a result, the cost of development is significant and rising costing hundreds of millions of dollars, with marketable results not seen for 10 to 15 years or more.

Life sciences companies depend on having access to an ample supply of capital funding to support their extensive research and development functions. Unlike their high-tech counterparts, life sciences companies operate within a highly regulated business model that often requires several rounds of private financing in addition to access to public markets. The lengthy product development cycle is also fraught with risk and rising costs. Fewer than 1 in 10 biopharmaceutical products that enter development actually succeed in securing FDA approval. Concurrently, the cost of drug development from the discovery phase through the clinical trials process has increased both in time-to-market and in cost. These business realities often make it difficult for companies to receive needed capital.

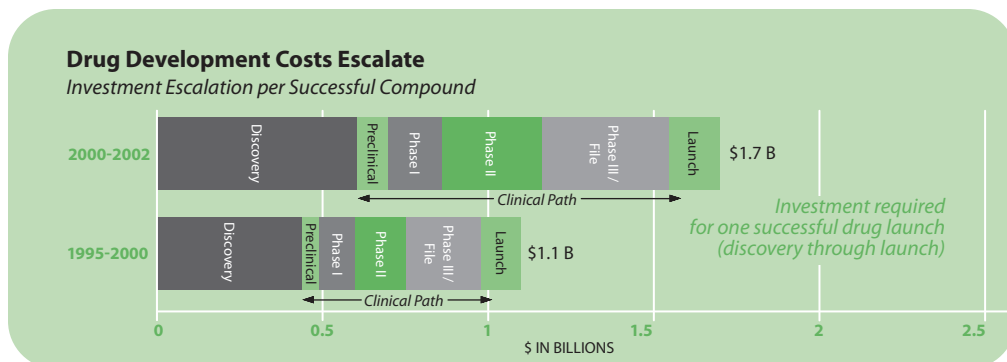


Figure 3.

Source: Windhover's In Vivo, The Business & Medicine Report and Bain drug economics model - 2003

Many early stage companies receive their initial funding through government-sponsored Small Business Administration (SBA) loans and through angel funding, which is especially important. Angel funding is early stage investment in start up companies by individuals who can afford exposure to high-risk investments and/or farsighted venture capital firms willing to make early investments. Angel funding provides fledgling companies with the first real opportunity to take research from government-sponsored labs, institutions or universities and investigate its practical applications. The early injection of capital allows for start-up companies to finish the scientific research, conduct initial product development and begin forming a business plan.

Angel support is essential to the successful development of future companies. In order to keep California competitive in the life sciences, the state should consider adopting an angel investment tax credit to provide incentives for the investment in early stage companies.

Once a company has developed a business plan and made advancements in their research, they need access to a larger more stable source of capital than what angel investing can provide. Companies at this stage receive their capital funding through three primary sources: second stage venture capital, public markets through initial public offerings (IPO) or in-licensing or product development agreements with larger companies. Often, a combination of one or more of these resources is required for successful product development. Partnerships with large existing biotechnology or other life sciences companies are a growing source of capital for many small and mid cap life sciences companies. These partnerships more often than not, exist through licensing and royalty agreements for existing intellectual property or treatments that are still in development.

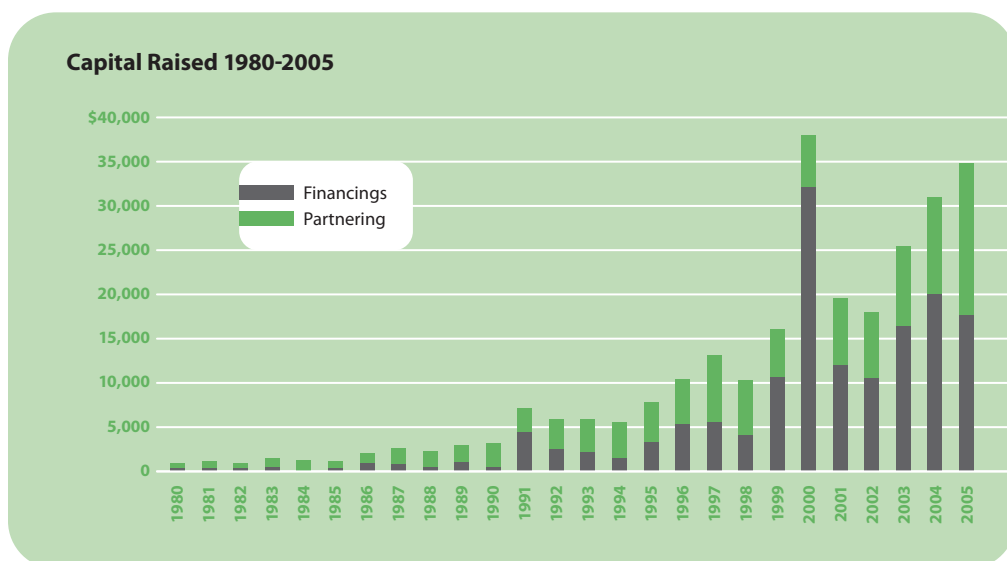


Figure 4.

Source: Burrill & Company

Elected officials in Congress and the State Legislature should adopt and maintain tax policies that are supportive of life sciences companies' needs throughout their product cycle from research and development to manufacturing.

An extension of the federal research and development tax credit will encourage companies to continue to invest in innovation and future technologies. The development of an R & D tax rebate is sound, forward-looking public policy that will support the next generation of life science research and attendant cures.

NET OPERATING LOSSES: TAX POLICY NEEDS A PRECISE FOCUS

The state's net operating loss (NOL) policy as it currently stands does not recognize the business realities of the life sciences industry. Many life sciences companies will operate for 15 years or more without generating a profit. Current state tax policy on net operating losses allows businesses to deduct their losses for only 10 years, after which time these losses expire. The average life science firm turns a profit 13 to 15 years after its incorporation and therefore, loses 30 percent or more of its operating losses as they expire.

Innovative tax policies developed in other states are providing possible solutions to this problem, while at the same time placing California companies at a competitive disadvantage in their search for capital. The state of New Jersey has a program in place that allows life sciences companies to securitize their losses prior to making a profit. This program allows a NOL selling company to receive an infusion of capital by selling the NOL to another company that takes the deduction. Capital from the NOL sale is then reinvested in the selling company in new equipment or additional employees.

California should adopt a tax policy that allows small and mid cap life sciences companies to sell their net operating losses. Such a policy could produce dramatic results for many small and mid cap life sciences companies that are struggling for needed capital.

SARBANES-OXLEY

Enacted in 2002 in response to accounting scandals from large publicly traded companies, the Sarbanes-Oxley Act imposes significant and costly regulatory requirements on companies of all sizes. While larger companies have the resources needed to comply with Sarbanes-Oxley certification and accounting requirements, smaller companies often do not. The result is that smaller companies are forced to spend valuable capital resources on accounting work that would otherwise be spent on research and development for cures and life-saving treatments.

For example, Section 404 regulations in the Sarbanes-Oxley Act require companies to detail internal controls over financial reporting. The implementation of Section 404 requirements can be disproportionately expensive for smaller companies. A May 2006 Government Accountability Office (GAO) report estimates that companies in the bottom 6 percent of U.S. market capitalization spend up to \$1.4 million on external auditors to secure Section 404 compliance.

Sarbanes-Oxley must be modified to fit the limited resources of smaller companies and recognize the high costs of compliance. These changes are needed to ensure that growing life sciences companies can continue to use public markets as a source of capital.

INTELLECTUAL PROPERTY/PATENT REFORM

Intellectual property is the intangible asset of scientific ideas, innovations and discoveries generated by research. No other industry is as dependent on developing and protecting intellectual property as the life sciences industry. Patents protecting intellectual property allow scientists and companies to secure their ideas and innovations. Unlike other technology intensive industries, life sciences companies are unable to take full advantage of their intellectual property after they receive product approval. Life science companies secure a 20 year patent on products as they enter the FDA approval process. Since the approval process takes 13-15 years, by the time a product is approved, only 5 to 7 years remain before the patent expires. As a result, life sciences companies lose 60 percent of their patent exclusivity before a product is even approved for sale.

It is the protection of intellectual property that secures the discovery through its full development and then delivery to doctors and patients. Due to the enormous investment that life sciences companies make in research and development, the intellectual property accumulated as a result of that research is often the most valuable, and sometimes the only, asset a company has. Successful intellectual property rights protections ensure that ownership of an innovation is clearly defined and defensible. Intellectual property provides the owners of the innovation with the ability to develop and refine their idea, or freely transfer or sell them to another party. Without adequate protection for these innovations, the industry could not attract investments to commercialize basic research. Without the investments, companies would be unable to develop the innovative and life-saving products that are the signature contribution of this industry.

Concerns about the patenting process among a variety of industries have prompted members of Congress to investigate the potential for reforms to the U.S. patenting system. These concerns focus on a variety of patenting issues, including but not limited to, harmonizing the U.S. patent system with the systems used by other major trading partners (Europe and Japan), the need for an administrative process for challenging issued patents, and reforming patent litigation rules and the challenge process.

With a time consuming product approval process and long product development cycle, a life sciences company depends on its intellectual property portfolio. Federal reforms to the patenting system must take unique the needs of the life sciences industry into account. Any changes to this system must provide inventors with clear and enforceable protections on the variety of potential uses of their innovations and not subject them to needless litigation.



Senator Dick Ackerman

Republican Leader, California State Senate

California has always been a leader in the innovation and advancement of new technologies. Our colleges and universities are among the top research facilities in the nation, leading the charge to find new, pioneering solutions to worldwide problems.

From San Diego to San Francisco, our state's biomedical industry is also leading the world. This industry is not only important to the millions of patients it helps, but it is also an important job creator and economically important to tens of thousands more.

Over the past thirty years, bioscience has made a tremendous impact on the way we treat and cure the afflictions of patients. These advancements have reduced hospital stays and slowed the spread of disease, reduced pain and suffering and increased the chances of surviving once fatal medical conditions.

The bioscience industry in California continues to grow in importance as a health provider and economic driver. The partnership between our universities and the bioscience industry will continue to bring innovative ideas to the industry and provide cutting-edge education for our college students.

When combined, the state's forward thinking bioscience industry and the state's public and private universities are a formidable team that drives the world's new discoveries in medicine. I will continue to support this important partnership.

An additional important component of intellectual property is a technology transfer policy. Since most basic research occurs in government-sponsored and academic institutions, it is essential to have a clear mechanism by which basic research can be transferred to the private sector and commercialized. A key national development in the use of intellectual property transfer policy occurred in 1980 with the enactment of the Bayh-Dole Act. A policy cornerstone to the modern life sciences industry, Bayh-Dole made significant changes to U.S. patent law and created a critical path for the commercialization of innovations developed in government-sponsored or supported institutions. Bayh-Dole has made it possible for the transfer of technologies from the university laboratory to the private sector where they can be transformed into practical applications.

As a result of Bayh-Dole, there has been a tremendous increase in the amount of intellectual property developed and licensed by universities. Bayh-Dole set out a pathway by which government-sponsored or supported institutions could license their intellectual property to private companies in hopes that they would be able to commercialize government-funded innovations. The legislation has been considered some of the most important legislation of the 20th century and is widely viewed as enormously successful. The Association of University Technology Managers and the Biotechnology Industry Organization estimate that 60 drugs currently on the market were originally derived from university research, including a hepatitis B vaccine now given to infants around the world.

Allowing for the licensing of university research has created a public-private partnership that has seen an explosion in life sciences patents. A demonstration of the impact of the legislation is the fact that the single largest biotechnology patent holder in the United States is the University of California.

Top 10 Biotechnology Patenting Organizations 1977-2003

INSTITUTION	NUMBER OF PATENTS	SHARE OF TOTAL BIOTECHNOLOGY PATENTS
University of California	1,585	1.77
U.S. Department of Health and Human Services	1,021	1.14
Merck and Co., Inc.	943	1.05
Genentech, Inc.	792	0.89
Yoder Brothers, Inc.	729	0.82
Pioneer Hi-Bred International, Inc.	693	0.77
Eli Lilly and Company	674	0.75
Abbott Laboratories	654	0.73
Smithkline Beecham Corporation	636	0.71
University of Texas	576	0.64

Figure 5.

Source: U.S. Patent and Trademark Office, Office of Electronic Information Products, Patent technology Monitoring Division, special tabulations (January 2005).

The cumulative result of this legislation is the cooperative relationship that exists between universities and the life sciences industry. This relationship has allowed innovative and successful companies to grow out of government research.

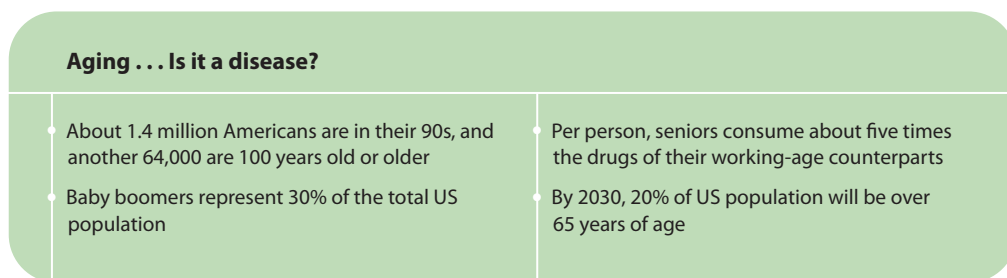
It is essential for the continued success of the life sciences industry that any intellectual property or governmental research legislation preserve the spirit and original intent of Bayh-Dole and not place any undue restrictions on the commercialization of government research.

The research, innovations and cures that come out relationships between universities and the life sciences sector must be nurtured, as they play a key role in addressing the health concerns of a growing population and changing demographic of patients.

AN AGING POPULATION

According to the United States Department of Health and Human Services (HHS), more than 36 million Americans were age 65 or older as of 2004. By 2050, that population is expected to rise to nearly 87 million people, growing more than three times faster than the overall population. This phenomenon is not unique to this country. The British Office for National Statistics reports that almost 20 million people in the U.K. were age 50 or older in 2002, with this population expected to rise to 27 million by 2031.

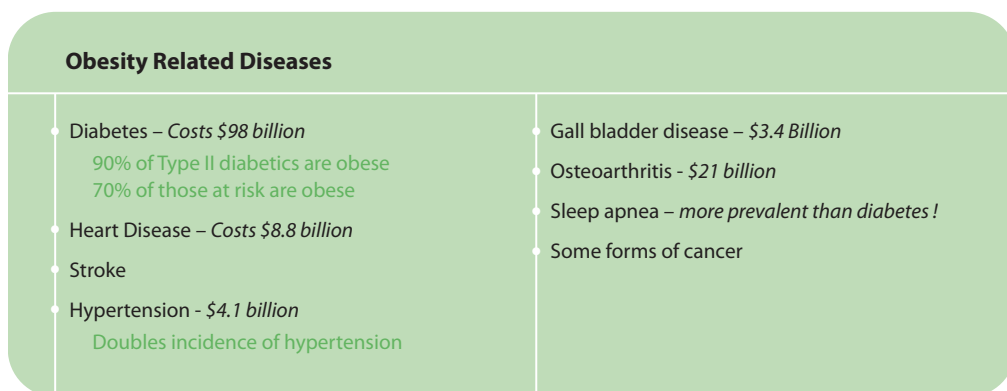
Figure 6.
Source:
Burrill & Company



Aging populations face rapidly increasing risks for diabetes and heart disease, among other conditions. In the United States, HHS reports that 19 percent of the population between the ages of 65 and 74 has been diagnosed with diabetes, while 73 percent of women and 60 percent of men in that age range have hypertension. The conditions afflicting this aging population are even more significant, including Alzheimer’s, arthritis and a range of respiratory conditions.

This generation faces healthcare costs that result from lifestyle choices made over the span of decades. Unfortunately and inevitably, those costs will rise. More than 70 percent of men and women between 65 and 74 are overweight, according to the HHS.

Figure 7.
Source:
Burrill & Company



The implications of this demographic shift are far-reaching and still not adequately assessed. The research of today may prove fundamental to our approach to aging in the future, as the life sciences industry turns its attention to the graying of America.

Medicines in Development for Older Americans*

DISEASE	PRODUCTS IN DEVELOPMENT	DISEASE	PRODUCTS IN DEVELOPMENT
Alzheimer's Disease/Dementia	27	Osteoporosis	20
Bladder/Kidney	9	Pain	41
Depression	19	Parkinson's Disease	17
Diabetes	48	Prostate	6
Epilepsy	7	Rheumatoid Arthritis	38
Eye Disorders	23	Sepsis	3
GI Disorders	23	Sexual Dysfunction	15
Lung/Respiratory	52	Skin Conditions	14
Musculoskeletal	6	Sleep Disorders	11
Osteoarthritis	11	Other	17

* some medicines are listed in more than one category

Figure 8.

Source: Burrill & Company

Effectively managing the medical issues of the Baby Boomers will require the timely success of this research. These treatments will mean more than mere life extension for millions; they will mean a quality of life into later years that will enable retirees to remain active, productive citizens.

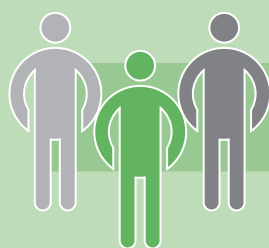
PERSONALIZED MEDICINE

Researchers and physicians know that their targeted patient populations do not uniformly respond to therapies. Some patients absorb, respond and recover from certain therapies differently than others. Over time, these results allow life sciences companies, researchers and practitioners to apply advanced technologies to the treatment of disease. The application of large disease databases, our advancing understanding of the human genome, and innovation in new product research all have contributed to the advance of personalized medicine. Patients and doctors are now empowered with exponentially more information about genetic profiles and therapeutic options to ultimately, enable individually tailored approaches.

Today's Medicine Challenge: One Size Doesn't Fit All

Patients are different

Medicines are not differentiated



About 30% of patients do not benefit from medicines¹

(100,000 deaths and 2.2 million nonfatal events from ADR in the US in 1994)

¹JAMA 1998, 279:1200

Figure 9.

Source: Bayer HealthCare Diagnostics and Burrill & Company

Since the arrival of Herceptin in 1998, life sciences companies have been at the forefront of products for personalized medicine as we now understand it. Herceptin is a treatment for breast cancer patients of a particular genetic profile. Studies show that 20-25 percent of women with breast cancer have the type of cancer (Her2+) that can be treated by Herceptin. Additionally, new molecular diagnostic and genomic tests such as technology from XDx will be making personalized medicine a reality. This capability to match specific patient profiles with ideal treatment regimes will shape medicine irrevocably, ultimately enabling medicine to be more targeted, more effective, and more personal.



Since 1999 Monogram Biosciences has developed the vital diagnostics needed to make personalized medicine a reality. Our HIV assays measure drug-disease interaction at the molecular level to provide a complete picture of each patient's individual virus, helping make the complexities of antiretroviral therapy easier to manage. This deep understanding of advanced diagnostics is now being used to develop our eTag technology, a versatile diagnostic platform supporting personalized patient care in oncology.

For patients and clinicians, our diagnostics yield superior results because they focus on direct indicators of disease-drug interaction to predict the likelihood of therapeutic success. By understanding the disease, the patient and the available drugs, we can empower treatment decisions that offer the greatest chance of success.

For payors, our diagnostics can identify patients who are most receptive to specific treatments and eliminate those for whom the treatment is likely to be ineffective. Given the rising cost of treatment, our diagnostics – and their ability to help match the right patient with the right drug – are an important tool in targeted therapy.

For pharmaceutical companies, our molecular diagnostics can help improve patient selection and provide important insight into patient profile characteristics during the clinical trial process, ultimately reducing development costs and bringing products to market faster. Monogram technology has been integral to the development of every HIV drug approved by the FDA in the past five years.

Monogram molecular diagnostics help deliver on the promise of individualized medicine — improving patient outcomes and contributing to a more cost-effective healthcare system.

One of the key advances that will build our understanding of personalized approaches to treatment will be our collection of biomarkers. A biomarker is a genetic marker that is associated with a disease or a susceptibility to a disease. In October of 2006, HHS announced a Biomarker Consortium involving the FDA and NIH. This consortium is expected to advance efforts to collect and understand useful biomarkers for individualizing treatment and understanding disease progression. Our ability to develop the diagnostics that identify these markers in patients will further the application of personalized medicine across all therapeutic sectors.

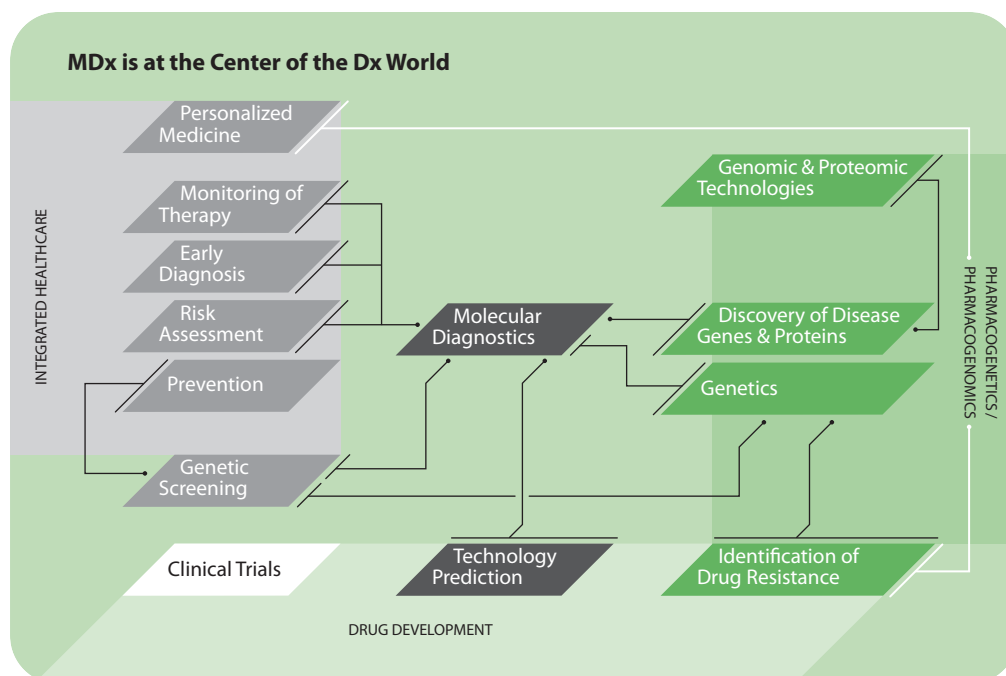


Figure 10.
Source:
Burrill & Company

This trend will also affect the overall healthcare equation in the United States. By applying these technologies to individual patients, doctors can focus solely on the therapies likely to be meaningful to their patients.

Personalized medicine will reduce waste and overall healthcare costs by lessening the application of expensive treatments to patients who receive only the side effects without the therapeutic benefit. These applications to individuals will reduce the use of therapies and procedures on patients who do not benefit, reducing side effects and the emotional burden of ineffective treatments. Furthermore, the healthcare system will benefit from more efficient treatments by enhancing providers' abilities to match the right therapy with the right prospective responder.

This type of personalized medicine is already at work in cancer and AIDS therapies.

A PIPELINE OF GREAT PROMISE

As the biopharmaceutical industry matures, its research into all types of diseases grows more productive. In fact, the pace of discovery is accelerating. Within the next five years, the clinical trial process will determine the success or failure of hundreds of new treatments.

In the chapters that follow, hundreds of products already approved by the FDA and in current use are detailed. These products are treating millions of patients, saving and extending lives, and helping people to return to their lives and loved ones as productive citizens and children at play.

There are more drugs and devices of Northern California origin in later-stage clinical trials than are approved and in use today (those in pre-clinical or phase I development are not included). This is a testament to Northern California's life sciences industry rapidly expanding its investment in product development.

Summary of Products in BayBio:IMPACT 2007*

INDICATIONS	# OF APPROVED PRODUCTS	# OF PHASE II AND PHASE III DRUGS AND DEVICES
Infectious Diseases	79	35
Cancer	32	169
Dermatology	25	14
Central Nervous System	24	51
Respiratory, Pulmonary	19	28
Cardiovascular	16	27
Metabolic and Endocrinology	16	17
Autoimmune and Inflammation	16	15
Women's Health	16	6
Ophthalmology, Optometry	13	6
Blood and Lymphatic System	8	11
Digestive System	6	8
Genetic Diseases	5	1
Kidney and Genito-Urinary System	5	2
Substance Abuse	4	2
Musculoskeletal	4	0
Dental	0	3
Clinical Devices and Diagnostics	105	5
Total	393	400

*includes products counted more than once for instances of use or trials in multiple conditions

Figure 11.

Source:
BayBio:IMPACT 2007

Hundreds of companies are approaching diseases in new and innovative ways. In many cases, partnerships with academic and non-profit research institutions and mature pharmaceutical companies are contributing to the advancement of product development. For some Northern California companies, the best possible course of action for fulfilling product potential is through partnerships with other companies.

This product pipeline is being advanced by an industry that remains dominated by small businesses. Small, entrepreneurial life sciences companies are finding a focus on their core competencies in drug research and development while allowing their partners to handle regulatory and marketing affairs. Approximately 60 percent of life sciences companies in Northern California have fewer than 50 employees.



Kim Popovits

President and Chief Operating Officer, Genomic Health

Life sciences research attracts people who push the frontiers of science on a daily basis. This entrepreneurial mindset is attracted to risk, diversity, and challenges. Couple this behavior with California culture, world class academic institutions and a dynamic venture capital community and you have a very unique formula for success.

For the life sciences, California is an incubator for a critical mass of very experienced people, future looking academic research and start-up funding. We sometimes have trouble getting people to move here or study here, but once they arrive, they never leave.

Our challenge is to keep this innovation engine we call the Northern California moving forward.

Though dominated by small businesses, the life sciences industry in Northern California has a cumulative product pipeline larger than the combination of several of the most complex drug companies in the world. Products in development in this region address virtually every medical need known.

At Exelixis, we are committed to making a meaningful impact on the lives of patients living with cancer and other serious diseases by advancing an ambitious and pragmatic approach to drug development. Our robust discovery and research infrastructure is focused on the development of first-in-class and best-in-class therapies that will potentially transform the treatment of cancer. Currently, we have eight compounds in clinical development and expect to advance at least three new compounds to clinical trials each year for the foreseeable future.



The compounds currently in our clinical pipeline are designed to simultaneously inhibit key cancer-related targets. These “spectrum selective” kinase inhibitors have been exhaustively optimized for potency, pharmacokinetics, pharmacodynamics and tolerability against their multiple targets. Consequently, they may provide improved efficacy and fewer side effects compared with combinations of individual drugs that have not been optimized for use together. Our preclinical oncology pipeline includes novel compounds designed to inhibit the activity of individual kinases that are points of convergence in critical cancer-related signaling pathways inside the cell. By specifically inhibiting targets that are common to many cancers, these compounds could provide potent anti-cancer activity against a broad array of tumor types and molecular defects without the side effects of chemotherapy or radiation.

By thinking larger, moving faster and charting our own course to our goal, we are transforming the challenges of our industry into opportunities for success for patients, investors and employees. To learn more about who we are, what we do and how we plan to realize our vision for improving the lives of patients, please visit www.exelixis.com.

To progress with this development, the industry requires highly skilled employees and a sustainable source of capital. As this broad pipeline expands, billions of dollars in new investments will be required to carry products through phase III trials, regulatory approval and into manufacturing and distribution.

These are the very jobs and investments that every state and nation clamors for – life sciences jobs not only generate high wages and desirable growth, they lead to treatments and cures. Developing a successful life sciences sector requires an active partnership between government and private industry.

THE REGULATORY ENVIRONMENT: FDA

The life sciences industry is one of the most heavily regulated industries in the United States. Life sciences products cannot be sold to the public without receiving FDA approval. Additionally, the FDA places strict requirements on the research process as well as manufacturing facilities. Life sciences companies accept the responsibility of ensuring their products are safe and effective. These regulations are an important component of the life sciences industry, but can add to drug development costs and should be streamlined when

possible. A close and productive working partnership between FDA regulators and industry developers is needed to ensure the continued development of new treatments and cures. The FDA is aware of its essential partnership with therapeutic companies. Its Critical Path Initiative is designed to make important reforms to hasten product approval times.

As a part of the regulatory approval process, companies must submit results of clinical trials demonstrating the safety and efficacy of their products. With patients needing access to innovative treatments, time is of the essence in ensuring that the FDA processes submitted applications efficiently. Median approval time for standard reviews is 12-14 months after submission.

While overall FDA review times have improved somewhat from their peak in the mid 1990s, government processing and approval delays add to the cost of drug development and, in many cases, unnecessarily increases the time that patients must wait for innovative treatments. While patient safety must remain paramount, unnecessary delays due to processing time and lack of appropriate staffing resources are unacceptable.

THE STATE REGULATORY ENVIRONMENT

Life sciences companies also face state level regulations, which often act as barriers to entry for companies who wish to expand. While California continues to lead the nation in the growth and development of life sciences companies, unnecessary or overly burdensome regulations hamper the ability of these companies to expand their production facilities.

California's intellectual and research and development infrastructure have fostered the creation of hundreds of life sciences companies and 900 in Northern California alone. As many of these companies have products nearing FDA approval, they need a manufacturing base to produce their products. The construction of these facilities must meet strict FDA standards, but duplicative state regulations often add unnecessary cost and delay to the process. For example, several existing state regulations duplicate pre-existing federal requirements, necessitating separate applications and permit approvals, which adds additional costs and delays to company activities. Life sciences companies need clear and consistent regulatory requirements that do not unnecessarily burden the approval of their facilities or the development of their products. Policies that are unclear and add unneeded burden serve may ultimately drive investment to other states.



ABD Insurance and Financial Services understands the life sciences industry. Since the birth of biotechnology in 1976, the firm has been a trusted partner to biotech, medical device and healthcare companies; providing creative and cost-effective answers to their most challenging insurance, risk management and employee benefits questions.

Whether you are a start-up or mature life sciences organization, conservation of capital and effective allocation of resources are increasingly important priorities in the drive to reach and sustain the commercialization of products. With the maturation of the biotechnology industry has come an evolved business model which offers new opportunities to tie the identification and financing of risk and the purchase of insurance products together in a

more logical and cost effective process. Structured, implemented and managed properly, strategic risk management programs will protect and conserve a company's assets in order to lengthen the available "runway" and increase the chances of achieving commercial success.

In key biotechnology centers across the country, new discoveries, emerging opportunities and the industry's rapid expansion have created unprecedented competition to hire and retain top talent. Best of breed companies recognize the importance of comprehensive, strategic employee and executive benefits programs in building strong, viable organizations and premier corporate cultures.

ABD has demonstrated a major commitment to the life sciences industry and was selected by the Biotechnology Industry Organization (BIO) and various regional life sciences group including BayBio and BIOCOM as the endorsed employee benefits broker for their member companies in the western U.S.

In an industry still trying to shake off its "old economy" label, ABD has earned a strong reputation for creativity, advocacy, innovation and responsiveness. To learn more about the ABD difference and their full range of insurance, risk management and employee benefits solutions, please visit www.cybersure.com.

Solving these problems requires proactive solutions and a cooperative partnership with government regulators.

California's state government entities need to be proactive and engaged to develop collaborative policies while working to avoid needless and costly regulations.

Industry representatives are ready and willing to work with government to communicate the impact of regulations and to propose possible solutions. Two case studies of industry partnership have produced tangible results and demonstrate the importance of working with industry to develop policies and regulations.

CALGOLD

California's CalGold website provides applicants with valuable information on the types of permits and regulatory approvals needed to start a business or construct a facility in a community. Although California's CalGold program has been instrumental in providing this information for many businesses, it had little or no readily available information on the requirements for life sciences facilities construction. Legislative changes sponsored by BayBio directed the responsible governmental agency to collect and produce the needed information.

California's fast-track permit approval system must be fully funded to live up to its potential.

An example of a cooperative partnership between the life sciences industry and government, this simple action has increased the availability of information with the goal of simplifying permitting procedures.

STATE FIRE AND BUILDING CODE

State fire codes control use and storage of chemicals used in basic research as well as manufacturing of life sciences products. Building and fire codes are updated periodically through the California Building Standards Commission in conjunction with the Office of the State Fire Marshall. In 2006, life sciences companies faced a critical issue with changes to these codes. While updates are a normal part the code development process, there was an unforeseen consequence to hazardous materials and building standards contained in the 2006 code revision process. The proposed fire and building code regulations placed severe limits on several chemicals essential to research, restricting the amounts that could be used on higher floors. These revisions, if passed, would have increased facilities reconstruction and renovation costs by 200 percent and effectively prohibited biomedical research above the third floor of a laboratory building.

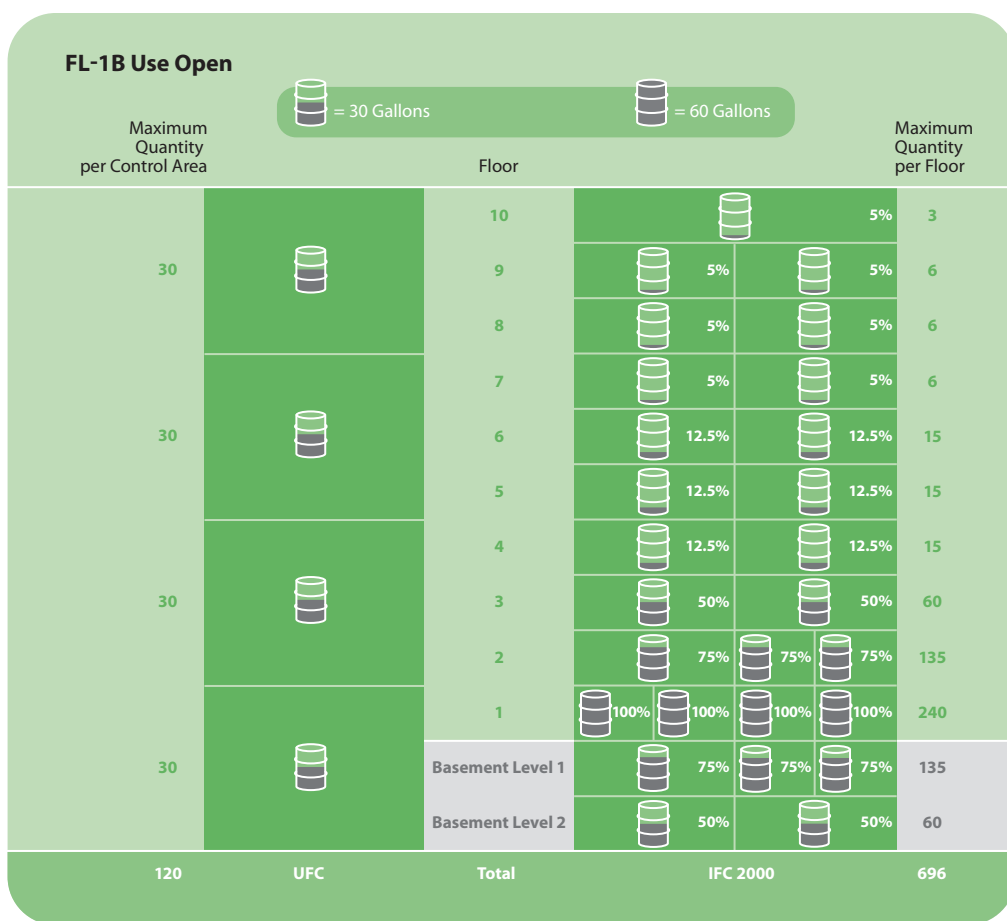


Figure 12.

Source: Reinhard Hanselka and Integrated Engineering Services

Fortunately, industry representatives were able to resolve this issue with state regulators through meetings during the rule-making process.

The result of industry involvement on this issue was the creation of an ad hoc committee of industry facilities experts to communicate with state regulatory bodies (in this case the State Fire Marshall’s Office) about the impact of new regulations. This kind of communication between industry and government regulators is an essential part of any successful industrial development strategy.

In the life sciences industry, the science and industrial developments are often far ahead of the regulations. As a result, regulations may either not address industry issues or needlessly hinder development because of duplicative requirements. Life sciences facilities need to meet federal standards on quality and safety.

To create a healthy regulatory environment, California should work to eliminate regulations that duplicate and overlap with existing federal requirements, make every effort to adopt electronic application standards and streamline the permits approval process.



Assemblyman George Plescia

Republican Leader, California State Assembly

California's economy is booming again – thanks to pro-growth economic policies that have enabled the industries of the future to prosper in our state.

Over the past three years, we worked closely with Governor Schwarzenegger to restore California as a land of opportunity and prosperity once again. We helped stop costly tax increase proposals and new job killer measures from taking effect. We worked together to fix our state's broken workers' compensation system – eliminating the fraud and abuse in the system that was driving up costs for employers, while ensuring injured workers receive quality care.

The results have been amazing. More than 600,000 new jobs have been created in California over the past three years. California's unemployment rate has dropped by 1.8 percent. Our credit rating has been raised several times by the major investment rating firms. Workers' compensation premiums have dropped by nearly half, with more reductions on the way.

Biotech workers and employers have been an integral part of this economic good news. The industry now employs a quarter of a million Californians, with an average salary of more than \$64,000 and rising.

But the benefits of biotechnology spread much farther than that. California's \$28 billion agriculture industry, for example, has benefited greatly from advances in biotechnology. The miles of farmland in the Central Valley might look the same as they have for generations, but now they are growing higher-yielding, genetically engineered crops.

California's health care system depends heavily on advances in biotechnology. Doctors are helping patients recover faster, and stay alive longer with better treatments and surgical techniques developed through biotech research. These advances are truly making a difference in the lives of millions of people.

To keep our state's economic engine roaring strong, we must continue to foster the pro-growth economic policies that have fueled California's comeback.

LEARNING FROM OTHERS – THE COMPETITIVE LANDSCAPE

As the nation's largest life sciences cluster, California is recognized as the birthplace of the life sciences industry. However, the circumstances that led to the development of the industry in California are being replicated in other parts of the country. Furthermore, many states are recognizing the need to use economic incentives such as revised tax policies to encourage life sciences companies to relocate to their state. Several states are partnering with local

government entities to actively recruit life sciences companies using tax incentives, expedited permitting, and land inducements. The following are examples of other states' initiatives to entice life sciences companies into their communities or foster the development of homegrown life sciences clusters.

FLORIDA

Perhaps the most obvious development in the attraction of life sciences companies comes from the state of Florida. One California research giant, The Scripps Research Institute, has already signed on to expand to the Sunshine State. Two others, the Burnham Institute and the Torrey Pines Institute for Molecular Studies, have announced their intentions to construct new facilities in Florida. They would join other Florida based life sciences companies including Viragen, Inc., DOR BioPharma, Dyadic International and Nabi Biopharmaceuticals.

California companies are taking active notice of the incentives the state of Florida has to offer. In a recent San Diego Union-Tribune article, Kelly Smallridge, president of Palm Beach County's business development board, was quoted as saying, "We continue to receive inquiries from the San Diego area, from companies who read about what's going on in the Palm Beach County and the state of Florida. Not only do you have a state that's very aggressive, but you have individual counties that are very aggressive."

That aggression has paid off with solid results for Florida. In May, the Scripps Institute agreed to open a lab in Jupiter, Fla., in a deal worth approximately \$450 million in land and tax incentives. With the location of Scripps, other California companies are looking to relocate to Florida. As part of their decision to move to Florida, the Torrey Pines Institute will receive \$80 million in incentives while Burnam is expected to receive \$300 million.

While all three institutions have confirmed plans to retain their La Jolla labs, it is clear that Florida's incentives are wooing expansions that might otherwise have been built in California. Wise fiscal management on the part of the state government has resulted in budget surpluses, giving Florida the freedom to offer valuable incentives that attract life sciences investments. At the same time, the state is working in an active partnership with local governments to secure land and other inducements to attract industrial investment. When courting the Torrey Pines Institute, both Boca Raton and Palm Beach Counties gathered \$32 million in land and money, which doubled to a \$64 million deal when coupled with state funds.

The state's investment will generate broad benefits to Florida citizens. Economists estimate that over the next 15 years the Scripps Institute will create a total of 545 direct jobs, generate an additional \$1.6 billion in income and boost Florida's economy by \$3.2 billion.

ILLINOIS

While not historically a major life sciences growth area, Illinois has stepped up and experienced dramatic growth in industrial development. Illinois was rated the top state in the nation for biotech growth in 2005 by *Business Facilities Magazine* and hosted BIO 2006, an international conference that draws many top industry representatives.

One key factor in the state's life sciences growth was investing in an opportunity to turn its crop production into a life sciences business opportunity. New technological processes convert soybeans into biodiesel and corn into ethanol, a cost-competitive gasoline known as E-85. Rising natural gas prices and increased uncertainty regarding foreign oil have led to increased interest in producing more E-85 and biodiesel as well as vehicles that utilize them. The state has invested significant resources to facilitate the development of this life sciences

sector. Illinois became the first to eliminate the state sales tax on E-85 and biodiesel blends of 11 percent or higher (B11), dramatically increasing E-85 sales and creating the largest biodiesel market in the nation. Illinois also invested \$500,000 to increase access to E-85 and allow more gas station operators to offer the 85 percent ethanol fuel. Since 2004, the number of E-85 retail sales locations in the state has increased from 14 to about 100, approximately 20 percent of the entire nation's E-85 stations. Additionally, Illinois provided more than \$1.5 million to the National Corn to Ethanol Research Center at Southern Illinois University Edwardsville, a pioneer of biofuels research, and \$4.8 million to the Lincolnland Agri-Energy Ethanol plant in Palestine, where more than 40 million gallons of ethanol are produced each year.

Though agriculture is an Illinois mainstay, the state is looking to broaden its life sciences industrial development. Illinois recently gained national exposure by becoming the first state in the Midwest and the fourth state in the nation to commit public funds to stem cell research. Thus far, the state is investing \$10 million in stem cell research, with another \$100 million being proposed.

Illinois is also helping life sciences companies, such as Astellas Pharma and Hospira, move to or expand in Illinois as well as investing to improve the state's infrastructure. Illinois has invested the following:

- **\$1 million for the Illinois Science + Technology Park, a 1.5 million square foot campus designed to commercialize scientific research in Skokie. Upon completion, a study conducted by Applied Real Estate Analysis, Inc. estimates that the campus will generate \$1.8 billion annually in statewide economic activity. Additionally, the site is expected to create 3,250 new on-site jobs, more than 10,000 additional jobs and 1,000 construction jobs.**
- **\$4.5 million to help launch the Peoria NEXT Innovation Center. This Center is designed to assist the growth of nanotechnology, bio-science, health care and agriculture start-up companies. Upon completion, it is expected to accommodate up to 20 firms, initially creating 200 jobs in the first three years and building up to 1,200 jobs over the next eight years.**
- **\$1.6 million for the new Biotechnology Laboratory Incubator at Southern Illinois University, Edwardsville. This new section is expected to house as many as 12 biology, chemistry or biochemical laboratories.**

NEW YORK

In New York State, the Office of Science, Technology, and Academic Research (NYSTAR) has focused its strategic plan on the life sciences industry. In the last year (2006?), New York City began developing a new bioscience research park, to be known as East River Science Park, and focused large grants on research at its top-tier state universities.

East River Science Park will be built on a City-controlled site on Bellevue's campus. Encompassing 870,000 square feet, the facility will be the largest commercial bioscience center in New York City and is expected to jumpstart the city's commercial bioscience industry by attracting top healthcare and pharmaceutical companies while providing expansion space for the City's existing companies.

New York's state government is also interested in increasing support for the state's educational institutions. With nearly \$3 million in grants to four universities, the state is

investing significant resources to attract the brightest scientific minds to New York. These faculty development awards are intended to attract a select group of world-class scientists and boost the long-term growth of the State's life sciences industry. Scientists who receive the funds will use them to conduct research in areas such as nanotechnology, information technology and protein crystallography.

EVOLVING TRENDS IN SITE SELECTION INCENTIVES FOR LIFE SCIENCES COMPANIES

A global life sciences economy means global competition for corporate offices and manufacturing facilities.

A variety of state and local incentives are available to life sciences firms depending on the geographic location, type of operation, investment, employment and tax impact of the company's facilities. Such incentives include tax rebates, exemptions, moratoriums, reductions, credits, deductions, infrastructure improvements, relocation and cash grants, which can be used to offset both start-up costs as well as the cost of ongoing operations. Total benefits provided to a company in a given region can range from a low of several thousand dollars per employee to cases in which employers have been offered incentive packages that amounted to millions of dollars per employee.

The menu of incentives is always under review by state, county and local governments who are engaged in serious economic development. Proactive government officials know they have to reach out to potential life sciences employers to attract new companies and to retain the ones they have. Complacency is not the answer.

REVIEWING LOCATION INCENTIVES: A GOVERNMENT-LIFE SCIENCES PARTNERSHIP

Many states and nations have identified the life sciences industry as a high-priority target for recruitment. Incentives in these regions can be quite extensive. As previously mentioned, when Scripps Research Institute was looking for a home for its new research center, the state of Florida, provided more than \$450 million in incentives, including more than \$300 million in grant funding and a free \$140 million facility. According to Scripps, the facility will employ 545 workers by its seventh year of operation—an incentives/employment ratio of \$826,000 per job. Another incentive example: When Zimmer announced its desire to expand its facilities in Warsaw, IN, state and local governments responded with more than \$6 million in incentives—an incentives/employment ratio of \$24,000 per employee.

Some states provide free training services to companies as a non-cash incentive that improves the quality of the local labor force. The Gambro Group worked with the Alabama Industrial Development Training Institute (AIDT) to provide training to the 150 new employees that the company expects to hire in Opelika (an Eastern Alabama city of 25,000 near Auburn University). The training program spanned 18 months.

Depending on the types of incentives programs that have been approved by legislatures, incentives vary greatly from one region to another. Total state and local assistance generally falls in the \$10,000 to \$40,000 per job range. For capital-intensive facilities, incentives can range from 10-30 percent of capital investment costs. However, the actual final incentives can vary markedly, depending on the types and proposed payroll of the jobs being created, the capital investment, the tax-generating potential of the project, and the level of competition for the new facility.

SELECTING THE RIGHT LOCATION AND THE RIGHT MATCH

Relocation advisors urge extensive due diligence to ensure a proper match between an expanding company and its potential new neighborhood. A host of issues come into play. But one thing is certain: The days of automatically expanding next door are over.

Executives have to evaluate all of their options prior to committing their companies to a long-term location. They must thoroughly explore labor market, real estate, utilities and incentives programs that can make the difference between enterprise success and failure. On the other hand, some executives allow one factor, such as incentives, to drive the entire location decision.

The best site selection approach for life sciences companies is to first identify the key criteria necessary for the success of the proposed facility, as well as the project's location drivers. Some examples of location drivers include the following:

- **Cultural and educational activities and a sense of community**
- **Proximity to commercial air service**
- **Available workforce for expansion**
- **Area university research and postgraduate training facilities**
- **Overall quality of life for employees**

Once these key drivers are identified, a company is better positioned to conduct a thorough analysis of potential site locations. A search may encompass multiple states or countries. Each city, state and country has thousands of elements of information that could be important in the site selection process, and the sheer volume of such information can be overwhelming to the site-seeking executive. By identifying key requirements up front, companies are better able to focus due diligence efforts on those factors that are most important to the success of the proposed project.

CONCLUSION

Proactive government bodies that recognize the value of cutting-edge life sciences companies moving into their communities are making efforts to engage, negotiate and encourage the industry's development.

Public sector agencies interested in demonstrating their commitment to the life sciences should consider creating economic development departments, making elected officials more accessible, developing economic incentives and maintaining the cultural and communal attributes valued by scientific based employees and their families.

California must make life sciences growth and investment a priority. The jobs and economic growth generated by this industry are the kind every state clamors for. The state government should constantly review and revise its relationship with industry to continue its leadership in the sector.