TAKING ACTION FOR TOMORROW

California Life Sciences Action Plan

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BAY AREA BIOSCIENCE CENTER

BIOCOM

C · H · I CALIFORNIA HEALTHCARE INSTITUTE

Southern California Biomedical Council

BAY AREA COUNCIL

Larta

rta sd regional technology alliance : san diego

sarta Sacramento Area Regional Technology Alliance

MONITOR GROUP

Bay Area Bioscience Center

On behalf of Northern California's Life Sciences community, BayBio thanks the officials at all levels of government with whom this Plan finds an audience. This effort represents more than two years of thoughtful contribution from many stakeholders in this biotech region. While Northern California strives to remain the global leader for this industry, our position garners increasing attention from would-be substitutes. To maintain our unmatched pace, an uncommon partnership is required between our government and the private sector — one that embodies creative problem solving and represents bold new thinking. As unrivaled as Northern California is today in the Life Sciences, so must be the commitment of all partners in carrying out this Plan.

Matt Gardner
President

BIOCOM

BIOCOM was pleased to work in partnership on developing a strategic plan to retain California's competitive edge in Life Sciences research and development. We hope this report and the subsequent discussion on its findings will enable the State of California to develop initiatives that will foster the growth of the entire industry.

Joe Panetta
President & CEO

California Healthcare Institute

As the global leader in biomedical innovation, California, more than any nation or region, has benefited from dynamic relationships among academic institutions, companies, technologies, sources of investment capital and governments. As competition and pressure on government budgets grows, sustaining innovation will require increased collaboration. No industry holds greater promise – for scientific progress, for the state's economy, for patients with unmet medical needs – and no industry faces more rigorous challenges to realize its full potential. The call to action implicit in this report is for California's Life Sciences community to engage with government leaders to ensure that the Golden State capitalizes on the next wave of bioscience innovation.

David L. Gollaher, Ph.D.
President & CEO

Southern California Biomedical Council

Because of its openness and innovative spirit, California has established itself as the bio-economy world leader. To maintain this leadership in an increasingly competitive world where many regions and countries now fiercely vie for larger shares of biocommerce, the SCBC calls on the California Life Sciences Community to nurture our state's culture of entrepreneurship. Leadership in biocommerce means a better and more accommodating environment for established firms and start-ups; it means a deeper pool of talent for growing companies; and it means a richer bank of resources for the entrepreneurs who are creating the businesses and the high-paying jobs of tomorrow.

Ahmed A. Enany
President & CEO

Bay Area Council

The statewide effort embodied in this report is at once thrilling as it is sobering. It reveals the promise of biotechnology, how it can slip away, and what must be done to ensure that the promise of the industry is fulfilled within the borders of California.

If there is an industry we must work to protect and nurture, this is it.

This report lays out a well-researched blueprint of required steps to preserve and expand the cluster. It is not preordained that biotech's birthplace of California will remain its headquarters and home base. The Bay Area Council is prepared to stand with our cohorts in Los Angeles, San Diego and Sacramento, to put our weight on the levers of public policy in Sacramento. The Bay Area Council is prepared to partner with the state government in its critical efforts. Finally, the Bay Area Council is prepared to engage the business community in the Bay Area on the required regional work.

It is time to act. Thankfully, the Action Plan can help guide the way.

Jim Wunderman
President & CEO

Larta Institute

Larta, as a hub for emerging technology entrepreneurs, investors, service professionals and policymakers, endorses this call to action. California has the greatest concentration of life sciences companies, resource providers, capital and talent in the world. Increasingly, however, it needs to deploy and focus those assets more effectively to meet new competitive challenges.

This call to action is a pointer to the barriers that have been erected through inattention or deliberate inaction and to the commitments that the State, the regions and leaders throughout California must put in place to capitalize on the value of the life sciences to economic growth and prosperity. Larta, as an economic development leader in the State, has developed significant relationships with important Life Sciences resources around the world, and pledges its support to help realize this vision.

Rohit Shukla
President & CEO

SDRTA

As a resource organization for emerging technology and Life Sciences companies, the San Diego RTA appreciates this call to action. We hope that by taking a collaborative and proactive approach we will be able to remove some of the obstacles that currently encumber — or threaten to impede — the maturation of this important industry. Both as a source of statewide prosperity and as a source of life saving technologies, the Life Sciences contribute significantly to all of us. We hope that our leaders will respond to this Action Plan with decisive attention and enact the needed reforms called for by the industry.

Tyler Orion
President & CEO

ACKNOWLEDGEMENTS

Taking Action for Tomorrow: California Life Sciences Action Plan is a joint effort of a number of groups: Bay Area Bioscience Center (BayBio), BIOCOM, California Healthcare Institute (CHI), Southern California Biomedical Council (SCBC), Bay Area Council, Larta Institute, Sacramento Regional Technology Alliance (SARTA), and San Diego Area Regional Technology Alliance (SDRTA).

Over 300 business and government leaders contributed to this synthesized Action Plan in some way by participating in interviews, completing surveys, attending one of the four regional Life Sciences Summits, and offering their views and expertise. This Action Plan benefits from their key insights on the four regions and on Life Sciences. Appendix A provides a list of the many contributors and participants involved in the creation of the four regional Life Sciences Strategic Action Plans.

The following individuals were the key contributors to this Action Plan:

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In addition, Lee Harrington of the Los Angeles Economic Development Corporation (LAEDC) and Julie Meier Wright of the San Diego Economic Development Corporation (SDEDC) reviewed a draft of the report and provided helpful commentary.

A Monitor Team, led by Matthew Le Merle, Nancy Michels, and Joan Chu provided the framework for, captured industry perspectives on key issues, and facilitated the drafting of the California Action Plan. Monitor consultants Marielena Gutiérrez, Ryan Kaiser and Steve Szaraz worked actively on this project.

Lily Rappoli and her team at the Design Studio at Monitor Group illustrated, designed, and created the layout of this report.

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EXECUTIVE SUMMARY 1

The California Life Sciences industry leads the world. The achievements of the over 2,500 California firms have established the gold standard for innovation and creativity. Indeed, three of the four regions where the industry has concentrated its activities — the Bay Area, the Los Angeles region, and San Diego — could stand proudly in their own right on the world stage. Beginning with efforts in the Bay Area more than 25 years ago, the State's Life Sciences industry has drawn from leading research institutions, an increasingly innovative workforce, and a willing and cooperative venture capital community. As a result, of the over 6,250 Life Sciences firms worldwide, 40% are located in California.[1] These California-based companies are leading the development of a new, global industry, which holds out the prospect of significantly enhanced health and well-being for the world's population.

Taken together, and with the growing achievements of the Sacramento region in bioagriculture and manufacturing included, this industry generates intellectual capital, draws and retains human assets, and distributes economic benefits to its core businesses.

But global industry trends present both challenges and opportunities, and California cannot afford merely to remain the best — it must strive to be better.

The challenges are considerable. Business models are changing and the structure of the industry will change with it. Firms will shift their attention from letting good science find a market to proactively and intelligently targeting markets with good science. Companies in the Life Sciences are quickly moving through their life cycles from development to commercialization and are bringing ever more products to market. The industry landscape will likely shift from a large number of small Life Sciences companies to a more limited population of large Life Sciences companies and new subsidiaries of multi-national pharmaceutical companies. Indeed, over time, research and development (R&D) productivity of smaller Life Sciences companies will drive increased convergence of the pharmaceutical and biotechnology industries.

The opportunities offered by these challenges are considerable, too.

All of the stakeholders in the wider Life Sciences industry in California must work together to maintain and enhance the position that the industry has achieved. In the face of these challenges and opportunities each of the regions came together for summit meetings that produced recommendations for sustaining and strengthening their Life Sciences endeavors. These recommendations fall under six broad themes:

- Improving the financial environment.
- Reforming and streamlining Federal, State, and local regulations.
- Accelerating technology commercialization and new business formation.
- Preparing adequate human capital.
- Resolving critical infrastructure needs.
- Inspiring more Life Sciences community collaboration.

Financial resources are vital to a Life Sciences company's success at every stage of its life cycle. Early on, seed funding is critical to the protection of intellectual property, as well as to the support of the research needed to demonstrate proof of concept. Later, additional capital is needed to see a product through pre-clinical tests, to assemble the necessary workforce, to formalize business operations, to enhance the emerging technology, and to develop both a regulatory and a sales and marketing strategy. While California is fortunate in the strength of its venture capital ecosystem, there are ways in which the industry can be further encouraged to grow and flourish. In some cases, this requires California to do nothing more than subscribe to generally applied national approaches. In others, California has the opportunity to apply its tremendous creativity to further enhance the strengths of the State's capital environment, and lead the nation with regard to fiscal policy and its implications to Life Sciences.

The regulatory environment can influence whether businesses move to or remain in a region, since the weight of the rules, policies, and requirements that Federal, State, and local governments place on businesses can affect the cost of doing business there. Items like permitting, zoning, disability and unemployment policies, and workplace safety regulations increase costs directly through fees and penalties and indirectly through the costs of ongoing compliance. Inefficiencies, like duplicative Federal, State, and local regulations or overly complex compliance processes, increase this regulatory burden. The very nature of Life Sciences businesses makes them particularly sensitive to these costs. State and local governments must work with the Life Sciences industry to identify regulatory and compliance inefficiencies, to streamline existing processes and to foresee potential issues in proposed regulations in order to encourage businesses to locate and to remain in California.

The Life Sciences industry depends upon the flow of ideas from research and development into the marketplace. Indeed, cutting-edge research focused on the development of new intellectual property (IP) is a primary driver of the innovative spirit and success of all competitive regional clusters. But unless this research can be quickly, effectively and efficiently transferred to the marketplace in a sustainable way, the benefit to the State economy is limited. Strengthening existing efforts to increase the collaboration between State agencies, regional leadership groups, and the appropriate officers at the private and public research institutions in California will do much to encourage the new business formation that enable truly competitive regional clusters.

Properly harnessed and leveraged human capital drives innovation and growth in every company, every industry, and every region. As a high-technology industry such as Life Sciences in California matures, sustainable competitive advantage depends increasingly on how the region and the companies in it develop and manage their human capital. Other states have not only identified workforce development and retention as a priority; they have set their sights on competition with California for these critical assets. For obvious reasons, the Life Sciences are particularly dependent on the availability of highly trained professionals and skilled technicians. Nationwide, 50% of the high-technology workforce has a Bachelors of Science degree, 17% a Masters of Science degree, 19% a PhD, and the remaining 14% a degree or diploma from a vocational school or community college.[2] The emerging pattern of growth in the Life Sciences suggests that new employment will likely consist of R&D (50%), manufacturing (25%) and commercial, marketing, management and support (25%) positions.[3] Given the importance of the Life Sciences to the California economy, it is critical for the supply of skilled labor to meet the industry's job creation needs across these functional areas.

In terms of infrastructure, California has opportunities to further streamline and simplify the processes by which new development occurs, and can preempt potential constraints to growth by proactively resolving issues in areas such as water, power and waste management that are of particular importance to the Life Sciences industry. If desired, California can also direct resources towards specific infrastructure issues in order to accelerate the development of the various fields within Life Sciences.

Finally, Life Sciences plays a critical statewide role as customer to many businesses, as partner in innovation to multiple industries, as creator of the livelihood for many in the region's workforce, and as contributor to the local, regional and statewide economy. Equally important, as developer of innovative technologies and as researcher on the cutting-edge of beneficial products, it plays an ever more important role in the well-being of all humankind. Such a community must have its thoughts and needs voiced through a powerful channel that reflects the unquestioned value of the region's Life Sciences. Such a voice will enable the Life Sciences to grow, to flourish, to bring prosperity to the region, and to improve the health of people all over the world.

COMPREHENSIVE LIST OF INDUSTRY STATEWIDE RECOMMENDATIONS

IMPROVING THE FINANCIAL ENVIRONMENT

- Ensure that the State pays sufficient attention to the long-term health of innovation and the economy and in particular continues Federal compliance with the exclusion of biologic drugs in any discussion of drug importation.
- Harmonize Net Operating Loss (NOL) carry forward rules with Federal tax law, which provides for carryover of up to 20 years.
- Allow large Life Sciences companies, either headquartered in California or employing a significant number of Californians, to purchase discounted tax credits / deductions from small R&D firms.
- Establish a Manufacturer's Investment Tax Credit tied to job creation for new and expanding Life Sciences investments.
- Maintain and expand the qualified basic R&D tax credits.
- Change the apportionment formula for corporate income tax from the current triple factor formula to a single sales factor formula.
- Instruct CalPERS to both fully deploy funds earmarked for Life Sciences investment and ensure that its asset allocation fully reflects the long-term value creation of the Life Sciences industry.
- Instruct the Business, Transportation and Housing Agency in conjunction with the Franchise Tax Board to examine the potential benefits of angel investor tax credits.

REFORMING AND STREAMLINING FEDERAL, STATE, LOCAL REGULATIONS

- Eliminate redundancy and duplication between State agencies and Federal agencies. Eliminate the State Department of Health Services inspections that duplicate U.S. Food and Drug Administration regulation.
- Adopt broad harmonization program among Cal/OSHA and OSHA, Cal/EPA and EPA and agencies such as the Nuclear Regulatory Commission.
- Improve zoning and permitting regulations and processes by establishing an electronic standard that directly links State and local processes.

List continues on next page.

COMPREHENSIVE LIST OF INDUSTRY STATEWIDE RECOMMENDATIONS (cont.)

ACCELERATING TECHNOLOGY COMMERCIALIZATION / NEW BUSINESS FORMATION

- Create a mandate for California State agencies, regional leadership groups, the University of California Office of the President, and University of California Technology Licensing Offices to collaboratively accelerate transfer of technology through improved commercialization practices, controls and incentives.
- Broaden the mandate and authority of the UC Directors of Technology Licensing Offices to encompass technology commercialization and new business formation activities.

PREPARING ADEQUATE HUMAN CAPITAL

- Instruct the Employment Development Department (EDD) to work with Life Sciences industry associations to forecast and communicate current and future Life Sciences industry employment needs by relevant skill category.
- Modify workforce training and development expenditures in better alignment with Life Sciences.
- Designate four regional academic centers to spearhead statewide efforts to develop more clinical science and laboratory programs and regional, intersegmental (community colleges, State universities) training facilities.
- Mandate public educational institutions, in collaboration with industry, to continue develop programs, including internships and rotations, that prepare students and scientists for work in the private sector in order to create a more versatile future workforce.
- Ensure state education officials place greater focus on science education throughout the public school system.

RESOLVING CRITICAL INFRASTRUCTURE NEEDS

- Continue to provide support for bio-research parks.
- Facilitate development of commercial space and revitalization efforts for start-up and young Life Sciences companies by creating and supporting enterprise zones.
- Continue to provide funding for the new centers of science and innovation: QB3, CITRIS, California NanoSystems Institute.
- Find acceptable solutions for the disposal of low-level radioactive waste and expedite decommissioning requirements.
- Ensure reliable sources of water and power.
- Establish an electronic index of California commercial real estate for investment attraction purposes.

INSPIRING LIFE SCIENCES COMMUNITY COLLABORATION

- Establish a California CEO Advisory Group for Life Sciences to present a shared voice for the industry in California.
- Appoint senior administration official(s) as a liaison to the Life Sciences industry to enable ongoing dialogue with the Governor's office.
- Foster education and awareness about Life Sciences by instructing government officials to become more active in Life Sciences regional organizations' advisory panels and summits through the California Assembly Select Committee on Biotechnology.
- Develop an Emerging Technology Business and Entrepreneurship Council that includes representatives from State agencies, legislators, and serial entrepreneurs to monitor the impact of policy on the entrepreneurial climate and to create a Governor's "Entrepreneur of the Year" award.

LIFE SCIENCES IN CALIFORNIA 2

By any and all measures, Life Sciences in California represents a remarkable engine of economic growth, productivity, and competitiveness. California's Life Sciences industry leads the world: nearly 40% of the estimated 6,250 Life Sciences companies in the world are located in the State, the Bay Area and San Diego rank number one and number three in the world for the number of firms located there, and six of the top fifteen, largest biotechnology companies in the world (by market capitalization)—Amgen, Genentech, Gilead Sciences, Allergan, Invitrogen, and Chiron,— make their home in California.[4] Historically, this engine has been fueled by the State's unique wealth of human, intellectual, and financial assets. These assets include the ideas produced by California's over 87 research institutions—including world-class public and private colleges and universities—by the talents of the men and women who choose to live in the State, by its natural resources, and by a favorable business climate that has seen the growth of four significant clusters of core and supporting Life Sciences: the Bay Area, the greater Los Angeles region, San Diego, and the Sacramento region.[5] Looking into the future, California Life Sciences faces strong prospects for growth, for the continued generation of cutting-edge innovations, and for sustaining an attractive investment and employment environment.

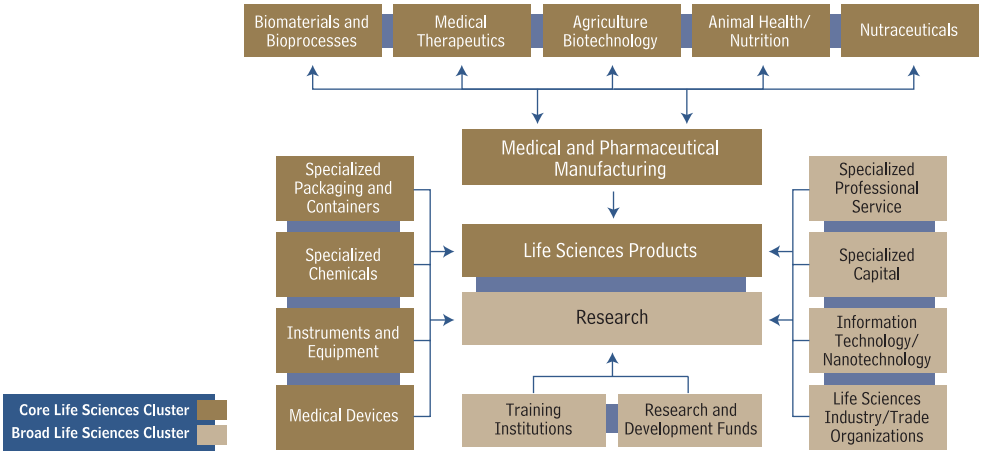
Clusters of Innovation

The real importance of Life Sciences to the wider California economy comes with a consideration of the wider sphere of economic activity around it and the benefits arising from its creation of new products, new companies, and new opportunities. This broader view comes from cluster theory. An industry cluster, as defined by Harvard University Professor and Monitor Group Partner and Co-Founder Michael Porter, is "a geographically proximate group of interconnected companies and associated institutions in a particular field, linked by customer, supplier, or other relationships." Looking at economic activity this way cuts across traditional industry classifications and recognizes the importance of cross-industry linkages to an innovative and competitive environment.

Considered as a cluster, then, Life Sciences recognizes and affirms the relationship among closely related "core" industry segments (such as biotechnology therapeutics, medical devices, and agricultural biotechnology). But it also includes those additional industries—among them specialized professional service firms (law firms, real estate developers), specialized capital providers (biotechnology venture capital),

research institutions, and industry associations — that regularly interact with core organizations. Further, it acknowledges connections with related industries and disciplines, such as information technology and nanotechnology, which are expected to increasingly converge with Life Sciences.

Exhibit 1: Life Sciences Cluster Definition



The theory underlying this notion of a "cluster of innovation" derives from an examination of the critical factors necessary for fostering innovation, competition, and growth in a wide variety of regions and industries. This theory has also provided the framework for the regional Life Sciences plans from which this summary has been drawn. The theory is described more fully in Appendix b.

Life Sciences Growth

From the outset, California Life Sciences have grown through a striking combination of innovation and entrepreneurship. Syntex Corporation (now Roche Bioscience), founded in Palo Alto in 1964, and Cetus Corporation (merged with Chiron), founded in Berkeley in 1971, lay down the roots for other efforts by academia and business to follow. A university researcher and a venture capitalist—following a model to be repeated time and again throughout California's Life Sciences industry—formed Genentech in 1976. A similar joint effort in 1973, by two Stanford geneticists, Stanley Cohen and Annie Chang, and two University of California, San Francisco biochemists, Herbert Boyer and Robert Helling, led to the development of a process to construct a DNA molecule containing the genetic material from two different species—the start of recombinant DNA technology.

After steady growth in the 1980's, core Life Sciences activity exploded to outpace the overall growth of the State (strong in its own right) by the 1990's. Life Sciences gross product doubled from $6.5Bn in 1991 to $13Bn in 2000, an 8% compound annual growth rate. By comparison, over the decade California's Gross State Product grew at an annual compounded growth rate of 6%. Employment for Life Sciences over this same period grew at 30%, compared with State growth in employment at 17%. Finally, the decade

saw wages and salaries for California Life Sciences grow at a 10% annual growth rate, compared to 4% for the State as a whole. And these numbers for Life Sciences do not include the employment and earnings associated with the wider members of the cluster — including research-only companies and related legal, venture capital and real estate companies.[6]

Not surprisingly, California Life Sciences has grown to play a strong role in the overall U.S. Life Sciences industry. Overall, California produced 16% of the U.S. Gross Domestic Product (GDP) for Life Sciences.[7] From 1999-2003, California ranked first in total biotechnology drug approvals by the FDA with 42, nearly double the approvals of the second-place state (New Jersey, 27) and three-times that of the third-place state (Massachusetts, 14). In another category, 510(k) medical device application approvals, California again led all other states with 682, more than double the number of the second highest state (Massachusetts, 317).[8] When compared with competing U.S. regional clusters, three of the four California clusters rank in the top six by employment for research, medical devices manufacturing, instruments manufacturing, or pharmaceuticals manufacturing (see Exhibit 2).

Exhibit 2: Ranking Life Sciences Clusters

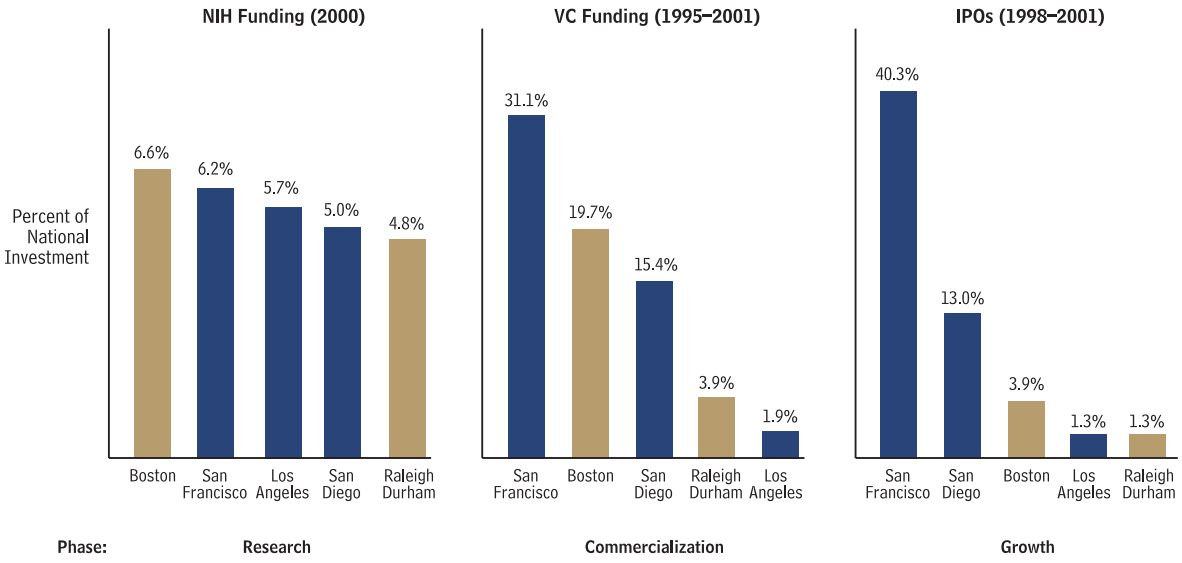
Pharmaceuticals Manufacturing	Instruments Manufacturing	Medical Devices Manufacturing	Research
1. Philadelphia	**1. Bay Area**	1. Minneapolis-St. Paul	**1. Bay Area**
2. Los Angeles	2. Boston	**2. Bay Area**	2. Houston
3. Newark, NJ	3. Bridgeport	**3. Los Angeles**	3. Boston
4. Middlesex-Somerset-Hunderson	**4. Los Angeles**	4. Boston	4. Washington DC
5. Chicago	**5. San Diego**	5. Chicago	**5. Los Angeles**
6. Bay Area	6. Indianapolis	6. St. Louis	6. Cincinnati

Source: California Technology, Trade and Commerce Agency

The Economic Importance of California's Life Sciences Industry

The ability of the four major California Life Sciences clusters – Bay Area, San Diego, greater Los Angeles region, and the Sacramento region — to create ideas, to attract capital, and to generate jobs makes them a crucial element of an economically healthy and competitive industry that leads the world and that contributes to the overall prosperity of the State. Almost 90% of California's Life Sciences activities are concentrated in the first three regions, and the fourth region shows promising growth arising out of developments in bioagriculture and Life Sciences manufacturing. In all regions, Life Sciences activities include all product types and all stages of the value chain, from early research to manufacturing, marketing, and sales.

Exhibit 3: Funding at Research, Commercialization and Growth Phases



Note: Does not include medical devices; Los Angeles includes Los Angeles, Orange, and Riverside Counties
Source: Brookings Institution, 2002; Monitor Group Analysis

The overall output of this remarkable engine of innovation can be broken into four categories: its accumulation of research horsepower and its creative output, its ability to amass the necessary capital to support these efforts, its contribution to the State's economy as a whole, and its direct creation of jobs and generation of wages.

Research and Development

In an industry built upon creativity and innovation, California's Life Sciences firms lead the world in the quantity and the quality of intellectual capital created. In sheer activity and output California institutions ranked in the top ten in 2002 for licensing income, licenses and options executed, start-up companies formed, U.S. patent applications filed, U.S. patents issued, and total research spending. The University of California system alone ranks in the top five in each of these categories — and leads all other institutions in start-ups formed, patents filed, and patents issued.[9] For Life Sciences in particular, over 87 centers of innovation in California attract talent from around the globe and drive research and development inside and outside the State. California has 19% of Life Scientists in the U.S. (1998), and California universities granted 17% of the Biological science PhDs in 1999.[10] The high caliber research conducted in the region has resulted in significant intellectual property development as California accounted for 21% of all U.S. Life Sciences patents in 1990-1999.[11]

In addition to bringing talent to the State, this climate of Life Sciences innovation and creativity attracts research and development funding in the form of Federal grants. In 2001, California's first-class public

and private universities accounted for 13% of all Life Sciences academic R&D dollars in the U.S.. Furthermore, Life Sciences accounted for 58% of all academic R&D in California at $2.6Bn.[12] With numerous research universities and institutions within the University of California (UC) and Cal State systems, as well as numerous private universities and research institutions, California received significant funding from the National Institutes of Health (NIH)—$2.9Bn in NIH grants in 2002. Nearly half (45%) of NIH funding in California was given to the University of California system.[13]

Capital

California's Life Sciences industry draws from the unparalleled access to capital that the State affords. California dominates the U.S. venture capital market: it is home to 44% of all deals and received 49% of all venture capital investments in biopharmaceuticals between 1995 and 2001 in the U.S.[14] Of course 2002 and 2003 have seen a significant decline in new money flowing into the venture capital industry and into Life Sciences, but this is as true of California as of any part of the nation. California has the highest concentration of Life Sciences-focused venture capital firms; the next highest concentration is in the Boston cluster. Between 1998 and 2001, California biopharmaceutical companies conducted 43 initial public offerings (IPOs).[15]

Place of Life Sciences in the California Economy

California's global leadership in Life Sciences rests on the output of an estimated 2,500 Life Sciences companies. And the footprint of the regional clusters are larger if the many out-of-state Life Sciences companies that have operations or facilities in California are included. In 2003, Life Sciences contributed $12Bn to the State economy. Separate from the measure of GSP, California-based Life Sciences companies produced $29Bn in revenue in 2002.[16] Moreover, at $104,000, labor productivity— the amount of output a worker turns out in a year—is 13% higher than the average for all industries in California.[17] Additionally, focusing on the companies involved in Pharmaceutical and Medical manufacturing as well as Medical Device manufacturing, the labor productivity jumps to $115,000—26% higher than the State average.[18]

Employment and Wages

Life Sciences has shown a continued ability to attract, grow, and retain high wage jobs, which in turn creates a ripple effect throughout the general economy as these employees live, work, and spend in the State. California currently has 112,000 jobs in the core industries of Life Sciences.[19] However, when the overall cluster businesses are taken into account, that figure nearly doubles to 220,000.[20] The average annual wage level for California in 2002 was $41,000, which was significantly higher than the national average of $34,000— and much of this difference is due to the high concentration of leading technology companies in the State.[21] In fact, Life Sciences wages average $67,000, nearly twice the national average wage and 66% higher than the average California State wage.[22]

CONCLUSION

California can be proud of a Life Sciences industry that generates more ideas, jobs, businesses, capital investment, and economic energy than any other in the world. The industry remains a vital and vibrant part of the California business landscape. Both in terms of its core businesses and its wider cluster of related ones, Life Sciences continues to create jobs and to attract talented labor and investment capital. Three of its centers of innovation and creativity—the Bay Area, San Diego, and the Los Angeles region—are world-class in their own right; a fourth, Sacramento, is taking steps to join them.

GLOBAL TRENDS IN LIFE SCIENCES 3

As California's Life Sciences industry looks to the future from its position of global leadership it faces a number of significant challenges and opportunities. During the next ten years, the industry as a whole will continue to be shaped by dynamic and uncertain scientific, financial, and social developments. These changes confront an industry just transitioning through adolescence: for example, results from the Human Genome Project are just beginning to bear fruit and powerful new therapeutics and devices are now beginning to reach the marketplace in greater numbers every year.

This section frames the key areas of greatest importance to the continued evolution of Life Sciences in California during the next ten years (see the outline of these trends and implications in Exhibit 4). Sustained competitiveness and maintenance of California's world leadership will depend upon the willingness of the stakeholders in the State's Life Sciences industry to work together to confront these challenges and turn them to their advantage.

Exhibit 4: Key Life Sciences Trends and Cluster Implications

KEY LIFE SCIENCES TRENDS	CLUSTER IMPLICATIONS
Maturing biotechnology business models	Increasing demand for manufacturing and commercial capabilities
Developing technologies in Life Sciences	Creation of new opportunity with convergence of IT and biotechnology
Emerging personalized healthcare model	Need to address global markets to find profitable scale of patient population
Rising cost of healthcare	Pressure to improve the cost and efficiency of drug development
New funding models	Need for creative capital solutions and understanding of biotechnology model
Changing regulatory environment	Converging global regulatory standards and emphasis on IP protection
Growing public interest in the ethics of Life Sciences	Risk of public unwillingness to accept certain technologies and applications
Increasing competition from other regions	Competition for California talent, capital, resources, IP
Expanding international scope of California companies	Opportunity in new global markets

Maturing Biotechnology Business Models

With an increasing number of products moving through the pipeline toward regulatory approval and sale in the marketplace, the traditional focus of biotechnology companies will shift from upstream research to more downstream activities like clinical development, manufacturing, and sales and marketing. Those biotechnology firms that choose to build in-house sales and marketing capabilities in order to receive a greater share of eventual commercial revenue will further resemble typical, vertically-integrated pharmaceutical companies, and will compete head-to-head with traditional pharmaceutical companies in many therapeutic areas. With over 370 clinical trials targeting more than 200 diseases being conducted by biotechnology companies alone (not to mention chemical compounds addressing the same therapeutic areas), such increasing competitiveness shows no sign of abating.[23] This trend not only decreases the gains of being first-to-market, it may also affect key consumer behavior by overwhelming physicians with the sheer volume of products competing for their share of mind. In many ways the medical devices industry is seeing similar changes as the rate of introduction of new technological advances ripples through this portion of the Life Sciences industry.

Faced with this accelerating competitiveness, many Life Sciences companies will continue to out-license molecules to vertically-integrated pharmaceutical companies or become acquisition targets for companies looking to bolster their development pipelines. Indeed, over time, research and development productivity of smaller Life Sciences companies will drive further merging of the pharmaceutical and biotechnology industries, simply because pharmaceutical companies need viable new drugs to fill their pipelines and biotechnology companies need funds to finance continued R&D. So too, many expect convergence between therapeutics and devices / delivery systems as Life Sciences companies begin to explore opportunities to combine products to better address patient needs.

The most immediate impact of these developments for California will be the increasing demand among maturing Life Sciences companies for commercial expertise, as well as for manufacturing capabilities and capacity. Although there is already a sizeable Life Sciences manufacturing presence in some parts of California, there will be a growing need to marshal the institutions and infrastructure essential to these requirements going forward.

Moreover, the California landscape will likely shift—perhaps through increased mergers and acquisitions activity —from an emphasis on small Life Sciences companies to a more balanced population of large biotechnology companies and new subsidiaries of large pharmaceutical companies alongside smaller research focused institutions. Along with this maturation, the industry needs to remain mindful of the importance of maintaining the innovation at the start of the pipeline.

Developing Technologies in Life Sciences

The Life Sciences cluster continues to see the emergence of new sub-technologies, sub-specialties, and entirely new areas of research (proteomics, functional genomics, and bioinformatics) as the Human Genome Project continues to bear fruit. This will ratchet up the demand for expertise in emerging areas of basic research. In the longer term, emerging technologies such as gene therapy and stem cell research

will also shape the global development of Life Sciences. Regions that can position themselves to capitalize on new, greenfield areas of research will be best positioned to benefit.

As the Life Sciences cluster matures, integration will take place with biotechnology, other technologies, and previously discrete, unrelated markets. Indeed, synergies among biotechnology, chemistry, physics, and information technology are already fueling innovation in many areas, from the more traditional pharmaceutical, digital health, and agricultural industries, to such emerging industries as industrial biotechnology, molecular and organic electronics, and DNA and biologically-based computers. As biology moves from a descriptive to a predictive science, both the resolution and complexity of experimental questions and answers will increase. We will see greater convergence in the form of cross-industry technologies and applications like bioinformatics and nanotechnology as the boundaries between information technology and the Life Sciences continue to blur. Successful regions will, therefore, need to leverage—and integrate—core strengths in the Life Sciences, information technology, mathematics, engineering, physics, and other disciplines yet to be determined. California is particularly well positioned to drive these new areas of convergence due to the State's leadership in all areas of information technology.

Increasingly Personalized Healthcare

A move toward personalized healthcare will continue as scientists leverage genomic information to gain a more fundamental understanding of diseases' biological process and of proteins at play in various disease states. Therapies developed by Life Sciences firms are creating higher levels of specialization for targeted patient populations. Indeed, biotechnology has enabled the development of many targeted drugs with diagnostic tests to determine a priori whether a drug will be effective for a particular patient's genomic profile. An early example of this is Genentech's breast cancer drug Herceptin, which is tremendously effective for a certain subset of patients with HER-2 gene expression. Interestingly, as pharmacogenomics yields drugs with a higher probability of success for smaller, targeted patient populations, companies will increasingly need to look to global markets to match investments against these patient populations. This wider market focus will have an impact on California as the Life Sciences industry becomes even more global.

Rising Cost of Healthcare

Concern over the rising cost of healthcare will influence the growth of new Life Sciences technologies. Public debates about re-importation and price controls are certain to become more heated in the context of renewed arguments over the recent Medicare bill and its overall cost projections for the future. Life Sciences will receive its share of scrutiny as these costs come under investigation, and particularly as newer biotherapeutics that are more expensive to produce enter the market. Despite the cost reductions that may accompany new innovations in treating more widespread illnesses like diabetes, cancer, and Alzheimer's disease, Life Sciences will need to be an active participant in the ongoing debate over increasing healthcare costs.

The Life Sciences industry's response to these rising costs will come in three parts. First, new drugs will need to be more efficacious and more cost-efficient. Second, companies will need to emphasize total

patient management economics that demonstrate the overall system cost savings that products can produce when expensive hospital visits are avoided. Third, there must be a decrease in the cost and time required to develop new Life Sciences products.

This last change is especially important. The current cost of developing and bringing to market a novel therapeutic can reach a fully burdened expense of up to $802M (see Exhibit 7). To flourish, Life Sciences companies will have to reduce this overall expenditure through more efficient discovery processes and better overall pipeline attrition rates. For California this makes it essential that government regulation is not so complex or burdensome to itself generate cost increases in development.

New Funding Models

The drive for innovation and creativity by Life Sciences companies necessarily makes them hungry for funding. Rather than satisfying this need for capital, however, the current model actually increases companies' needs. While clinical trials and FDA approvals (which are only one step in the drug development process) may take as much as 12–15 years for a single therapeutic agent, the current venture capital model remains predicated on an exit strategy in the relatively near term.[24] This misalignment often leads developing Life Sciences companies to pursue a first positive discovery more aggressively than they might wish, because they are under increased pressure to develop value claims in order to raise additional funding and go public within a reasonable period of time.

Over the coming decade the demand for capital by Life Sciences companies will only increase, leading to the broadening of the sources of funding in two ways. Larger corporations are increasingly likely to provide capital through joint ventures or acquisitions. Also, angel investors may step in to fund Life Sciences ventures where timelines are inconsistent with venture capital requirements. Indeed, because of the competitive changes already outlined, this broadening may occur even if the venture model does change to better match Life Sciences needs.

Changing Regulatory Environment

The national and international regulatory environment will continue to influence the development of Life Sciences. Potential constraints on some types of research, including stem cells and genetically-modified foods, will help determine a region's breadth and depth of scientific expertise in certain areas. Other parts of the globe will certainly embrace this research if the U.S. chooses to de-emphasize it, but the long-term effects of trends like the shift in stem cell research towards China and other non-U.S. regions are unclear. To date, California has been very progressive in its support of stem cell research and other developing technologies. The evidence, however, suggests that the movement towards stricter regulations in the U.S. as a whole relative to other countries will likely continue and, perhaps, intensify.

International regulatory trends will also grow in importance. It seems probable that markets will converge on a global set of regulatory standards that will govern how therapeutic agents are brought to market. In addition, there will likely be a convergence in the kinds of clinical trial data used in various countries. As a result, the overall process of drug approval should become more standardized across

various geographies. Increasing numbers of U.S. companies are already conducting at least a portion of their clinical trials in Europe to shorten overall time to market. Over time, this international clinical trial presence will give U.S. companies greater access to international resources and may encourage them to move a portion of their operations overseas. This trend presents a challenge for the region and implies that California should work to remain attractive to Life Sciences companies already located in or considering locating in the State.

International intellectual property rights also represent a major uncertainty. How these legal rights develop will do much to shape the extent to which California firms can and will address new, international markets in the next ten years, particularly in developing nations.

Public Sentiment

Public perception of the Life Sciences continues to be an important factor shaping regulatory control, access to expanded markets, and the availability of a capable and willing workforce. Public opinion with regards to biotechnology, particularly stem cell research, cloning, and genetically-modified foods, covers a wide range of points of view, some more and some less well informed.

While much of the concern about Life Sciences is grounded in fact and in differing judgments about the ethical treatment of various scientific endeavors, some concern is the product of miscommunication between industry and the public. The extent to which public opinion will embrace the advanced research needs of the Life Sciences depends on its ability to reach out to the community, educate it, and engage it in open debate – and this is particularly true in California. To ensure the continued success of the region's Life Sciences clusters, industry, government, and the public will need to communicate openly so as to develop a shared vision of what is doable— and what is right to do.

Increasing Competition from New Regions

Other U.S. regions have been developing their own strategies and taking actions to build and nurture Life Sciences clusters in order to challenge California's dominance in Life Sciences. In each case, as Exhibit 5 illustrates, State government has played a key role in the efforts to capture and catalyze Life Sciences growth. These state-level initiatives share a common focus on three issues: providing increased funding for State research institutes and centers; finding vehicles for addressing the financing needs of the industry; and supporting the facilities needs of the industry at all stages of the business system.

In addition, each state has identified approaches for addressing specific weaknesses in order to improve overall Life Sciences competitiveness.

Moreover, the arena for this competition has, in fact, become truly global. Three decades ago, the Life Sciences industry consisted, in effect, of a group of start-ups in the U.S. that used genetic engineering to produce human protein drugs. Today, the Life Sciences have burgeoned into a global industry with more than 6,250 companies throughout the U.S., Canada, Europe, Australia / New Zealand, and Asia that apply revolutionary science and technologies to diverse fields such as agriculture, environment, health care, and industry.[25] Exhibit 6 illustrates this growing global activity.

Exhibit 5: Examples of Domestic Competitor Regions' Initiatives

State	Examples of Research Strategies	Examples of Finance Strategies
Alabama		■ Alabama Site Development Program (Facilities).
Alaska		■ Alaska Growth Capital (Facilities).
Arkansas		■ Arkansas Capital Corporation (Facilities). ■ Tax-credit for constructing biotechnology facilities.
Connecticut		■ Biotechnology Facilities Fund (Facilities). ■ TSF.
Delaware	■ $85 million to the Delaware Biotechnology Institute.	
Georgia	■ $300 million for endowments for Eminent Scholars and building state-of-art laboratories and core research facilities.	
Illinois	■ Part of $2 billion, 5-year VentureTECH initiative to fund Post-Genomics Institute, Biomedical Research Facility, Medical Resonance Imaging Center.	■ TSF.
Maryland		■ Economic Development Opportunities Fund (Facilities). ■ Maryland Industrial Development Finace Authority (Facilities). ■ TSF.
Massachusetts	■ Mass Life Sciences initiative (collaborative private sector and government initiative). ■ New England Healthcare Institute.	■ Mass Development (Facilities). ■ TSF. ■ Publicly Supported Fund: BioVentures Investors LLC.
Michigan	■ $59 million to fund 5 laboratories with specialized equipment.	■ TSF: $50 million per year for a 20-year effort to develop Michigan Life Sciences Corridor.
New Jersey		■ NJEDA Technology Funding Program (Facilities). ■ Tenant Outfit Allowance at Technology Center of NJ (Facilities). ■ TSF.
New York	■ $15 million for 4 Strategically Targeted Academic Research Centers with bioscience focus.	
Ohio		■ TSF: $4.4 million then $24.3 million into biomedical and technology transfer fund. ■ Publicly Supported Fund: EBTC Bioinvestment Fund; BioVentures Development Fund.
Pennsylvania		■ Multiple economic development programs (Facilities). ■ TSF.
Texas	■ $800 million for science, engineering, research and commercialization activities of which $385 million to construct and expand reseach and science facilities.	
Wisconsin	■ $317 million to build series of state-of-the-art research centers at University of Wisconson at Madison.	■ Technology Development Loan Program (Facilities). ■ TSF. ■ Publicly Supported Fund: State of Wisconsin Investment Board.

Note: TSF refers to Tobacco Settlement Funds
Source: State Government Initiatives in Biotechnology 2001; CTTCA; Signs of Life: The Growth of Biotechnology Centers in the U.S., Brookings Institute

Consequently, California's centers of innovation no longer compete solely with domestic rivals. Establishing a Life Sciences cluster as a core component of economic development is an explicit priority of more than 100 cities and regions around the world. Most of these regions already focus on California as a source from which to recruit talent, companies, and ideas to jump-start their industries. During the next ten years this competition for talent, ideas, and innovation will only intensify.

Exhibit 6: Examples of Global Competitor Regions' Initiatives

Region	Examples of Government Role
Canada	■ Government funds and coordinates majority of early discovery research. ■ In 2001, Canadian National Research Council committed continued financial support to Life Sciences industry. ■ $76 million allocated towards National Institute of Nanotechnology. ■ $63 million committed to improve infrastructure of Lava Technology Park. ■ $190 million to create Genome Canada to increase research activity in genomics.
Europe	■ Public policy decisions have shown strong support for Life Sciences industry. ■ Europe unveiled strategic vision for future of European biotechnology up until 2010. ■ France alone has allocated $130 million to create more start-ups and improve critical mass of its mature biotechs.
Israel	■ Office of the Chief Scientist supports many biotech start-ups in early stages. ■ Several first class scientific research institutions. ■ High per capita expenditure on R&D.
China	■ Government has devoted great efforts to research and development of Life Sciences and its commercialization. ■ In the past two years, China has invested 10 billion yuan in Life Sciences. ■ China is only developing country participating in international human genome project. ■ Government funds nearly 200 major biotechnology laboratories.
Japan	■ Government investing $2.4 billion in science and technology over next five years. ■ Reforms of Japan's science and technology efforts to encourage academia-industry cooperation and encourage entrepreneurship.

Source: **Beyond Borders: The Global Biotechnology Report 2002**, Ernst & Young; Bejing Times; **Bridging the Gap** Ernst & Young 1999

Expanding International Scope of California Companies

As this global competitive pressure increases, California Life Sciences companies are actively moving into new international markets for their products. The U.S., Europe, and Japan currently represent a large portion of global Life Sciences sales, and these regions will remain strong markets over the next ten years. The large populations of China and other parts of Asia represent significant markets for human therapeutics and medical devices, and California firms will move to address them by entering a complex web of sales and marketing arrangements. They may also locate portions of their operations in these new geographies. These developments can benefit California by bringing a more global set of companies to establish headquarters here, but they can also damage the State if companies shift their operations out of California. This is a particular risk for later-stage business cycle activities like manufacturing.

These trends carry significant implications for California and its regional Life Sciences clusters. Most significantly, the trends imply a much more complex environment, which in turn requires more and better integrated planning.

Challenges and Possibilities

California's Life Sciences industry should be justifiably proud of its achievements, but it cannot rest on its laurels. The global trends in the industry are toward increased competitiveness both within the U.S. and internationally, toward a concentration of assets through joint ventures and mergers, toward a focus on downstream activities within firms, and toward increased regulatory and public scrutiny of the core research and business decisions driving the industry. While these trends pose potential difficulties for the Life Sciences as a whole, they also offer opportunities for growth and success for those best positioned to take advantage of them. California's Life Sciences industry needs to marshal all of the considerable resources at its disposal — its human, intellectual, and financial assets, the State's natural resources, and a hard-earned reputation for innovation and creativity — and work with all stakeholders, and especially State government, to sustain the leadership position it has achieved.

PRIORITY INDUSTRY ISSUES AND RECOMMENDATIONS 4

The stakeholders that comprise the California Life Sciences industry have a shared need to take action to meet the industry's challenges head-on. This will be critical to ensure that California maintains and extends its position of global leadership into the next decade. While its achievements deserve recognition, the State's Life Sciences industry cannot afford to indulge itself: the lessons of history are full of examples of champions who cease to strive and in so doing sacrifice primacy to other, more eager competitors. The best must continue to strive to get better. And other regions—in the U.S. and abroad—have not been idle: they have looked long and hard at California and have taken steps to copy what works and to avoid what even the region's most vocal advocates see as hurdles or impediments.

When the industry met during the Life Sciences summits convened in San Francisco, Los Angeles, San Diego, and Sacramento over the past year they resolved to focus on truly actionable steps that would have both an immediate and a long-term impact. The following industry recommendations are distilled from those summits, from follow-on conversations with key stakeholders and from careful analysis of the global trends facing the Life Sciences industry. These recommendations fall into six large categories of issues:

- Improving the financial environment.
- Reforming and streamlining Federal, State, and local regulations.
- Accelerating technology commercialization and new business formation.
- Preparing adequate human capital.
- Resolving critical infrastructure needs.
- Inspiring more Life Sciences community collaboration.

All regions found work to be done in these areas, and all agree that tackling these from a position of strength will do much to maintain and enhance California's Life Sciences leadership.

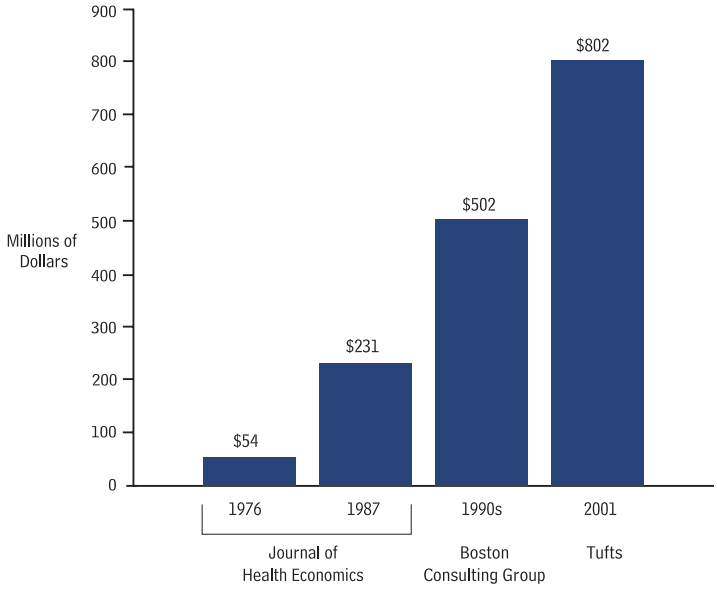
IMPROVING THE FINANCIAL ENVIRONMENT 5

THE ISSUE

While California's State government has actively supported the growth and development of Life Sciences through legislative and fiscal policies designed to strengthen both industry companies and State-funded academic institutions, there is room for continued reform. The unique life cycle of companies in sectors of this industry, where the lag between R&D and commercial viability is long and expensive, makes the need for targeted tax incentives particularly important (see Exhibit 7 for trend of increasing cost to bring a product to market in biotechnology sector). In addition, Life Sciences particularly strong need or capital suffers from policies that might discourage investment or that limits the freedom of capital to move into the industry. Forward-looking steps by the State in this fiscal arena will have a great impact on the State's competitiveness in Life Sciences: they will help increase the number of new companies formed in California and the number of large pharmaceutical companies considering whether to locate R&D facilities there.

World-class success often requires large risks, and California's Life Sciences ought not to be penalized for taking the risks (and suffering the losses) peculiar to their industry. California's biomedical industry invests four times more on R&D (approximately 45% of its operating expenditures) than other high technology industries.[26] Holding steady—or worse, discontinuing—the qualified basic R&D tax credits would only increase the burdens on entrepreneurs, investors, and established companies. Similarly, the ability to carry forward net operating losses is very important for the fiscal health of the emerging technology and biotechnology sector because of the extended timelines for product development and marketing and the high failure rate (often due to the uncer-

Exhibit 7: Trend of Estimated Drug Development Costs



Source: Ernst & Young

tainties of the FDA approval process). Early stage and growing companies sustain many years of losses, and the inability to carry these losses forward diminishes the attractiveness of doing business in California and can also affect Life Sciences companies' abilities to raise additional capital. While current Net Operating Loss (NOL) carryover rules do give biotechnology and biopharmaceutical companies preferential treatment on their NOLs, State lawmakers can and should do more. California is only one of 4 states that do not conform to the Federal standard of full utilization of net operating losses, which costs the State as it competes with 39 other states that offer this kind of incentive and that are aggressively trying to attract Life Sciences and technology growth industries.[27]

The State should also foster a climate that encourages investment in Life Sciences, an industry particularly sensitive to fluctuations in available capital, especially at the start-up and early stage levels. The State should explore a "convert to cash" mechanism with fundable tax credits for R&D and net operating losses. This particular approach benefits both the small R&D firms and larger companies: small firms can sell credits for needed cash to larger profitable companies, who, in turn, benefit from credits applied to their own R&D efforts. Angel investor tax credits can also provide incentives to venture capital to aid fledgling companies, and are under consideration by other states eager to foster Life Sciences competitiveness: Wisconsin offers a 12.5% tax credit, Iowa offers a 20% tax credit, Maryland offers a 33% tax credit, and Kansas recently passed a 50% tax credit (up to $250,000). In addition to providing incentives like these, the State should free up capital already earmarked for Life Sciences investment. For instance, the California Public Employees' Retirement System (CalPERS) has a $166Bn fund, of which a portion has been earmarked for investment in Life Sciences, and of that amount, only a fraction has currently gone to Life Sciences ventures. The State should work with the gatekeepers of these funds and with the industry to match these funds to appropriate opportunities statewide.

Indeed, the State should be particularly attentive to those policies that directly affect California's Life Sciences industry's ability to compete on a national and a global stage. As the global industry moves through its adolescence, its needs will shift from R&D to manufacturing. With current worldwide manufacturing capacity insufficient to produce potential FDA-approved products, competition among regions to host the extensive new manufacturing facilities is especially fierce. The expiration of California's Manufacturer's Investment Tax Credit (MIC) removed a valuable incentive for companies to either remain or to locate their manufacturing facilities in the State. So, too, the current 3-component formula (property, payroll, and double-weighted sales) provides a disincentive to locate additional facilities (and jobs) in California and discourages new Life Sciences companies and facilities from moving to the State. Finally, State government should consider the implications for its Life Sciences industry as it debates the importation of prescription drugs — and particularly biologic drugs — from foreign countries. While other states and localities may have rushed to judgment on this issue, concerns about the threat of non-FDA approved drugs are real and importing foreign price controls could undermine California's economy by hindering future drug development.

INDUSTRY RECOMMENDATIONS

- **Ensure that the State pays sufficient attention to the long-term health of innovation and the economy and in particular continues Federal compliance with the exclusion of biologic drugs in any discussion of drug importation.**
- **Harmonize Net Operating Loss (NOL) carry forward rules (NOL) with Federal tax law, which provides for carryover of up to 20 years.**
- **Allow large Life Sciences companies, either headquartered in California or employing significant numbers of Californians, to purchase discounted tax credits / deductions from small R&D firms.**
- **Establish a Manufacturer's Investment Tax Credit tied to job creation for new and expanding Life Sciences investments.**
- **Maintain and expand the qualified basic R&D tax credits.**
- **Change the apportionment formula for corporate income tax from the current triple factor formula to a single sales factor formula.**
- **Instruct CalPERS to both fully deploy funds earmarked for Life Sciences investment and ensure that its asset allocation fully reflects the long-term value creation of the Life Sciences industry.**
- **Instruct the Business, Transportation and Housing Agency in conjunction with the Franchise Tax Board to examine the potential benefits of angel investor tax credits.**

REFORMING AND STREAMLINING FEDERAL, STATE, AND LOCAL REGULATIONS 6

THE ISSUE

The very nature of Life Sciences businesses makes them particularly sensitive to the weight of the rules, policies, and requirements that Federal, State, and local governments place on them. Life Sciences companies currently operate under as many as four levels of regulatory requirements: Federal, State, county, and city. Permitting, zoning, disability and unemployment policies, and workplace safety regulations can increase costs directly through fees and penalties and indirectly through the costs of ongoing compliance. Inefficiencies, like duplicative Federal, State, and local regulations or overly complex compliance processes, increase this regulatory burden. In addition, this regulatory environment affects the cost of doing business in a state and thus directly influences whether businesses move to or remain in a region. Government—both State and local—needs to consider the business context of Life Sciences companies when proposing or implementing regulations and partner with the private sector to ensure that these companies can efficiently deal with reasonable government oversight without compromising their ability to compete effectively.

State regulations often duplicate or expand upon Federal ones, which increase the burden to ensure compliance, creating costs associated with processing, tracking, paperwork, and filing. For example, under current Federal Food and Drug Administration (FDA) rules products take on the order of 12–15 years to commercialize, requiring an $800M plus investment before any revenues are generated.[28] These Federal regulations preempt rules by California's equivalent agencies—but when the State Department of Health Services adds complexities over and above these Federal rules to issues like cross-border trade and re-importation, it places further burdens on an already complex and expensive process. The requirement that the Food and Drug Branch of the State Department of Health Services has to inspect drug or device manufacturers prior to issuing or renewing a license should be eliminated. Instead, this inspection should take place once every two years, but not prior to the company manufacturing and selling its product. Inspection prior to manufacturing duplicates FDA requirements. Facilities that are registered with the FDA, and whose products are listed with the FDA should be exempt from the inspection altogether.

Similarly, California has set its own job safety and health standards, thereby creating duplicate—and in some cases completely different—standards to those established under Section 18 of the Occupational Safety and Health Act of 1970 for OSHA. If such redundancy were not enough, concurrent Federal jurisdiction has not been relinquished. So, too, California's agreement with the Nuclear Regulatory Commission to establish its own regulations for sources, byproducts, and the use of small quantities of nuclear material within its boundaries creates unnecessary duplication and, in some cases, adds additional

and sometimes unnecessary burdens to existing NRC and EPA (Environmental Protection Agency) regulations. The State should adopt an action plan to quickly align Cal/OSHA, Cal/EPA, and radioactive and biohazardous materials and waste laws and regulations with the Federal programs to remove the additional burdens on California industry that create an uncompetitive economic climate.

Inconsistent and uncoordinated zoning and permitting practices can hinder the rapid growth of California Life Sciences companies. Local jurisdictions have different building requirements, some of which favor the Life Sciences more than others. Some cities, like South San Francisco, are models of effective commercial infrastructure planning focused on attracting Life Sciences research and development companies. The city's commitment is exhibited in thoughtful and flexible planning, zoning, and permitting practices that send a signal to Life Sciences companies and to contractors that building there is easy and that local government is cooperative and attentive to their needs. On a larger scale, the Smart Permit Project, an output of the Joint Venture Silicon Valley's (JVSV) Smart Valley project, brought together multiple jurisdictions to create common application standards and set up pilots in Milpitas (Express Permit), San Carlos (parts of the Tidemark permit software), and in Sunnyvale (a geographic information system-based permit system). Unfortunately, not all California cities or regions are as committed to meeting the cluster's needs.

Streamlining the process could involve setting up a zoning board comprised of members from industry, government, and real estate development to serve as a sounding-board for land usage issues. In addition, Life Sciences enterprise zones, as discussed elsewhere in this plan, could be established. These zones would create space that Life Sciences companies could move into without having to worry about extended zoning and permitting processes. The Life Sciences community should inform local building and planning officials about the special needs of the industry, especially Life Sciences companies, and lobby more vigorously for permitting facilities for Life Sciences projects.

INDUSTRY RECOMMENDATIONS

- **Eliminate redundancy and duplication between State agencies and Federal agencies. Eliminate State Department of Health Services inspections that duplicate U.S. Food and Drug Administration regulation.**
- **Adopt a broad harmonization program among Cal/OSHA and OSHA, Cal/EPA and EPA, and agencies such as the Nuclear Regulatory Commission.**
- **Improve zoning and permitting regulations and processes by establishing an electronic standard that directly links State and local processes.**

ACCELERATING TECHNOLOGY COMMERCIALIZATION/ NEW BUSINESS FORMATION 7

THE ISSUE

Life Sciences in California owes much of its world leadership to the flow of ideas from research and development into the marketplace. But unless this research can be quickly, effectively and efficiently transferred to the marketplace in a sustainable way, the benefits — to creators, to industry and to the State as a whole — are limited. Strengthening existing efforts to increase the collaboration between State agencies, regional leadership groups, and the appropriate university officers at the private and public institutions in California will do much to encourage the new business formation that marks a truly competitive set of industry clusters.

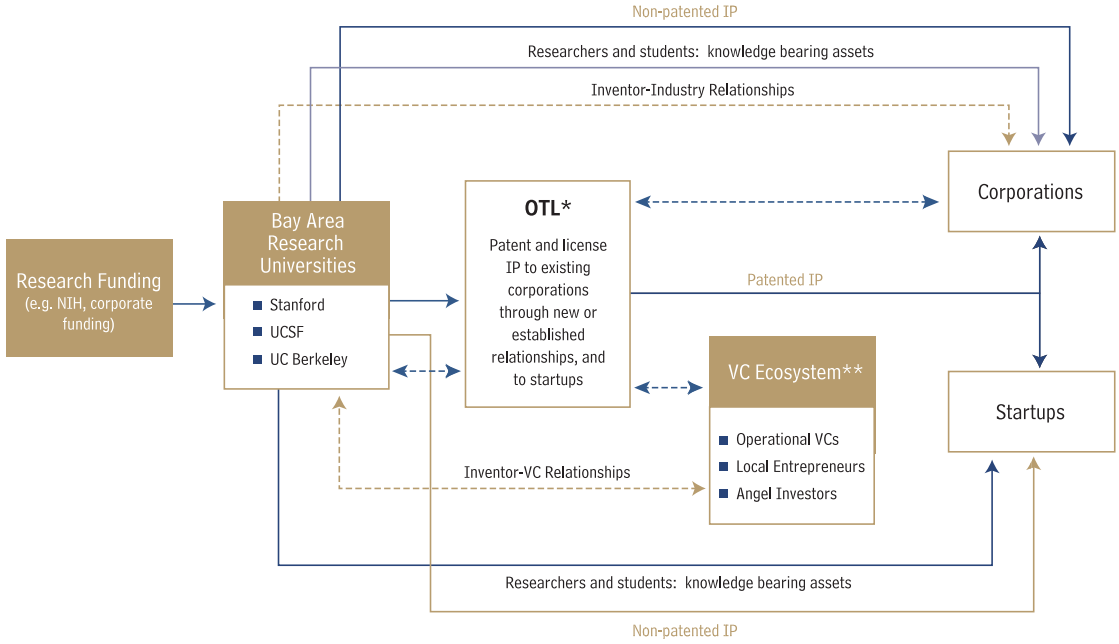
Continued competitiveness requires active leadership by the State government in setting technology commercialization priorities, providing incentives for improving the rate at which ideas are brought into the marketplace, and fostering collaboration and communication between relevant research and business entities. The State can play a crucial leadership role in enabling a virtuous cycle wherein increased technology transfer activity — both the amount of IP transferred and the rate at which it reaches the marketplace — yields increased royalties and revenues to research organizations, which can then set aside a percentage of those revenues and royalties to further bolster and promote entrepreneurial pursuits and industry partnerships with an increasing amount of intellectual property.

In particular, the State should work toward — and provide incentives for — making technology commercialization a shared top priority by all relevant Life Sciences stakeholders. Under the State's mandate, the University of California Office of the President and University of California Technology Licensing Offices should implement initial market research and analysis before the patent process in order to involve a number of key outside players who would be instrumental in the commercialization of the technology and/or research. Such a step would do much to minimize the perceptions of excessive bureaucracy and the lack of awareness surrounding the entire technology transfer process. Time is often a critical factor in Life Sciences agreements and should be used as an evaluative metric in assessing the performance of the OTLs. In addition, all parties should work to create a standard for the documentation required to commercialize university technologies — something presently lacking and which slows down the process. Indeed, specific issues relative to the valuation and ownership of licensed intellectual property should be clarified and resolved in order to lower barriers and costs to completing this process.

Differing priorities and channels for the flow of IP from research universities, research institutions (Federal, State, and private), and established Life Sciences companies constitutes a clear impediment to a

more efficient and effective technology commercialization process. Private research institutions and established Life Sciences companies have a strong commercial focus and design their research processes to maximize IP creation with commercial value. By contrast, State and Federal laboratories often focus resources on basic research or research that benefits the general R&D community as a whole. Although these institutions may have technology licensing functions, such activities are generally not their primary focus. Relevant State agencies, regional Life Sciences organizations, and local universities should conduct formal analyses to better understand the creation and flow of IP to determine points of leverage to increase both the effectiveness and volume of technology transfer for the Life Sciences as a whole (see Exhibit 8 for visualization of IP flow). The State can use this map to better match incentives against these leverage points. Local universities, in particular, should conduct formal analyses to better understand the creation of IP by and the flow of IP from faculty, researchers, and students. In addition, local Offices of Technology Licensing (OTLs) should be tasked to produce explicit recommendations for or against the procurement of additional staff and the adoption of new IP management-related processes.

Exhibit 8: Example of Technology Commercialization Process



The directors of technology transfer offices stand at center of this complex relationship between inventors, university technology transfer officers, and the entrepreneurs and established companies that want to bring products to market. To enable the directors of technology transfer offices to be apt facilitators for new business formation, they must be afforded flexibility around university risk policy and empowered to support timely licensing and collaboration deals. Such a reevaluation of risk policy in the case of technology commercialization may well require a shift in emphasis by universities themselves, from a focus on

the risks to academic reputation brought on by conflicts of interest or by the perception of trading on their academic stature to a calculation of the financial risks and rewards inherent in an entrepreneurial venture that involves ideas with commercial potential.

Finally, additional support is needed to commercialize university-generated IP. A possible solution could be the creation of intermediary entities that partner with universities. Network T2 might serve as a model: it pulls together universities (including the California Institute of Technology, UC San Diego, and USC) and other research institutions (including Harbor-UCLA Research and Education Institute and Keck Graduate Institute) with a goal of connecting their innovations with the marketplace. Programs Network T2 will implement include those that identify and introduce promising technologies to the business and investment world, facilitate relationships with industry around the development of technologies, and mentor spin-out companies.

Such involvement from intermediary (including for-profit) entities could provide an alternative approach to commercialization in creating a strong academic-commercial interface. In Southern California, the NeXus Bioscience model employs a collaborative approach to the research, product development and commercialization process. Each technology is first evaluated for its highest and best commercial use in order to determine where it would most effectively compete in the marketplace. Then, if necessary, complementary technologies are bundled together to create a commercially viable product or platform technology.

INDUSTRY RECOMMENDATIONS

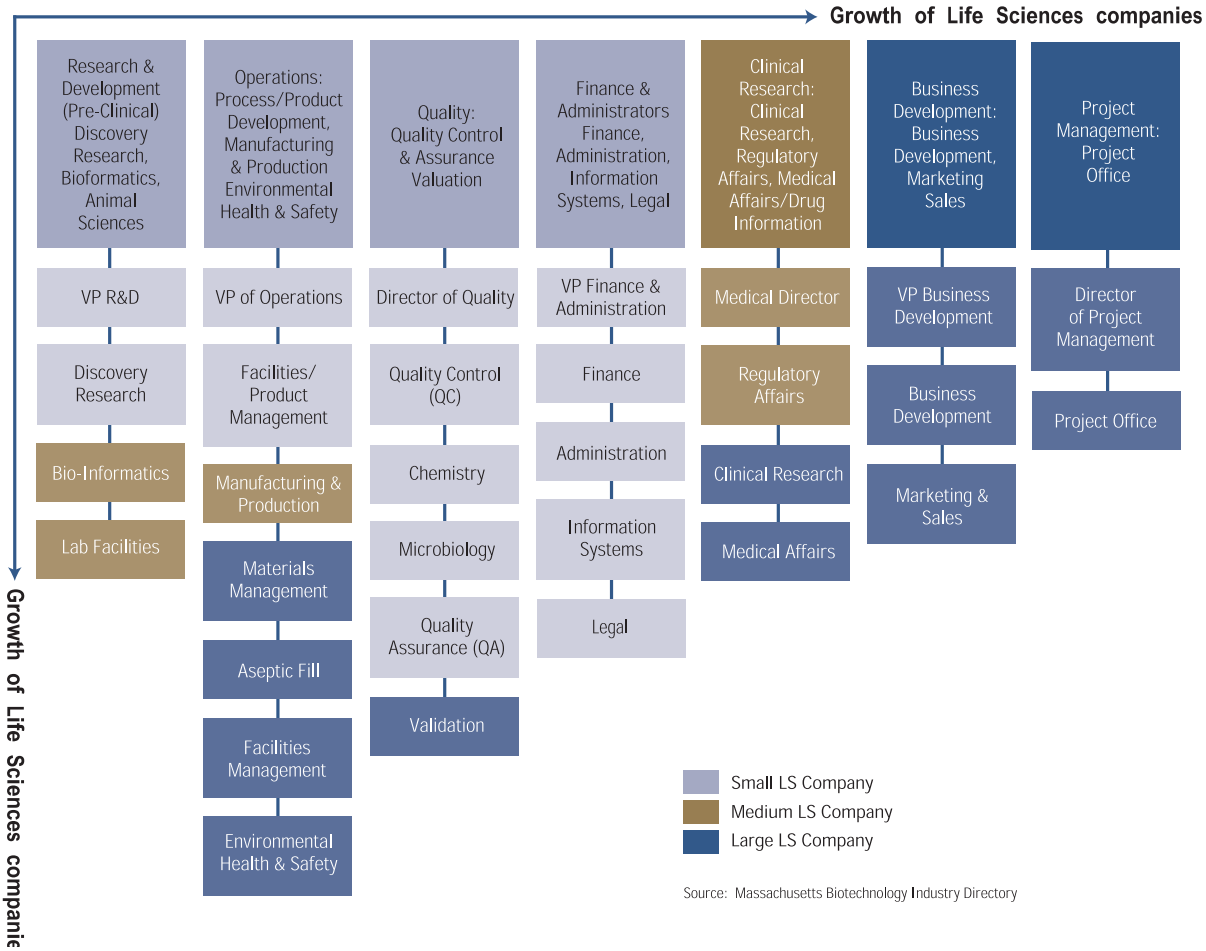
- **Create a mandate for California State agencies, regional leadership groups, the University of California Office of the President, and University of California Technology Licensing Offices to collaboratively accelerate transfer of technology through improved commercialization practices, controls, and incentives.**
- **Broaden the mandate, authority, and resources of the UC Directors of Technology Licensing Offices to encompass technology commercialization and new business formation activities.**

PREPARING ADEQUATE HUMAN CAPITAL 8

THE ISSUE

Properly harnessed and leveraged human capital drives innovation and growth in every company, every industry, and every region, and especially in Life Sciences. The industry is increasingly relying heavily upon highly-trained specialists in the fields of laboratory support, regulatory affairs, research and development, business development, quality control, and sales and marketing (see Exhibit 9). As Life Sciences in California matures, sustainable competitive advantage will depend increasingly on how the State and the companies in it develop and manage their human capital. Indeed, other states have not only identified workforce development and retention as a priority; they have set their sights on competition with California for these critical assets. Connecting the existing talent pool of human assets across the entire

Exhibit 9: Life Sciences Human Resource Needs



Source: Massachusetts Biotechnology Industry Directory

value chain to the Life Sciences industry and addressing gaps in necessary skills and capabilities represent a significant challenge to the State and to the Life Sciences industry.

To minimize the gap between Life Sciences cluster employment demand and labor supply, there must be a clear articulation of changing needs to all relevant constituencies. Life Sciences companies, more than those in any other industry, exist in close cooperation with academia. This relationship provides both important discoveries and the human capital with the skills required during the different stages of a Life Sciences company's development. Programs and curricula suffer when skill sets and vocabulary vary widely within an industry. The State must help Life Sciences to speak with a single voice and with great consistency in the way it defines skill categories and business needs. First, all parties should come to common understanding of those needs. As a necessary step toward that goal, the State can leverage existing work on these issues: for example, it can turn to the Radford Biotechnology Survey, which features information on industry-specific positions, annual trends and forecasts. In addition, the State should consider a resource similar to the Massachusetts Biotechnology Council's (MBC) Industry Directory, which provides standard descriptions for each type of job in a biotechnology company's growth cycle in the therapeutics sector. The Employment Development Department (EDD) could expand upon this by including other Life Sciences sectors.

Misalignment of programs with industry needs or burdensome administrative processes effectively cut off necessary support for employment training and workforce development. For example, the California Employment Training Panel (ETP) provides funding for various types of employee training. This program would be an excellent source of funds for biotechnology firms if the administration of contracts could be made less onerous, if opportunities in biotechnology were reclassified as "advanced training" to allow for ETP approval of biotechnology firms, and if the ETP allowed consortium-style training (the aggregation of employees from multiple employers). So, too, if the State reprioritized the discretionary Federal Workforce Investment Act (WIA) State funding, perhaps focusing on three specific issue areas that included Life Sciences, it would strike an ideal target: an industry with a high percentage of entry-level jobs that pay relatively high wages and that provides "easy" career pathways leading to high level opportunities. Models for this usage of WIA funds do exist. The San Diego Workforce Partnership — whose governing board, the San Diego Workforce Investment Board shares responsibility with the Policy Board for overseeing funding and policy development under the WIA — has collaborated with the San Diego & Imperial Counties Community Colleges Association (SDICCCA) to create the Workforce Alliance Project. This program is designed to foster a stronger dialogue between industry and education to address the challenge of training San Diegans to fill the high-demand, high wage occupations that are shaping that region's economy.

The State must continue to foster the educational collaboration between industry and academia. Efforts like the Applied Biological Technologies Initiative of the California Community College Chancellor's Office Economics and Workforce Development Program, the Molecular Biology Interdisciplinary Group (MBIG), and the ARC program, provide examples that the State should use to focus the development of clinical science and laboratory programs and regional, intersegmental (community colleges, State univer-

sities) training facilities. These programs, each in their own way, create a cooperative atmosphere in which research and instruction can flourish, often driven by employee needs assessments, surveys of local industry, and hands-on learning.

The State should take a leadership role in insuring that practical training conducted in partnership with industry — including internships and rotations — remains a priority in public educational institutions. San Francisco City College, Skyline College, and Solano College have each worked with Genentech on these issues. For example, Solano College's collaboration with Genentech on an AS degree in biotechnology and a certificate program specifically focused on biomanufacturing provides a model for the kinds of programs that provide students with unique opportunities to train on equipment used in the industry, that increase the number of degree graduates to meet industry demand, and that build invaluable links between academia and industry. UC Davis' Advanced Degree Program (ADP) for corporate employees works from the other side of the equation by allowing industry researchers to earn a Ph.D. while continuing to work. These graduates aid in the general exchange of information between academia and industry and also provide academia with first-hand knowledge of industry needs and trends. The Biotechnology Training Program at Moorpark College provides another example where essential technical experiences and training are offered in partnership with local industry (Baxter Healthcare Corporation and Amgen) to balance basic science courses with practical laboratory applications.

Finally, the State cannot overlook a more general focus on science education throughout its public school system. The California Board of Education Curriculum Commission's Science Subject Matter Committee should meet on a regular basis to allow input from Life Sciences industry thought leaders and use that input as they set public school system priorities, determine appropriate curricula, and initiate changes at all levels of education. Inclusion of industry thought leaders could also ensure continuing relevancy in the classroom, especially if their contributions are part of the more general efforts by the Science Subject Matter Committee to disseminate a science curriculum framework.

Emphasis on an across-the-board improvement of K-12 science education would lay the foundation for a deeper, more talented and more informed pool of potential Life Sciences employees at all levels. Science education is not a priority in the curriculum of many K-8 schools: the STAR (Standardized Testing and Reporting) program, instituted by California in 1997, only requires that students be tested in the sciences beginning in grade 9. Such a policy sends a strong message to schools that science education is irrelevant prior to high school. Not surprisingly, the science and math scores in many California schools rank below the national average. In addition to curricular efforts, teacher training in the sciences, particularly at the primary levels, should be emphasized. Science is a subject best learned in a hands-on environment, where students can learn and explore in ways that are impossible when the subject is only heard in a lecture or read in a text. Primary school teachers must have the ability to acquire the resources necessary to teach science in a fully integrated — and compelling — fashion. The Center for Biophotonics, Science and Technology (CBST) provides one example of the kinds of ambitious programs that should reach into the K-12 system and help shape future talent.

INDUSTRY RECOMMENDATIONS

- **Instruct the Employment Development Department (EDD) to work with Life Sciences industry associations to forecast and communicate current and future Life Sciences industry employment needs by relevant skill category.**
- **Modify workforce training and development expenditures in better alignment with Life Sciences.**
- **Designate four regional academic centers to spearhead statewide efforts to develop more clinical science and laboratory programs and regional, intersegmental (community colleges, State universities) training facilities.**
- **Mandate public educational institutions, in collaboration with industry, to continue to develop programs, including internships and rotations, which prepare students and scientists for work in the private sector in order to create a more versatile future workforce.**
- **Ensure State education officials place greater focus on science education throughout the public school system.**

RESOLVING CRITICAL INFRASTRUCTURE NEEDS 9

THE ISSUE

California's infrastructure forms the foundation upon which a vital Life Sciences industry has grown and thrived. Many of today's leading technology companies are concentrated around major universities and Federal, State, and private institutions performing cutting-edge research. California's research universities, together with Federal, State, and private laboratories, form a core infrastructure that supports a strong network of both established and developing Life Sciences companies (see Exhibit 10). These companies often build upon technology invented at local research institutions and develop commercial applications to further this technology. The State has a significant opportunity to build upon its strengths in intellectual infrastructure to ensure that research and innovation remain a competitive strength over the next ten years.

Attention to the commercial infrastructure is also important to a vital and competitive Life Sciences industry in particular, and to California in general. This type of physical infrastructure is particularly critical for Life Sciences companies because of their specialized building and real estate financing needs. These needs vary greatly depending on a company's level of maturity. Start-ups and early stage companies typically require only small work spaces of 2,000 to 10,000 square feet, together with access to wet lab facilities. Large manufacturers often require campus-like sites and significant infrastructure support. For the Life Sciences to flourish in California, the necessary plans, incentives, and policies must all be in place to encourage the development of commercial infrastructure that meets today's needs as well as tomorrow's.

Exhibit 10: California University Spin-Off Companies

Institution	Biomedical Spinoffs*
Stanford University	94
UC San Diego	63
UC San Francisco	60
UC Berkeley	39
The Scripps Research Institute	33
Caltech	24
UC Davis	18
UC Los Angeles	18
The Salk Institute	16
USC	16
UC Irvine	9
Lawrence Berkeley/Lawrence Livermore National Labs	7
The Burnham Institute	7
UC Riverside	5
UC Santa Barbara	5
UC Santa Cruz	3
City of Hope	1
TOTAL	**397**

Note: Number of biomedical companies founded by faculty or alumni, or based on university technology
Source: CHI Survey, 2001; National Science Foundation; CHI; LARTA; Monitor Group Analysis

California presents a unique set of infrastructure challenges and opportunities. Life Sciences commercialization benefits from a concentrated and critical mass of research and business activity—and California's Life Sciences have, in the past, flourished where the two have come closely together. Unfortunately, and unlike those in some other regions, California's academic institutions now sit in densely populated and highly expensive urban areas where space in proximity to research activity comes at a premium. Research institutions, local communities, developers, and State government will need to cooperate to identify areas where facilities (e.g., bio-research parks) can be located, to secure those areas, to provide incentives for development and for companies to locate there, and, most importantly, to maintain a level of ongoing support to keep these areas vital. For example, in the Los Angeles region initiatives currently underway at the University of Southern California, the California Institute of Technology, the University of California, Irvine, and the University of California, Riverside mark positive steps in this direction. Continued and increased support from the relevant stakeholders is vital to creating the environment to foster innovation at all phases of the Life Sciences commercialization process.

Companies have different needs for specialized facilities, depending on company type and the stage of their development cycle. Medical device, instrumentation, and biotechnology companies that approach commercialization need affordable manufacturing capabilities and significant infrastructure support, such as reliable water and appropriate waste water treatment facilities, while biotechnology start-ups want affordable wet lab space. When deciding where to build manufacturing plants, many Life Sciences companies value proximity to their R&D facilities. They also tend to gather in clusters, in order to take advantage of the infrastructure that is already in place. Knowing this, specific locations may be targeted for development, to provide incentives for companies to build manufacturing facilities in these areas. Such a strategy would direct industry growth in such a way as to make it less reliant on the regional transport infrastructure and its limitations (e.g., infill development).

Enterprise zones provide one means of providing necessary space in close proximity to research institutions and free from the sometimes crippling zoning and permitting constraints on Life Sciences companies. Indeed, the concept of enterprise zones was created in California to stimulate business development in areas that were economically disadvantaged and to spur job growth in areas of high unemployment. More recently, regions like Buffalo Niagara and Kansas City are creating enterprise zones that provide tax incentives for new investment and job creation.

A coordinated effort to attract prospective Life Sciences companies and to serve the needs of established and growing California companies would also include sharing information about available commercial real estate. An electronic index accessible by Life Sciences companies and by local and State governments would make it easier to match needs against available sites throughout California. In partnership with real estate brokers, REITs, economic development agencies, and municipalities, an infrastructure such as North Carolina's electronic real estate index is possible with current technology. The Los Angeles region's one-time use of an "asset map" to provide a catalog of attractive investment options in the region serves as another example of coordinating information on real estate to serve growing companies.

These efforts at supporting and developing existing intellectual and commercial infrastructure need also to look forward to insure that established regional Life Sciences initiatives retain their competitive edge. Areas of convergence (outlined in the previous section on global trends) like bioinformatics, deserve special attention. Towards that end, the public and private sector should continue to fund new centers of science and innovation on the leading edge: centers like the California Institute for Quantitative Biomedical Research (QB3), the Center for Information Technology Research in the Interest of Society (CITRIS), and the California NanoSystems Institute (CNSI). Such institutions, worthy of support in their own right, also provide invaluable lessons about the formation and operation of new kinds of initiatives to support scientific advances not yet discovered.

The regional Life Sciences summits raised two related infrastructure issues critical to the continued success and competitiveness of California's Life Sciences industry: the availability of reliable sources of water and power and the existence of appropriate procedures to govern the disposal of low-level radioactive waste and to expedite plant and waste-site decommissioning. In addition to being a regional quality of life issue, water is essential to all laboratory processes, and Life Sciences industry growth depends on the ability to ensure reliable water for the region. All residents face the prospect of water shortages, but most fail to consider solutions until forced to do so by a drought. Better polices for the allocation of water resources are needed before conditions become critical. Industry leaders must make certain that the California Department of Water Resources and the Metropolitan Water Administration understand their urgent needs for solving this problem, especially now, when complex water purchase and distribution agreements are being negotiated both statewide and between states in the western region.

Policies regarding the disposal of low-level radioactive materials require equally urgent attention. Current State regulations regarding the decommissioning of buildings in which radioactive materials have been used stipulate that a zero radiation level must be achieved before decommissioning is complete. In addition to being more rigorous than existing Federal laws, the State's mandate is virtually impossible to accomplish due to naturally occurring levels of background radiation. As a result, vacated buildings cannot be decommissioned, and companies often face either long-term liabilities for lease payments or risk lawsuits from the landlord.

The standards for decommissioning low-level radioactive waste (LLRW) sites should also be clarified as soon as possible as they are posing an urgent problem for Life Science companies. Temporary standards are needed urgently to provide immediate relief, at least until the end of the California Environmental Quality Act (CEQA) process. The State should immediately establish working groups that include all decision makers and stakeholders, including environmental groups, to find ways to reduce the burden of compliance on Life Sciences companies. The industry needs certainty in site licensing and termination requirements. Furthermore, California does not have a low-level radioactive waste disposal site, leaving companies with few options for disposing of the waste generated through product research and development.

INDUSTRY RECOMMENDATIONS

- **Continue to provide support for bio-research parks.**
- **Facilitate development of commercial space and revitalization efforts for start-up and young Life Sciences companies by creating and supporting enterprise zones.**
- **Continue to provide funding for the new centers of science and innovation: QB3, CITRIS, California NanoSystems Institute.**
- **Find acceptable solutions for the disposal of low-level radioactive waste and expedite decommissioning requirements.**
- **Ensure reliable sources of water and power.**
- **Establish an electronic index of California commercial real estate for investment attraction purposes.**

INSPIRING LIFE SCIENCES COMMUNITY COLLABORATION 10

THE ISSUE

This summary document has drawn from the collective thinking of a broad set of constituencies that make up the California Life Sciences industry. Through surveys, interviews, discussion forums and four regional summits, the California Life Sciences industry has come together to identify the ways in which it can maintain and enhance its world-leading position. In the previous sections, the critical issues and recommendations of the industry have been presented. The industry offers this summary Action Plan with the thought that it will provide a basis for all interested parties to begin to work together in a coordinated and powerful fashion.

This marks the first time that the entire Life Sciences industry in California has conducted an exercise of this nature. Each regional cluster has established its success based on a unique combination of factors, and has done so often in healthy competition with other clusters. To ensure its continued global leadership and guarantee that its voice is heard and heard clearly, California Life Sciences must mobilize together with sufficient resources to develop and manage a robust and aggressive plan.

A common theme has emerged from this industry self-examination: the concern that without formal mechanisms in place the Life Sciences voice may not be heard. Life Sciences in California needs to continue to work to create a sustainable community that promotes and protects the interest of its members, provides opportunities for the exchange of ideas and for networking, works with State and local government to create a regulatory environment that encourages economic development, and fosters the "critical mass" of companies that signals to others that the chance of success is greater inside that community.

The industry would hope that Government at all levels will show support for and work with the Life Sciences industry in this endeavor to maintain and enhance its success. As an example, under the Wilson Administration, the Governor's Council on Biotechnology offered a useful connection between the government and industry. This 16-member Council—all of whom were CEOs of California biotechnology companies—met quarterly to advise the Governor on the factors necessary to promote the biotechnology industry in California. This CEO group was instrumental in mobilizing industry to convey their perspectives on Medicare legislation to the Office of the Governor.

The principal goals of such community collaboration would be to: increase public awareness and support for the Life Sciences as a driver of the State economy and a significant contributor to improved quality of life and general well-being; develop and implement strategies to attract and retain Life Sciences companies and activities in the State; promote and advance Life Sciences issues to policy makers and civic leaders.

INDUSTRY RECOMMENDATIONS:

- **Establish a California CEO Advisory Group for Life Sciences to present a shared voice for the industry in California.**
- **Appoint a senior administration official(s) as a liaison to the Life Sciences industry to enable ongoing dialogue with the Governor's office.**
- **Foster education and awareness about Life Sciences by instructing government officials to become more active in Life Sciences regional organizations' advisory panels and summits through the California Assembly's Select Committee on Biotechnology.**
- **Develop an Emerging Technology Business and Entrepreneurship Council that includes representatives from State agencies, legislators, and serial entrepreneurs to monitor the impact of policy on the entrepreneurial climate and to create a Governor's "Entrepreneur of the Year" award.**

MOVING TO ACTION 11

Energized by the efforts of the members of the Life Sciences community to assess their present position and current prospects, the Life Sciences industry offers this summary Action Plan as a means of uniting its various parts and as a framework for discussions with relevant partners, and especially with those in State government. The plan calls for an integrated discipline of public policy and private initiative. California Life Sciences has generated knowledge, attracted professionals, promoted human welfare, and generated economic returns at a remarkable rate. The recommendations contained in this plan, distilled from a year's worth of discussion and analysis, provide actionable steps that can assist Life Sciences and California in competing and winning in this new century.

The Life Sciences now extends more broadly than the narrow confines of its birth in the Bay Area. Los Angeles and San Diego have built centers of innovation worthy of international reputations. Sacramento is even now moving forward to join ranks with them. While they may differ in small respects as to how best to move forward, they agree on the general outline of themes that require their attention and on the more immediate and critical things that all must do, and do together in an integrated fashion.

What were once the inspired ideas of only a few entrepreneurs and scientists now comprises a global industry with increasingly sophisticated research and development, sales and marketing, and manufacturing capabilities actively competing to bring new products and therapies to the world marketplace. Other states in the U.S., and indeed other countries, look to California not only as a worthy model to emulate, but also as an especially rich trove of innovation and talent from which to entice or to acquire the assets for their own success. The assets shared by Life Sciences and by California — the extraordinary human, financial, and natural capacity assembled in this State — continue to offer a springboard for growth and achievement. This plan and its focused recommendations for the next ten years come with the hopes that the momentum built over the past year will not be lost, indeed that it will increase and that the first-class science, innovation, and entrepreneurial talent that characterize California's Life Sciences will continue to thrive along with this State into the twenty-first century.

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appendix a

Beginning in January 2003, the four regional industry clusters—the Bay Area, the greater Los Angeles region, the Sacramento area region, and San Diego— each convened and conducted Life Sciences summits at which they discussed their respective regions opportunities and challenges, and created specific regional recommendations. The four regional Strategic Action Plans can be found at

www.monitor.com/cgi-bin/iowa/ideas/index.html?article=90

In total, over 300 businesses and government leaders contributed their views and expertise.

Bay Area Life Sciences Strategic Action Plan

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Sacramento Life Sciences Strategic Action Plan

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CLUSTERS OF INNOVATION THEORY

appendix b

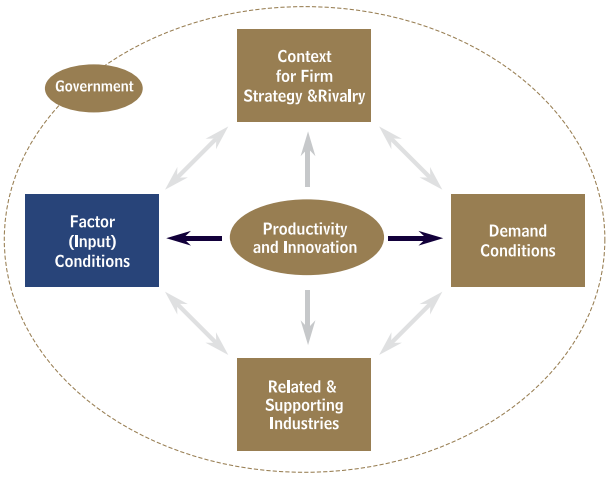
The working team employed the Cluster of Innovation theory as a basis for defining the regional Life Sciences clusters and for structuring such choices as those relating to prioritizing investments, allocating resources, and planning growth. In addition, the working team drew on learnings derived from the Monitor Group's experience in the area of regional competitiveness.

Conventional thinking places clear boundaries between industries and focuses exclusively on an industry's internal structure and dynamics as the space for competitive advantage. Cluster thinking does not disregard the relevance of the "inside" of an industry, but broadens the terrain for competitive advantage to capture cross-industry linkages. The broader cluster approach to Life Sciences recognizes and places value on the cross-industry interactions among multiple constituencies in the Life Sciences cluster, its inputs, related industries, buyers, and government (Exhibit 11).

The broad perspective enabled by the idea of clusters permits a comprehensive understanding of the prosperity of a region. At a high level, prosperity depends on a region's ability to create a business environment that fosters innovation and productivity (Exhibit 12). Strong, competitive clusters are a critical component of a good business environment and are the driving force behind regional innovation and rising productivity. Clusters allow companies to operate more productively in sourcing inputs, accessing information, technology, and needed institutions, coordinating with related companies, and measuring and motivating improvement. Clusters allow each member to benefit as if it had greater scale or as if it had joined others without sacrificing autonomy.

Cluster theory implies that the four key determinants of a region's business environment must be considered as the region plans for its future success. However, it is

Exhibit 11: Determinants of a Regional Business Environment



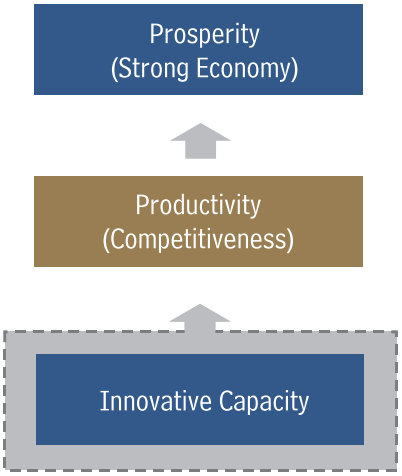
Source: Clusters of Innovation: Michael Porter, Monitor Group, Harvard Business School, Council on Competitiveness

important to note that the theory recognizes the unique nature of each cluster. Thus, the four determinants have differing degrees of relevance depending on the cluster and region in question.

In the Life Sciences cluster, the primary determinant of the regional business environment is factor or input conditions. The quality of specialized inputs and related conditions are particularly important to the success of the Life Sciences.

The additional determinants are the Context for Firm Strategy and Rivalry, Demand Conditions, and Related and Supporting Industries. Context for Firm Strategy and Rivalry refers to the "rules, incentives, and pressures governing the competition in a region." The presence of rivals creates healthy competition between local firms. The quality of Demand Conditions has "a strong influence on the process of creating and improving products and services." These Demand Conditions are present to the extent that sophisticated local customers create an efficient feedback mechanism to catalyze innovation. Related and Supporting Industries stimulate the efficient communication and flow of ideas within and across clusters (Exhibit 11).

Exhibit 12: Prosperity Chain



Source: Clusters of Innovation; Michael Porter; Monitor Group; Harvard Business School; Council on Competitiveness

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