REPORT OF THE SENATE SELECT COMMITTEE ON TOBACCO SETTLEMENT FUNDING

JANUARY 2007

General Assembly of the Commonwealth of Pennsylvania
JOINT STATE GOVERNMENT COMMISSION
108 Finance Building
Harrisburg, Pennsylvania 17120

The release of this report should not be interpreted as an endorsement by the members of the Executive Committee of the Joint State Government Commission of all the findings, recommendations and conclusions contained in this report.

JOINT STATE GOVERNMENT COMMISSION
ROOM 108 FINANCE BUILDING
HARRISBURG PA 17120-0018

717-787-4397
FAX 717-787-7020

E-mail: jntst02@legis.state.pa.us
Website: http://jsg.legis.state.pa.us

The Joint State Government Commission was created by act of July 1, 1937 (P.L.2460, No.459) as amended, as a continuing agency for the development of facts and recommendations on all phases of government for the use of the General Assembly.

JOINT STATE GOVERNMENT COMMISSION

Senator Roger A. Madigan, Chair

EXECUTIVE COMMITTEE

Senate Members	House Members
Joseph B. Scarnati, III President Pro Tempore	Dennis M. O'Brien Speaker
Dominic F. Pileggi Majority Leader	H. William DeWeese Majority Leader
Robert J. Mellow Minority Leader	Samuel H. Smith Minority Leader
Jane Clare Orie Majority Whip	Keith R. McCall Majority Whip
Michael A. O'Pake Minority Whip	David G. Argall Minority Whip
Michael L. Waugh Chair, Majority Caucus	Mark B. Cohen Chair, Majority Caucus
Jay Costa Jr. Chair, Minority Caucus	Sandra Major Chair, Minority Caucus

MEMBER EX-OFFICIO

Senator Roger A. Madigan, Commission Chair

David L. Hostetter, Executive Director

SENATE SELECT COMMITTEE

Jane Clare Orie, Chair

Constance H. Williams, Minority Chair

Gibson E. Armstrong

Jake Corman

Andrew Dinniman

Jim Ferlo

Robert C. Wonderling

CONTENTS

EXECUTIVE SUMMARY

The biotechnology or life sciences industry represents one of the most promising sectors for the growth of Pennsylvania's economy. Pennsylvania's strong combination of academic centers, advanced medical facilities, and well-trained, industrious workforce give it a sound foundation. These advantages were enhanced when Pennsylvania became the only state to devote the entirety of its tobacco settlement funds to health-related initiatives, including a substantial investment in the life sciences industry. Three of the programs funded under the Tobacco Settlement Act have been enormously significant to the growth of the Commonwealth's life sciences industry: the Commonwealth Universal Research Enhancement (CURE) Program, the three regional Life Sciences Greenhouses, and the Health Venture Investment Account. These programs are of vital importance to the continued growth of the biosciences in this Commonwealth.

At the same time, Pennsylvania faces considerable challenges that must be addressed if the potential of the life sciences industry is to be fulfilled. The industry has become global and highly concentrated; only a few centers throughout the world are expected to be fully competitive as the bioscience sector matures. Since many regions in the United States and elsewhere hope to take advantage of the growth of this industry, competition among them is fierce. The most important single factor hampering the development of Pennsylvania's life sciences industry is a shortage of venture capital.

The programs initiated by the Tobacco Settlement Act have greatly improved the climate for bioscience growth as compared to what it was when the Act was signed in 2001. The CURE Program has made grants of almost $300 million to fund cutting-edge basic medical research in Pennsylvania's academic and hospital-based research centers. The Greenhouses have afforded a wide variety of invaluable support services to Pennsylvania's fledgling biotech companies, including direct investment, establishment of bioscience venture capital funds, training and workforce development, incubation space, recruitment of expertise, and management consulting services by seasoned entrepreneurs and Greenhouse staff. The Health Venture Investment Account has catalyzed the creation of four investment funds providing needed seed and development capital to Pennsylvania-based bioscience enterprises. Besides their own efforts, these programs have leveraged private and federal funds to further enhance the industry's growth. This report sets forth in detail how the programs initiated by the Act have been used effectively to lay the foundation for a thriving bioscience industry in Pennsylvania.

Recognizing the crucial importance of Pennsylvania's life sciences industry to the Commonwealth's economic future, as well as its potential contribution to the health and well-being of people around the world, the members of the Senate Select Committee on Tobacco

Settlement Funding agree that the industry merits as much effective support as the state can reasonably give to it. Accordingly, the members of the Committee advance for the consideration of the General Assembly the recommendations set forth in this report. (The report also lists other recommendations advanced by Committee members and by witnesses at its public hearings.)

CHAPTER 1
INTRODUCTION

This staff report is a product of the Senate Select Committee on Tobacco Settlement Funding (the Committee). The Committee was established pursuant to 2006 Senate Resolution No. 241[1] and was charged to review research and economic initiatives established under the Tobacco Settlement Act[2] and to provide recommendations to the Senate on a vision for the future. The Senate adopted the resolution on June 30, 2006. Prior to the first public hearing of the Committee, Senator Jane Clare Orie as prime sponsor of SR 241 requested the Joint State Government Commission to draft the Committee's report.

The resolution specified that the Committee consist of four Senators, including a chair, appointed by the President pro tempore, and three Senators appointed by the Minority Leader. The membership consisted of Jane Clare Orie, Chair; Constance H. Williams, Minority Chair; Gibson E. Armstrong, Jake Corman, Robert C. Wonderling, Andrew Dinniman, and Jim Ferlo. The Committee held four public hearings as follows: in Pittsburgh on August 28, 2006; in Villanova on September 14, 2006; in Harrisburg on September 26, 2006; and in Harrisburg on October 18, 2006.[3] The first three hearings focused on gathering information on the use of the tobacco funds and the state of the biotechnology industry in the three regions of the Commonwealth as defined by the Life Sciences Greenhouses. The final hearing received recommendations on how the Commonwealth can support the growth of the industry. Much of this report is based on the testimony received at these hearings. The written submissions of the witnesses participating in those hearings are available from the Commission. Upon the conclusion of the hearings, the members of the Committee submitted their recommendations to the Joint State Government Commission for inclusion in the report.

At the first hearing, Senator Orie stated the purpose of the Committee as twofold: to determine how the tobacco funds expended under the bioscience support programs have been used by the recipients thereof, and to make recommendations for how these funds can be used in the future to help expand this industry in Pennsylvania.

The Select Committee and the Joint State Government Commission wish to express appreciation to the witnesses for their assistance in the performance of this study.

[1] The resolution appears in this report as Appendix A.
[2] Act of June 26, 2001 (P.L.755, No.77); 35 P.S. § 5701.101 et seq.
[3] A list of witnesses appears in this report as Appendix B.

CHAPTER 2
THE STRUCTURE OF THE LIFE SCIENCES INDUSTRY

The biomedical research and development industry in Pennsylvania is vitally important to all segments of the Commonwealth. The industry's products and processes contribute greatly to a healthy and productive citizenry and workforce. These outputs and the persons producing them substantially strengthen the Commonwealth's economy. Biotechnology, along with information science, promises to be a leading growth industry in Pennsylvania in the coming decades.

The life sciences industry can be usefully visualized as a continuum that is comprised of the following fundamental elements: basic research; emerging biotechnology, medical device and diagnostic companies; mature industry; and global pharmaceutical companies. Largely because of Pennsylvania's decision to invest a substantial portion of the tobacco funds in the industry, the Commonwealth has strong institutions all along this continuum.[4]

Academic and Medical Research Institutions

The foundation of life sciences industry lies in academic and medical research institutions. The rich diversity of such institutions—medical schools, public and private academic institutions, independent hospitals, foundations, and private biotechnology and pharmaceutical companies—is perhaps the primary source of strength in biomedical research in the Commonwealth.

As with other advanced technologies, rapid development in the life sciences requires a critical mass of world-class expertise in a particular location. While the Internet and other forms of communication have afforded people the ability to communicate with each other nearly instantaneously around the world, it is still necessary for experts in a particular field to co-locate to share their thoughts and ideas. The universities provide human capital in the form of faculty, researchers, and students. The co-location of human capital, support staff, and ancillary businesses tends to occur in the presence of large research universities.

The universities also provide the physical plant to carry on basic and advanced research. For the life sciences, the universities provide an added benefit in the form of university medical centers. The hospitals associated with such centers provide essential clinical environments to conduct research. In the case of research institutions that are not associated with medical centers

[4] Testimony of Dennis M. "Mickey" Flynn, President, Pennsylvania Bio, September 26, 2006.

or hospitals, working partnerships are forged between the researchers, who provide expertise and facilities, and hospitals, which provide the clinical environment in which applied research can occur.

In 2005, the University of Pennsylvania ranked second in NIH funding and the University of Pittsburgh ranked ninth, while the Commonwealth as a whole ranked fifth among the states.[5] Because NIH awards are allocated by a peer-review process by groups composed of objective experts in biomedical research, success in obtaining these awards may be considered a revealing measure of competitive excellence. Pennsylvania biomedical research institutions, including those independent of medical centers like the Wistar Institute, make important contributions to biomedical research. Basic biomedical research in Pennsylvania's well-regarded research institutions, supported by private biomedical companies, is very strong and attracts significant federal funding, and Pennsylvania should continue to receive a generous share.

Chapter 3 lists some of the numerous medical discoveries supported by programs established by the Tobacco Settlement Act that have the potential to create significant economic opportunities, as well as improving the health and longevity of people around the world.

Research Funding

The Tobacco Settlement Act authorized the Pennsylvania Department of Health to establish a health research program called the Commonwealth Universal Research Enhancement (CURE) Program.[6] Money received through the tobacco settlement is used by the CURE Program to fund health research in Pennsylvania. Of the tobacco funds received, 12.6 percent are awarded to institutions that receive funding from the NIH. These awards are referred to as "formula funds" because they are awarded on the basis of a formula calculated using an institution's average NIH awards for the past three consecutive years. The remaining 5.4 percent are awarded by competitive peer review; these funds are referred to as "nonformula funds."[7] An additional one percent of the tobacco funding is assigned on a formula basis for cancer research, based on the amount of funding awarded by the National Cancer Institute.[8]

---

[5] Ibid.

[6] Pennsylvania Department of Health, *2004-2005 Annual C.U.R.E. Report*, (Harrisburg: Pennsylvania Department of Health), 1.

A complete listing of the funding allocation under the Tobacco Settlement Act appears in this report as Appendix C.

[7] Tobacco Settlement Act, §§ 306(b), 906.

[8] Tobacco Settlement Act, § 909.

The Department of Health allocates the CURE program funding under guidelines set forth in the Tobacco Settlement Act.[9] The Health Research Advisory Committee[10] sets the research priorities for the allocation of CURE funding. The priorities for formula funds are broadly defined to cover any biomedical, clinical, or health services research, as defined by the Act, in order to allow grantees the maximum flexibility to use these funds in the most effective ways possible. On the other hand, the research priorities for the competitive non-formula grants (the 30 percent portion), have been much more narrowly focused, and these priorities have changed each year. The non-formula research priorities for the past six years have included cancer, infectious disease, cardiovascular disease, major mental disorders, lung disease, pregnancy outcomes, neurodegenerative disorders, tobacco use and cessation, obesity, vaccine development, and gene-environment interactions. For-profit entities located in the Commonwealth have always been eligible to apply for the non-formula funds, but only three have ever actually applied.[11]

Other than selecting research priorities, the Health Research Advisory Committee has no role in selecting the grantees for the competitive awards. Pursuant to section 905 of the Tobacco Settlement Act, these projects are peer reviewed and rated by at least three nationally recognized physicians, scientists or researchers from the same or a similar discipline as the research grant proposal under review. Reviewers are selected from outside of Pennsylvania and must certify that they have no conflict of interest. The Department then funds the highest ranked proposals each year.

In FY 2004-2005, the fourth year of the CURE Program, health research grants totaling $72 million were awarded from Pennsylvania's share of the national tobacco settlement. Formula grants totaling $52,214,051 were awarded to 39 institutions in FY 2004-2005. These grants have funded 151 research projects and research infrastructure projects, the majority focused on biomedical research. Through these grants, researchers are addressing a broad range of research needs such as cancer, cardiovascular disease, diabetes, genetics, HIV/AIDS, immunology, infectious diseases, nutrition, maternal and child health, proteomics, tobacco and substance abuse, and vision. Over the span of the CURE Program's existence, the Department of Health has awarded over $300 million in CURE Program grants to fund 669 important health research projects. These grants afford significant benefits to Pennsylvania's citizens by funding new research, laboratory construction, researcher recruitment, and a broad range of studies, including those aimed at improving the delivery of health care for the underserved.[12]

---

[9] Tobacco Settlement Act, Chapter 9, § 901 et seq.

[10] Testimony of Patricia W. Portzebowski, Director, Bureau of Health Statistics and Research, Pennsylvania Department of Health, before the Committee, September 26, 2006. In this report, a footnote to the name of an institution indicates that the information regarding that institution was supplied by the witness identified by the footnote on the topic of the chapter, unless otherwise indicated.

[11] Submission to the Committee by Pennsylvania Department of Health, October 18, 2006.

[12] *2004-2005 Annual C.U.R.E. Report*, 1.

A hallmark of CURE[13] research funding is that it has fostered scientific and medical collaboration on a wide variety of innovative research projects that could not have occurred under other federal or foundation mechanisms. One example is the work on health disparities in populations adversely affected by hypertension and cardiovascular diseases. This work involved faculty from the University of Pennsylvania, Cheyney University and Dickinson College and has led to important new findings on this critical issue. The funding arrangements generally require the creation of Centers of Excellence, which create cross-institutional collaborations that often include institutions not commonly involved with medical research.

The medical research funds provided through the CURE initiative have become particularly important in the past three years with the progressive constraints in the budget for medical research generated from the National Institutes of Health. In 2006, for the first time in 30 years, the National Institutes of Health budget failed to increase, and the National Cancer Institute budget declined. These constraints on federal funding make access to the CURE funds particularly vital to enable Pennsylvania institutions to remain vigorous.

The committee received testimony advocating that at least one percent of the tobacco funds should be spent to support research on the treatment and prevention of lung cancer. With federal funding for cancer research on the decline, CURE funds are increasingly needed in the battle against this disease. In contrast to the prevention and treatment advances made in many cancers, lung cancer continues to resist stubbornly. Each year lung cancer claims more lives than breast, prostate, colon, liver, kidney, pancreas, and skin cancer combined. The five year survival rate for lung cancer victims has remained unchanged for 40 years at 15 percent. Nearly 8,000 Pennsylvanians will have died of lung cancer in 2006, many of whom are nonsmokers.[14]

Technology Transfer

Technology transfer is the process of transferring scientific findings from one organization to another for the purpose of development and commercialization.[15] The Bayh-Dole Act of 1980 is widely viewed as a landmark in the development of university technology transfer because it enabled universities and other federally funded research organizations to obtain intellectual property rights. Prior to Bayh-Dole, fewer than 250 patents were awarded to universities annually; since its enactment, universities are annually awarded over 1,500 patents, and spin off over 2,000 companies.[16]

---

[13] Testimony of Dr. Robert C. Young, President, Fox Chase Cancer Center and Member, Health Research Advisory Board, September 26, 2006.

[14] Testimony of Dr. John B. Hill, Lung Cancer Alliance of Pennsylvania, before the Committee, September 26, 2006.

[15] Testimony of Christopher Yochim, Associate Director of Global Discovery Alliances, AstraZeneca Pharmaceuticals, before the Committee, September 14, 2006.

[16] Christina Gabriel, Vice Provost, Carnegie Mellon University, "University Research and the Market: The SBIR Opportunity," Presentation to Board on Science, Technology, and Economic Policy, U.S. National Academy of Sciences, October 3, 2002.

The technology transfer process typically includes the following stages:

- Identifying new technologies
- Protecting technologies through patents and copyrights
- Forming development and commercialization strategies, such as marketing and licensing to existing private sector companies or creating new start-up companies based on the technology.

The priority given to each of these factors varies from institution to institution.[17]

Another outline of the process of development of a biotechnology[18] product identifies the following sequence of stages:

Basic Research	→	Translational Research	→	Clinical Research	→	Medical Advance
Laboratory		Laboratory		Hospital		
Test tube/Petri Dish		Animal Model-Testing		Patient Testing		
Basic Discovery		Preclinical Development		Clinical Development		

The advent of modern technology transfer, characterized by increasing collaboration between academia and the biotech industry, is a relatively recent phenomenon. Given the long development timeline for life science products, the growing number of late stage biotech therapeutics in recent years shows the benefit of this alliance.

Academic and research institutions engage in technology transfer for a variety of reasons, such as recognition for discoveries made at the institution, compliance with federal regulations, attraction and retention of talented faculty, local economic development, attraction of corporate research support, and acquiring licensing revenue to support further research and education.

Discoveries made in basic research emanating from academia have enabled the identification of novel therapies and other advances in health care. Dozens of therapeutic agents in use today have their origins in academic research. But discoveries in life sciences face a long process to move from bench to bedside. Navigating the processes of regulatory approval, manufacturing, and labeling requires expertise and resources that generally have not been found in academia until relatively recently.

As technology transfer becomes an ever more significant link between the academic world and research-based companies, more academic institutions and corporations employ experts in technology transfer to facilitate the identification, evaluation, and negotiation of rights to intellectual property. Most of these professionals come from scientific backgrounds and are

---

[17] Testimony of Christopher Yochim, September 14, 2006.

[18] Testimony of George C. Prendergast, President and CEO, Lankenau Institute for Medical Research, before the Committee, September 14, 2006.

also well versed in the state and federal regulations governing technology transfer. Their professional organization, the Association of University Technology Transfer Managers (AUTM), has supported, promoted, and improved academic technology transfer worldwide.

University intellectual property plays an increasingly important role in the worldwide transition of advanced economies from a manufacturing base to a knowledge base. Many states are therefore developing programs to enhance economic development through technology transfer from local research universities. As academic institutions become focal points for economic development, benefits can accrue to the region in the form of start-up companies and increased venture investment that often translate into new jobs.[19] Despite the huge growth in patents and spin-off companies, the processes through which intellectual property rights are negotiated and granted is often arduous. University-based research scientists face complex practical and legal issues that they may be ill prepared to handle.

Responding to the problems arising from technology transfer in the life sciences, universities have revisited their technology transfer procedures. Each of the universities contributing to research in the life sciences has invested substantial resources in its technology transfer operations. The University of Pittsburgh, Carnegie Mellon University, University of Pennsylvania, and Penn State University have achieved notable success in meeting the needs of faculty researchers seeking to move their innovations to market.

In FY 2005, the University of Pittsburgh[20] finalized 141 invention disclosures and executed 58 licenses and agreements. In its 2004 survey of licensing and commercialization activities, AUTM ranked Pitt sixth nationally in the number of start-up companies created that year. Since FY 2001, Pitt has played a direct role in organizing or sponsoring 35 new companies, many of which have operations in western Pennsylvania, and eight start-up companies licensed technology developed at Pitt in 2005.

Carnegie Mellon University[21] has been recognized by the Kauffman Foundation as having one of the ten best university tech transfer offices in the United States. The university has added staff that specializes in life sciences technology transfer in order to accelerate the commercialization of discoveries made possible by tobacco funding. Carnegie Mellon's technology transfer process has been described as a "go in peace" program. It strives to maintain simple, clear, and fast operations to move innovations from the university to market as quickly as possible. To this end, it has developed a standard arrangement that gives the university a five percent equity ownership for a nonexclusive license and a six percent equity ownership for an exclusive license. Veteran innovators can move through the process quickly, while less experienced innovators are given mentoring and access to other resources.

---

[19] Testimony of Christopher Yochim, September 14, 2006.

[20] Testimony of Dr. Steven E. Reis, Associate Vice President for Clinical Research, University of Pittsburgh, before the Committee, August 28, 2006.

[21] Testimony of Mark Kamlet, Provost and Senior Vice President, Carnegie Mellon University, before the Committee, August 28, 2006.

Carnegie Mellon has partnered with the Pittsburgh Life Sciences Greenhouse to develop a template for licensing technology and has developed a specialized training program for faculty and students to create a more entrepreneurial climate on campus. The university participates with Penn and consultant Pepper Hamilton in a "boot camp" for chief scientists at life sciences start-up companies.

The University of Pennsylvania[22] has developed partnerships with a number of life sciences companies, such as GlaxoSmithKline, Merck, and Wyeth to help move university research to the marketplace. Since 1991 nearly 100 companies have been founded with the help of Penn's Center for Technology Transfer (CTT), with over two thirds being created since tobacco funds began flowing. Last year alone, CTT launched nine companies, completed 2100 commercial transactions, and signed 106 commercialization agreements. CTT also helped faculty file 355 new invention disclosures and 450 patent applications, 138 of which were approved.

Penn State's[23] technology transfer office is a key participant in the development of new life-sciences business ventures in central Pennsylvania. Since 1993 the university has spun off 49 companies, and is responsible for between 150 and 200 intellectual property disclosures annually. It has launched a new program, called Discovery@Penn State, to accelerate the movement of life-sciences innovations from lab to bedside. An ambitious goal of the program is to double the annual count of start-ups from five to ten. In order to meet this goal, Discovery@Penn State partnered with two private sector companies to implement several key functions: evaluate PSU's intellectual property, evaluate the market, identify key commercialization activities and challenges, and create pre-company focused projects.

But technology transfer assistance from universities and Greenhouses can only go so far without sufficient funding. Adequate start-up funding is crucial to all enterprises, but is especially difficult to secure for life sciences. Because the failure rate of life sciences ventures can be significantly higher than other types of innovative technology start-ups, and because of the lengthy period between investment and profitability, there can be shortfalls of risk capital flowing into the life sciences market. For example, a new researcher requires between $750,000 and $1 million per year for over several years to develop new ideas. Usually this money comes from the institution where the research is being conducted. After basic and applied research have been successfully conducted, the intermediate stage of research, consisting of the development of manufacturing processes and the regulatory reviews, can cost more than $10 million and last up to ten years.[24]

---

[22] Testimony of Steven J. Fluharty, Vice Provost for Research, University of Pennsylvania, before the Committee, September 14, 2006.

[23] Testimony of Eva J. Pell, Senior Vice President for Research and Dean of the Graduate School, Pennsylvania State University, before the Committee, September 26, 2006

[24] Joint State Government Commission, *Opportunity in the Age of Biology: Biomedical Research in Pennsylvania (*Report of the Working Group on Biomedical Research) (Harrisburg: October 2000), 9, 10.

Life Sciences Greenhouses

An imbalance currently exists in the funding available to the industry for product development, in that basic research is more amply funded than translational or clinical research. Consequently, the industry has chronic difficulty in commercializing the ideas it develops or taking the inventions from the laboratory to the marketplace.[25] To some extent, this is a problem throughout the industry. For instance, in the field of pharmaceutical drugs, out of every 5,000 to 10,000 drug compounds identified, only one will clear preclinical trials and the three phases of clinical trials to obtain approval by the Federal Drug Administration and go into large-scale manufacturing. The cost of developing a new medicine is about $800 million and the process of approval lasts at least 10-15 years.[26]

Once a promising potential medical advance is identified through scientific research, a fertile environment is needed for new companies to form. Available seed financing is required to overcome the formidable barriers to commercialization of research findings. The demand for pre-seed and seed stage capital outstrips supply, and solid management teams with the requisite life sciences expertise can be difficult to assemble. There is a shortage of venture capital available to companies in the earliest stages of development, particularly in central Pennsylvania.[27]

To respond to this challenge, the Tobacco Settlement Act authorized the Department of Community and Economic Development (DCED) to establish the Commonwealth's three regional Life Sciences Greenhouses: the Pittsburgh Life Sciences Greenhouse, BioAdvance (the Greenhouse serving the Philadelphia region), and the Life Sciences Greenhouse of Central Pennsylvania. Each of the three Greenhouses shared an equal portion of one-time funding of $100 million. They support regional growth of biosciences and commercialization of medical advances by providing necessary pre-seed and seed capital, business development services, partnering arrangements, enhanced tech transfer, and other support services. Through flexible programs and investments such as these, the Greenhouses provide the basis for long-term regional growth. The testimony before the Committee included statements of 21 Pennsylvania life sciences entrepreneurs that the support of the Greenhouses was essential to the development of their particular enterprise.

Demand for the services provided by the Greenhouses is strong. Through June 2005 there have been 702 requests for funding, asking for a total of $234.5 million. Sixty-nine companies and 22 university-based projects were funded based on their technical merit and prospects for growing sustainable businesses in Pennsylvania. The total amount invested by the Greenhouses as of FY 2005-06 is $30.4 million. The early stage funding, combined with

---

[25] Testimony of Barbara J. Dalton, General Partner, EuclidSR Partners, L.P., and Chairman, Mid-Atlantic Capital Alliance, before the Committee, October 18, 2006.

[26] PhRMA, *Pharmaceutical Industry Profile 2006*, 2, available at http://www.phrma.org/profiles.%26_reports/ (visited January 19, 2007).

[27] Testimony of Melvin L. Billingsley, President and CEO of the Life Sciences Greenhouse of Central Pennsylvania, before the Committee, September 26, 2006.

management, technical, and marketing assistance helps fledgling companies leverage public and private investments. As of FY 2005-06, funding of $222.5 million has followed the initial Greenhouse investment, an aggregate leverage of 7:1.[28]

The Greenhouses are part of a long-term, progressive plan designed to improve the health and welfare of Pennsylvanians by: 1) accelerating the commercialization of health care technologies; 2) stimulating the formation of sustainable companies that provide high-quality jobs, and 3) ensuring that the Commonwealth remains at the forefront of an industry that has the potential to fuel economic growth for years to come.[29] Capitalizing on regional strengths, the Greenhouses are recognized nationally and internationally as models for success.[30]

Each Greenhouse was allowed to create a business model that fits the particular strengths and weaknesses of its region. The legislators who shaped the Act wisely recognized that there is no "one size fits all" solution when it comes to growing a strong life sciences cluster. They expected the Greenhouses to serve as a catalyst for change. It is both likely and desirable that each Greenhouse model will change over time, as the community in which it operates grows and new challenges and opportunities emerge. Perhaps the most ingenious part of the Greenhouse initiative is the opportunity for the Commonwealth to receive a return on its investment in three different ways. The economic engine represented by capital-intensive life sciences companies is reflected in the huge multipliers from R&D expenditures and high-paying jobs in this industry cited by the Milken Institute. Second, the benefits to human health will accrue as the new biomedical products are brought to market. New diagnostics and treatments will reduce the high costs of hospitalization and keep our residents productive. Finally, the Greenhouses pay the Health Account 50 percent of net returns from investments, once a specified threshold is reached. These returns will increasingly make the Commonwealth a true partner in the success of the Greenhouses as it will see a financial return as the latter succeed.[31]

The strategic plans of the respective Greenhouses are described here, while their specific activities are detailed in chapters 3 and 4.

Pittsburgh Life Sciences Greenhouse

PLSG[32] provides incubator services, mentoring and guidance, and aid in attracting capital. PLSG's programs include technology generation, early risk capital, human capital, and laboratory and office (incubation) space. PLSG sponsors an executive-in-residence program that links corporate leaders to start-up firms and assists entrepreneurs in attracting federal research and development funding for start-ups. Its SBIR training program has become recognized as a

---

[28] Pennsylvania Department of Community and Economic Development, *Pennsylvania Tobacco Settlement: Investing in the Health of Pennsylvania, Annual Report (2005-2006),* 2, 3; testimony of Dr. Doros Platika, President and CEO of Pittsburgh Life Sciences Greenhouse, before the Committee, August 28, 2006.

[29] Testimony of Melvin L. Billingsley, September 26, 2006

[30] *DCED Tobacco Settlement Report (2005-2006)*, 4.

[31] Testimony of Barbara S. Schilberg, Managing Director and CEO, BioAdvance, before the Committee, September 14, 2006.

[32] Testimony of Dr. Doros Platika, August 28, 2006.

standard of excellence and a source of best practices. In all, PLSG has assisted 170 companies through its various programs, with more than half of those companies taking advantage of multiple PLSG programs.

In the decade prior to the establishment of PLSG, the Pittsburgh region averaged a new life science company formation rate of one to three companies per year. To achieve regional critical mass, the initial focus of PLSG programs was to increase the rate of new company formation—a strategy that has been rewarded with an increase in new company formation to 15-20 companies per year.

The initial $33 million commitment from the tobacco funds to the PLSG included $19 million earmarked for investments and $14 million for programs such as company incubation. The state funds were matched by $70 million from local foundations. The foundation money was earmarked primarily to support the generation and commercialization of technology from Pitt and Carnegie Mellon.

A vital task is to reduce the rate of company attrition. While this was not part of the original PLSG mandate, it has become as important as the original focus on new company formation. It would be a devastating blow to the region if newly formed companies failed or had to leave the region to obtain second-stage gap financing.

PLSG believes it is well positioned to be the catalyst that helps the region reach the next level. It has built an infrastructure that provides a comprehensive menu of resources and services to insure success. Both in absolute and relative terms, southwestern Pennsylvania's progress has been recognized as among the most notable in North America. These results support PLSG's multi-pronged approach toward addressing all the critical elements required for regional sustainability. PLSG programs have been recognized as a model for best practices and have been adopted by other regions and across technology platforms for their ability to address all key technology-based economic development elements needed for success in the life sciences industry, namely, technology generation, early risk capital, human capital (both executive and technical workforce training), and incubation space.

The Greenhouse plans to expand these efforts and increase regional commercialization to 30-40 companies per year—a rate of new company formation associated with sustainability. Historically, southwestern Pennsylvania has attracted only ten cents of investment capital for every $2 of NIH support. PLSG aims to achieve the goal of attracting $1 of investment capital for every $2 of NIH research support, a second measure of industry sustainability.

BioAdvance (Philadelphia Region)

In the Philadelphia economic region (which includes parts of Delaware and southern New Jersey as well as southeastern Pennsylvania), BioAdvance[33] has made significant strides in investing, attracting capital, and leveraging funds. BioAdvance began to address the funding gap

[33] Testimony of Barbara S. Schilberg, September 14, 2006.

between basic research and marketable products by strengthening the early stage capital continuum in two ways. First, BioAdvance placed $20 million of its tobacco fund allocation into the Greenhouse Fund. Demand for this funding has been significant: since its inception, BioAdvance has received over 250 proposals seeking $240 million in funding. The Greenhouse has invested over $10 million to date in 30 companies and projects. Of those, 21 are seed investments ranging from $250,000 to $700,000, and nine are pre-seed investments of $5,000 to $200,000 in technologies and companies that BioAdvance is evaluating for a larger investment. The second BioAdvance initiative was assisting in the creation of BioAdvance Ventures, a $26 million venture capital fund managed by Quaker BioVentures.

Despite the early stage of the companies in which BioAdvance has seeded investments, they are a remarkably strong group. The amounts subsequently raised by these companies validate the original investments and provide the capital needed for these companies to expand. If the current crop of enterprises receiving BioAdvance capital succeeds, they will help move the Philadelphia region into the top tier rank. BioAdvance stresses the need to repeat this year after year, with a new group of companies leveraging seed capital to secure the next stage of financing.

As important as its functions in raising capital funding, BioAdvance provides advice on business strategy, introduces companies to potential investors, and provides marketing and financial support. BioAdvance also helps companies locate experts, consultants, facilities, manufacturers, lawyers, and other resources. Business supports are provided to regional life sciences companies, even those in which BioAdvance made no investment, as part of BioAdvance's Greenhouse function.

One of the goals of BioAdvance is to be able to make a larger investment in each company than it currently can, to ensure that they are competitive with companies in other regions. Companies have not been able to access the non-formula CURE funds for company research, even when they address the priorities set by the CURE Board. BioAdvance supports efforts to make this funding available to companies for qualified research.

Life Sciences Greenhouse of Central Pennsylvania

Central Pennsylvania has a sound foundation upon which to build a thriving life sciences industry: a legacy of excellence in engineering, manufacturing, and the physical sciences, manifested in numerous institutions of higher learning and established life sciences companies. However, barriers to commercialization of discoveries remain. Demand for pre-seed and seed stage capital outstrips supply, scientific expertise can be difficult to assemble, and there is a shortage of venture capital available to companies in the earliest stages of development. LSGPA[34] is actively addressing these barriers through its funding programs, business development services, and partnerships. Its clients include university-based researchers and technology development groups, emerging companies, and companies seeking to expand or relocate.

[34] Testimony of Melvin L. Billingsley, September 26, 2006.

Demand for LSGPA's services is high, and its program is highly competitive. Each application is thoroughly reviewed from both a scientific and business viewpoint. Unfunded companies benefit from business planning tools, market research, connections to more appropriate sources of capital, and similar services. Funded companies receive not only crucial early stage capital, but the benefit of all LSGPA staff expertise, which includes entrepreneurship, engineering, mergers and acquisitions, technology transfer, pharmacology, pharmaceutical marketing, biologics manufacturing, government contracting, and general business development.

Venture Capital

Besides the Greenhouses, the other main funding mechanism for life sciences research supported by tobacco funds is the Health Venture Investment Account. The funding consisted of a onetime appropriation of $60 million to private venture firms that provide financial resources to early stage start-ups and emerging life sciences companies. Four private venture firms were selected by the Tobacco Settlement Investment Board (TSIB) to manage and leverage the funds and received the following amounts from the tobacco funds: PA Early Stage Partners, $20 million; Quaker BioVentures, $20 million; Birchmere Ventures, $10.8 million; and Commerce Health Ventures, $9.2 million.[35]

Following is an investment summary of these four funds using data provided by TSIB.[36] These funds have invested a total of $26.29 million of the $60 million appropriated through the Health Ventures Investment Account along with an additional $164.56 million of other fund money. The companies have, in turn, further leveraged $814 million, which is a leverage ratio of TSIB funds to other funds of 30:1.

Further details regarding the investment activities of these four venture capital funds are set forth in chapter 4.

[35] Pennsylvania DCED, "Health Venture Account" http://www.newpa.com/default.aspx?id=40.
[36] Testimony of Barbara J. Dalton, October 18, 2006.

Investments of TSIB-Selected Venture Capital Funds

Fund	Total syndicate $M A	Fund commitment $M (including TSIB) B	Total TSIB commitment $M C	Total leverage (total non-TSIB to TSIB) (A-C) / (C)	Number of companies*	Jobs impact
Birchmere Ventures	13.76	4.94	1.78	7:1	2	35
New Spring/ Commerce Health Ventures	206.20	31.20	2.74	74:1	8	386
PA Early Stage Partners	113.25	15.10	3.97	28:1	8	68
Quaker BioVentures	481.15	113.32	17.80	26:1	16	544
Total	$814.36	$164.56	$26.29	30:1	34	1,033

* The four Funds have invested in a total of 30 individual companies with five companies receiving co-investments by one or more of the four Funds.

SOURCE: Pennsylvania Venture Capital Coalition; *DCED Tobacco Settlement Annual Report (2005-2006)*, 6, 7

Small Business Innovation Research (SBIR) Program

The United States Department of Health and Human Services has invested $120 million in grants to small businesses in Pennsylvania through the Small Business Innovative Research (SBIR) Program[37] over the past five years. The SBIR Program awards research funding for the commercialization of new products and technologies developed by American small businesses. Every federal agency that expends more than $100 million on extramural research and development is required to participate in the SBIR Program by designating at least 2.5 percent of its total R&D expenditures to support research by small businesses. For many small life sciences businesses, SBIR grants have been a primary source of seed funding, which in turn has allowed them to develop promising technologies that have enabled them to leverage strong follow-on investment from the private sector. In many cases, the SBIR review process validates the research of a start-up company and thereby helps support the decision by private investors to back the company with venture capital.

[37] Testimony of Steven G. Zylstra, President and CEO, Pittsburgh Technology Council, before the Committee, August 28, 2006.

SBIR is administered as a three phase program. Phase I awards typically are at a level of $100,000 and are provided for companies to complete a proof-of-concept study around a new technology. Phase II awards are more substantial grants, usually in excess of $750,000, that support research and development costs for product development. Phase III, which is not generally accompanied by a financial award from a particular federal agency, refers to the stage where the small business takes the new product into the commercial marketplace. This is when additional capital from the private sector becomes essential.

The Life Sciences Ecosystem

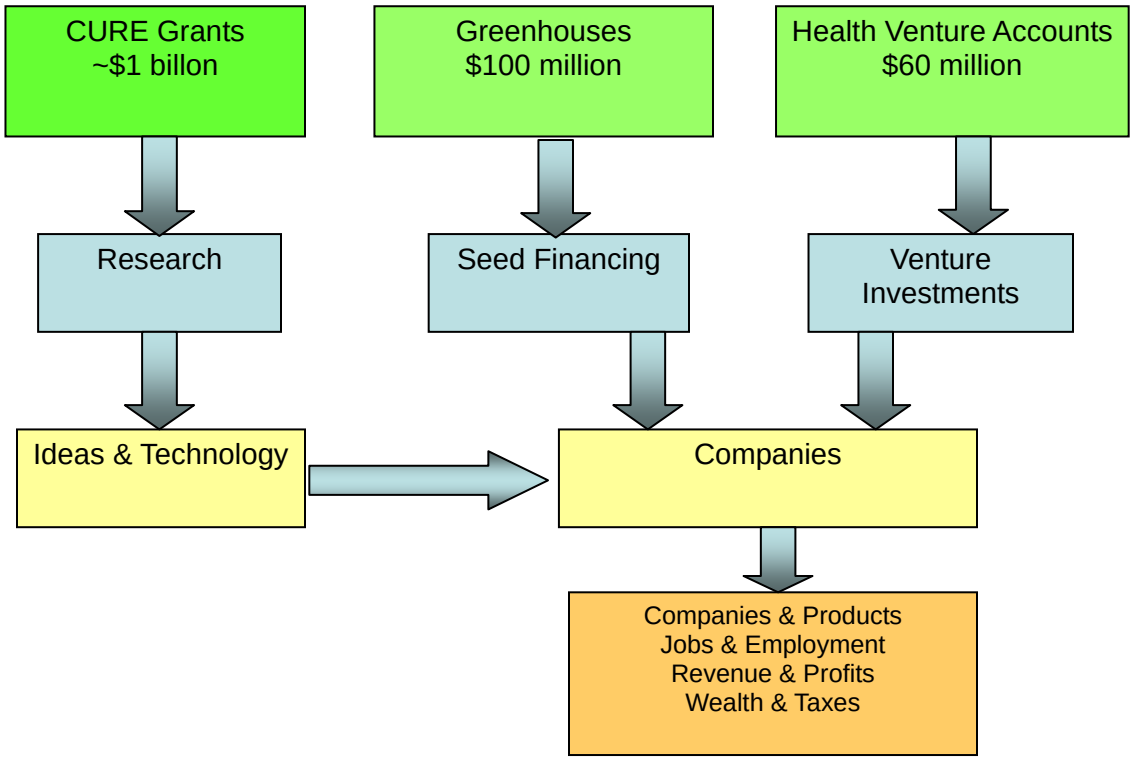
The following chart images the life sciences industry in Pennsylvania as an ecosystem, illustrating the importance of investments to the growth of the system. There must be investments in research to spur new ideas and technologies, which then require a commercial entity to develop into a marketable product. The commercial organism hosting the nascent advance requires a favorable development environment, nurtured by adequate seed capital. After the initial stage of financing, the ecosystem must support with venture capital the growth of these established, but still very young, companies.

One key aspect of venture investing that is difficult to show on this chart is the time, and therefore additional funding, that new companies in the life sciences area typically need for sustainable growth. Like growing an individual company, developing a life sciences cluster takes time and requires the support of patient capital. Each new firm will very likely require additional funding and continuing support from investors. The remaining capital that has not yet been invested by the funds will probably be needed mostly to back the next group of emerging companies.

The Commonwealth has made great strides toward providing commercialization funding with the help of the TSIB program, but significant work remains if the Commonwealth is to remain competitive with other regions around the country. Continued support under the Tobacco Settlement Act for the Greenhouses and the venture community will help them continue to foster strong companies, ensuring that the success to date is not just a temporary victory. While the Commonwealth is arguably at the forefront of the U.S. life sciences industry, and while its universities receive billions of dollars in research funding to develop new technologies, Pennsylvania lags in the availability of investing capital compared to the number of available investment opportunities. If no further support is provided to the seed financing and venture investment phases, the ecosystem is destined to fail.[38]

[38] Testimony of Barbara S. Schilberg, September 14, 2006; testimony of Barbara J. Dalton, October 18, 2006.

TSIB Life Sciences Entrepreneurial Ecosystem



SOURCE: Prepared by Pennsylvania Venture Capital Coalition.

.

CHAPTER 3
MEDICAL RESEARCH AND TOBACCO FUNDING

This chapter describes the medical research projects supported by the tobacco funds, arranged according to the three regions as defined by the Life Sciences Greenhouses.

Southwestern Pennsylvania

The comparative significance of biomedical research can be usefully measured by the amount of NIH funding received, and in those terms the greater Pittsburgh area ranks first in tissue engineering, robotics, and computer science, and ninth overall.[39]

Since 2001, the University of Pittsburgh Cancer Institute[40] (UPCI) has used tobacco funding to invest in a variety of cancer-related research projects improving cancer prevention, diagnosis, and treatment. The money has been spent to support research that has made important discoveries in the following areas:

- the role of viruses and cancer
- new ways to identify viruses that may cause cancer
- how known cancer-causing viruses cause cells to develop into tumors
- stress and cancer
- the role of stress on impaired immune function and cancer
- the cellular changes that lead to cancer and the differences between cancer cells and normal cells
- the role of environmental pollutants in cancer
- the role of estrogen and other hormones on the development of hormone-dependent cancers

[39] Testimony of Dr. Doros Platika, August 28, 2006.

[40] Testimony of Maryann Donovan, Associate Director for Research Services and Advancement, University of Pittsburgh Cancer Institute, before the Committee, August 28, 2006.

- the relationship between tumor and immune cells, so that new ways to improve immune function, either by vaccines or by recruiting activated immune cells to the tumor, can be developed

- the tumor microenvironment, specifically how a blood supply is directed to the tumor and how features of these new blood vessels can be used to target therapy to the tumor

- the key proteins and pathways critical for transformation with a goal of developing therapy to molecules requisite for tumor cell growth

- the role of DNA repair in the development of cancer and in resistance to cancer therapy

- new biomarkers for cancer detection and cancer therapy.

Supplementing this medical research have been investigations leading toward improved psychosocial interventions to help cancer patients and their families cope with the stress caused by a cancer diagnosis and developing better methods to identify individuals at risk for stress-related illnesses and conditions, with improved interventions to reduce the stress these individuals experience.

UPCI scientists have published their research in peer-reviewed journals, have presented their results in major national and international meetings, and have used the preliminary results supported in part by tobacco funding to secure additional grants funding from the National Cancer Institute, other federal agencies, and private foundations. Because researchers at the UPCI are focused on translational research, many of their results have been used to develop better therapies. For example, these results are being used to improve cancer diagnosis so that patients with cancer can be identified early when cancer is treated more successfully. They have also been used to improve the ability to use molecular methods to identify very small numbers of metastatic cells in lymph nodes that would have been missed by conventional screening. Other investigators are testing improved vaccine strategies using small proteins, called peptides, that stimulate a cancer patient's immune system to recognize and destroy the tumor. Clinical trials are in process to document the effectiveness of these new vaccines. Other investigators are using combinations of proteins to develop an early diagnostic test for ovarian cancer.

While cancer has been a major focus of research at the University of Pittsburgh,[41] Pitt has performed important medical research on other diseases and conditions as well. One of Pitt's recent successes is the development of Pittsburgh Compound B or PIB, an imaging dye that identifies amyloid plaques, a specific marker of Alzheimer's disease, in the living brain. While PIB itself was not developed with tobacco funds, researchers at Pitt's Alzheimer's Disease Research Center are using PIB in nonformula tobacco-funded studies to aid in differential diagnosis of dementia of unknown origin. Results from an early pilot study suggest that patients

[41] Testimony of Dr. Steven E. Reis, August 28, 2006.

who are PIB positive are likely to have Alzheimer's disease, even if their dementia has an atypical presentation. PIB is also being used in CURE-funded research to investigate a protein known to clear plaques in the normal brain. As the absence of this protein contributes to the progression of Alzheimer's, there is a potential for translating this basic research finding into a drug therapy for that disease.

Pitt has also used CURE funding for key infrastructure initiatives. For example, Pitt was extremely fortunate to recruit one of the world's leading structural biologists, Dr. Angela Gronenborn, to lead the School of Medicine's new Department of Structural Biology, a discipline essential to fundamental understanding of the cause of almost every disease process. In order to entice Dr. Gronenborn to leave her secure and highly productive position at NIH, Pitt needed to provide an unrivaled facility for structural biology research, including highly sophisticated equipment for magnetic resonance imaging and spectroscopy, cryo-electron microscopy, and X-ray crystallography. Tobacco formula funds were used for this equipment, which is a shared resource available to all faculty members who need it. Additional formula funding has enabled the Gronenborn lab to conduct studies of neurodegeneration that complement the Alzheimer's studies previously described. Such scientific leverage and interdisciplinary collaboration are essential to translate rapidly emerging information and novel research methods into useful diagnostic procedures, pharmaceuticals, and medical devices.

Dr. Steven E. Reis is conducting a CURE-funded study entitled, "Novel Strategies for Reducing Heart Disease Risk." The goal of this study of 2,000 participants, which is being conducted in collaboration with the Pittsburgh Theological Seminary and the Urban League of Pittsburgh, is to reduce racial disparities in cardiovascular disease (CVD) in Pennsylvania. CVD is the nation's number one cause of death, and African Americans have a substantially higher risk of CVD than whites. This study has identified race-specific risk factor profiles for CVD risk, has designed and successfully implemented a program to reduce CVD risk and disparities, and has led to an improved understanding of the biology of atherosclerosis. The wealth of data collected by this study has enabled the Pitt researchers to obtain both NIH and industry funding for three ancillary investigations that focus on the effects of sleep, stress, and emerging risk factors on CVD and on the risk stratification of children to identify CVD risk in their parents. This study has had a direct impact on the citizens of western Pennsylvania. The researchers and their collaborators in the community have received hundreds of phone calls, letters, and anecdotes indicating that this work has resulted in increasing health awareness, identification of previously undiagnosed subclinical and preclinical disease, disease prevention, substantial alterations in lifestyles, and sustained changes at the community level, including the development of new programs focused on health and disease prevention in underserved areas.

The other leading academic research institution in the Pittsburgh area is Carnegie Mellon University.[42] It is the youngest of the top 25 research institutions in the United States, in part because of its aggressive investments in research linking life sciences with information technology. Carnegie Mellon has pursued a targeted life sciences strategy that takes advantage

[42] Testimony of Mark Kamlet, August 28, 2006.

of its strengths. Tobacco funds have been invested to start and expand programs in computational biology, biomedical imaging, neurobiology, and medical robotics, all of which are emerging fields that build upon core capabilities to address major health care problems.

Carnegie Mellon's efforts are producing research results in important areas. Work in biomedical imaging has led to breakthroughs in discovering the biological basis for autism. The NIH has invested in research to use Carnegie Mellon's fluorescent probe and imaging technologies to speed early detection of cancer. In June 2006 the National Science Foundation awarded an Engineering Research Center in Quality of Life technologies to couple Carnegie Mellon's leadership in robotics with Pitt's strengths in rehabilitation and geriatric research in order to advance technologies to aid the disabled and enable the elderly to live independently. In short, the tobacco funding has enabled Carnegie Mellon to transform its traditional strengths into powerful assets for significant life sciences research.

Finally, Carnegie Mellon has responded to the challenge in the tobacco legislation by creating a new collaborative environment for research with Pitt. These two universities have together created a model for how educational institutions can work effectively to build upon each other's strengths. Carnegie Mellon and Pitt operate nine joint life sciences centers, which have been largely responsible for the research and commercial success the universities have achieved.

Philadelphia Region

With over 80 percent of its research funding supporting biomedical research, the University of Pennsylvania[43] sits at the heart of the region's life sciences sector. Penn has received over $750 million in sponsored research funding in the past fiscal year. CURE funding of $70 million has gone into Penn since 2001, of which $50 million has been awarded as formula funds, and $20 million as non-formula funds.

One project, headed by Dr. Caryn Lerman, Professor and Director of Penn's Tobacco Use Research Center, has been funded to identify the biological antecedents of nicotine dependence in the children of dependent smokers. She has used these experimental results to obtain several individual NIH grants as well as ensure the renewal of her prestigious Center grant. Dr. Barry Ziober used CURE funding in a study to develop strategies for genomic analysis of head and neck cancers. As a result of this work, Dr. Ziober was able to identify a genetic signature that distinguishes between normal and tumor tissue, permitting earlier detection and treatment of these cancers.

Outside of the Cancer Center, formula funds have been awarded to several distinguished members of Penn's Genomics Institute. One such investigator is Dr. Junhyong Kim, professor of biology and an expert on the rapidly expanding field of bioinfomatics. He has applied formula funds to develop a training program for postdoctoral fellows in the development of new computational tools for the analysis of large complex data sets, such as those from genetic screening of diseases or epidemiological studies of patient populations. Dr. Ralph Brinster,

[43] Testimony of Steven J. Fluharty, September 14, 2006.

Mellon Professor of Physiology in the School of Veterinary Medicine and one of Penn's most honored scientists, used formula funds to investigate a variety of cell transplantation techniques to restore spermatogenesis in animals. His research has revealed ways to improve the health and reproductive fitness of livestock, while providing valuable insights into the origins of infertility in men. These examples, selected from nearly 40 projects supported by CURE formula funds at Penn, give a sense of their diversity and potential.

Thomas Jefferson University[44] is the fourth largest recipient of CURE funds. CURE support has enabled Jefferson to attract notable researchers from around the world. The Kimmel Cancer Center[45] research staff now includes Dr. Richard Pestell, a world-renowned expert on hormone-responsive cancers, notably breast and prostate cancer. His team is the cornerstone of a new multidisciplinary breast care center, and their work has led to the formation of LightSeed Therapeutics, a company with new therapeutic approaches to these cancers, using light-activated caged compounds. Jefferson is now home to Dr. Charles Yeo, the new chief of surgery, who is one of the nation's top experts in pancreatic cancer.

Dr. Scott Waldman at Jefferson has taken a basic observation in colon cancer and developed it with CURE support into a diagnostic test to identify the colon cancers that require chemotherapy. He and his associates developed this work into a multimillion dollar clinical trial backed by the National Cancer Institute and preliminary development of a targeted therapy. This progress has been accomplished in partnership with a Pennsylvania startup biotechnology firm, Targeted Diagnostics and Therapeutics.

CURE support enabled Jefferson to hire Dr. Arthur Feldman, who leads a top team in heart failure research. Dr. Feldman and his team have identified new therapies and launched a consortium of medical centers, mostly in Pennsylvania, to improve care of heart failure. Dr. Feldman's diagnostic and therapeutic intellectual property is a key asset of a Pennsylvania start-up biotechnology firm, CardioKine.

CURE support for infrastructure lab construction and for research project support has enabled Jefferson to attract Dr. Thomas Force. He recently led a team that published the newsworthy finding of cardiac disease associated with some of the new cancer therapies, such as Gleevec for chronic leukemia. This work will enable clinicians to prevent patients who defeat cancer from succumbing to heart disease, while also yielding unexpected knowledge about heart function.

CURE support to Jefferson has enabled Dr. Bonita Faulkner to study the cardiovascular problems that follow from obesity. She has spent over 20 years reaching out into the African American and Hispanic American communities to understand the causes of high rates of

---

[44] Testimony of Dr. Steven E. McKenzie, Vice President for Research, Thomas Jefferson University, before the Committee, September 14, 2006.

[45] Established in 1991, TJU's Kimmel Cancer Center has been designated a clinical cancer center by the National Cancer Institute. Since its inception, the Center has grown from 30 basic science researchers to 150 researchers and physicians. http://www.kimmelcancercenter.org/kcc/kccnew/about/index.htm .

hypertension and type 2 diabetes and developing clinical programs to prevent these conditions from wreaking havoc on the blood vessels and heart. In this project, CURE has enabled new community partnerships and interventions on the front lines.

Finally, important research at Jefferson relating to neurological disease has been made possible by CURE funding. These initiatives include studies of Alzheimer's disease by Dr. Sam Gandy; community outreach to bring the optimal mix of pharmaceutical and non-pharmaceutical care to Alzheimer's patients and their families in their homes by Dr. Laura Gitlin; and novel therapeutic approaches to Parkinson's disease by Dr. Lorraine Iacovitti and Dr. Jay Schneider. These and similar studies provide the intellectual property underpinning for a new Pennsylvania startup biotechnology company, Lazarus Therapeutics.

At Temple University,[46] CURE formula funds have allowed the university to support established researchers and junior faculty, develop core research facilities, and support graduate biomedical education and research. Formula funding has supported 50 graduate research fellowships in basic medical sciences and the M.D./Ph.D. program, where mentored, original research is developing the next generation of physicians and scientists.

Among the research assets at Temple developed in part by formula funding is a flow cytometry core facility, which supports over 20 federally funded projects. This facility allows researchers of cancer, HIV, and other diseases to measure physical and chemical characteristics of cells. A proteomics core facility has been established to provide accessible proteomics capability for biological and biomedical research. With state-of-the-art instrumentation and a highly trained staff, the facility offers researchers the ability to study proteins affected by cancer and other diseases and the effects of treatment on them. The bioinformatics core facility allows university life sciences researchers to work with enormous amounts of information, such as gene expression and genomics data.

Non-formula funding of projects relating to the health of Pennsylvania communities has resulted in measurable improvements in target populations. Among these are advances made in the management of chronic obstructive pulmonary disease by Dr. Gerard Criner, Internet-based telemedicine programs to low-income patients with cardiovascular disease and obesity under Dr. Alfred Bove and Dr. Guenther Boden, and a program led by Dr. Ralph Spiga to develop advanced treatments for mentally ill patients who abuse drugs.

The Wistar Institute,[47] a National Cancer Institute designee, is comprised of 33 laboratories that have been credited with a number of important life sciences discoveries.[48] Beginning in 1999, Wistar was able to use $250,000 in Commonwealth funding to establish a

---

[46] Testimony of Kenneth J. Soprano, Vice President for Research and Graduate Studies, Temple University, submitted to the Committee, October 18, 2006.

[47] Testimony of Meryle J. Melnicoff, Director of Business Development, Wistar Institute, before the Committee, September 14, 2006.

[48] The Wistar Institute, "Saving Lives through Science," http://www.wistar.org/about_wistar/overview.html, October 23, 2006.

genomics laboratory. The resources and personnel supported by Pennsylvania's investment were leveraged into a $4.3 million award from the NIH. Since then, the genomics lab has supported the research of approximately 40 researchers at Wistar and collaborating institutions.

First year CURE funding supported genomics researchers at Wistar and six other leading cancer centers in Pennsylvania in the establishment of the Pennsylvania Cancer Alliance Bioinformatics Consortium. The genetic information made available by the consortium allows scientists to examine and analyze thousands of genes in tissue samples. In 2003, Wistar applied for a patent on new uses of biomarkers for cutaneous T-cell lymphoma, a process developed by Dr. Louise Showe. These analyses provide for more detailed classifications of cancers, which may lead to therapies effective against the individualized properties of the cancer afflicting the patient. In 2006, Wistar entered into a partnership with a multinational pharmaceutical company headquartered in Pennsylvania to further develop its capacities to identify and classify cancers. It also entered into discussions with a private company that wishes to develop commercial uses for its cancer identification system.

Central Pennsylvania

The leading life science research institutions in central Pennsylvania are Pennsylvania State University, along with the associated Hershey Medical Center, and the Geisinger Health System and its Weis Center for Research.

Comprised of 14 colleges and 8 major research institutes, Penn State[49] is the ninth largest recipient of National Science Foundation grants. Its research expenditures totaled $638 million in fiscal year 2005. The university's strong academic and clinical research programs have lent themselves to the establishment of 49 companies since 1993. Tobacco funding has contributed to the hiring of 58 new faculty members, who have attracted an estimated $91 million in research funding. Moreover, tobacco funds awarded in the amount of $1.8 million for the years 2002 through 2004 have been leveraged to attract $25.7 million from the NIH, a return on investment of over 14:1.

One of Penn State's great strengths is its heterogeneous intellectual capacity. Its outstanding medical research blends with expertise in engineering and physical sciences, creating the cluster of collaborative expertise necessary for successful research and innovation in the life sciences. The university's researchers, clinicians, and faculty produce between 150 and 200 intellectual property disclosures annually.

In deciding how to invest the tobacco funds that were awarded to it, Penn State reviewed data about serious health problems affecting people in Pennsylvania. On the basis of that review, it developed a competitive peer-reviewed grant process that has resulted in the allocation of formula funds to support cancer and neuroscience research, and research involving genomic, proteomic, and bioinformatic approaches to understanding disease.

---

[49] Testimony of Eva J. Pell, September 26, 2006.

An example of the university's interdisciplinary research is the development of left ventricular devices for heart patients. Faculty in cardiology, surgery, bioengineering, and mechanical engineering teamed up for the last three decades to develop the life-extending device. Software developed at the university has also been instrumental in the developing field of bioinformatics. Specifically, two papers published by faculty and students that provide software tools for decoding genetic sequences are the most frequently cited papers in the life sciences.

Tobacco funds at Penn State have supported many notable research endeavors; in many of these projects, those funds have augmented support from other sources.[50] A five year award of $1.3 million from NCI was received for basic research on mammalian polyamine metabolism in the development of cancer. This research project under the direction of Dr. Anthony Pegg, may bear fruit in the development of antitumor and cancer chemopreventive drugs. A $1 million NIH award was made to Dr. Ian Zagon to support a Phase II clinical trial to evaluate new treatments for pancreatic cancer, which has a death rate of 98 percent. In laboratory studies, researchers discovered opioid growth factor (OGF), a compound that controls the growth of both healthy and abnormal cells; deeper understanding of OGF may lead to new treatments to stem the growth of pancreatic cancer cells.

Tobacco funding has supported medical research for other diseases and conditions as well. The funding backed research otherwise supported by a five year award of $7.1 million from the National Heart, Lung, and Blood Institute to Dr. Lawrence Sinoway to study how blood vessels respond to common stressors. The researchers have made great progress in understanding why blood vessels and the nerves that control them become abnormal in heart failure patients, and a series of clinical trials are planned over the next two years to test the hypotheses. The development of the Center for BioMetals and Disease under Dr. James Connor has resulted in seven externally funded grants totaling $3 million. Among the topics being actively explored is the role of metals in autism, Alzheimer's disease and Lou Gehrig's disease, and the use of selenium as a anti-cancer agent. Finally, a state-of-the-art diabetes registry system and research center in the Penn State Diabetes Center has been established under Dr. Robert Gabbay. The registry covers over 10,000 patients with diabetes, providing caregivers with valuable information to ensure that clinical goals are achieved and screening tests are performed appropriately.

The Weis Center for Research[51] at Geisinger Clinic has received $600,000 in CURE formula research funding, with an additional $150,000 committed through the end of 2007 (an average of $129,000 per calendar year). The funds were used to support five projects, two of which are ongoing.

Funds were used to partially support the purchase of a protein mass spectrometer that is used in advanced proteomics research, and an upgrade of equipment used for gene microarray analysis. The projects supported were early stage translational research projects of potentially

---

[50] Testimony of Jay Moskowitz, Associate Vice President for Health Sciences Research, Pennsylvania State University, before the Committee, September 26, 2006.

[51] Testimony of David J. Carey, Associate Chief Research Officer, Geisinger Health System, and Director, Weis Center for Research, before the Committee, September 26, 2006.

high impact that used cutting-edge approaches and were judged to have a high likelihood of leading to sustainable research projects. Examples of projects that received support include a study of gene expression in fibrotic liver disease, molecular analysis of aortic aneurysms, and protein modifications related to cellular growth. To date, projects supported by the formula fund grants have led to one funded NIH grant application with a total budget of more than $1 million and several applications that are pending NIH review. These projects have also helped generate discoveries that may prove patentable and helped spawn the creation of two biotechnology spin-off companies to commercialize the discoveries.

CURE funding has supported research at the Geisinger Medical Center that promises significant public health benefits. For example, researchers at Geisinger have identified gene expression profiles in liver biopsies associated with different stages of liver disease. These gene products are currently being tested for their ability to serve as blood-based diagnostic markers for liver disease. Current blood-based tests are not reliable, while liver biopsy and other invasive tests carry associated risks, especially in obese patients, that may preclude their use. Hence there is a pressing need for a better non-invasive test to identify patients with early stage liver disease. The development of a clinically useful blood test for liver disease could have significant commercial value, thus generating additional economic benefit and associated job growth.

A similar project has identified novel biomarkers for aortic aneurysmal disease, which are being tested as blood-based diagnostics. No such tests currently exist, and many asymptomatic patients with an aneurysm are undiagnosed. Since aneurysm rupture is a major cause of death in the elderly, improved diagnosis should lead to significant reduction in mortality. The formula-based research funds provided the equipment and technical support for the microarray expression analysis for these projects.

CHAPTER 4
ECONOMIC IMPACT OF TOBACCO FUNDING

This chapter details the economic benefits to the Commonwealth from the funding streams established by the Tobacco Settlement Act. The first section lists those benefits statewide; the remaining three sections detail them within the three regions as defined by the respective Life Sciences Greenhouses.

Statewide[52]

The tobacco funds provided through the CURE Program between 2001 and 2005 have had direct and indirect benefits to Pennsylvania's economy. The direct spending to all recipients of CURE funds was $298 million, which went toward institutional expenditures for capital improvements, goods and services, researchers, research staff, subcontractors, and meetings. These initial investments have led to indirect income of $246 million to businesses and individuals in the state.

This investment of the tobacco funds through the CURE Program has thus produced a $544 million net expansion of the state's economy, created and maintained more than 4,000 high-paying jobs, and strengthened the ability of recipient organizations to compete nationally for federal funding and attract world-class researchers. It has produced $32 million in additional tax revenues to the Commonwealth and has brought $138 million in additional federal medical research. Future tax revenues of $49 million to $135 million per year are expected to be generated from these investments. Further economic benefits from CURE funding can be anticipated because it is widely known that it takes ten years or more to attain commercialization outcomes from research. Significant creation of new biotechnology companies, new medical therapies, and an improvement in the health of Pennsylvanians can therefore be anticipated within the next decade.

It is estimated that tobacco funds for health care research have directly resulted in 2,242 high paying jobs. In addition, there has been a demand for 1,794 indirect jobs throughout the Commonwealth. More dramatic employment gains are expected as initial discoveries become commercialized. By the year 2015, 6,000 to 18,000 new jobs should be created.

---

[52] Tripp Umbach, *The Economic Impact of Tobacco Funding for Commonwealth Universal Research Enhancement (2001-2005) on the Commonwealth of Pennsylvania* (Pittsburgh: January 26, 2006). Tripp Umbach is a consulting firm based in Pittsburgh. Among its specialties is economic impact analysis.

The transfer of research currently funded by the tobacco funds will have a lasting economic impact and may reduce health care costs if discoveries are fully incorporated into medical practices by 2015. CURE-funded research between 2001 and 2005 is forecast to have a total annual statewide impact of $788 million to $2.3 billion by 2015. This can be attributed to start-up companies, commercial applications, attraction of new companies, and growth of existing Pennsylvania-based companies.

While health care cost savings attributable to current research activities are not known, research that results in earlier, accurate, and more effective diagnosis and treatment will likely reduce health care cost expenditures and improve the health of Pennsylvanians as well.

Southwestern Pennsylvania

Academic and Medical Research Centers

Research, in and of itself, exerts a far-reaching economic impact on a region's economy. In fiscal year 2005 the University of Pittsburgh[53] was awarded $603 million in sponsored research funding. Of this, 79 percent was for research in the health sciences, and $431 million of this funding was from NIH. The most immediate economic impact of research funding is jobs. The Association of American Universities estimates that 28.4 jobs are created in Pennsylvania for every $1 million spent on academic research and development. Thus, for FY 2005 Pitt supported an estimated 17,100 jobs based on its sponsored research support. Tripp Umbach estimates that the average salary for each research job created is $67,000, significantly more than the average wage in Pennsylvania of $42,000. Jobs attributable to research include not only direct employment but also indirect jobs created for supply and equipment vendors, contractors and laborers for the construction and renovation of laboratory facilities, administrators and managers who support the research infrastructure, as well as jobs indirectly supported by the disposable income of the scientific workforce. Pitt research expenditures grew by $90 million during the last two years, a 17 percent increase. As a result, Pitt supported 2,500 more jobs in FY 2005 than in FY 2003. With continued high levels of research support, Pitt will continue to be a source of thousands of local jobs based on research alone.

Pitt uses CURE funding, with appropriate limitations and Commonwealth oversight, where the need or the opportunity is greatest. CURE formula funds might be used to provide start-up funding for promising young scientists, collect the pilot data needed to support an application to the NIH to provide bridge funding for established investigators who face a temporary funding gap, or to purchase equipment that will allow faculty to conduct cutting-edge research. The CURE funding balances the use of funds from NIH, other federal agencies, corporations, and foundations, since they often restrict funding to cover the cost of a particular research project with a narrowly defined purpose.

---

[53] Testimony of Dr. Steven E. Reis, August 28, 2006.

Carnegie Mellon[54] has invested tobacco funds to start and expand programs in computational biology, biomedical imaging, neurobiology, and medical robotics. Through this investment, 47 new faculty positions have been added, and the life sciences research budget has doubled over the past six years. Carnegie Mellon has generated ten new start-up companies in the life sciences in the last five years that have leveraged over $2 million in private investment. A key to Carnegie Mellon's growth has been leveraging its tobacco funding of $11 million into nearly $80 million in commitments from other federal and private sources. To accelerate the commercialization of projects using tobacco funds and other financial support, Carnegie Mellon overhauled its technology transfer process, revamped its Center for Technology Transfer to encourage and better support faculty interested in creating new companies, and added staff dedicated to work with life sciences start-ups and licensing.

Enterprises

Including the health services subcluster, there are 3,229 life sciences firms throughout southwestern Pennsylvania employing more than 115,000 people with a total annual payroll in excess of $5.5 billion. The 13-county region's health services subcluster encompasses 2,807 companies employing more than 100,000 people with a total annual payroll of $4.6 billion. The 260 companies in the region's bio research subcluster employ more than 8,500 people and are responsible for a $555 million total annual payroll, which represents an increase of nearly 20 percent over three years. Even as total regional technology jobs and total venture capital technology investments in the region have decreased, the life sciences sector has grown in both jobs and revenues in each of the past 10 years.

The rate of formation of new life sciences companies surpassed 25 companies in 2005. A report issued by the Economy League of Pittsburgh noted that 28 new life sciences companies had been formed locally in that year. Pitt contributed a total of ten new technology companies, seven of which were in the life sciences, ranking it sixth nationally. Carnegie Mellon generated four companies, which is proportionate to Pitt's, adjusted for federal research funds.[55]

Pittsburgh Life Sciences Greenhouse programs have been a critical component of the founding and early growth of Cellumen Inc.,[56] the Cellular Systems Biology Company. Cellumen has licensed technology and collaborated with scientific staff at Carnegie Mellon and Pitt. The executives in residence program has been instrumental to Cellumen in helping with branding, implementing an account management program, and providing key market information that has guided early growth. Otherwise, Cellumen could not have afforded as high a grade of talent so early in its history. The company also received a $100,000 convertible note to transition a key technology and another $100,000 for corporate development.

---

[54] Testimony of Mark Kamlet, August 28, 2006.

[55] Testimony of Dr. Doros Platika, August 28, 2006.

[56] Testimony of D. Lansing Taylor, President and CEO, Cellumen Inc., before the Committee, August 28, 2006.

Based in Pittsburgh, RedPath Integrated Pathology Inc.[57] provides specialized diagnostic testing of patients for cancer. It is among the small but growing group of companies applying complex molecular analysis to clinical practice, in order to improve patient care through accurate diagnosis and decrease health care costs. The company has been operating for more than two years and already makes an operational profit. RedPath's capital is less than $2.5 million in angel investments, economic development funds, and debt; an additional $6.5 million in venture funding is anticipated. The company has eleven employees. In growing a biotech business in the Pittsburgh area, backing from the Greenhouse or Innovation Works has opened the door to other potential investors.

Renal Solutions Inc.[58] chose to locate in Pennsylvania because of favorable past experiences in Pittsburgh, a network of potential life science funding sources, and the availability of a skilled workforce. RSI has raised $40 million from venture capital firms and currently employs 37 people and generates $10 million annually. RSI received $100,000 from PLSG, an amount that may seem small, considering it expects to spend almost $70 million to bring new services and products to the marketplace. However, this investment came during a critical point in the company's product development cycle and helped the company address key problems with its technology and development of a clear value proposition for future investors.

PLSG has been an important support resource for Fluorous Technologies,[59] through the executive in residence and SBIR advance programs. The executive in residence facilitated access to consulting services that the company required, but could not afford on its own, for CFO-level advice and strategic business plan development.

BodyMedia Inc.,[60] a Pittsburgh-based biotechnology company, has developed wearable body monitoring systems and online programs for tracking energy expenditure and energy intake of individuals in free-living environments. BodyMedia provides 40 jobs in Pittsburgh and southwestern Pennsylvania and generates a significant amount of revenue for Pennsylvania's economy. Because of strong revenue growth, Body Media will be hiring additional senior staff, particularly in the areas of sales and marketing.

---

[57] Testimony of Mary Del Brady, President and CEO, RedPath Integrated Pathology Inc., before the Committee, August 28, 2006.

[58] Testimony of Peter M. DeComo, President and CEO, Renal Solutions Inc., submitted to the Committee, August 28, 2006.

[59] Testimony of Phillip E. Yeske, President and CEO, Fluorous Technologies Inc., before the Committee, August 28, 2006.

[60] Testimony of Astro Teller, Chairman and CEO, BodyMedia Inc., before the Committee, August 28, 2006.

Support Structure

The life sciences sector has been enhanced since the creation of the PLSG[61] in April 2002, largely through the assistance of the tobacco funding. Pennsylvania's initial commitment of $33 million in tobacco funds was matched by $70 million from local foundations. Since its creation in April 2002, PLSG has supported the region's life sciences industry through a variety of important services that historically have been in short supply in western Pennsylvania.

PLSG has helped create a regional critical mass of more than 150 companies and has helped bring a number of life sciences products to market. It has invested $4.4 million in direct capital investments to 32 companies and university-based projects, and $1.45 million to three Opportunity Fund B initiatives. These company- and university-based projects and Fund B initiatives have leveraged more than $93 million and $15-30 million, respectively. Together with the foundation funds, PLSG programs and investments have leveraged more than $200 million in additional capital.

The PLSG investments have helped to attract life sciences companies such as Rheogene, Renal Solutions, Revivicor, Crystalplex, BTF Microbiology, NanoDymanics, and Farfield Scientific. These investments have attracted very able individuals to join or help run regional life science enterprises and have directly or indirectly created 5,594 jobs with an estimated average salary range of $65,000 to $80,000. Since the PLSG programs were implemented, the annual rate of new life science company formation in the region grew from one to three companies formed per year to as many as 28.

The tobacco funds have helped the region's academic research institutions qualify for grants from the National Institutes of Health. CURE funding has helped the region's research hospitals and universities by providing much needed funding for expanded investments in research-related equipment and for the personnel necessary to lead health-related research endeavors. In addition, more than 80 companies have participated in the SBIR Advance program, through which PLSG's investment of about $300,000 has attracted over $8.5 million in SBIR funds.

To address the lack of life science venture capital in the region, PLSG invested $15 million as a limited partner in PA Early Stage. PLSG has also partnered with NewSpring Ventures, which in turn has retained more than $9 million in state investment funds for the region and provided access to a fund exceeding $150 million. PLSG is currently negotiating a collaboration with another nationally prominent venture capital organization for potential investment in southwestern Pennsylvania.

[61] Testimony of Dr. Doros Platika, August 28, 2006; testimony of Steven G. Zylstra, August 28, 2006

Besides financial assistance, PLSG has provided a wide range of invaluable services to entrepreneurs. The "executive in residence" program helps to link start-up life sciences firms with experienced corporate leaders. The Greenhouse also leads a program to help small businesses capture research and development funding from the federal government.

In collaboration with the local companies, the Community College of Allegheny County, and the Pittsburgh Technology Council, PLSG has attracted over $2.4 million in Department of Labor workforce training grants to prepare individuals for careers in the life sciences. The program has already trained 900 people in the first year and has committed to training an additional 1,000.

Venture Capital Funds

Birchmere Ventures[62] is a $47 million early stage investment fund primarily focused on western Pennsylvania companies. Since 1996 Birchmere Ventures has managed $145 million across three funds in 36 companies, 30 of which are based in Pennsylvania. Notable Pennsylvania investors that are participating in Birchmere Ventures' include Carnegie Mellon, Pitt, Case Western Reserve University, Highmark, National City Bank, the Pennsylvania State Employees' Retirement System, PNC Equity Management, and UPMC Health System. The Birchmere Venture funds have invested a total of $25 million in COPD Partners, CyOptics, Plextronics, Protez Pharmaceuticals, and PTC Therapeutics. Of the $10.8 million the fund received from TSIB, $3.3 million has been allocated as of August 15, 2006; this allocated amount was split evenly between investments in COPD Partners and Protez Pharmaceuticals. Based on Birchmere Ventures' experience, the Pittsburgh region warrants a $100 million dedicated life sciences fund.

NewSpring Capital,[63] associated with Commerce Health Ventures, is a $41.75 million fund focusing on western Pennsylvania companies. NewSpring has made investments in 34 companies, 29 of which are located within Pennsylvania. These companies have aggregate revenues in excess of $1.6 billion, and since NewSpring began investing the revenues of these companies have grown at a compounded annual rate in excess of 45 percent. NewSpring's Healthcare Fund has made nine investments since its formation in December 2003. The fund has invested $35 million in these companies out of total investments of $211 million in the companies from all sources. Four investments have been in life sciences companies, two in medical device businesses, and three in services businesses. While the life sciences and medical device companies are in the pre-revenue stage, the services businesses are expected to generate $240 million in revenues this year. These companies employ over 2,000 people in Pennsylvania.

---

[62] Testimony of Gary G. Glausser, Partner and CFO, Birchmere Ventures, before the Committee, August 28, 2006. See also *DCED Tobacco Settlement Report (2005-2006)*, Tab 6.

[63] Testimony of Michael A. DiPiano, Managing General Partner of NewSpring Capital, before the Committee, September 14, 2006; *DCED Tobacco Settlement Report (2005-2006)*, 6 (see also Tab 7).

Four PA Early Stage investments totaling over $4 million have been made in southwestern Pennsylvania companies: Cellumen, Renal Solutions, Logical Therapeutics, and Azidex Pharmaceuticals.[64]

Southeastern Pennsylvania

Southeastern Pennsylvania is home to what some consider the highest concentration of pharmaceutical and life sciences firms in the world. The life sciences sector employs over 53,000 people directly and over 300,000 indirectly. The sector contributes $4.6 billion in direct earnings and $13 billion in indirect earnings to the region.

Academic and Medical Research Centers

The research enterprise of the University of Pennsylvania[65] strengthens and grows the economic base of the Philadelphia region and the rest of the Commonwealth as well. Penn's research operations employ over 21,000 people in the region, including 2,300 faculty researchers. Penn's use of CURE funding to attract highly skilled labor to the Philadelphia area has helped expand the Commonwealth's tax base. Penn has leveraged CURE funding to provide important benefits, such as its Center for Technology Transfer, which have been responsible for the formation of almost 100 new companies. Over two-thirds of these startup companies were created in the last five years; most are still active and headquartered in southeastern Pennsylvania.

The CURE funding awarded Penn has been used for capital improvement projects such as new building construction, facilities renovations, and the purchase of core equipment. These physical improvements have been essential to Penn's ability to recruit and retain world-class biomedical scientists, pave the way for new and significant external partnerships, and bring in additional workers and outside vendors.

In the course of a study commissioned by the Pennsylvania Cancer Alliance, Tripp Umbach determined that one-third of Penn's $70 million in CURE funding has been used to pay the salary and employee benefits of 164 new employees while sustaining 243 positions with an average research position salary of $67,000.

As detailed in chapter 3, CURE support has enabled Thomas Jefferson University[66] to develop potential therapies that have led to the creation of several promising spin-off companies, including LightSeed Therapeutics, Targeted Diagnostics and Therapeutics, CardioKine, and Lazarus Therapeutics.

---

[64] Testimony of Dr. Doros Platika, August 28, 2006.
[65] Testimony of Steven J. Fluharty, September 14, 2006.
[66] Testimony of Dr. Steven E. McKenzie, September 14, 2006.

Temple University[67] has received $26 million in CURE funds during the first five years of the program. Temple received $11.9 million in formula funds to support a total of 124 research and research infrastructure projects. In the first year of the CURE Program, $2.1 million in formula funds were leveraged into external awards of $8.2 million, almost four times the amount of formula funds received. Tripp Umbach has estimated that by 2015, the total economic impact of the commercialization of tobacco funded research performed at Temple between 2001 and 2005 will be between $87 million and $255 million annually. New and sustained employment from these ventures is expected to be between 670 and 2,000 full-time high-paying jobs. It is further estimated that Temple's research will save the Commonwealth between $17 million and $53 million in health care costs.

Wistar Institute[68] has leveraged tobacco funds with grants from the NIH and a corporate sponsor, enabling early stage research to be further developed and new cancer therapies to be created by a major Pennsylvania company. Wistar will receive royalties when patents are licensed, while the Commonwealth can expect long term economic benefits from the success of the company and more cost effective treatments.

Enterprises

Immune Control[69] is a small, vibrant biotechnology company that sponsors two clinical trials, spending $4 million a year, most of it locally. Without the support of BioAdvance capital, under the management of Quaker BioVentures, Immune Control's initial financing of $11 million would have been much more difficult, if not impossible, to obtain. Another biotech company founded in 1990 was financed with $175 million, all of it from outside the Philadelphia region; by contrast all of Immune Control's current investors are local. This illustrates how much the Philadelphia venture capital scene has revived in the last decade, largely due to the tobacco funds.

Protez Pharmaceuticals[70] was founded in 2003 to discover and develop novel antibiotics to address the growing problem of drug-resistant bacteria. Protez raised $800,000 in convertible debt from BioAdvance Greenhouse and Ben Franklin Partnerships, won an NIH grant of $2.9 million over 2 ½ years, and recently closed $21 million in Series B financing. The early stage financing by BioAdvance Greenhouse and Ben Franklin helped position Protez for the NIH grant and new financing.

NuPathe,[71] based in Conshohocken, is a specialty pharmaceutical company developing innovative products for the treatment of neurological and psychiatric diseases. BioAdvance has assisted NuPathe with contacts and market research on its first product, and this support added

---

[67] Testimony of Kenneth J. Soprano, October 18, 2006.

[68] Testimony of Meryle J. Melnicoff, September 14, 2006.

[69] Testimony of Stephen Roth, President and CEO, Immune Control Inc., before the Committee, September 14, 2006.

[70] Testimony of Christopher M. Cashman, President and CEO, Protez Pharmaceuticals Inc., before the Committee, September 14, 2006.

[71] Testimony of Jane H. Hollingsworth, Chairman and CEO, NuPathe Inc., before the Committee, September 14, 2006.

credibility to the company, thereby helping it attract more capital. NuPathe has recently completed a $15 million round of funding from venture capital investors. Without the seed investment from BioAdvance, NuPathe might not have reached that goal.

Support Structure

BioAdvance[72] has placed $20 million of its tobacco fund allocation into the Greenhouse Fund. Demand for this funding has been significant: since its launch, the Greenhouse Fund has received over 250 proposals seeking $240 million in funding. BioAdvance has invested over $10 million to date in 30 companies and projects. Of those, 21 are seed investments ranging from $250,000 to $700,000, and nine are pre-seed investments of $5,000 to $200,000 in technologies and companies that being evaluated for larger investments. BioAdvance provides business support, in addition to the funding itself, to help the start-ups move toward success.

The number of seed investments in the region has tripled under the leadership of BioAdvance. Twenty-one of the investments are in companies at the seed stage, where investments provide $200,000 to $700,000 each and the rest are pilot investments that are as small as $5,000. BioAdvance provided the first institutional capital for 16 of these recipients.

BioAdvance's investment helped launch eleven companies in southeastern Pennsylvania. Three companies have been acquired in multimillion dollar transactions, to larger companies in Pennsylvania and New Jersey, while five companies have advanced to institutional venture financing, building strong syndicates and drawing capital to the region from as far away as India and Israel.

Since receiving funding from BioAdvance, 30 recipients have attracted an additional $96 million in capital in 2006 from private equity, federal grants, and revenue-generating collaborations, which is well over the $40 million of capital received from BioAdvance recipients in 2005. BioAdvance dollars are being leveraged at almost a 10 to 1 ratio, which is expected to increase in the coming years.

In addition to its investment activities, BioAdvance has committed $2.5 million to support an initiative to strengthen education, training, and workforce development in bioinformatics and research collaborations in the Philadelphia region.

Venture Capital Funds

Quaker BioVentures[73] now has $280 million under management for venture investment in life sciences companies, solely in the Mid-Atlantic region. It is headquartered in Philadelphia, and much of its investment activity is concentrated in southeastern Pennsylvania. It manages, in partnership with BioAdvance, a $26 million early stage venture fund, BioAdvance Ventures. TSIB is one of the largest investors in Quaker BioVentures and is also the largest investor in

---

[72] Testimony of Barbara S. Schilberg, September 14, 2006.

[73] Testimony of P. Sherrill Neff, Managing Partner, Quaker Bio Ventures, before the Committee, September 26, 2006; *DCED Tobacco Settlement Report (2005-2006)*, Tab 4

BioAdvance Ventures. Other major investors in BioAdvance Ventures include Cephalon, GlaxoSmithKline/SR One, Wyeth, Drexel, Jefferson, Fox Chase, Wistar Institute, and Ben Franklin Partnerships. The Fund has invested or committed $97.2 million of its own money (plus $18.1 million in tobacco funds) in Pennsylvania companies that employ a total of 549 Pennsylvania citizens. In addition, the Fund has attracted $380.8 million into these companies from other venture capital firms. The total leverage ratio of all investments to tobacco funds is 26:1.

Since 2003 Quaker BioVentures has invested in a total of 21 companies in its first fund, and 16 of these companies are headquartered in Pennsylvania. In total, it has invested $17.8 million of the TSIB money allocated to it for management, has invested $113 million out of the aggregate Quaker funds in Pennsylvania, and has attracted a total of $481 million in total funding into the companies invested within Pennsylvania. The Pennsylvania companies are pursuing a broad range of human therapeutics, clinical diagnostics, medical devices, and health care services. These companies employ a total of 544 people across the state.

Central Pennsylvania

Academic and Medical Research Centers

The Pennsylvania State University[74] has applied tobacco formula funding toward integrated, high-quality programs in teaching, research, and service. Penn State improved its facilities by allocating $6.5 million of tobacco funding towards $124.5 million in matching funds. The tobacco funds have enabled Penn State to recruit a number of world-renowned faculty members, and assist faculty members in competing for NIH, National Science Foundation, and other research funding. With the help of tobacco funding, Penn State's Huck Institutes of the Life Sciences assisted the life science colleges in recruiting 58 co-funded faculty members, who have a current funding of $91 million and pending research funding of $142 million.

Penn State has developed an internal funding program with its tobacco funds to support significant preliminary research for federal grant proposals, such as the NIH. Parallel and collaborative competitions are run at both the College of Medicine and at University Park, and proposals developed by faculty are formally reviewed for scientific and technical merit. With many of these research projects still in progress, it is difficult to determine the return on investment. However, seven projects that were initially funded by Penn State during the first two years of the tobacco funds program at a total cost of $1.8 million have leveraged awards from the NIH and other external sponsors totaling over $25 million.

The Weis Center for Research of Geisinger Clinic[75] has received $600,000 in research funding through the formula fund program, which led to an NIH grant of more than $1 million; several other applications are still awaiting review. Sixty-three percent of the funds supported

[74] Testimony of Eva J. Pell, September 26, 2006.
[75] Testimony of David J. Carey, September 26, 2006.

direct research costs, with 37 percent for overhead (compared to a federal indirect cost rate of 53.8 percent). Of the direct costs, 63 percent were used for personnel, funding an average of 2.0 FTEs per year. Twenty-three percent of direct costs were used to support purchase of new equipment or equipment upgrades. The projects have helped to generate discoveries that may lead to novel intellectual property and have spawned two biotechnology spin-off companies.

Enterprises

GlucoLight Corporation,[76] a company based in Bethlehem developing non-invasive glucose monitoring devices for both hospital and consumer use, was founded in 2003. Following an initial investment from Ben Franklin Partnership, LSGPA provided funding of $500,000 in 2004 at a critical early stage, which helped pave the way for concurrent and later investment. The LSGPA investment was leveraged in March 2005 by $2 million and in December 2005 by $4.5 million. GlucoLight has grown to 14 employees and recently moved from the Ben Franklin incubator to a 7,100 sq. ft. facility in the Lehigh Valley. The company anticipates that an FDA pivotal trial for a hospital product will commence by mid-2007.

ProSanos Corporation,[77] a company dedicated to the compilation and analysis of health care related data, recently consolidated all corporate operations in Harrisburg. The local talent pool, early stage funding from LSGPA, and proximity to many of the world's largest pharmaceutical and biotech companies led ProSanos to relocate. ProSanos now employs 18 highly skilled people and expects to hire more in the next year. ProSanos' growth has been aided by $750,000 in investment from LSGPA, which came at critical periods when specific product, hiring, and development milestones occurred.

NanoHorizons Inc.,[78] a company based in State College that custom develops and manufactures nanoscale materials, had been funded by an angel investment firm in California. An additional $1 million in funding, a sum that is most difficult to raise at the seed stage, was required to make the company viable. LSGPA took the initiative to assist the company by investing $500,000, providing a valuable advisor, making connections to angel investors, introducing strategic partners, and helping to facilitate the licensing of a technology to another start up company in central Pennsylvania. LSGPA invested an additional $250,000 in 2004. NanoHorizons has since attracted $2.5 million in follow-on funding, including funding from private investors, and employs approximately 20 individuals. The company intends to expand significantly over the next three years.

Azevan Pharmaceuticals[79] is developing vasopressin antagonists, which may be useful in the treatment of a variety of behavioral disorders and may also have applications in the treatment of cardiovascular disease. The company received $500,000 from LSGPA at a critical stage

---

[76] Testimony of Ray Krauss, CEO, GlucoLight Corporation, before the Committee, September 26, 2006.

[77] Testimony of Dr. Jonathan Morris, CEO, ProSanos Corporation, before the Committee, September 26, 2006.

[78] Testimony of Robert F. Burlinson, CEO, NanoHorizons Inc., before the Committee, September 26, 2006.

[79] Testimony of Neal Simon, CEO (Interim), Azevan Pharmaceuticals, before the Committee, September 26, 2006.

between receipt of the first SBIR grant and initial venture funding. This early investment, as well as business planning advice, has enabled the company to continue its progress before eventually attracting venture funding of $5.5 million in July 2005.

Support Structure

LSGPA[80] began operations in the fourth quarter of 2002; since then it has committed a total of $11 million, which was leveraged by $32 million in follow-on funding. In addition, $3.4 million was committed to relocation efforts and the building of incubators with wet lab space, projects that leveraged more than $111 million. Completed transactions comprise 37 technology development fund I deals, representing investments of approximately $100,000 each; six technology development fund II deals, of roughly $250,000 each; and nine gap fund deals, of up to $750,000 each. LSPGA clients include university-based researchers, technology development groups, emerging companies, as well as companies seeking to expand or relocate. As of June 30, 2005, LSGPA was responsible for the creation or retention of 448 jobs.

The demand for the LSGPA's services is high, with applications received from 138 different entities representing 14 Pennsylvania counties, 13 different states and four countries. Funded companies receive crucial early stage capital and the benefit of all LSGPA staff expertise, which includes entrepreneurship, engineering, mergers and acquisitions, technology transfer, pharmacology, pharmaceutical marketing, biologics manufacturing, government contracting, and general business development. Even companies who do not receive funding from LSGPA benefit from business planning tools, market research, connections to more appropriate sources of capital, and similar services.

Venture Capital Funds

PA Early Stage Partners is a family of venture capital funds that makes investments in seed, start-up and early stage information technology and life sciences companies typically as a lead or co-lead investor. It has a total of 52 Pennsylvania-based companies in the portfolios of its three funds; Fund III, which invests in life sciences companies, commands $86 million in capital. This fund is focused on investments in central Pennsylvania. Approximately 68 people are employed by the life sciences companies receiving tobacco venture investment support through this fund. Overall, PA Early Stage has directly or indirectly invested almost $119 million in Pennsylvania life sciences and technology companies.[81]

---

[80] Testimony of Melvin L. Billingsley, September 26, 2006

[81] *DCED Tobacco Settlement Report (2005-2006)*, 6, and Tab 5; http://www.paearlystage.com, November 6, 2006.

CHAPTER 5
THE STATE OF PENNSYLVANIA'S BIOTECH INDUSTRY

Strengths

Pennsylvania's excellent academic and medical institutions, pharmaceutical companies, and skilled and hard-working labor force have made it a strong contender—or even a global leader—in the life sciences field, especially in medical devices, pharmaceutical manufacturing, and contract research and development.

Pittsburgh Region. Southwestern Pennsylvania has almost all of the elements required for strong and healthy industry growth: the continuum of the life sciences; world-class basic research; emerging biotechnology, medical device and diagnostic companies; mature industry; support organizations, a strong philanthropic community; a highly skilled workforce; ideal geographic location; high quality of life; and a competitive cost of doing business. In a survey conducted in 2005, BioEnterprise ranked Pittsburgh among the top three Midwestern cities in life sciences entrepreneurship, ahead of Chicago, Detroit, and the State of Wisconsin.[82]

Philadelphia Region. Greater Philadelphia ranks first among all the metropolitan areas in the United States in economic impact from the life sciences and supporting industries. The region employs more than 53,000 workers in the core life sciences, second only to New York. An additional 310,200 people are employed in medical laboratories, physicians' offices, medical equipment suppliers, hospitals, and other industries supporting this core sector. "Direct, indirect, and multiplier jobs in the region total over 276,000, representing 11 percent of the region's employment. The life science sector contributes $4.6 billion in direct earnings and $13 billion in indirect earnings, accounting for nearly 13 percent of all earnings in the region. The region demonstrates both breadth and depth across the entire continuum of life sciences—from academic research to the world's largest pharmaceutical companies."[83]

Central Pennsylvania. This region, which comprises 49 counties, has a solid foundation upon which to build a thriving life science industry, including a legacy of excellence in engineering, manufacturing, and the physical sciences. The region boasts more than 60 institutions of higher learning and more than 200 established life science companies, with

[82] Testimony of Dr. Doros Platika, August 28, 2006.
[83] BioAdvance, *Annual Report for Reporting Period July 1, 2004 through June 30, 2005*, 2.

concentrations in medical devices, pharmaceutical manufacturing, and contract research and development. Total research exceeds $680 million. As of June 30, 2002, the industry employed 18,176 persons in this region, working in 658 establishments and earning $810.2 million in wages.[84]

By almost all measures, the biotech or life sciences industry in Pennsylvania is strong and vibrant. The Commonwealth's medical centers, hospitals, colleges and universities, research institutions and biotechnology and pharmaceutical companies are among the best in the world. These institutions are able to attract substantial funding for basic research projects from the NIH and other federal agencies, as well as some of the best researchers at all stages of biomedical research. A recent report by Milken Institute assessed some of the best comparative measures of research strength worldwide. According to the Milken analysis, Penn ranked fifth in the world in biotech publication. In biotech patents, Penn ranked 15th, Thomas Jefferson University ranked 20th, and Pitt ranked 48th. Penn ranked 12th in biotech transfer and commercialization.[85] Along with a strong research base, established commercial enterprises are available, especially for medical devices in southwestern Pennsylvania and pharmaceuticals in the southeastern part of the Commonwealth.[86]

To a great extent, the strength of Pennsylvania's life science industry is attributable to the allocation of its tobacco funds.

> Pennsylvania has invested more of its tobacco settlement dollars in medical research activities than any other state. Medical research is a highly competitive field both nationally and internationally, and Pennsylvania's bold investment has already enhanced the Commonwealth's leadership position as a center for biomedical advances within a rapidly expanding biomedical industry. Looking into the future, the Commonwealth can expect development of new start-up businesses and jobs created through intellectual property transfer and venture capital funding. While many states have attempted to play catch-up and invest more of their tobacco funds in medical research, to date all have failed to capture the breadth and depth of Pennsylvania's approach.[87]

The impact of the tobacco funding has been augmented by the regional Greenhouse structure, because each Greenhouse can formulate and implement a development strategy adapted to the strengths and weaknesses of the region it serves.

---

[84] Life Sciences Greenhouse of Central Pennsylvania, *Annual Report for the period July 1, 2005 through June 30, 2006*, 5, 6.

[85] Milken Institute, *Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization* (Santa Monica, Cal.: September 2006).

[86] Testimony of Gary G. Glausser, August 28, 2006.

[87] Tripp Umbach, *Economic Impact*, 3.

Needs and Weaknesses

Because of its vast potential as a growth industry, life science has attracted attention among political policymakers in other states and other regions of the world. "Nationally, competition is intense among states to develop viable biomedical science and life science sectors."[88] Reflecting the widespread perception that the life sciences field will continue to be one of the most significant growth sectors in the advanced economies around the globe, about forty other states currently have some kind of program to assist one or more of the life science industries. However, the life science sector requires highly sophisticated physical and human capital, as has been mentioned elsewhere in this report. For this reason, only a few regions around the world—perhaps as few as six—can be truly world-class centers that take full advantage of the opportunities afforded by this industry.

Despite its current position as a national leader, thus, Pennsylvania does face significant challenges that must be addressed if it is to maintain or improve its position. The most frequently mentioned of the challenges that face Pennsylvania's bioscience industry is the shortage of venture capital. This is a particularly urgent need in the bioscience sector because of the process for developing a bioscience product from research to commercial viability is so demanding.

> The progress from basic research to new diagnostic and therapeutic products is long, arduous and inevitably expensive. At the outset, academic medical centers, universities and other research institutions conceive new avenues for inquiry and generate substantial new knowledge regarding human biological processes; in the end, biotechnology and pharmaceutical companies refine manufacturing processes to transform the new technology into new products, manage regulatory reviews for marketing and reimbursement approvals, and deliver the products to clinical settings. Somewhere in the continuum from idea to application, inspiration gives way to operation, as focus shifts from basic to applied research and then to product development and delivery. While each segment of the continuum presents its own challenges, the area of transition from research to commercial development is a particular obstacle to both delivering new medical therapies and realizing the full economic and health benefits of the biomedical industry.[89]

While all regions must face the need for raising risk capital in a field where much initially promising research never eventuates in a commercially viable product, other areas benefit from more generous access to venture capital than there is in Pennsylvania. For all industries, Pennsylvania attracts only one-fourth the investment funds California does and only one-third the funds available in Massachusetts. Life sciences and health care investing follows this trend. Promising investment opportunities are languishing due to a lack of available capital. In the Philadelphia region, the availability of risk capital for emerging companies falls behind other

---

[88] Tripp Umbach, *Economic Impact*, 14.

[89] Joint State Government Commission, *Opportunity in the Age of Biology*, 49. See pp. 49-52 of the report for a full discussion of this issue.

leading bioscience regions. Early stage capital is at most half what it should be to compete with those other life science hubs, as measured by the relative proportion of capital available to translate innovations from emerging medical schools into viable commercial products.[90] The ratio of early stage venture capital to NIH funding to medical schools is one third as favorable in the Philadelphia metropolitan area as it is in the metropolitan areas of Boston, San Diego, and San Francisco.[91]

In Pittsburgh every two dollars of research funding attracts ten cents in venture capital investment and 25 cents in Pennsylvania as a whole, whereas in such self-sustaining biotech hubs as California, Massachusetts, New York, New Jersey, and Connecticut, those two research dollars draw one to two dollars of venture capital.[92] Greater venture capital must be attracted to the Pittsburgh region, and this need is more urgent for commercialization than for basic research.[93]

A problem area in Pennsylvania that is presumably related to the scarcity of venture capital was identified by Steven G. Zylstra of Pittsburgh Technology: "With a few significant exceptions, particularly in the medical devices sector, many of our region's life sciences firms remain in an early stage of development, and unfortunately there are far too few of those firms."[94] Barbara Schilberg in her testimony for Bio Advance similarly noted that "Greater Philadelphia lags other regions in the creation of new high growth life sciences companies."[95]

Despite these problems facing the life science industry in Pennsylvania and the strong competition it faces from elsewhere, the overwhelming consensus of the witnesses before the Committee affirmed that Pennsylvania can successfully compete in this sector if the Commonwealth supplies adequate support for the industry.

---

[90] BioAdvance Annual Report, 4.

[91] Ibid., 25. The ratio for 2004 is 1:6 for Philadelphia, 1:2 for the three other areas. For North Carolina, which is significant as the "metropolitan area" of the Raleigh-Durham Research Triangle, the ratio is 1:13.

[92] Pittsburgh Life Sciences Greenhouse Annual Report (November 2005), 9, 72.

[93] Testimony of Mary Del Brady, August 28, 2006.

[94] Testimony of Steven G. Zylstra, August 28, 2006.

[95] Testimony of Barbara S. Schilberg, September 14, 2006.

CHAPTER 6
FINDINGS AND RECOMMENDATIONS

Recommendations of the Select Committee

The Joint State Government Commission received the following sets of recommendations from the members of the Select Committee.

JANE C. ORIE, CHAIR
GIBSON E. ARMSTRONG
JAKE CORMAN
ROBERT C. WONDERLING

CONNIE WILLIAMS, MINORITY CHAIR
ANDREW DINNIMAN
JIM FERLO

SENATE SELECT COMMITTEE TO
REVIEW RESEARCH AND ECONOMIC DEVELOPMENT INITIATIVES ESTABLISHED UNDER THE TOBACCO SETTLEMENT ACT
ROOM 168, MAIN CAPITOL BUILDING • HARRISBURG, PA 17120-3040 • (717) 787-6538

November 14, 2006

David Hostetter, Esq.
Executive Director
Joint State Government Committee
108 Finance Building
Harrisburg, PA 17120

Dear Mr. Hostetter:

On June 30, 2006, the Pennsylvania Senate adopted S.R. 241 to establish a select committee to review the research and economic development initiatives that were made possible through the Tobacco Settlement Act of 2001.

At the conclusion of appropriate hearings and public meetings, S.R. 241 requires the committee to offer a final report on its findings and recommendations by November 30, 2006.

Among the key initiatives and programs that have been evaluated by the special committee include the Commonwealth Universal Enhancement (CURE) Program, the Regional Biotechnology Research Centers (Life Sciences Greenhouses) and the Health Venture Investment Account.

Having served as members of this special committee, and having reviewed and considered the extensive testimony obtained through this committee's hearings and public meetings, we are writing to offer our findings and recommendations regarding the impact of the research and economic development initiatives made possible through the Tobacco Settlement Act of 2001

Key Findings and Recommendations:

Initially, the committee wishes to go on record with its first finding, gleaned from its review of the research and economic development advancements funded through the Tobacco Settlement: the committee recognizes and applauds the wisdom of Pennsylvania's decision to invest 100 percent of its tobacco settlement funds towards the betterment of the health of our citizens. It is, therefore, the committee's first recommendation that Pennsylvania continue to utilize 100 percent of tobacco settlement funding for the health of the Commonwealth's citizens.

- Commonwealth Universal Research and Enhancement Program

The committee has gathered broad input regarding the CURE program and its impact on the health of Pennsylvania's citizens. The CURE program, which is funded with 19 percent of the Commonwealth's annual allocation of tobacco settlement funds, supports the following endeavors

1. 70 percent of CURE funding is allocated for research hospitals and universities that secure funding though the National Institutes of Health

2. 15 percent is allocated to support clinical and health services research projects

3. 15 percent is allocated for other research

The committee finds that the CURE program is playing an essential role in advancing the development of cures and therapies to address many of the most debilitating diseases and ailments facing the nation and the Commonwealth.

Pennsylvania's strong core of university and hospital-based research institutions have utilized funding through the CURE program to leverage additional and growing investments from the

National Institutes of Health, which have further enabled the development and enhancement of critical research capabilities within the Commonwealth.

Key recommendations regarding the CURE program include the following:

1. Flexibility of funds: Flexibility on the use of CURE funds has enabled the program to serve the diverse needs of Pennsylvania's research institutions. Funds are currently used to support research personnel, technology acquisition and renovation and construction costs for research laboratories.

   This committee recommends that any contemplated changes to the CURE program recognize the broad and diverse funding needs associated with health research activities.

2. Health Research Advisory Committee: The Health Research Advisory Committee works in conjunction with the Department of Health to establish the health research priorities of the Commonwealth. These priorities serve as a road map to the Department of Health as it distributes funding to research initiatives. As a guideline, the Committee is to consider the research priorities of the U.S. Department of Health and Human Services.

   This committee recommends that the Health Research Advisory Committee include broad representation from key health research professionals from all segments of Pennsylvania's life sciences community. In particular, the committee suggests the inclusion of additional representatives from the life sciences industry, including

representatives from the small business community. We believe this recommendation is consistent with the Commonwealth's goal to transfer life sciences related research from the research lab to the patient.

3. "Other Research": The tobacco settlement agreement designated 15 percent of CURE funding to support "other research". To date, funding under this provision has been used to support projects that are very similar in nature to the projects funded with the remaining 85 percent of CURE funds.

   This committee recommends that the 15 percent designated to support "other research" be further defined so as to require these funds to be utilized to support life sciences R&D activities conducted in Pennsylvania-based small businesses.

   Specifically, the committee understands that during the past five years, Pennsylvania small businesses have secured approximately $100 million in research funding through the National Institutes of Health's Small Business Innovative Research (SBIR) program. The committee suggests that small business should be eligible to receive matching grants for Phase I R&D dollars secured through the SBIR programs of federal agencies that support health research, including but not limited to the National Institutes of Health, the Centers for Disease Control and the Department of Defense.

   The Committee also supports funding for additional, non-SBIR related R&D projects in small businesses. (A seventy percent/ thirty percent formula is contemplated.)

   As the Commonwealth already has developed an extensive network of small-business support organizations, the committee recommends that the Department of Health and the Health Research Advisory

Committee utilize existing state infrastructure to evaluate applications for SBIR matching grants and other non-SBIR research grants targeted towards small businesses. These state partners would include the Small Business Development Centers, the Life Sciences Greenhouses, the Ben Franklin Technology Partners and the Industrial Resource Centers.

4. Performance Reporting: As required by section 910 of the Tobacco Settlement Act, recipients of CURE grants are subject to a performance review to be conducted by the Department of Health at the conclusion of specific research projects.

   The Committee recommends that the Department of Health provide an annual report to the General Assembly that specifically describes the performance of research projects funded through the CURE Program. In addition to the information mandated under section 910, generalized information regarding technology transfer activity at said recipients should be provided.

5

- Regional Biotechnology Research Centers (Life Sciences Greenhouses)

Pennsylvania's Life Sciences Greenhouses were created through a one-time allocation of $100 million generated from proceeds of the tobacco settlement agreement. These regional centers have supported commercialization activities in the life sciences industry cluster by increasing the availability of risk capital, providing access to regulatory and reimbursement expertise and by serving to further enhance the profile of Pennsylvania's emerging cluster of life sciences companies among national industry leaders.

Key recommendations regarding the Life Sciences Greenhouses:

1. Sustainability: The Committee finds that the Life Sciences Greenhouses have developed strong regional strategies to support the growth and development of our Commonwealth's diverse group of life sciences related industries. The Greenhouses have leveraged state funds to secure additional funding from the private sector, federal government and philanthropic communities. Those funds have been invested wisely in life sciences companies that can be expected to pay strong dividends to the Commonwealth in the form of life saving technologies, new jobs and tax revenues. Moreover, many firms will repay cash loans and investments, which will be used to make renewed investments.

The Committee recognizes the long-term nature of developing life sciences related firms. As such, the Committee strongly supports the identification of a long-term funding strategy to support the continued activities of the Life Sciences Greenhouses.

- Health Venture Investment Account

Utilizing proceeds generated from the tobacco settlement agreement, the Commonwealth invested $60 million in life sciences-focused venture capital funds. To be eligible to manage these funds, firms were required to leverage two dollars of private investment for every dollar of state investment.

The investment of this funding has served to attract an astounding $800 million and more in new private sector funding to support the creation and development of countless life sciences firms.

Key recommendations regarding the Health Venture Investment Account:

1. Sustainability: As returns are generated from the initial round of venture capital investments, current law requires proceeds to be returned to the Heath Endowment Account. Given the ongoing struggles of Pennsylvania's emerging life sciences, firms, the Committee recognizes the need to continue stimulating the venture capital markets that support this industry.

   To that end, the Committee urges the General Assembly to adopt legislation to redirect proceeds payments to the Health Venture Investment (HVIB) account to support renewed investments in Pennsylvania venture capital firms and to clarify the HVIB's prudent discretion in the selection of venture capital investment.

   Additionally, the Committee supports efforts to identify other sources of ongoing funding to support additional rounds of investments in life sciences focused venture capital firms.

In conclusion, the Committee has found this process to be an extremely worthy exercise to determine the impact of the tobacco settlement agreement on the health and economic vitality of the Commonwealth and its citizens.

During the process of gathering this information, testimony was also submitted in support of improvements to Pennsylvania's business tax climate so as to further support the growth and development of the Commonwealth's life sciences industry. Among those recommendations include the elimination of Pennsylvania's cap on net operating losses, a change in the apportionment formula of the corporate net income tax to reflect a single sales factor approach and an expansion in the state's R&D tax credit. The committee wishes to express its support of these measures to ensure Pennsylvania's emerging position as a leader in the life sciences industry.

Sincerely,

JANE C. ORIE, Chair

JAKE CORMAN

GIBSON ARMSTRONG

ROB WONDERLING

Select Committee to Review Research and Economic Development Initiatives established under the Tobacco Settlement Act

HARRISBURG, PA

November 21, 2006

Honorable Jane C. Orie, Chairwoman
Select Committee on Tobacco Settlement Funds
168 Main Capitol Building
Harrisburg, PA 17120

Dear Senator Orie:

Thank you for your introduction of SR 241 and your leadership in examining the health and economic development initiatives made possible by the Commonwealth's investment of Tobacco Settlement funds. The hearings, as set forth in SR 241, gave us an excellent opportunity to learn more about the wonderful research being conducted by our universities and private business partners. We were pleased to learn that some of this research has been or is in the process of being commercialized in the Commonwealth.

After reviewing the testimony provided, we would like to offer the following recommendations for inclusion in our priorities to be sent to the Joint State Government Commission.

- Expand the Health Research Advisory Committee (HRAC) to include the Secretary of the Department of Community and Economic Development (DCED). Because this addition will bring the number of members to ten, we recommend that the Governor be given one additional appointee, in order to bring total membership to an odd number, 11.
- Require that four (4) members of the HRAC be from the biotechnology industry.
- Set aside a portion of the funding under Sec. 906 (3) dedicated to "other research projects" specifically for private industry applicants.

- **Under Section 905 (c) include at least one industry representative (for the purpose of evaluating the need and commercial viability) to the department-appointed peer review panel, used in evaluating the applicants for non-formula funding.**

We recognize the excellent contributions of the three regional greenhouses and the venture funds established to carry out health research priorities and economic development initiatives. We encourage the continued investment of Tobacco Settlement funds to both the greenhouses and the venture funds.

We look forward to discussing our recommendations with the entire Select Committee, however, we wanted to forward our initial recommendations to you in advance for your consideration.

Sincerely,

Constance H. Williams
17th District

Andrew E. Dinniman
19th District

Jim Ferlo
38th District

Additional Recommendations

The following suggestions were made at the hearings of the Committee by members of the Committee:

1. Develop a strategy to facilitate removal of local barriers, such as plumbing, sewerage, and zoning, to life sciences businesses and include DCED, DEP, Center for Local Government, and the Governor's Task Force in this discussion.

2. Strengthen the link between research and commercialization, especially between start-up and mid-stage companies, so that researcher-entrepreneurs who are starting new companies are prepared for later stages of business development.

3. Consider further proposals to improve the business tax structure for biotech, such as tradability of net operating losses (NOLs) and stricter treatment of Delaware holding companies.

4. Develop a statewide comprehensive approach to the life sciences industry, including research, start-ups, and later stage companies. In developing the plan, consideration must be given to legal, municipal, financial, and quality of life aspects of business development. The plan should also address commercialization and retaining the Commonwealth's human and intellectual capital.

Witness Recommendations

The following recommendations were presented by the witnesses who made presentations at the hearings held by the Committee:

1. Review the current CURE non-formula funding structure and practice to make it more open to for-profit companies. To carry out this goal, these funds can be structured as one fund open to all competitors (Flynn) or split between a fund that makes grants based on federal SBIR grants and another that is open to all competitors (Kennedy). (Zylstra, Platika, Yeske, Flynn, Kennedy)

2. Support construction of facilities and infrastructure to attract and retain researchers and entrepreneurs by broadening the permissible uses of CURE formula funding, enacting additional support funds, or both. (Taylor, Del Brady, Teller, Carey)

3. Invest in basic research at for-profit companies (Teller).

4. Invest in basic research at medical centers that are independent of academic institutions. (Carey)

5. Witnesses voiced concern that lack of adequate physical plant is a major obstacle to commercialization. However, funding for construction must be balanced with continued support for research projects. (Kamlet, Carey, Pell, Teller, Taylor)

6. A dramatic, immediate increase in public support is needed to establish a successful biotech cluster in Pennsylvania. (Kamlet, Cashman)

7. Educate the entities involved in product development how the process works and encourage universities, scientists, and industry to collaborate in that process. (Melnicoff)

8. Any changes to existing programs should retain the features of the programs that have made them generally successful. Fluharty)

9. Assist start-up companies to raise capital to commercialize their discoveries. (Platika, Taylor, Del Brady, Teller, Schilberg, DiPiano, Flynn, Neff, Kennedy)

10. Broaden the time horizon for comprehensive planning on public support for life sciences development to about 25 years. (Yochim)

11. Direct at least one percent of the tobacco funds toward lung cancer research and early detection programs. (Hill)

12. Enact the provisions of 2006 House Bill 2653 (P.N. 4336) or similar measures enhancing public support for the tobacco programs that assist the life sciences industry. This legislation would direct three percent of the tobacco funds to the Greenhouses and another three percent to the Health Venture Investment Account. The bill would also recirculate returns from HVIA investments back to HVIA; currently these returns go into the General Fund. (Zylstra, Schilberg, DePiano, Flynn, Neff, Kennedy, Dalton, Platika, Billingsley)

LIST OF SOURCES

BioAdvance. *Annual Report for Reporting Period July 1, 2004 through June 30, 2005*.

BioAdvance. *Annual Report for Reporting Period July 1, 2005 through June 30, 2006*.

Gabriel, Christina. "University Research and the Market: The SBIR Opportunity." Presentation to the Board on Science, Technology, and Economic Policy, U.S. National Academy of Sciences. October 3, 2002.

Commonwealth of Pennsylvania. Department of Community and Economic Development, *Pennsylvania Tobacco Settlement: Investing in the Health of Pennsylvania*. Annual Report 2005-2006.

_____. Department of Health. *2004-2005 Annual C.U.R.E. Report*. Available at http://www.dsf.health.state.pa.us/health/cwp/view.asp?A=175&Q=246613 (visited January 9, 2007).

_____. General Assembly. Joint State Government Commission. *Opportunity in the Age of Biology: Biomedical Research in Pennsylvania*. Report of the Working Group on Biomedical Research. Harrisburg: October 2000.

Life Sciences Greenhouse of Central Pennsylvania. *Annual Report for the Period July 1, 2004 through June 30, 2005*.

Life Sciences Greenhouse of Central Pennsylvania. *Annual Report for the Period July 1, 2005 through June 30, 2006*.

Milken Institute. *Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization*. Santa Monica, Cal.: September 2006.

PhRMA. *Pharmaceutical Industry Profile 2006.* Available at http://www.phrma.org/profiles.%26_reports/ (visited January 19, 2007).

Pittsburgh Life Sciences Greenhouse. *Annual Report*. November 2005.

Pittsburgh Life Sciences Greenhouse. *Annual Report*. November 2006.

Tripp Umbach & Associates. *The Economic Impact of Tobacco Funding for Commonwealth Universal Research Enhancement (2001-2005) on the Commonwealth of Pennsylvania*. Pittsburgh: January 26, 2006.

Wistar Institute. "Saving Lives through Science." http://www.wistar.org/about_wistar/overview.html . October 23, 2006.

APPENDIX A

2006 SENATE RESOLUTION NO. 241, PRINTER'S NO. 1606

PRINTER'S NO. 1606

THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE RESOLUTION

No. 241 Session of 2006

INTRODUCED BY ORIE, WONDERLING, ERICKSON, RHOADES, RAFFERTY, PILEGGI, PIPPY, CONTI, WAUGH, ROBBINS, BROWNE AND STACK, MARCH 17, 2006

REFERRED TO PUBLIC HEALTH AND WELFARE, MARCH 17, 2006

A RESOLUTION

Establishing a select committee to review research and economic development initiatives made possible by the Tobacco Settlement Act to provide the Senate with recommendations on a vision for the future.

WHEREAS, It is the intent of the Senate to continue to provide for the health and economic vibrancy of this Commonwealth and its citizens through the judicious use of tobacco settlement funds; and

WHEREAS, It is the intent of the Senate to continue to fund research and economic development initiatives; and

WHEREAS, It is the hope of the Senate that such programs have made great strides in contributing to the health of the residents of this Commonwealth and in contributing to their well-being through economic development programs; and

WHEREAS, The Senate seeks to determine the impact of initiatives established through tobacco settlement funds on the health of the residents of this Commonwealth; and

WHEREAS, The Senate seeks to determine the impact of such

initiatives on the economic development of this Commonwealth; therefore be it

RESOLVED, That the Senate establish a select committee to review research and economic development initiatives established under the act of June 26, 2001 (P.L.755, No.77), known as the Tobacco Settlement Act, and to provide recommendations to the Senate on a vision for the future; and be it further

RESOLVED, That the committee consist of four members of the Senate, including the chair, appointed by the President pro tempore of the Senate and three members of the Senate appointed by the Minority Leader of the Senate; and be it further

RESOLVED, That the committee hold hearings and receive testimony from this Commonwealth's world-class academic research institutions and hospitals, leaders from this Commonwealth's life sciences investment community, economic development entities and members of this Commonwealth's emerging biotechnology and life sciences industries; and be it further

RESOLVED, That the committee conduct no more than three hearings in places and times it deems necessary in this Commonwealth; and be it further

RESOLVED, That the committee make a report of its findings and any recommendations by November 30, 2006.

APPENDIX B
LIST OF WITNESSES BEFORE THE COMMITTEE

First Hearing
August 28, 2006
Pittsburgh

Steven G. Zylstra
President and CEO
Pittsburgh Technology Council

Maryann Donovan
Associate Director for Research Services and Advancement
University of Pittsburgh Cancer Center

Dr. Steven E. Reis
Professor of Medicine, School of Medicine
Associate Vice Chancellor for Clinical Research, Health Sciences
University of Pittsburgh

Gary G. Glausser
Partner and CFO
Birchmere Ventures

Mark Kamlet
Provost and Senior Vice President
Carnegie Mellon University

Dr. Doros Platika
President and CEO
Pittsburgh Life Sciences Greenhouse

D. Lansing Taylor
President and CEO
Cellumen, Inc.

Mary Del Brady
President and CEO
RedPath Integrated Pathology, Inc.

Astro Teller
President and CEO
BodyMedia, Inc.

Philip E. Yeske
President and CEO
Fluorous Technologies, Inc.

Peter M. DeComo
Chairman and CEO
Renal Solutions, Inc.

Second Hearing
September 14, 2006
Villanova

Steven J. Fluharty
Vice Provost for Research
University of Pennsylvania

Dr. Steven E. McKenzie
Vice President for Research
Thomas Jefferson University

George C. Prendergast
President and CEO
Lankenau Institute for Medical Research

Barbara S. Schilberg
Managing Director and CEO
BioAdvance

Michael A. DePiano
Managing General Partner
NewSpring Capital

Christopher M. Cashman
President and CEO
Protez Pharmaceuticals, Inc.

Jane H. Hollingsworth
Chairman and CEO
NuPathe, Inc.

Stephen Roth
President and CEO
Immune Control, Inc.

Christopher Yochim
Associate Director
Global Discovery Alliance
AstraZenica Pharmaceuticals
Vice President, Eastern Region
Association of University Technology Managers

Meryle J. Melnicoff
Director of Business Development
Wistar Institute

Third Hearing
September 26, 2006
Harrisburg

Eva J. Pell
Senior Vice President for Research
Dean of the Graduate School
Pennsylvania State University

Jay Moskowitz
Associate Vice President for Health Sciences Research
Pennsylvania State University
Vice Dean for Research and Graduate Studies
Penn State College of Medicine

David J. Carey
Associate Chief Research Officer and Director
Weis Center for Research
Geisinger Clinic and Health System

Melvin L. Billingsley
President and CEO
Life Sciences Greenhouse of Central Pennsylvania

Ray Krauss
CEO
GlucoLight Corporation

Dr. Jonathan Morris
President and CEO
ProSanos Corporation

Neal Simon
CEO (Interim)
Azevan Pharmaceuticals

Robert F. Burlinson
CEO
NanoHorizons, Inc.

Dennis M. “Mickey” Flynn
President
Pennsylvania Bio

P. Sherrill Neff
Managing Partner
Quaker BioVentures

Patricia W. Portzebowski
Director, Bureau of Health Statistics and Research
Pennsylvania Department of Health

Dr. Robert C. Young
President
Fox Chase Cancer Center
Member, Health Care Advisory Board

Dr. John B. Hill
Medical Oncologist (Retired)
Member, Cancer Institute and Lung Cancer Alliance

Fourth Hearing
October 18, 2006
Harrisburg

Dr. Robert C. Young
President
Fox Chase Cancer Center
Member, Health Care Advisory Board

David J. Carey
Associate Chief Research Officer and Director
Weis Center for Research
Geisinger Clinic and Health System

Melvin L. Billingsley
President and CEO
Life Sciences Greenhouse of Central Pennsylvania

Dennis M. “Mickey” Flynn
President
Pennsylvania Bio

Brian D. Kennedy
Vice President of Government Relations
Pittsburgh Technology Council

Barbara S. Schilberg
Managing Director and CEO
BioAdvance

Barbara J. Dalton
General Partner
EuclidSR Partners, L.P.
Chairman
Mid-Atlantic Capital Alliance

Kenneth J. Soprano
Vice President for Research and Graduate Studies
Temple University

Monell Chemical Senses Center

APPENDIX C
ALLOCATION OF TOBACCO SETTLEMENT FUNDS

The Tobacco Settlement Fund was created to receive amounts paid annually to the Commonwealth from tobacco corporations under the Master Settlement Agreement (§ 303(a)).[96] Two subordinate funds were established within TSF: the Heath Endowment Account for Long-Term Hope (Health Account), (§§ 303(b)) and the Health Venture Investment Account (HVIA), (§§ 303(c)). Investments are made by the Tobacco Settlement Investment Board (§ 304). An additional one-time appropriation of $100 million funded the creation of the regional biotechnology research centers (generally referred to as the Life Sciences Greenhouses) (§ 5101(a)(2)).

The annual payments deposited into TSF are distributed as follows:

Health Account

Eight percent of the annual amounts received from the tobacco companies under the MSA (MSA receipts) is allocated to the Health Account (§ 306(b)(1)(i)). The Health Account also receives the jurisdictional payment and strategic contribution payments from the MSA and the earnings derived from the investment of money in TSF, the Health Account, and the HVIA (§ 303(b)). The purpose of this account is to meet extraordinary or emergency health care needs of the citizens of Pennsylvania as identified by the Governor (§ 307).

Home and Community-Based Services

Thirteen percent of the MSA receipts is allocated to home and community-based services (§ 306(b)(1)(ii)). These funds are used to pay enrolled providers for home and community-based care services provided to funded or assisted individuals (§ 503).

Tobacco Use Prevention and Cessation

Twelve percent of the MSA receipts is allocated to tobacco use prevention and cessation programs (§ 306(b)(1)(iii)). The Act mandates that these programs be designed to reduce tobacco use and the burden of tobacco-related diseases, with a priority for serving the uninsured

[96] Citations are to the Tobacco Settlement Act (act of June 26, 2001 (P.L.755, No.77); 35 P.S. § 5701.101 et seq.

and low-income populations. These efforts are to be designed to counter tobacco influences, increase health-related messages, and enforce applicable laws related to tobacco access (§ 703).

Uncompensated Care

Ten percent of the MSA receipts is allocated to an uncompensated care program (§ 306(b)(1)(v)). This program compensates qualifying hospitals for a portion of the uncompensated care provided to patients (§ 1103(a)).

Health Investment Insurance

Thirty percent of the MSA receipts is allocated to the health investment insurance program and to the purchase of Medicaid benefits for workers with disabilities (§ 306(b)(1)(vi). Funds under the former allocation are used for contracts to provide basic health care insurance for eligible adults and outreach activities (§ 1303(a)). Funds under the latter allocation provide medical assistance to certain disabled workers (§ 1503(a)).

PACENET

Eight percent of the MSA receipts is allocated to expand the Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier program by lowering the income eligibility requirements (§§ 306(b)(1)(vii), 2302, and 2303).[97]

Health-Related Research

Nineteen percent of the MSA receipts is allocated to health-related research through the Commonwealth Universal Research Enhancement (CURE) Program (§§ 306(b)(1)(iv), 903(a)(1)). The CURE Program funds biomedical, clinical, and health services research projects under the direction of the Department of Health, with the advice of the Health Research Advisory Committee.

Except for one percentage point of the MSA receipts, this segment is allocated as follows (§ 906):

- 70 percent of the funds (or 12.6% of the MSA receipts) for research pursuant to the National Institutes of Health (NIH) funding formula. The formula distributes the grants as follows (§ 908(b)):

[97] PACENET is otherwise funded under the State Lottery Law (act of August 26, 1971 (P.L.351, No.91); 72 P.S. § 3761-101 et seq. The formerly applicable income requirements are stated in § 519(b) of the State Lottery Law.

(1) 20 percent to each institution that receives more than an average of $175 million during the three immediately preceding federal fiscal years from the NIH.

(2) 17 percent to each institution that receives more than $175 million during the preceding federal fiscal year in federally sponsored research and development obligations as reported by the National Science Foundation (NSF) and receives more than an average of $60 million during the three immediately preceding federal fiscal years from the NIH.

(3) The remaining funds to eligible institutions based on the ratio of the institution's three-year average awards from NIH to the three-year average of all such NIH awards to eligible Pennsylvania-based institutions.

- 15 percent (or 2.7% of all MSA receipts) for clinical and health services research projects by eligible applicants.

- 15 percent (or 2.7% of all MSA receipts) for other research projects by eligible applicants.

The remaining one percentage point is allocated for grants to institutions that conduct research in Pennsylvania and have received funding during each of the three immediately preceding federal fiscal years from the National Cancer Institute (NCI). These funds are distributed to eligible institutions based on the ratio of the institution's three-year average award from the NCI to the three-year average of all such NCI awards to eligible Pennsylvania-based institutions.

Health Venture Investment Account

HVIA is initially funded by a one-time appropriation of $60 million in the 2001-2002 fiscal year (§§ 303(c), 5101(a)(2)). Its purpose is to make venture capital investments in health care, biotechnology, and other health-related businesses. TSIB is permitted to invest funds from this account in limited partnerships or comparable investment entities if the investment guidelines and strategies of the recipient entity require that at least 70% of the entity's investments will be made in companies located in Pennsylvania or in companies willing to relocate significant business operations in Pennsylvania (§ 305(f)).

There have also been temporary transfers of tobacco funds in recent fiscal years under Act 91 of 2002, Act 41 of 2005, and Act 66 of 2006.[98] For example, one-fourth of the 12 percent for tobacco use prevention and cessation programs was withheld during fiscal year 2006-2007. Along with portions of other programs withheld, this money was then appropriated to the

[98] Act of June 29, 2002 (P.L.614, No.91), act of July 7, 2005 (P.L.174, No.41), and act of July 5, 2006 (P.L.296, No.66).

regional biotechnology research centers and medical assistance long-term care.[99] All tobacco funds transferred within an Act lapsed at the end of the fiscal year of the transfer. However, some of the transfers appeared in more than one Act.

[99] General Appropriation Act of July 2, 2006 (No.2A).