NATIONAL VENTURE CAPITAL ASSOCIATION

Funding innovation. Empowering entrepreneurs.

Venture Capital and Entrepreneurship in Pennsylvania

2012

Pennsylvania was ranked 10th for overall venture capital investment in 2011.

Venture Capital Investment In Millions
2011 State Ranking

Rank	State	VC $
1	California	$14,506
2	Massachusetts	$2,982
3	New York	$2,284
4	Texas	$1,461
5	Illinois	$683
6	Colorado	$619
7	Virginia	$608
8	Washington	$542
9	New Jersey	$540
10	Pennsylvania	$520

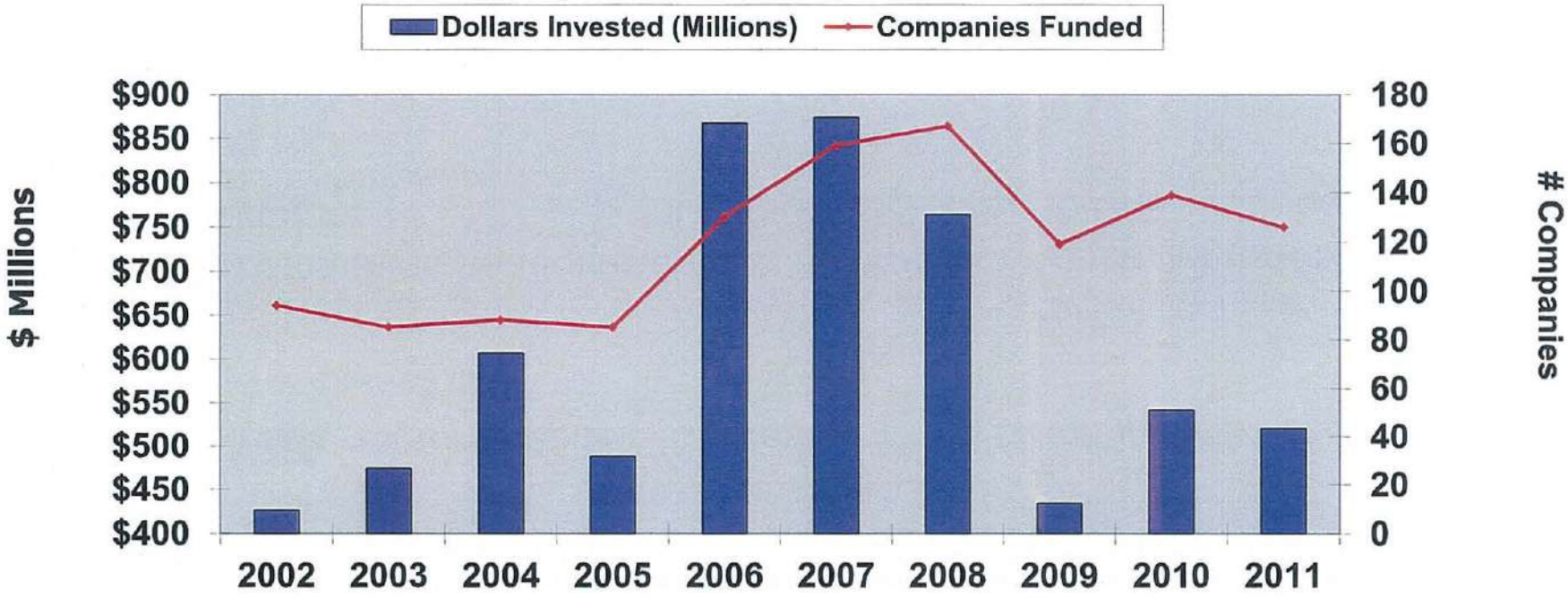
Rank	State	VC $
11	Georgia	$343
12	North Carolina	$325
13	Florida	$294
14	Maryland	$283
15	Minnesota	$275
16	Arizona	$247
17	Oregon	$239
18	Utah	$223
19	Ohio	$203
20	Indiana	$178

Venture-backed companies are a critical engine of economic growth for Pennsylvania.

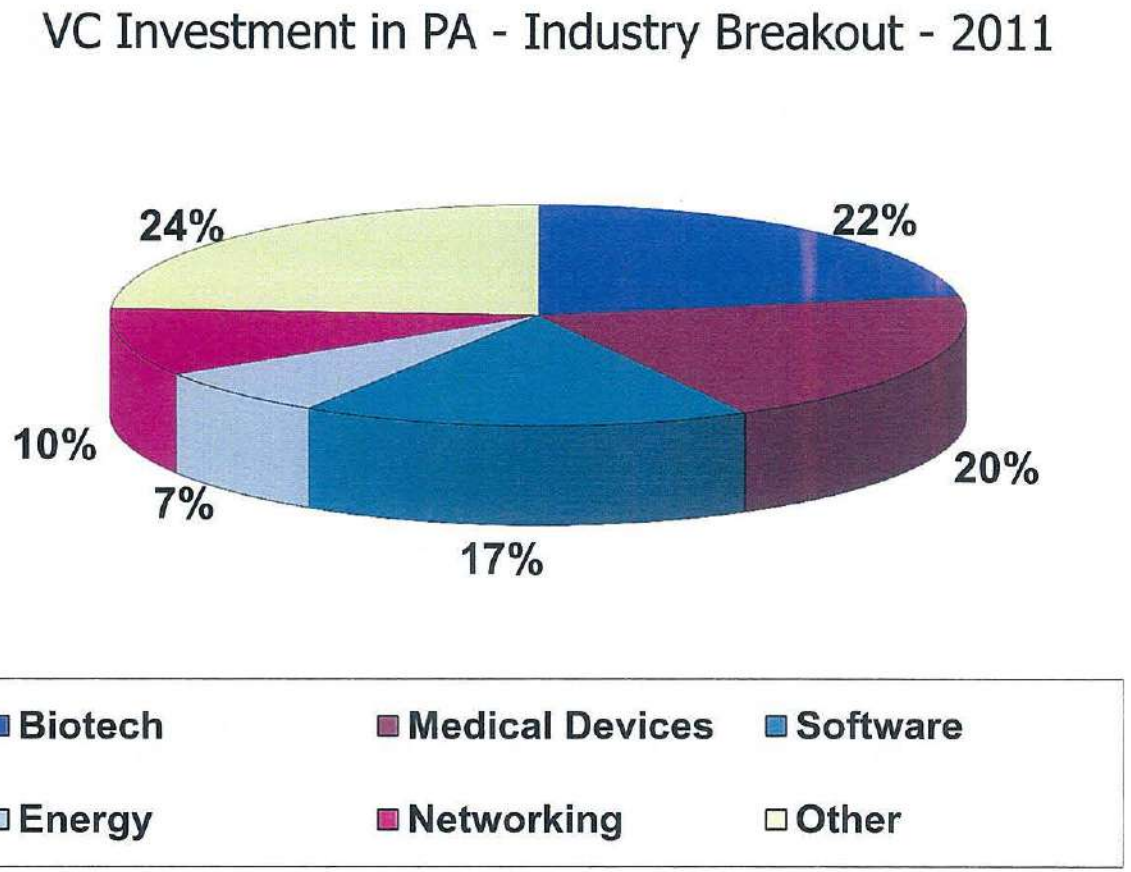
- Since 1970, venture capitalists invested $13.5 billion in 1,181 companies in PA.
- Public companies headquartered in PA that were once venture-backed accounted for 783,527 U.S. jobs and $238 billion in U.S. revenue in 2010.*
- Pennsylvania ranked #3 in jobs and #4 in revenues for venture-backed companies headquartered in the state in 2010.*
- One U.S. job was created for every $16,930 of venture capital dollars invested in the state of Pennsylvania.

* According to 2011Global Insight study

From 2002 – 2011, venture capitalists invested $5.9 billion into Pennsylvania companies.

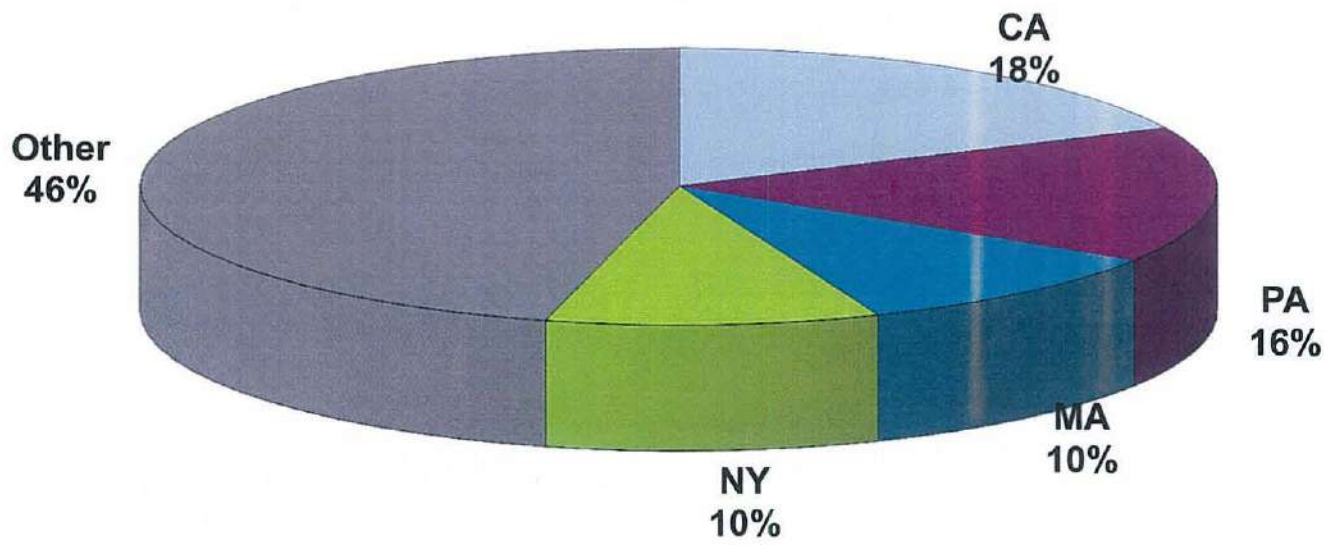


The highest venture funded industries in Pennsylvania are Biotech, Medical Devices, and Software.



84% of venture capital investment into PA companies comes from out of state.

In 2011, venture capital dollars invested in PA companies came from venture firms headquartered in:



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NATIONAL VENTURE CAPITAL ASSOCIATION
Funding innovation. Empowering entrepreneurs.

Life Sciences Leadership for the Next Decade:

Nurturing a Life Science Ecosystem for Job Creation and Economic Development in Pennsylvania

May 2012

Full Report

The Life Science Leadership Advisory Council

Table of Contents

Appendices

Introduction

The Life Science Leadership for the Next Decade report contains the recommendations of the Life Science Leadership Advisory Council (LSLAC). This report is the result of a collaborative effort of the Council and reflects the vision and insight of industry, government, and institutional partners in Pennsylvania's life science and economic development community.

This report was prepared by the Life Science Leadership Advisory Council. The Council includes more than 40 individuals representing all segments of the life science community. A listing of the Council members can be found on page 37 of this report.

Through a series of meetings, conversations, and analysis, the Council identified Pennsylvania's competitive advantages and opportunities to enhance the industry's strength and facilitate future job creation. Input and feedback were collected from the Council from October 2011 through April 2012. This report contains the final results and recommendations as compiled by Fourth Economy Consulting. This report is intended to be a tool and strategy for sustainable, continued action by both public and private industry partners in their support of the life science industry and its economic, job creating impact.

Executive Summary

The Life Science Leadership Advisory Council is providing this report and recommendations to help the Commonwealth of Pennsylvania fully realize the opportunities inherent in its life science resources and assets.

An unmatched concentration of global biopharmaceutical, medical device, and diagnostic companies; world-class academic and private research organizations; capital, facilities; talent; infrastructure; and nationally-recognized health care delivery systems – in both urban and rural settings – it's all here in Pennsylvania. Already, Pennsylvania's life science industry is an economic powerhouse employing more than 79,000 people directly and generating annual wages of $7.2 billion. The life science industry in Pennsylvania is also a leading source of scientific innovation that is improving the health and quality of life of people across the state and around the world through the development, manufacturing and commercialization of products across all sectors of health care.

These remarkable outcomes have been the result of entrepreneurship, investment by industry, and partnership with visionary leaders in government. But additional opportunities remain untapped, and there is the potential for economic gains to be missed if continued partnership, commitment and leadership are not sustained.

The continued health and future growth of the life science industry in the Commonwealth is dependent upon ongoing investment in this industry – investment of private dollars, of public funds, and of energy and commitment to creative public-private initiatives. A convergence of factors has led to the situation in which the Commonwealth finds itself:

- Longer Research and Development Cycles: Improving upon existing devices and therapies and developing new ones presents exceptional scientific challenges and requires more time and resources than ever before;
- Tougher Regulatory and Reimbursement Environments: Product marketing and reimbursement approvals face unprecedented hurdles and delays, which exact an economic toll;
- An Uncertain Macroeconomic Environment: Changing economic conditions across the globe, coupled with rapidly evolving trends in outsourcing, supply-chain management, and market introduction are challenging the strategy and finances of large and small enterprises alike;
- Constricted Capital Flow: Capital markets have responded to the global recession and the above points by dramatically constricting capital access;
- State Challenges: State-level budget constraints and fiscal responsibility have led to the reduction of state-funded initiatives to support the industry.

The strategy to meet these challenges, outlined in this report, removes obstacles for growth and aligns private industry and public policies to make the Commonwealth more business-friendly; it provides public- and private-based incentives to retain and attract companies and top-notch talent; and it nurtures the life science ecosystem to cultivate research into cures.

With Pennsylvania's unique strengths and attributes as our foundation, the Life Sciences Leadership Advisory Council envisions a decade of opportunity in the Commonwealth characterized by significant life science industry retention and growth. It is a decade during which entrepreneurship is fostered, company formation is optimized, overall wages and jobs grow by 30-50%, medical innovation accelerates, and Pennsylvania is revered globally as the top destination for locating and growing a life science business.

This strategy requires the collaborative effort of academia, industry, the investment community and government to work to minimize parochial interests and recognize that all parties are responsible for the plan's final outcome. It looks to continue or expand Pennsylvania's proven, existing programs, to borrow and refine the successful tactics used by other nations and states to spur job growth in the Commonwealth, to recognize the value of collaboration across multiple and competing interests and seeks to do so in the service of a long-term vision.

This strategy must be seen as a plan to advance the life sciences over the next decade. This plan recognizes that many of the recommendations in this report will face funding challenges in the short-term future. The good news is that some of the proposals herein are already underway. Others require new public-private partnerships to succeed. Still others call for new private investment as well as resources from the Commonwealth.

This report is a living document that requires months and years of follow-through before it can be fully realized. It will evolve as the industry and the environment evolve. It is the roadmap for all interested stakeholders to follow if Pennsylvania is to achieve continued global leadership in the life sciences.

Goals and Priorities Summary

The Life Science Leadership Advisory Council has identified five high-priority goals for Pennsylvania's life science community to pursue in order to successfully grow and expand the industry's role in the Commonwealth. In order to achieve these goals, it is critical to keep in mind the following tenets:

- Involve all sectors of the life science community
- Confirm Pennsylvania's life science leadership in the international arena
- Showcase Pennsylvania's assets to demonstrate the opportunities for the life science industry
- Develop and support public-private partnership models
- Continue investment in initiatives with demonstrated success

The goals and actions outlined below are the result of the direct input of more than forty industry, government, and academic representatives from Pennsylvania's life science community. The Council proposes that each of these priorities be placed under immediate consideration for continued collaboration and cooperative efforts.

GOAL 1

Promote the life science industry as a key driver of Pennsylvania's economic competitiveness

Action 1.1	Adopt the recommendations outlined in this report as a long-term life science economic development strategy
Cost / Timeline	This action has limited cost and can be implemented immediately
Benefits	Following the recommendations of the Life Science Leadership Advisory Council will ensure that all stakeholders are engaged and aligned with the main priorities of the life science community

GOAL 2

Ensure the continued growth and vitality of the Pennsylvania life science community through ongoing monitoring, evaluation, and action of its stakeholders to maintain the industry's competitiveness

Action 2.1	Create an engaged public-private life science team with executive-level leadership to focus on growing and expanding the life science industry in Pennsylvania
Cost / Timeline	This action has limited cost and can be implemented immediately
Benefits	Undertaking this action will formally appoint a representative group that will be responsible for coordinating and enacting the recommended steps of the Life Science Leadership Advisory Council

GOAL 3

Support the research and development of emerging life science technologies including previous and new life science investments

Action 3.1	Establish a long-term strategy for the use of Tobacco Settlement funding and other sources of investment (both public and private) that support life science industry growth, including health-related research and commercialization
Cost / Timeline	The cost will vary and can be ramped up over time
Benefits	This action will support ongoing research and development of critical life science technologies
Action 3.2	Form a Life Science Commercialization Network (LSCN)
Cost / Timeline	The cost is unknown, but action could be undertaken immediately
Benefits	A network like this would act as a catalyst to attract additional private investment
Action 3.3	Increase funding of the state research and development tax credit to $100 million
Cost / Timeline	This action will cost $45 million over the current R&D tax credit, and can be phased in
Benefits	This action can accelerate the pace of technology commercialization and job creation

GOAL 4

Seek investment capital to support early and mid-stage life science companies

Action 4.1	Identify mechanisms, including use of pension system investment that can be used to encourage the formation of new venture funds or attract existing funds, including corporate venture funds, to establish a presence and/or invest in the Commonwealth
Cost / Timeline	The cost for this action is unknown, but it can be implemented immediately
Benefits	This action will support diversification and an increase in capital available for Pennsylvania's job creating companies

GOAL 5

Encourage the creation of a tax system and business climate that provides a supportive environment for life science and other technology-based industry job creation

Action 5.1	Develop an ongoing economic model to support changes to Pennsylvania's business climate (see page 21 for a current list of examples)
Cost / Timeline	This action has no cost and can be undertaken immediately
Benefits	This recommendation will make Pennsylvania a more competitive place to do business

Further details on each of these priority goals and actions are included in the full report. It is important to note that additional recommendations and actions may be suggested as the strategy evolves over time. Factors such as the economy, business climate, and industry restructuring may shift priorities and the strategy outlined in this document. The plan presented here is expected to be a point-in-time analysis and list of recommendations. This report is expected to be reviewed annually to assess the relevance of the recommendations, and to respond to any new opportunities and challenges that may develop throughout the year.

Overview

Pennsylvania is an international leader in the life sciences industry. Beyond Pennsylvania very few locations have the breadth and depth of assets involved in the industry. The Commonwealth is home to pharmaceutical, biotechnology, medical device, and diagnostics companies, as well as world-class academic research institutions, strong urban and rural healthcare delivery systems, and a robust support infrastructure that includes legal, regulatory and financial resources.

Competition among states for investment and jobs related to the industry is intense and global. The industry is in transition, especially in the pharmaceutical research, development, and manufacturing sectors. Firms in these sectors are changing the way they do business including outsourcing many core functions.

The goal for this strategy includes identifying both short-term and long-term actions that provide support for all aspects of the industry across their development cycle. The strategy seeks to support all companies ranging from emerging start-ups to global pharmaceuticals and outlines tactics that focus on:

- Growing emerging and young firms
- Attracting other companies to the state, and
- Retaining Pennsylvania companies and talent

FIGURE 1:
Life Science Wages in 2008 and 2011

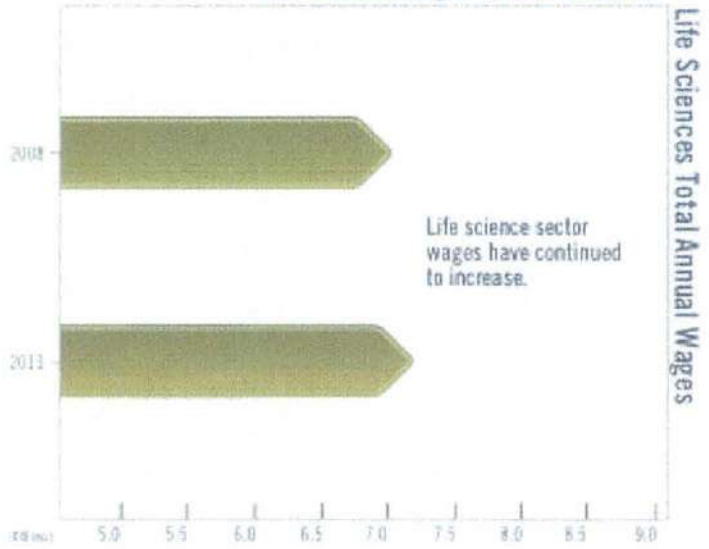
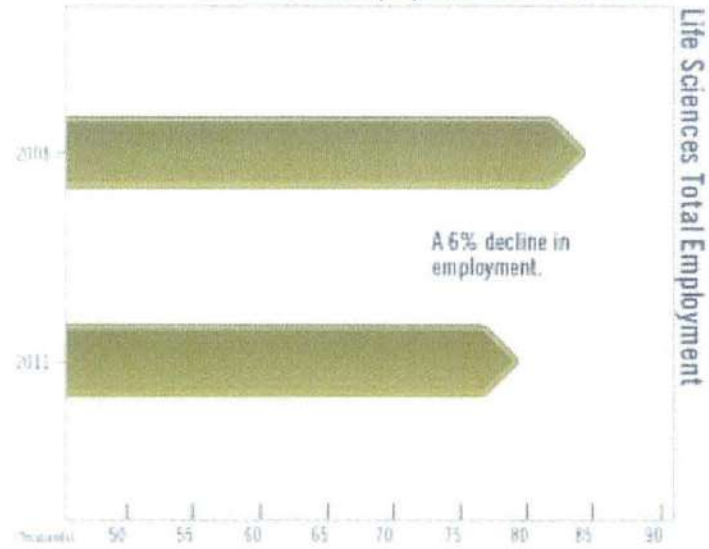


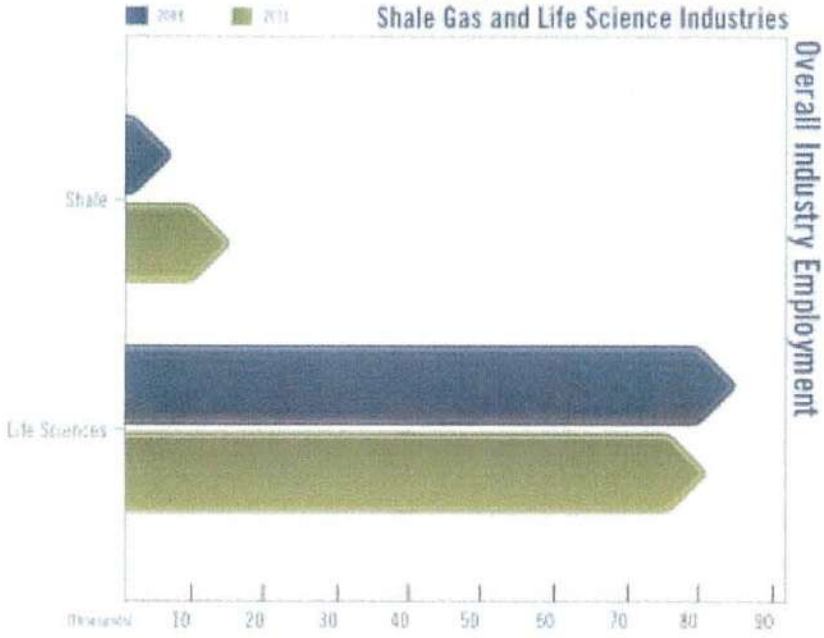
FIGURE 2:
Life Science Employment in 2008 and 2011



Life Science Industry Impact

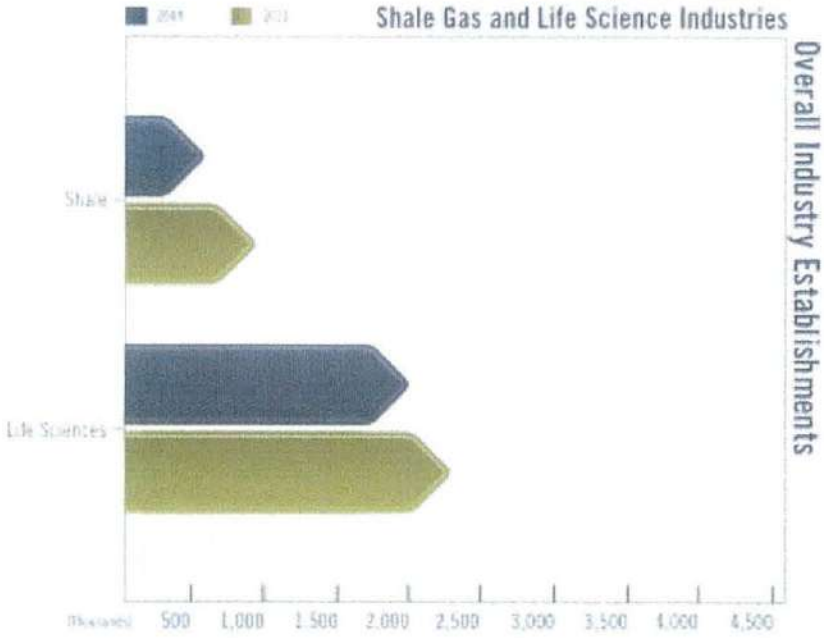
Pennsylvania boasts a robust life science supply chain. It includes world-class academic research institutions and a full-spectrum of companies from early-stage to mature pharmaceutical, medical device, and diagnostic companies. Today, the life science industry in Pennsylvania employs over 79,000 individuals, earning over $7.2 billion in wages. These companies are supported by many other specialized firms. It is recognized that the life science industry has one of the most significant economic multiplier impacts with 5.8 indirect jobs created for every direct life science job. In real terms, it is estimated that nearly 460,000 indirect jobs are currently supported by the life science industry.

FIGURE 3:
Employment Comparison between Shale Gas and Life Science Industries



The life science industry is a significant contributor to the Commonwealth's tax base and overall economy. The industry provides a significant wealth-creating wage to its employees with average salaries of $90,267. This is double the average annual Pennsylvania private sector wage of $45,348. Though employment levels are down from 2008 (Figure 1), annual wage levels continue to rise (Figure 2).

FIGURE 4:
Establishment Comparison between Shale Gas and Life Science Industries



Though the industry has experienced almost a 6% decline in overall life science employment, it has fared better than other industries in the state. Employment in other areas such as construction (down 15%), manufacturing[1] (down 12%), and information technology (down 11%) have not proven to be as resistant to the economic downturn. The actual number of life science firms has actually experienced a 13% increase between 2008 and 2011. This is accounted for by the addition of 300 firms in the category of research, testing, and medical laboratories. The growth in the number of firms in this industry

segment represents an opportunity for future industry growth and expansion.

Over the past few years, interest in developing the shale gas industry has been at the forefront of economic development efforts around the state. However, compared to the overall employment in the shale gas industry (Figure 3) and number of establishments (Figure 4), it is clear that the life science industry continues to be a major economic driver of Pennsylvania's economy, and cannot be dismissed.

The evidence clearly proves that Pennsylvania's industry has significant future potential to drive job growth and will remain a global leader.

Goals and Recommendations

The goals and actions outlined in the Executive Summary of this report are more fully detailed in the following section.

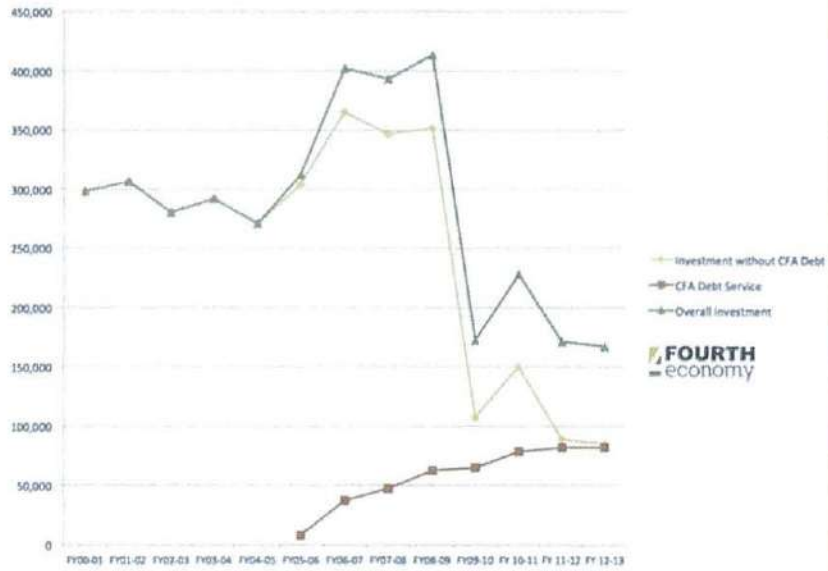
GOAL 1

Promote the life science industry as a key driver of Pennsylvania's economic competitiveness

Action 1.1:

Adopt the recommendations outlined in this report as a long-term life science economic development strategy

In order to retain the Commonwealth's significant employment base and support the growth and creation of new firms, Pennsylvania must clearly define its desire to be a place where companies want to invest and grow. As with other industries, the life science industry has experienced changes in the financial and programmatic support due to shifts in the economic climate. Pennsylvania must make the life science industry an economic priority by articulating a clear strategy that underscores the economic potential for both the private and public sector and outlines the commitment to long term stability and growth of the industry.



State-related life science economic development factors that drive a business decision to invest or grow in a particular location are often unique to each company or sector, though market access, workforce, tax structure and infrastructure are among the more critical. While companies may weigh each criterion to varying degrees, life science industry investments remain increasingly competitive, demanding the highest valued resources and financial support from their target locations. Pennsylvania has historically been a global leader because of its availability of human capital to support research and industry growth. From entry-level to PhD-level employees the state has continually produced a highly educated and dependable workforce. As global economic conditions begin to improve, it is critical for states seeking to attract and retain life science companies to develop and maintain competitive programmatic, infrastructure and human capital assets.

Pennsylvania's economic development investment has been reduced in recent years due to state budget constraints as shown on Figure 6. In FY11-12, the Opportunity Grant Program, Customized Job Training grants, and the Industry Development Fund, all utilized by the Governor's Action Team to support industry attraction, expansion, and retention, were combined into a single highly flexible program, Pennsylvania First, which was funded at $25 million. Other programs that

support the life sciences include the Ben Franklin Technology Development Authority and the Life Science Greenhouses. Combined the state is currently investing approximately $50 million in economic development efforts. CURE funds provide an average of $70 million per year in additional funding, although roughly 75% of those funds are used for research purposes.

The Governor's proposed budget for FY 2012-13 further reduces economic development spending by $3.6 million from 2011-2012 figures. This is a total reduction of $60.9 million from the end of the previous administration with several programs consolidated or eliminated in the past two years. The figure provided also breaks out Commonwealth Financing Debt service as this funding is going to pay off previous commitments rather than being available for new investments.

Programs such as the Ben Franklin Technology Development Authority (BFTDA) which supports the Ben Franklin Technology Partners ($14 million), the Life Science Greenhouses ($3 million), and the newer Discovered and Developed in PA program ($9.9 million) are level-funded in the Governor's proposal. The Keystone Innovation Zones and partner universities ($2 million) received reduced funding from the BFTDA, but at level BFTDA funding future support will not be possible.

One major impact to the state's colleges and research universities that are performing health research is a redirection of all funding for the Health Research Priorities otherwise known as the Commonwealth Universal Research Enhancement program (CURE). Last year the CURE program supported $55.8 million in research funding and if the Governor's proposal passes they will received no funding. Careful deliberation should be given to determine if the elimination of the funding is warranted.

GOAL 2

Ensure the continued growth and vitality of the Pennsylvania life science community through ongoing monitoring, evaluation, and action of its stakeholders to maintain the industry's competitiveness

Action 2.1:

Create an engaged public-private life science team with executive-level leadership to focus on growing and expanding the life science industry in Pennsylvania

An interdisciplinary, public-private team with executive-level leadership should be constituted to monitor and assess opportunities and challenges to Pennsylvania's life sciences to properly and efficiently address issues in a timely manner. This team should meet on a regular basis to address current performance of programs that support the industry, and identify industry and governmental barriers that may be limiting job creation. The team would be charged with developing and submitting to the Legislature an annual life science industry economic impact report and reviewing its recommendations.

Initially this group may consider focusing on the areas of immediate interest identified by the Life Science Leadership

Advisory Council, including:

- An industry-supported venture capital model
- Further development of the Commercialization Network concept
- Strategies to support the retention of Pennsylvania innovations
- Improvements to the Preferred Drug List processes
- Pennsylvania's approach to the insurance exchanges included in the federal "Affordable Care Act"

Coordinating Pennsylvania's Life Science Related Programs

Pennsylvania has a variety of state-level programs across multiple government agencies that directly impact the life science industry (Figure 5). Coordinating the efforts of the various programs will be mutually beneficial for both the public and the private sectors as it holds the promise of cost savings and increased impact from investment. It will also provide new companies, or companies looking to expand or relocate, with a clear understanding of the growth prospects available in the state.

Many of the states, with which Pennsylvania competes in the life sciences have either a state office or a defined working relationship with a life science non-profit organization to provide companies with a clear point of entry. Figure 6 highlights other states and their lead economic development-related life science organizations.

FIGURE 5:
State-Level Programs Impacting the Life Science Industry in Pennsylvania

Agency or Authority	Program
Tobacco Settlement Investment Board	• Health Venture Investment Account
Ben Franklin Technology Development Authority	• Ben Franklin Technology Partners • Technology Grant Program • University Research Program • Keystone Innovation Zone Program and Tax Credits
Commonwealth Financing Authority	• Venture Capital Investment Program • Venture Capital Guarantee Program • Second Stage Loan Program
Pennsylvania Department of Community and Economic Development	• Machinery and Equipment Loan Fund • Pennsylvania First (formerly Opportunity Grant Program and CJT) • Job Creation Tax Credit • Pennsylvania Industrial Development Authority • Research and Development Tax Credit – Sale and Assignment • Keystone Opportunity Zone • Life Science Greenhouses • Discovered and Developed in PA
Pennsylvania Department of Health	• Commonwealth Universal Research Enhancement
Pennsylvania Department of Public Welfare	• Preferred Drug List (PDL)
Pennsylvania Department of Revenue	• Research and Development Tax Credit
Pennsylvania Office of the Budget	• Redevelopment and Capital Assistance

FIGURE 6:
Pennsylvania's State Competition and their Primary Life Science Organizations

State	Lead Entity	Type of Entity	Funding Pledged	Years of Investment
CA	California Institute of Regenerative Medicine	State and grant funded nonprofit	$3 billion (voter approved)	2004 and ongoing
KS	Kansas BioScience Authority	State funded nonprofit	$580 million	2004 and ongoing
MD	Bio 2020	State-led strategy with funding to a variety of efforts	$1.3 billion	2009 and ongoing
MA	Massachusetts Life Science Initiative	State-led strategy with funding to a variety of efforts	$1 billion	2008 and ongoing
NC	North Carolina Biotechnology Center	State and grant funded nonprofit	Unknown	1984 and ongoing
NJ	New Jersey Economic Development Authority	State related entity	Unknown - a portion of fund goes to life science investment	Decades and ongoing
OH	Third Frontier - Ohio Department of Development	State agency	$2.3 billion (voter approved - est. 40% life science)	2002 and ongoing
TX	Cancer Prevention Research Institute	State agency creaed to conduct and support research	$3 billion (voter approved)	

GOAL 3

Support the research and development of emerging life science technologies including previous and new life science investments

Action 3.1:

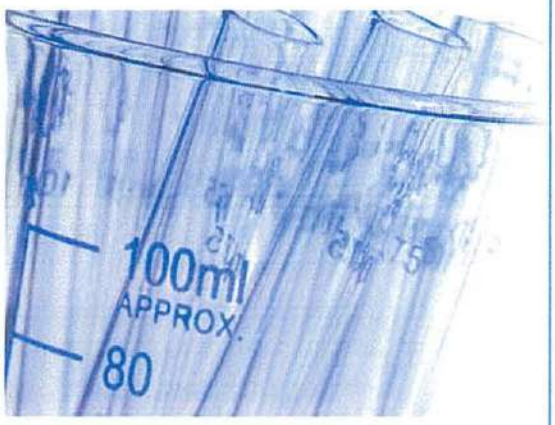
Establish a long-term strategy for the use of Tobacco Settlement funding and other sources of investment (both public and private) that support life science industry growth, including health-related research and commercialization

Pennsylvania has enjoyed great success with its various programs promoting research, commercialization, and company formation. The life science community should explore opportunities for continuing to improve and build upon these efforts. Recommendations to strengthen these efforts include:

- **Allow funds to evergreen for all investment programs:** the investment funds that have provided millions of dollars for early-stage development over the past 8 years should be universally reinvesting the returns from these investments into additional venture and equity funds
- **Create an ongoing unified life science impact report:** the programs offered to life science companies should utilize consistent metric reporting systems to track results across the sector and compare the successes of different programs
- **Increase the flexibility of the programs:** allowing this would make it easier to adjust to meet industry needs or changing priorities based on the industry's economic development goals.

- **Encourage proportionate funding for R&D and commercialization efforts:** the amount of funding invested in research and available for commercialization efforts should be more proportionate. With a stronger focus on commercialization, the discoveries resulting from research can be better leveraged to create new companies and jobs.

As the global economy prepares to rebound, it is imperative that states and communities are positioned to support renewed job creation and expansion of firms. In the past decade, Pennsylvania has been a state that has continued to witness diversification of its economy and growth in technology industries, including the 'eds and meds' sector. The recession has had its impact on Pennsylvania, but our economic base is still intact and is poised for expansion. Investment in the life science industry should continue in order to realize the expected returns of the previous investments – job growth and economic stability.



Supporting Information: Tobacco Settlement Funding Overview

Pennsylvania's approach to the life science industry and technology-based economic development has made it a pioneer in these areas. In June 2001, Pennsylvania made a bold and unprecedented commitment to the life science industry by dedicating up to $1.6 billion in funding from the Tobacco Master Settlement Agreement to support research, encourage early-stage funding, and enhance venture capital in the state. The resulting three novel, highly-effective programs have worked in a coordinated way to advance both healthcare and Pennsylvania's high-growth companies (Figure 7). These programs are:

- Commonwealth Universal Research Enhancement (CURE) Fund - supports Pennsylvania's leading research institutions and the health priorities developed by an Advisory Panel to the Department of Health
- Life Science Greenhouses (LSGs) - fill a critical gap in seed-stage funding for emerging companies
- Health Venture Investment Account (HVIA) - encourages venture capitalists to focus on Pennsylvania-based companies pursuing Series A through later-stage financing

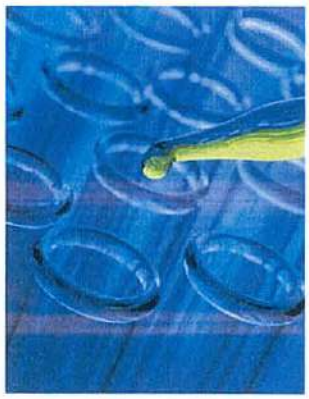
Collectively, these three programs and others have leveraged billions of dollars, created thousands of jobs, and contributed to Pennsylvania's reputation as a leader in the field of life science.[2] The following information highlights the performance of these programs and other state programs that have been used to support the life science industry in Pennsylvania.[3]

Commonwealth Universal Research Enhancement (CURE)

Established under Chapter 9 of Act 2001-77 (the Tobacco Settlement Act), the CURE program awards grants to Pennsylvania-based organizations for biomedical research, clinical investigations and health services research. Studies funded by the grants aim to improve the delivery of health care, promote health, prevent disease and injury and translate research advances to community health care practice.

Two types of health research grants are awarded: (1) formula grants, which are distributed by a pre-determined formula to institutions that already received funds from the National Institutes of Health (NIH) and the National Cancer Institute (NCI); and (2) non-formula grants, which are selected through a competitive peer review process.

Health research funds are awarded to projects that are consistent with the program's research priorities. These priorities are determined by the Department of Health in conjunction with the Health Research Advisory Committee. In developing the research priorities, consideration is given to the national health promotion and disease prevention objectives as applied to Pennsylvania. Priorities focus on critical research areas and the disparities in health status that occur among various populations within the Commonwealth.



In accordance with the Tobacco Settlement Act of 2001, the Department of Health requires institutions receiving $400,000 or more in formula funds to describe the initiatives and activities that they propose to undertake to enhance the commercialization of research results.
During the tenth year of the CURE program (FY 2010-11) health research grants totaling over $61 million were awarded from Pennsylvania's share of the national tobacco settlement (73% formula, 27% nonformula). Over the past decade the Department of Health has awarded approximately $698 million in CURE Program grants to fund over 1,600 health research projects. As of June 2011, 292 research grants had been completed, with the following outcomes:

- Findings published in 1,424 peer-reviewed publications
- Filing of 69 patents
- Leveraging of additional $946 million in research funding, a leverage ratio of approximately 2.3 on the original awards of $413 million; and
- 97% of the grants that have undergone final performance review with 83% receiving outstanding or favorable performance reviews.

Half of the non-formula funds for FY 2011-12 will be devoted to the commercialization of research related to cancer diagnostics and therapeutics. A goal of this initiative is to commercialize innovations derived from prior research endeavors.

A 2011 audit by the State's Auditor General of the CURE program reported that over $126M or 40% of the funds contracted and distributed to grantees by the Department of Health in the past four years remain unspent by the grantees. This is an open issue under discussion with the Department of Health and universities, but the value of academic institutions, and basic research specifically, should not be underestimated. Feedback received during this process suggests that a more transparent and expert-reviewed application and decision-making process for the award of funds would allow for improved management of the program. Careful deliberation should be given to determine if the elimination of the funding is warranted.

Life Science Greenhouses (LSGs)

In 2001, the three regionally-focused Life Science Greenhouses were created to address the funding gap for life sciences and create dedicated industry-focused investment mechanisms. The Life Sciences Greenhouses serve start-up companies throughout the state and are located in:

- Pittsburgh – Pittsburgh Life Science Greenhouse
- Central Pennsylvania – The Life Science Greenhouse of Central PA
- Philadelphia – BioAdvance: the Life Science Greenhouse of Southeastern PA

The LSG program has been effective in stimulating commercialization, as evidenced by the number of companies formed, the number of jobs and diversity of products emerging from these companies, and the level of follow-on investment from private industry, foundations, and federal sources. The following information is from the November 2011 Life Science Greenhouse report to the Legislature and represents the consolidated impact from October 2002 through June 30, 2011.

$60.2 million in committed funds

- 254 projects funded (out of 1,433 applications received, requesting $1.4 billion in funding)
  - 230 total companies funded; 134 were companies in operation for 3 years or less
  - 24 university technology projects funded
- 3,246 jobs created as a result of LSG supported projects or activities
- 2,743 jobs retained as a result of LSG supported projects or activities
- $2.4 billion received by companies after LSG investment, from venture capital, private, and industry sources (including M&A activity)
- $119 million raised outside of Pennsylvania and state dollars
- 13,009 indirect jobs created (Milken Multiplier Jobs Created x 6.3)

While no formal impact benchmarking study or program evaluation has yet been performed, these numbers compare or exceed the metrics of other reported technology-based economic development programs operating throughout the U.S.

Health Venture Investment Account

When the original state investment in the life science industry was contemplated, Pennsylvania had limited venture capital resources available to support company investment and growth. Start-ups would begin in the state but as they required additional financing they were forced to move to places like Massachusetts and California. The Health Venture Investment Account was designed to be a catalyst for venture formation in the state, bringing new capital and even new investment teams to the state. In total, $66 million was committed to four venture capital funds, which spurred a total investment pool of $258 million for Pennsylvania companies and a syndicate of over $2 billion in capital available (Figure 8). The charts below provide additional detail on how these numbers were derived and relate to each of the four venture capital firms.

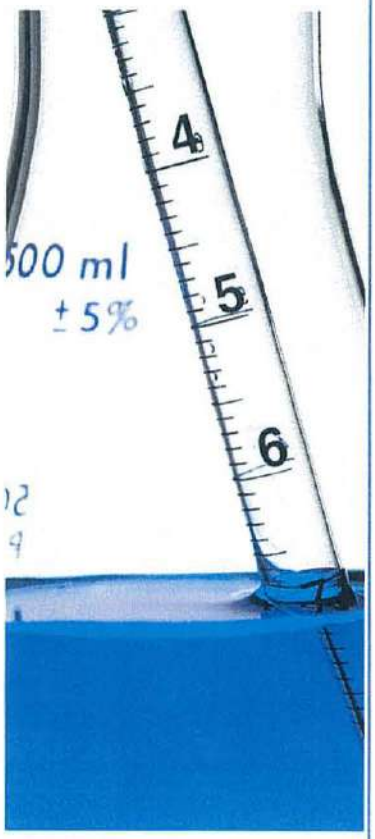
FIGURE 8:
Combined Health Venture Investment Account Activity
All Funds, totals from inception through June 30th, 2011

Fund	Total Syndicate - in millions (A)	Fund Commitment - in millions incl. TSIB (B)	Total TSIB - in millions Funds Invested (C)	Total Leverage Ration (A-C)/C
Quaker	$822.7	$150.1	$28.1	28:1
Novitas Capital	$672.1	$59.4	$13.8	48:1
Birchmere	$158.4	$22.4	$8.0	19:1
Commerce Health	$363.8	$26.95	$8.4	42:1
TOTAL	$2,017	$258.85	$58.3	34:1

The funding provided by the Health Venture Investment account allowed for investment in 31 Pennsylvania companies, creating 1,141 jobs (Figure 9). These job numbers are expected to increase as several of these companies mature. These

figures are conservative, as they do not include figures on companies that have exited from the investment portfolio of these entities.

Other Programs Supporting the Life Sciences



Ben Franklin Technology Partners (BFTP)

The Ben Franklin Technology Partners are a critical source of early-stage capital and new company growth support services for the life science industry. Since 2001, active support from the BFTP has helped their portfolio companies through:

- 271 company investments
- Over $56.5 million in invested funds
- More than $1.2 billion in follow-on financing
- 3,458 high-wage, sustainable jobs created and retained

Governor's Action Team (GAT)

In addition to the funding programs supported by the Tobacco Settlement Investment Board and BFTP program, the Governor's Action Team proactively works with companies looking to locate or expand operations in Pennsylvania. Over the past three years GAT has made 32 offers to life science companies, which resulted in:

- 3,461 jobs pledged to be created
- 6,295 jobs pledged to be retained
- Over $34.5 million offered in assistance, leveraged over $664.3 million in total investment

Of these offers, 13 were related to new attraction efforts and 18 were business expansions of existing Pennsylvania companies. The remaining project was a retention effort, which kept the company from seeking a new location outside of Pennsylvania. A variety of economic development programs were included in the offers to life sciences companies. These programs included tax credits, low-interest loans, and grants.

Action 3.2: Form a Life Science Commercialization Network

In order to leverage the investment in research funded by CURE and continue the record of investment by the Life Science Greenhouses and the Ben Franklin Technology Partners, the Department of Health may wish to identify life science technology commercialization as a priority for the non-formula funds and could partner with DCED to co-administer the funds, should the funds continue.

The funding could be allocated to a set of programs to form the Life Science Commercialization Network which would act as a catalyst to attract additional private investment. Funding should be provided on a competitive basis to organizations and initiatives which can demonstrate:

- a high likelihood of supporting technology commercialization
- a track record of investments
- examples of success or offer novel but well developed ideas about how to accelerate the pace of technology development
- private investment and ability to have program sustainability in the future

An advisory board can provide guidance on the approach of the Network. Similar to programs in other states and federal agencies, this board should include national industry experts who provide unbiased advice on the approach and mechanics of the Network.

The first year allocation of this funding, if available, may be allocated for the following life science investment and business support purposes with subsequent years being allocated competitively:

- $9 million for the Life Science Greenhouse Initiative
- $4 million for the Ben Franklin Technology Partners
- $2 million to link together the university-based

Technology Transfer Offices (TTO) and support capacity at Universities that engage in life science research but lack a formal TTO. Funding should be prioritized to direct commercialization services such as proof of concept grants and/or employment of Executives-in-Residence to help build companies from University technology.

- $1 million to support regional innovation groups focused at identifying viable companies and bridging the university-industry-marketplace gap with prioritization to efforts that have demonstrated success such as the Science Center's QED Proof of Concept and Quorum initiatives.
- $1 million to support Network partners pursuit of federal funding from networked competitive grants and SBIR programs
- $500,000 to engage the angel investment community in the life sciences sector as mentors and investors. Funding would support education and engagement of angel investors in the life science community network and especially in the commercialization activities described above.

All funds provided should be considered evergreen to allow for future sustainability of these efforts and for increased investment and leverage.

FIGURE 10:
Start-up comparisons between Pennsylvania, Massachusetts, and North Carolina

Startups	Licenses	IP Disclosures	IP Apps	Issued Patents	Funding (in millions)	$/License (in billions)	$/startup (in millions)	$/App (in millions)	$/Issued (in millions)
Pennsylvania	29	243	1,004	680	220	2.8	11.5	96.3	4.1
Massachusetts	45	448	1,725	1,144	466	4.9	10.9	109.0	4.3
North Carolina	24	203	609	323	122	2.3	11.1	93.6	6.9

Supporting Information: University Collaboration and Commercialization

Pennsylvania has world-class universities and research capacity, but they mostly operate independently with limited coordination around opportunities. There could be a platform developed for universities to coordinate their research and commercialization efforts with state economic development priorities; collaboration between universities helps attract federal R&D dollars, federal and private lab partnerships, and opportunities to work with industries to accelerate commercialization.

Recently the Nanotechnology Institute (NTI), a collaboration of founding members Drexel University, University of Pennsylvania, and Ben Franklin Technology Partner of Southeast Pennsylvania, have been demonstrating significant success in fostering collaboration among many regional and national private and public sector organizations. The outcomes include a significant improvement in patents, startup companies created and follow on funding.

Accelerating commercialization in particular holds opportunities for economic development. A review of data from the Association of University Technology Managers (AUTM) shows that colleges and universities in Pennsylvania are as efficient as those in Massachusetts or North Carolina in securing patents, issuing licenses and spinning out companies per research dollar. However, those start-ups are much more likely to make another state their home base, versus North Carolina, where on average 86% of all start-ups stay in North Carolina.

Overall, this data highlights that, given the proper tools (additional capital) and support (ecosystem), Pennsylvania colleges and universities have great opportunities for increasing the commercialization of R&D efforts, including opportunities to create jobs in the Commonwealth.

Action 3.3: Increase funding of the state research and development tax credit to $100 million

The Research and Development (R&D) Tax Credit was established in 1997. The credit was modeled after it Federal counterpart. The majority of states (32) have similar provisions. Taxpayers are eligible to apply for a credit for their R&D activities in the relevant tax year only to the extent that they exceed the average of the same activities in Pennsylvania during the prior 4 years. Since the program's inception, credits awarded have consistently lagged behind demand. This has effectively diminished the value of the credit to less than half of its statutorily prescribed value of 10%.

GOAL 4 Seek investment capital to support early and mid stage life science companies

Action 4.1:
Identify mechanisms, including pension system investment, that can be used to encourage the formation of new investment and venture capital funds

Pennsylvania's fiscal situation makes the thought of devoting new funding to a life science strategy difficult. There are however choices that can be made to restructure or reposition funding for economic development purposes. Four financing models are proposed for consideration.

State Gaming Revenue

State gaming revenue currently is being invested in select communities through a local share process. A serious look at the impact and projects that these funds are being invested in would reveal that a better structure could be established that can support more significant job growth and job retention for the Commonwealth. Politically this would be a difficult discussion but in light of the current state financial situation and the need for investment in job creation the timing may be now to consider this an opportunity. As of 2011 almost $381 million has been generated for the Local Share accounts and $476 million for the Economic Development and Tourism Fund which supports bond payments for water infrastructure

projects.

Wage Tax Increment Financing Program

Another approach to creating the financial support needed for the industry would be to develop a wage tax increment financing program to support future investment. This model is becoming increasingly popular with states wishing to dedicate funding for economic development. In this model, the state would dedicate to future industry investment a portion of any increased tax revenue from an industry's payroll tax that occurs naturally. Earlier in this report, it was shown that Pennsylvania's life science industry increased wages and resulting tax contributions even despite the employment loss. A percentage of the associated tax revenue increase should be set aside and dedicated to components of this strategy.

Example: If an industry sector contributes $100 million in income tax revenue in year x and the following year contributes $110 million then a percentage such as 50% of the increase in tax revenue is directed to a fund to support that industry's future growth.

Adoption of either of the previously described financing models would allow the state to restore, and in some cases, realign the state's economic development programs such as GAT related programs, the Ben Franklin Technology Development Authority and others to support capital investment, retention and expansion of employment opportunities by bioscience companies.

Pension Funds

It is important to explore mechanisms to encourage venture fund formation and/or attraction through the use of existing resources, such as pension funds. For example, several states have preferences to invest a portion of pension funds to incentivize certain kinds of fund managers, such as incentivizing minority and women-led funds. The pension funds should also be guided to choose in-state fund managers whenever consistent with fiduciary duties. New Jersey in particular has partnered with a private fund of funds manager that focuses on investing in promising regional funds and also matching the capital received from the state. These models prove that it may be possible to establish a preference to encourage early stage funds or out-of-state funds that are willing to locate here. An evaluation of strategies used in other states would be a first step to identify the most effective solutions.

Corporate and Stakeholder Venture Funds

As traditional venture capital becomes increasingly difficult to come by, due to the economic climate and regulatory and marketing hurdles, corporations have been stepping up to fill the gap. Corporate venture funds were involved in 25 percent of early stage U.S. biotechnology financing deals during the first half of 2011, compared with 15 percent for all of 2010, according to PricewaterhouseCoopers and the National Venture Capital Association. The funds represented 12 percent of total investment, compared with 5.3 percent last year.

Corporate funds don't have to raise money from outside investors, allowing them to take a longer view on development. Also, funding startups to develop medicines is often cheaper, and less risky, than drug makers doing the work in-house. If the drug works, the startup will likely become a partner with the corporate parent company later in development or be acquired.

In addition to private companies there are several groups of Pennsylvania-based stakeholders that can support a more robust investment climate. These include College and University endowments, hospital endowments and non-profit health insurers. These stakeholders have a significant stake in the future economic growth in the state and could do more to insure a strong discovery climate exists to support their goals.

Companies such as Amgen, GSK, Novartis, Roche, Astra Zeneca etc have developed their own Venture Capital funds in order to continue to develop a pipeline of new technology. The state and industry leaders should convene a group to assess the opportunity and viability of forming a Pennsylvania focused public-private partnership to invest. This approach may be difficult as multinational companies are less concerned about geography and may be less inclined to partner. An alternative would be to identify disease focused funding vehicles that draw on foundations and corporate sponsors depending on the disease area.

Another model to consider is South Carolina Launch. SC Launch was created in 2006 as collaboration between the South Carolina Research Association and several South Carolina's universities. The program provides a suite of support services, mentoring and seed capital to early-stage SC firms with potential for high-impact in certain sectors, including Life Sciences. Activities are funded by an Industry Partnership Fund, whereby private donors receive a 100% state tax credit for their contribution. The support of over 350 donors has resulted in over $160M in follow-on capital for SC Launch portfolio companies.

Supporting Information: Capital Availability

In 2011 the availability of capital is impacting all sizes and types of life science companies. Early-stage investment capital has become scarce and there have been a limited number of later stage deals completed. There are some issues related to reporting of angel investment round deal but overall the charts that follow illustrate the most recent time period as compared to previous times. Even federal research funding is contracting thereby limiting the ability of many of the states' research institutions to focus on new discoveries.

Within this restrictive capital climate, Pennsylvania compares well to neighboring states such as Maryland and New Jersey in the amount of venture capital invested and the number of deals over the past two years.[4] Furthermore, overall investment in biotech and medical devices is showing some renewed growth nationally (2011 Q3 up 26% and 16% respectively from 2010 Q3) and Pennsylvania is investing in those sectors at about the same rate as the rest of the country. These numbers are still down significantly from previous years. Nevertheless, there is still a gap in venture capital relative to the amount of NIH dollars secured within the Commonwealth. This reflects a national lack of seed funding to support new growth and company formation. In 2011 Q4, seed funding represented merely 2% of total investment dollars nationally.[5] For biosciences in particular, the financing in early and seed stage rounds.

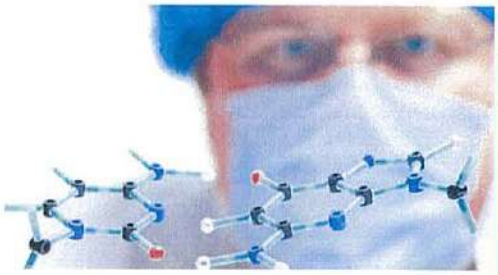
Pennsylvania's State-level Competition

Industry employment and firm data provided earlier in this report illustrates that the state is still home to a significant share of the industry with several subsectors showing the ability to grow even in this economic climate. It is imperative

that we act now to continue to find new ways to leverage the talent pool, infrastructure and scientific resources to reverse course.

Like many other states, Pennsylvania's short-term budget situation is has not yet recovered. Still, our economic competition is finding the resources to grow the life science sector, because they recognize the job creating and human health impact potential.

In Southern California for example, the life science industry is expected to add roughly 6,000 jobs over the next two years alone after adding over 5,000 in the previous two years. The recent growth brings Southern California's total life science employment to almost 42,000 positions, still below Pennsylvania's totals. Like Pennsylvania, the communities near San Diego are facing retraction in venture and angel capital, and in state and federal dollars. However, they have been able to adapt, grow, and evolve in spite of market fluctuations. A shift share analysis demonstrates that Southern California's unique support system for life sciences was the main contributor by far to growth over the past two years. Not only has that infrastructure supported the life science community itself, it has also added 31,000 jobs and $6.1 billion in economic activity to several other key industries, such as Real Estate, Financial Services, and Recruitment & Administrative Services.[6]



Other state life science models include:

- The **California** Institute of Regenerative Medicine was created in 2004, providing $3 billion in state bond financing to support industry growth. Despite California's economic situation, more than $1.2 B million was awarded as of January 2012.
- **Ohio** is renewing funding for the Third Frontier program, a ten-year, $1.6 billion initiative designed to support the overall technology industry in the state, with a new four-year, $700 million bond, approved by voters in May 2010 which will bring the total investment to over $2.3 B.
- **Maryland** established the Bio 2020 initiative, which will invest $1.3 billion over the next 10 years to support the MD Biotechnology Center, double the biotechnology investment tax credit, and provide funding for incubator and capital projects devoted to the biosciences.
- **North Carolina** has invested more than $1.2 billion in the past 10 years to support the bioscience industry in the state. Investments have supported research facilities, workforce development, direct company incentives, and the North Carolina Biotechnology Center.
- **Texas** created the Cancer Prevention and Research Institute in 2007, which provides $3 billion in state bond financing over 10 years to support cancer research, facility development, and related programs.
- **Kansas** created the Kansas Bioscience Authority in 2004 with more than $500 million to support venture capital creation, bioscience infrastructure, and attraction of federal funds. The funding mechanism for this initiative is a unique formula that provides a percentage of the annualized tax payment increase by the industry to the Authority.

Each of these initiatives utilizes public funding to leverage private investment in targeted areas of opportunity. While no clear figures are available for Pennsylvania's current state related investment in the life science it is estimated to be less than $10 million if the CURE funding is redirected as proposed in the 2012-2013 budget.

- The most significant life science economic development competitor to Pennsylvania is **Massachusetts**, ranked first in the nation by the Milken Institute's Technology and Science Index. With the Massachusetts Life Science Initiative created in 2008 over $1 billion is being invested over ten years to support:
- Bridging the gap between NIH funding and commercialization
- Creation of the Massachusetts Stem Cell Bank
- Establishment of Massachusetts Fellowship Grants and Life Science Innovation Centers
- Life Science Investment Fund Tax Incentives

FIGURE 11:
State Business Climate Ranking Index

	SSBC	MEC	EC	TF	CS	CR
TX	2	43	36	11	92	1
KS	26	19	19	32	96	2
PA	11	31	35	27	104	3
OH	4	32	27	47	110	4
NC	26	23	25	39	113	5
MD	26	44	39	45	154	6
MA	26	48	47	36	157	7
CA	22	47	40	48	157	8
NJ	26	49	44	50	169	9

SSBC: Site Selection Business Climate Rank (11/2009) - Top 25 states ranked
MEC: Average Wage Cost for Biosecience Manufacturing Employment Rank (2009)
EC: Average Cost of Energy Rank (2/2009)
TF: State Business Climate Tax Rank (2010)
CS: Composite Score of Rankings
CR: Rank of States based on Composite Score

In addition, their state's Bio affiliate, MassBio, provides several programs aimed at supporting continued industry growth including:

- **Innovation Services:** connecting researchers to seasoned mentors who help guide new company creation; new technologies are directed from tech transfer offices to buyers, and emerging entrepreneurs can receive training from successful, seasoned serial entrepreneurs.
- **Workforce Programs:** training high school science teachers in a bioscience curriculum that they bring back to their classrooms; job shadowing for hundreds of students annually; funding college interns at life sciences companies throughout the state; working with community colleges to develop bioscience core competencies to help fill technician-level positions in the industry.
- **BioReady Communities:** identifying and marketing communities across the state with buildings and land sites available for development as laboratory or biopharma manufacturing facilities.

GOAL 5

Encourage the creation of a tax system and business climate that provides a supportive environment for life science and other technology based industry job creation

Action 5.1:

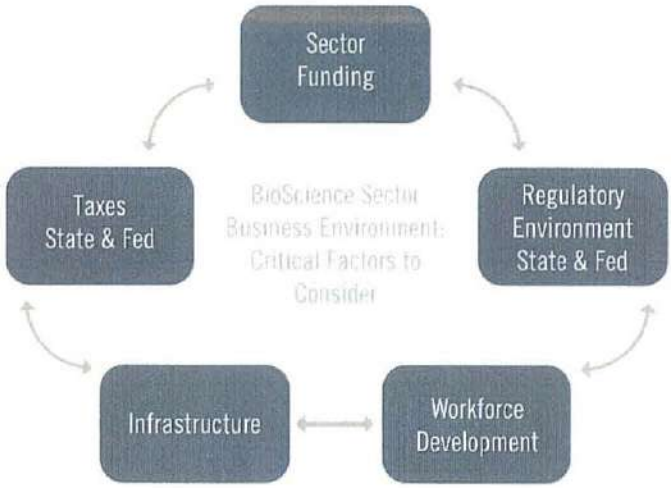
Develop the economic case to support changes to Pennsylvania's business climate

Tax Policy Reforms

Tax policy is one of the most visible factors that contribute to a state's business environment. For the life science industry in Pennsylvania there are clearly other issues to consider as well, but tax policy can have significant long-term impacts on the state's more mature life science companies.

As Figure 12 illustrates there is interplay between taxes, the regulatory environment, sector specific funding opportunity and infrastructure. Companies may have different values placed on various business climate inputs but when they compare states there are clearly differences that must be considered. A composite ranking (Figure 12) demonstrates that Pennsylvania is in the middle of the pack in various national business climate rankings but is near the top amongst some of the chosen benchmark states. There is room for improvement as the state considers future business climate programs and policies.

FIGURE 12:
Business Environment Factors



In the fall of 2011, the Corbett Administration released its Business Tax Reduction Plan. The plan outlines a strategy to enhance Pennsylvania's tax competitiveness. The primary tenets of the proposal are: maintain the phase-out of the Capitol Stock/Franchise Tax (CSFT); establish a single sales factor for the apportionment of CNI income; eliminate the cap on NOLs; reduce the CNI rate to 6.99%; and establish tradable NOLs. Most elements of the proposal would be phased in over the next decade.

Adopt a single sales factor for the apportionment of income

Since life science companies pay higher wages and require high-value assets, they are disproportionately taxed using the CNI's current 3 factor apportionment formula which utilizes a sales factor of only 90%. Adopting a single sales factor for the apportioning of CNI income would eliminate a penalty that they currently face.

Uncap the Net Operating Loss provisions of the Corporate Net Income (CNI) Tax

Pennsylvania is a severe outlier with respect to its inadequate treatment of NOLs. Uncapping the Net Operating Loss (NOL) component of the CNI would permit technology and life science companies to recoup their losses incurred in the start up and early product development stage of their existence.

Reduce the rate of the CNI to 6.99%

Reducing the rate of the CNI is perceived as a meaningful improvement. The life science industry currently bears a disproportionate burden of Pennsylvania's uncompetitive tax policies. Two structural components of Pennsylvania's Corporate Net Income (CNI) Tax – apportionment/single sales factor and uncapping NOLs - should be addressed by public policy leaders before the CNI's rate is reduced.

Continue the phase out of the Corporate Stock and Franchise Tax

A plan to phase-out the Capitol Stock/Franchise Tax (CSFT) was adopted in 2000. The CSFT is widely regarded as an unfair tax because it taxes companies without regard to profit. Unfortunately, the 10 year phase-out plan was not adhered to. There should be no further delays to the phase-out of the CSFT.

Offer Tradable NOLs

The Corbett Administration's tax reduction plan envisions establishing a $20 million tradable NOL program. 48 states and the Federal Government allow a business to deduct 100% of its business losses subject to its corresponding taxable income. Tradable NOLs is perceived as having merit but should not be established until Pennsylvania uncaps its NOL provisions.

Angel Investor Tax Credit

An Angel Credit could have a modest, at best, impact because Angels are reluctant to invest in long-term ventures, such as therapeutics; though they do invest some in devices and other companies, the credit can't be sector-specific so the aggregate impact will be small.

The House has approved House Bill 1503. The Bill provides for the Angel Investor Tax Credit. The Credit would provide qualified investors with a 25% tax credit. The Angel Credit would likely be funded at $10 - $15 M annually. While this proposal may offer some benefit, it should not be authorized until the R & D Tax Credit has been fully funded and structural improvements to the CNI (single sales factor and NOL) are completed.

Keystone Opportunity Zones

Pennsylvania's Keystone Opportunity Zone (KOZ) program eliminates specific state and local taxes within specific underdeveloped and underutilized areas, spurring capital investment in real estate and job growth. Depending on the situation, the tax burden may be reduced to zero through exemptions, deductions, abatements, and credits for the following:

- **State Taxes:** Corporate Net Income Taxes, Capital Stock & Foreign Franchise Tax, Personal Income Tax, Sales & Use Tax, Bank Shares and Trust Company Shares Tax, Alternative Bank and Trust Company Shares Tax, Mutual Thrift Institutions Tax, Insurance Premiums Tax

- **Local Taxes:** Earned Income/Net Profits Tax, Business Gross Receipts, Business Occupancy, Business Privilege and Mercantile Taxes, Local Real Property Tax, Sales and Use Tax

The KOZ program could be used as a tool to spur development in the life sciences industry. Unfortunately, the current fiscal environment makes it very unlikely that local taxing authorities would consider this concept. A new model must be developed to facilitate the utilization of the excess capacity of buildings and sites which currently exist and that are well suited for the expansion or creation of life science companies. Current industry trends suggest that the excess space should be targeted for smaller, more specialized firms. The state must be open to additional models as they passed a bill that allows for a Neighborhood Improvement Zone, which is being implemented in Bethlehem, PA. This version of a tax incentive zone allows for the collection of local wage tax receipts for use in financing development in a geographic area. **Analysis will need to be conducted but it would seem possible that a fund could be created that utilizes tax revenues for investment to modify existing underutilized properties in a type of Building Improvement Zone effort.**

State Regulatory Environment

Government regulation has the ability to wipe out any industry-directed support in tax policy and economic development programs. The bioscience industry is among the most heavily regulated industries in the nation. It is important for each state to remember that adding statutes or regulations on a basis that establishes different requirements in each state, for practices that are ultimately governed by the FDA, adds to the cost of doing business, and ultimately to the cost of bringing products to patients. For the 2009-10 legislative cycle, approximately 2,700 separate pieces of legislation will be introduced in state legislatures throughout the United States that would impact the bioscience industry. Three primary regulation areas exist for bioscience companies: environmental regulations, physician consultant registration requirements, and the Preferred Drug List. Environmental regulations, from facility sitting to waste water treatment, are often administered in an inconsistent fashion and therefore add a possible critical hurdle to a bioscience company seeking to expand operations in the state.

The Preferred Drug List (PDL) is the mechanism for states to identify drugs that are preferred in their fee-for-service Medical Assistance programs. Being categorized as preferred versus non-preferred is critical for drug manufacturers. The PDL is seen by regulators as a potentially effective mechanism for controlling costs in the short term, but members of the Pennsylvania bioscience community have raised concerns over the lack of transparency in the process and limited ability to add innovative drug therapies to the PDL. This impact on potentially limiting access to innovation can actually increase overall healthcare spending as well as reduce investment. These concerns raise the possibility that Pennsylvania supports the expansion of firms through its economic development programs but then restricts their growth through inconsistent use of the PDL process. New York, Ohio and Kansas have a transparent approach to the PDL and serve as a good model for future changes.

Improve the Preferred Drug List (PDL) Process

Pennsylvania should review the Preferred Drug List process and make improvements to better balance the intention of the programs with its impacts. Pennsylvania is encouraged to actively secure bioscience industry input as it plans and implements these changes.

Work with Industry

Develop protocols for seeking industry input into implementation of Affordable Care Act provisions. The State can maintain its responsibilities to implement these programs and at the same time allow for an open dialogue with industry on approaches that will limit the negative industry impacts that may result if not considered.

Pennsylvania's Approach to the Insurance Exchange

Now that Pennsylvania has announced that it will build a state-run exchange, the Administration should consider pathways in the development of the exchange that supports a system of innovation, encourages the development of new therapies, devices and diagnostics through fair reimbursement policies and access to innovative therapies. Patient access to the therapies prescribed by their treating physician needs to be protected, particularly for those with rare and chronic conditions.

Appendix 1:
The Role of Federal Government

The federal government plays a major role in the ability of Pennsylvania life science companies to create new medical treatments and create jobs within the Commonwealth. The federal government impacts the industry through policy, tax, and regulatory and financial mechanisms while creating an environment for biotechnology companies to operate. It is important for the state to engage with federal officials on issues of importance to its native industries, such as the life science industry in Pennsylvania. At the first meeting of the Life Science Leadership Advisory Council the point was made that we need to consider specific recommendations that can be carried out by our federal delegation. The following are areas that the state should work with the federal delegation.

Tax Exempt Bonds

Universities, as non-profit educational institutions, qualify for tax-exempt bonds that offer the advantage of tax-exempt interest. However, in order to retain tax-exempt status of the bonds, universities must use the funds, and facilities financed by the funds, in accordance with IRS regulations. One important condition is that any bond financed facility may not be used for more than a minimal "private business use". Bonds issued to universities are typically part of a larger bond issue for other state purposes, and measurements of the limits on private use (10% of the total issue over the life of the bond) are complicated. But, generally, due to the complexities of calculating the de minimis use of bond financed facilities which are part of a much larger bond issuance, universities are overly cautious in permitting "private use" of facilities that have active tax-exempt bond financing.

Under the Internal Revenue Code, "private business use" is defined as "use (directly or indirectly) in a trade or business carried on by any person other than a governmental unit." I.R.C. 141(b)(6). Private business use may be found even in situations where the private entity does not occupy the tax-exempt space, but enjoys special legal entitlements of use, or special economic benefits, as may be the case in the licensing terms in a sponsored research agreement. Research sponsored by a commercial entity is considered "private business" for IRS purposes unless it falls within one of two safe harbors described in Rev. Proc. 2007-47. (26 CFR 1.141-3: Definition of Private Business Use)

The first "safe harbor" stipulates that research will not be considered private business if the resulting license is competitively priced and the royalty rate or other consideration for the license isn't included in the research agreement. This means that industry sponsors can't be given any preference in the use of the results of research that they have funded. The second "safe harbor" ensures that industry or federally sponsored research will not be considered "private business" if it's general research determined by the university, if the resulting patent or product is owned exclusively by the university, and if the sponsor receives only a nonexclusive royalty free license.

The consequence of failing to adhere to these conditions, or to fall within the de minimis exception, is that the IRS can revoke the tax exempt status of the bond issue, causing the entire debt on the state bond issue to be due immediately.

Based on input from Pennsylvania life science stakeholders, this limit needs to be modified to reflect the real world collaborations between industry and academia, which is not necessarily industry in search of less expensive resources, but rather unique tools that could not otherwise be developed or shared.

H-1B and EB Visas

Congress created the H-1B program in 1990 to enable U.S. employers to hire temporary, foreign workers in specialty occupations. The law capped the number of H-1B visas issued per fiscal year at 65,000. Since then, the cap has fluctuated with legislative changes. In most years, demand for new H-1B workers exceeded the cap: From 2000 to 2009, demand for new H-1B workers tended to exceed the cap, as measured by the numbers of initial petitions submitted by employers who are subject to the cap.[7]

The life science industry annually employs thousands of H-1B visa-holders, the vast majority of whom received their advanced degrees from U.S. schools. Because of the constant shortage of specialized technical workers, these employees are essential for the continued success and competitiveness of the U.S. life science industry.

However, several issues are hampering the program from being truly effective in complementing the U.S. workforce and driving the country's life science and tech industries. The life science and technology industries have long called for the government to increase the number of H-1B visas due to the lack of U.S. engineers and scientists available to fill vacancies. In addition to simply increasing the number of guest workers, many have advocated for closing loopholes that make it easy to bring in workers with ordinary skills who compete with U.S. workers, instead of focusing on scientists, engineers, and other doctoral graduates who can complement our existing workforce.

Alternatively, others argue that instead of issuing more temporary visas, the U.S. should give more visas to foreign students educated in the U.S. Every year approximately 140,000 employment-based (EB) visas are available for highly-skilled immigrant employees sponsored by a U.S. employer, representing 16% of all visas issued annually. Like the H-1B system, the EB system faces several roadblocks to being able to effectively advance the U.S. economy. For instance, there is a seven percent country limit, meaning that regardless of size, each country receives the same number of visas. Other flaws exist in the processing of visas, leading to a serious backlog. Many argue that students with advanced degrees from American universities in science, technology, engineering, or mathematics should be exempt from the EB visa cap.

Patient Protection and Affordable Care Act

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA). PPACA legislation will extend healthcare coverage to an estimated 32 million additional patients and reform insurance regulations to facilitate greater patient protection. These changes will ripple through the sector, not only increasing volumes, but also potentially straining the system and forcing cost cutting and other restrictions. PPACA is also a first attempt by legislators to break the historical cost-quality equation. By focusing on comparative effectiveness and employing technology and new delivery models, proponents hope to control costs while improving health outcomes.
Reform focuses specifically on four key areas: insurance markets, government programs, delivery systems, and revenue/subsidies. Although life sciences manufacturers are not the primary focus of the legislation, biopharmaceutical products and medical devices and equipment will still experience some direct impacts (e.g., new taxes and rebates).

- Reform began in 2010 and will continue to unfold in phases over many years, creating long-term uncertainty for the life science industry. Some of the expected changes for life science companies and other stakeholders include:
- Increased and greater access to health insurance for people in the Commonwealth
- New products and services created by health plans due to mandatory coverage requirements

- Increased focus on comparative effectiveness
- Acceleration of physicians leaving private practice
- Changes in decision-making authority as providers take greater responsibility for medical cost management
- Greater role of states in setting policies, negotiating reimbursements, and executing formulary decisions
- New systems for collecting, sharing, and analyzing data
- Specific new taxes and fees that will have a detrimental effect on bioscience innovation and likely deter company growth and job creation.

Changes resulting from the PPACA could result in as much as a 14% decrease in industry revenues in 2015, with lower profits and margins for life science manufacturers. Medical devices manufacturers could experience similar declines due primarily to the fact that physicians may lose decision-making power over devices. Pricing pressure will result largely from an increased emphasis on controlling costs, availability of generics, and cost effectiveness.[8] Specifically, There is the potential for serious negative consequences for Pennsylvania's medical device and diagnostics industry and its 576 establishments with 19,617 employees. The device industry is facing a 2.3% excise tax, beginning on January 1, 2013 on all sales. This will have a disproportionate impact on Pennsylvania in that there is such a large device sector in the Commonwealth – thus likely hampering future job creation and innovation. The same holds true with regard to an annual pharmaceutical fee which began in 2011. This fee is based on overall product utilization for government payers. This fee does exclude manufacturers of rare diseases but only if they received the orphan drug tax credit. While most rare disease drug manufacturers were able to get the credit, it was not accessible to all, including several Pennsylvania companies. As a result, these companies that could not get the orphan drug tax credit have to pay the fee, which was clearly not the intent. This will serve to stifle innovation and deter new product development and the hiring of employees to work on such development.

As these changes unfold, innovation in reducing illness and saving lives will become an increasingly valuable part of the solution. Recent medical advances, particularly those related to prescription medicines, have provided enormous clinical and economic value. As summarized by the Congressional Budget Office "Many examples exist of major therapeutic gains achieved by the industry in recent years...anecdotal and statistical evidence suggests that the rapid increases that have been observed in drug-related R&D spending have been accompanied by major therapeutic gains in available drug treatments."[9] For instance, The Centers for Disease Control and Prevention has identified "new drugs and expanded uses for existing drugs" as contributing to the decline in heart disease and stroke mortality.[10] Academic researchers have associated new medicines with declines in mortality for breast cancer[11] and other cancers,[12] reduced disability rates among elderly persons,[13] and increased productivity among workers with conditions like rheumatoid arthritis.[14] With the proper support, Pennsylvania has the ability to be one of the primary laboratories for such improvements.

The legislation included authorization for the creation of two important bodies of interest to the life sciences industry. In the case of one of these bodies-- the Patient Centered Outcomes Research Institute (PCORI), it is important that their efforts to identify cost-effective treatments do not have the effect of deterring access to innovative new therapies that are critical to improving health outcomes. The second body is the Independent Payment Advisory Board (IPAB) which will have the authority under certain scenarios to unilaterally implement policies that cut Medicare costs. The IPAB will consist of non-elected appointees who will lack accountability to either the legislative or executive branch, and its decisions will not be subject to judicial review. The dangers of such unlimited power being housed within IPAB have led to significant efforts

to repeal the provisions of PPACA that authorize its creation. These efforts should be supported by the Congressional delegation.

Another related issue of utmost importance is the deficit reduction proposal that would require companies to provide Medicaid level rebates for those drugs provided to Medicare beneficiaries through private plans under Medicare Part D. This unsound policy proposal would not only have a devastating impact on the industry in Pennsylvania but would also likely increase premiums for seniors and undermine the highly successful Medicare Part D program. The experience with Medicare Part D shows that comprehensive drug coverage reduces costs and is part of the long-term answer to the cost issue as well. Medicare Part D has provided broad access to medicines, with high beneficiary satisfaction rates and at lower costs than originally anticipated.[15] Moreover, Part D has shown reductions in non-drug spending associated with gaining comprehensive drug coverage. Harvard research shows savings in hospital and skilled nursing facility costs of about $1,200 per newly insured beneficiary,[16] or savings to Medicare of $13.4 billion in 2007,[17] the first full year of the Part D program. This represents more than one quarter of Part D's total cost during that time.[18] Again, while PPACA provides opportunities for patients and for the innovative Pennsylvania life science community, any benefits that might be gained would be greatly offset by the adoption of a policy that extends Medicaid price controls to a highly functional Medicare Part D program where companies already negotiate discounts with the health plans providing coverage for the services.

CMS Reimbursement

As the healthcare system advances towards a model of greater personalized care and preventative treatment, the successful delivery of novel diagnostics becomes increasingly important. However, without changes to the reimbursement system, these devices won't be able to deliver their potential benefit to patients and the healthcare system. The reimbursement system must provide a clear and consistent pathway to obtain affirmative coverage, appropriate and timely coding, and market-based payment for diagnostic tests. The national Biotechnology Industry Organization, BIO, recommends that the following reforms be made to diagnostic reimbursement policy:[19]

- CMS should clarify the evidentiary standards that must be met by novel diagnostics. Manuals should contain criteria that local contractors should consider when contemplating coverage for new diagnostics.
- Create an independent panel to advise CMS, which would consist of experts who are best suited to comprehensively address policy issues related to diagnostics. This body would advise CMS on issues related to coverage as well as reimbursement assessment regarding the crosswalk and gap-fill payment options for diagnostics.
- Develop a system for assigning temporary codes for novel diagnostics until permanent codes are established so that patients will have greater access to important new diagnostic tests.
- The CMS process for establishing payment rates for new diagnostics should be transparent and predictable. The manufacturer should be able to choose its preferred reimbursement pathway including the existing crosswalk or an enhanced gap-filling methodology. In addition, a new market-based option should be authorized.
- Require CMS to base gapfilling pricing procedures on prescriptive factors that include the potential benefit of the test on patient outcomes and to the healthcare system.
- Develop a new market-based system that establishes reimbursement methodology for novel diagnostics that reflect both the potential benefit that these tests will have on patient care and the healthcare system, and the value placed upon them in the market.

Like the Device and Diagnostic sector, the Health IT sector provides similar promise in fostering advancing healthcare. However, the current Medicare fee-for-service system penalizes physicians who take important steps like implementing innovative outreach or web-based programs to help their beneficiaries receive preventative services.

According to a recent Brookings study, there is enough evidence on these reforms that physicians should at least have the option of payments that better reflect their ability to improve health and lower costs. This would include payments at least in part on the basis of whole episodes, as in Medicare's Acute Care Episode (ACE) demonstration, which provides hospitals and physicians with a prospectively fixed amount for a bundle of orthopedic and cardiac services. It should also include broader per-beneficiary payments to beneficiaries' primary care providers. These payments would partially replace traditional fee-for-service payments, with savings resulting from that shift plus the ability of physicians to choose services more efficiently based on the needs of patients. Physicians would receive more flexibility and (if their actions can reduce other healthcare costs) potentially more resources. At the same time, they would start to be accountable for showing improvements in quality of care and avoiding unnecessary costs. These reforms will require some improved capabilities at CMS.[20]

On the biopharmaceutical front, CMS is of vital importance to ensure that therapies manufactured by companies in the Commonwealth are accessible to Medicare beneficiaries throughout nation. With federal debt reduction and budget balancing being a major focus, Medicare reimbursement for covered therapies seems to be an easy target to try and recoup savings. The Pennsylvania congressional delegation needs to be aware that certain proposals would have a significant and adverse impact to biotech manufacturers in the state.

As mentioned earlier the Medicare Part D program is working well. Many biotechnology products are reimbursed through the Medicare Part B program, which is also working very well. The switch from Average Wholesale Price based reimbursement to an Average Sales Price plus 6% methodology that was enacted under the Medicare Modernization Act has served to significantly save money specific to Medicare based reimbursement for therapeutics. However further cutting of this reimbursement will likely make it difficult for health care providers to be able to make therapies available for Medicare beneficiaries. There are other means available to recoup savings out of the federal health care system while preserving access to therapies that are life-saving in nature, of which a disproportionately high number are manufactured by Pennsylvania companies.

Federal Corporate Tax

Just as the corporate tax is of vital importance on the state level and plays a major role in the viability of biotechnology companies, the federal corporate tax is of incredible importance. In the global environment of today, the United States is competing against other nations in terms of enticing companies to locate in particular country. Locating in a specific country for the biotechnology industry brings with it future product development, hiring of employees from the most high-tech positions all the way to administrative positions and further broadens the tax base of a particular country.

The United States corporate tax rate of 35% is not competitive with many European countries, let alone Asian countries as well as Australia. Moreover, a company in the Commonwealth faces a 9.99% state corporate tax in addition, making an effective corporate tax rate that is not competitive with other nations. In order to truly generate more economic opportunities in the state, corporations will need to have some relief from the burdensome effect of a high federal and state corporate tax rate. Unfortunately, in the biotechnology arena, the United States is losing out to other parts of the

world on developing new facilities and products, and the job creation associated with such development because the corporate tax rate is not competitive.

FDA Regulation

The national Biotechnology Industry Organization (BIO) has issued its report, "Unleashing the Promise of Biotechnology", which articulates its policy agenda in support of industry growth. Specific to the FDA, the report underscores the importance of the Food and Drug Administration (FDA), as this agency is vital for the success of the biotechnology industry. The report specifically calls for an expedited approval process for innovative therapies, the creation of an independent stand alone FDA, separated from the Department of Health and Human Services and enhancements to FDA's access to external scientific and medical expertise.

Most notably the FDA is an agency where funding has been significantly constrained. The agency is now reliant on user fees as a means to exist. The ratio of budget funding for the agency to user fees is nearing a 50-50 split and needs to be addressed as an FDA reliant more and more on user fees is not an independent agency, but instead one reliant on funding from manufacturers the agency is regulating.

With Pennsylvania life science companies at the forefront of future product development, in both the device and rare disease fields as mentioned earlier, as well as the larger pharmaceutical industry, a functioning and successful FDA is of great importance.

Recommendations to the Pennsylvania Congressional Delegation

- Support a restructuring of the rules related to tax exempt bonds that negatively affect collaborations between universities and companies.
- Revise the Visa allotments and rules under the H-1B and EB programs in order to support the filling of critical positions that cannot be accommodated by the current U.S. work force and also allow foreign born entrepreneurs to remain in the country if they are growing a company that is resulting in job creation.
- Support repeal or significant revisions to the existing device manufacturer federal excise tax – such as the incorporation of a threshold for paying the fee based on a sliding scale once that threshold is reached.
- Drive efforts to amend the annual pharmaceutical fee in order to allow specific products to be exempt from the fee if they are licensed solely for the treatment of rare diseases, regardless of whether the orphan drug tax credit was exercised.
- Ensure that implementation of PCORI does not discourage use of new innovative therapies that provide important health benefits to patients.
- Maintain the current Medicare Part B program for biopharmaceuticals and prevent reimbursement cuts to providers which result in unrealistic payments and discourage the use of therapies necessary for the treatment of serious diseases affecting beneficiaries.
- Repeal the provisions in PPACA establishing the Independent Payment Advisory Board, which lacks accountability to any elected body and yet is given unbridled authority to cut Medicare costs.
- Ensure the continued success of the Medicare Part D prescription drug program by preventing efforts to extend Medicaid required manufacturer rebates to the Federal Government for drugs reimbursed by Part D health plans.

- Support efforts to reduce the effective corporate tax rate in the United States to 25% as a maximum.
- Support a strong and effective FDA by passing legislation that creates an independent FDA, expedites drug product approval, and facilitates the capacity of companies to bring important products for rare diseases into the marketplace.

Appendix 2:
Members of the Life Sciences Leadership Advisory Council

A special thank you to the members of the Life Science Leadership Advisory Council who shared their time and ideas as this plan was developed. Members of the Council are:

Pennsylvania Bio Association

Christopher P. Molineaux, President

Chairman Of PA Bio Board

David R. King, Partner, Quaker Partners (2011)
Vincent Milano, President & CEO, Viropharma Incorporated (2012)

Appointments From The Governor's Administration

Todd Shamash, Deputy Chief of Staff for the Governor
Andrew Ritter, Deputy Secretary / Office of Legislative Affairs
Leslie Gromis Baker, Director of Governor's Federal Operations

The Department Of Community & Economic Development

Richard Hudic, Executive Deputy Secretary
Carolyn Boser Newhouse, Deputy Secretary of Innovation & Investment Governor's Action Team
Michael Rossman, Director

Pennsylvania Department Of Health

Secretary **Eli N. Avila**, MD, JD, MPH, FCLM

Pharma Task Force Representative

Domenick Argento, Sr. Manager, State Government Affairs, Amgen, Inc., Task Force Chairman

Bio Representative

Fritz Bittenbender, Vice President Alliance Development and State Government Affairs

Team Pennsylvania Foundation

Matthew A. Zieger, Chief Operating Officer

Pennsylvania House of Representatives, Life Science Caucus Chairs

The Honorable **Tim Briggs**
The Honorable **Scott Petri**, Legislative Chairman
The Honorable **Doug Reichley** (Retired)
The Honorable **Matt Smith**

Pennsylvania Senate, Life Science Caucus Chairs

The Honorable **Andrew Dinniman**

The Honorable **John Pippy**

University City Science Center

Stephen S.Tang, Ph.D.

The Life Science Greenhouse of Central Pennsylvania

Melvin Billingsley, Ph.D., President & CEO

Biotechnology Greenhouse Of Southeastern PA, Bioadvance

Barbara Schilberg, Managing Director & CEO

Pittsburgh Life Sciences Greenhouse

John Manzetti, President & CEO

Representatives from Venture Capital Business

James A. Datin, Executive Vice President & Managing Director, Safeguard Scientific

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Penn State University - College of Medicine

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Kenneth J. Blank, Ph.D., Senior Vice Provost

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Jane H. Hollingsworth, CEO, Nupathe, Inc.
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Paul Touhey, President & CEO, Fujirebio Diagnostics

PA Bio State Public Policy Chairman

Timothy J. Sullivan, State Government Affairs Manager, Glaxosmithkline

Appendix 3:
Endnotes

[1] Pharmaceutical manufacturing is included as part of the overall manufacturing statistic.

[2] The Life Sciences Greenhouses and the Health Venture Investment Account have leveraged $3.7 billion in new investment, and $1.9 billion and $1.8 billion respectively on investments of almost $120 million, for a combined leverage ratio of 30:1.

[3] The results expressed in this report were received by participating organizations and have not been independently verified.

[4] PricewaterhouseCooper/National Venture Capital Association MoneyTree Report, Data: Thompson Reuters Investments by State Q1 2010 - Q3 2011

[5] MoneyTree_Q3_2011

[6] 2012 Southern California Economic Impact Report, BIOCOM, http://biocom.org/?m=sp_view_doc&file=Shared%20Documents/Images/Home%20page/BIOCOM_EconomicImpactReport.pdf

[7] http://www.gao.gov/products/GAO-11-26

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[9] Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," October 2006.

[10] Centers for Disease Control and Prevention, National Center for Health Statistics. "Health, United States, 2006: With Chartbook on Trends in the Health of Americans," Hyattsville, MD, 2006.

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[13] "Intensive Medical Care and Cardiovascular Disease Disability Reductions," forthcoming in David Cutler and David Wise, eds., Health at Older Ages: The Causes and Consequences of Declining Disability Among the Elderly, Chicago: University of Chicago Press, 2008 (with Mary Beth Landrum and Kate Stewart).

[14] Integrated Benefits Institute, "A Broader Reach for Pharmacy Plan Design," May 2007.

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[16] J.M. McWilliams et al. "Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage," Journal of the American Medical Association, July27, 2011.

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[18] 2008 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, page 112, Table III.C17.

[19] http://www.bio.org/articles/recommendations-novel-diagnostics-coverage-and-reimbursement

[20] http://www.brookings.edu/opinions/2011/0520_medicare_reform_mcclellan.aspx