

Corbett Praises Life Sciences Companies in PA for Improving Health Globally and Creating Jobs Locally

Pennsylvania Governor Tom Corbett, who has made job growth a priority of his administration, continues to point to the life sciences industry as an example of a key economic driver in the Commonwealth.

The life sciences is a \$40 billion industry in Pennsylvania and currently employs more than 79,000 people. The governor this summer highlighted the industry's success during a two-day tour of four life sciences operations in Southeastern Pennsylvania. Corbett learned how these companies are improving the lives of patients with serious illnesses while creating employment opportunities for Pennsylvanians.

"The life sciences industry continue to be a key economic driver that is advancing global health and providing thousands of high-paying jobs for our citizens," Corbett said. "By supporting the growth of the industry – from helping entrepreneurs



Governor Corbett poses with leadership from Merck & Co. Inc. during recent visit.

transform ideas into commercial products to supporting the establishment and expansion of biotech companies – we are ensuring the biotech economy will continue to grow and flourish in Pennsylvania."

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CEO Roundtable Features Insight from Industry Leaders

The life sciences industry convened on September 18, 2013 at the Desmond Hotel and Conference Center in Malvern to glean insights from a cross-section of business leaders.

The panel featured Dr. Neal Walker, President and CEO of Aclaris Therapeutics, Adrian Adams, President and CEO of Auxilium Pharmaceuticals, and Sean McDonald, President and CEO of Precision Therapeutics.

Each panelist contributed a unique perspective to the discussion. With diverse backgrounds ranging from serial entrepreneurship, strategic acquisitions and innovative technology development, the panel offered practical tips and solutions for navigating a life sciences company through today's often challenging environment.

The conversation focused on change management, maintaining company culture despite growth, and creating an environment that encourages innovation.

Adams said about the impact of growth on a company's culture, "One of the challenges of growing is determining how to evolve while still maintaining the essence of your culture. We've achieved this by allocating a specific area of the company that is innovation-focused and maintains an entrepreneurial mindset."

Prior to joining Auxilium, Adams served as Chairman and Chief Executive Officer of Neurologix, a company focused on development of multiple innovative gene therapy development programs. Before Neurologix, Adams served as President and Chief Executive Officer of Inspire Pharmaceuticals, Inc., where

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The Future of Life Sciences Comes to Philadelphia November 13th



**LIFE
SCIENCES
FUTURE**

Event replaces Biotech series and will reflect the rapidly-evolving landscape in healthcare

Pennsylvania Bio will be joined by a wide range of partners, November 13, to present Life Sciences Future. A conference unlike any other, Life Sciences Future will focus on the newest scientific advancements while training an eye towards what's next on the horizon. The program is designed to highlight connectivity, new technology and funding.

The conference has been developed with the Association's diverse membership in mind - biopharma, medical device and diagnostics, healthcare IT, contract research organizations, medical research institutions, and the investment community. Pennsylvania Bio collaborated with representatives from each industry sector to design a meeting agenda that is relevant and engaging for all attendees.

Dr. Siddhartha Mukherjee, Oncologist, Cancer Researcher and Award-Winning Science Writer, to Deliver Keynote Address

Dr. Mukherjee is a gifted physician and writer bringing new insights into the causes and cure of cancer. He wrote the 2010 book, *The Emperor of All Maladies: A Biography of Cancer*, which won the Pulitzer Prize for General Nonfiction and the Guardian Prize, was nominated for the National Book Critics Circle Award and was described by Time Magazine as one of the 100 most influential books of the last 100 years, and by *The New York Times Magazine* as among the 100 best works of nonfiction.

A cancer specialist, Dr. Mukherjee has devoted his life to caring for cancer patients. As a researcher, his laboratory is on the forefront of discovering new cancer drugs using innovative biological methods.

"I have heard Dr. Siddhartha Mukherjee speak at a Wistar Institute Authors Series event and he is a fascinating speaker," said Craig Zappetti of Saul Ewing. "I bought his book and could not put it down. He does a fantastic job making a complex subject easy to understand for the lay reader. He also brings to life the very human aspect of this disease and how it affects everyone it touches. I highly recommend this book and if you get the opportunity to attend Life Sciences Future to hear Dr. Mukherjee speak, it is time well spent."

Dr. Mukherjee is equally devoted to and effective in communicating the story of cancer through his writings. As he notes, the disease now touches in some way the lives of every man, woman and child in the world, while scientists and physicians work tirelessly to bring new treatments and hope to its victims.



Dr. Siddhartha Mukherjee

Dr. Mukherjee has been published in *Nature*, *New England Journal of Medicine*, *Neuron*, *Journal of Clinical Investigation*, *The New York Times*, and *The New Republic*. His work was nominated for inclusion in Best American Science Writing, 2000.

Forward-Thinking Industry Leaders Share Insight and Debate Hot-Topic Issues

In addition to the featured speakers, Life Sciences Future will include programming that gives attendees insight and best practices to stay on the cutting edge of the rapidly evolving industry.

The conference will feature a series of debates on issues affecting the life sciences. The debates will offer attendees a chance to dig deeper and explore all sides of the most controversial topics. The planning committee has kept an ear to the ground for the latest trends, technology and court rulings to identify the topics that have the industry buzzing. Life Sciences Future takes these topics from the water cooler to the podium, where attendees will hear representatives from both sides of the aisle weigh in.

Attendees will also have an opportunity to hear several “short takes” presentations throughout the day. Inspired by the popular TED Talk Series, short takes will feature experts speaking on an array of topics, from funding to personal liability and everything in between. Full list of speakers:

“Personalized Medicine: Bridging the Unmet Needs of Healthcare”
Urmi Ashar, President and CEO, Advanced Technology Healthcare Solutions

“Authentication of Cell Lines used in Cancer Research”
Dr. Michael Baird, CSO, DNA Diagnostic Center

“Surge in Biotech IPOs”
John Carroll, Fierce Biotech

“Not All the Smart People in Your Industry Work for You: The Power of Collaborative Innovation”

Michael Docherty, Founder and CEO, Venture2 Inc.

“Sunshine Act: Putting a Cloud Over Physician Relationships”

Judy Fox, Director, Transparency Compliance, CIS

“Back to the Startup: Part 2”

Matthew Gillin, CEO, Relay Network

“Going Social: Using Digital Media for Advocacy”

Howard Greenstein, CEO & President, The Harbrooke Group, Inc. and counsel to Bravo Group

“Nightmare on Elm Street: The Perverse Vortex for Individuals Subject to DOJ Investigations”

Christopher Hall, Partner, Saul Ewing, White Collar Practice

“China’s Charging Ahead: Time to Get on Board or Get Out of the Way”

David Iwinski, Managing Director, Blue Water Growth LLC

“Getting Under the Skin of Translational Science”

John Kemnitzer, Senior Director, Regenerative Technologies Product Development, Integra Life Sciences

“Spit Speaks: What Your Saliva Can Tell About You”

Stephen Lee, Executive Vice President and Chief Science Officer, OraSure Technologies, Inc.

“I’ll Have That to Go: The Future of Mobile App Development in Life Sciences”

Debra Loggia, Head of Sales, NorthPoint

“Patients Are Your Best Salespeople”

Robbie McCarthy, Principal and Managing Director, The Patient Experience Project

“Mobile Real-Time Diagnostics and Surveillance: Turn Your Smartphone into a Convenient, Low-Cost Lab”

Max Perelman, Co-Founder, Biomeme

“Turn Your Tortoise into a Hare: Accelerate the Journey from Bench to Bedside”

Ross Tonkens, Director, Science & Technology Accelerator Division, American Heart Association 

PA Bio Recognizes Board Members for Years of Service

As the voice of advancement for the life sciences industry in Pennsylvania, PA Bio has significantly evolved since its founding in 1989. Despite several difficult years for the industry, PA Bio has shown tremendous growth and solidified itself as an anchor of strength in the Commonwealth.

"Our continued growth is due in large part to the dedication of our Board of Directors," said Chris Molineaux, President and CEO of Pennsylvania Bio. "We have been fortunate to work with tremendous leaders whose years of service and industry stewardship have helped Pennsylvania Bio become the successful trade association it is today."

Pennsylvania Bio is grateful for the commitment and service of nine board members leaving the Board of Directors this year: Manya Deehr, Esq., John Gerard, Kenneth Guito, M.B.A., David R. King, Sean McDonald, Steven Nichtberger, M.D., H. Joseph Reiser, Ph.D., Paul Touhey, and Christopher Yochim.



Manya Deehr, Esq.

Manya S. Deehr has been a long-standing member of the Pennsylvania Bio community. She has spent her entire professional career working with life sciences

companies across the globe, at one point delivering the keynote address at the annual Japanese Patent Lawyers meeting in Nagoya, Japan. In the Pennsylvania region, she supported numerous life sciences companies as a partner and member of the life sciences steering committee at the law firm of Morgan Lewis. She left the practice and was integral in establishing, growing and exiting two life sciences companies in the region—Velcera, Inc. and Eurand Pharmaceuticals, Inc. She holds a degree in biochemical sciences from Harvard University and a law degree from University of Wisconsin, Madison. She is currently a principal in the Life Sciences Law Group, LLC and serves as CEO of Pediva Therapeutics, LLC.



John Gerard

John Gerard has over 28 years of experience with KPMG LLP, specializing in merger and acquisition transactions, venture capital financings, and initial/secondary offerings.

He has worked with both Global 50 accounts and very small entrepreneurial private companies. John is an Audit partner at KPMG and currently serves as the East Region Managing Partner of Audit and previously served as the Partner-In-Charge of the Pennsylvania Audit Practice as well as the Mid-Atlantic lead partner of KPMG's

Life Science practice. John began his professional career in 1984 when he joined KPMG. In 1995, he was admitted to the partnership and began a series of leadership roles and responsibilities. He spent three years in the Transaction Services (TS) practice of KPMG, working on global acquisitions in various industries. John has been an active business leader throughout the states of Pennsylvania and Delaware.



Kenneth Guito

Kenneth Guito currently holds the position of General Manager, Sanofi-Topaz, Inc., a subsidiary of Sanofi Pasteur. His responsibilities in this role include oversight

of integration for the new organization, all operational activities, registration of primary indication for the lead product and development of secondary indications, securing commercial supply and support of product launch. Prior to this roll, he held the position of Senior Director, Corporate Development at Sanofi Pasteur where he was responsible for executing the strategic directive for the organization's continued growth. This was accomplished through the evaluation of in-licensing and acquisition opportunities, leading the execution of transactions and facilitating integration once transactions were completed.

He began his professional career in the pharmaceutical industry with Schering-Plough. That career has spanned 30 years, including the last 20 years focused on vaccines and immunotherapy. Mr. Guito joined Sanofi Pasteur (then Connaught Labs) in 1990 and has held positions of increasing

responsibility in Clinical Affairs, Product Development, Regulatory Affairs and the Strategic Project Office. During his career, he has been a principal force in bringing eight products through the pipeline leading to commercial success.

Mr. Guito served on the Board of Directors for Pennsylvania BIO since 2006; Board of Directors for Ben Franklin Technology PARTners since 2011; and the Ben Franklin Technology PARTners Pocono Northeast Advisory Board since 2010. He has also served on the Board of Directors for Women's Resources of Monroe County since 2006.

He received his Bachelor of Science degree in biology from Trenton State College (now The College of New Jersey) and his Masters in Business Administration from Villanova University.



David R. King

David R. King is an experienced lawyer and executive with deep and broad experience in the growth and funding of new entrepreneurial ventures in

a number of industries, especially those relating to the life sciences. David started his career with Morgan Lewis, where he created and was a leader of the venture capital and emerging business practice. After more than 25 years with Morgan Lewis, David left the practice of law to become CEO of Principia Pharmaceutical Corporation, and then negotiated the sale of Principia to Human Genome Sciences, Inc. In 2001, he became president of Delsys Pharmaceutical Corp., a drug delivery company that was acquired later that year by Elan Corporation. Thereafter, David became a co-founder and the CEO of BioRexis Pharmaceutical Corporation, which was acquired by Pfizer, Inc. in 2007. After the sale of BioRexis, David became a venture partner with Quaker Partners, a life sciences venture capital firm with \$700 million under management, investing in the Mid-Atlantic region of the US. David retired from Quaker in March 2013, and is currently an advisor to Atonarp, Inc., a Japanese company that produces chip-scale and miniaturized spectrometer for use in multiple applications.



Sean McDonald

Sean McDonald, Precision Therapeutics' President and CEO, has dedicated the past decade to developing innovative technology with the goal of improving outcomes

for cancer patients. Because of Sean's passion, leadership and vision, Precision Therapeutics remains at the forefront of personalized diagnostics and research for individualized cancer therapy. Precision offers the most comprehensive personalized medicine solution today through a portfolio of products developed to help guide physicians and patients with difficult clinical decisions throughout the cancer care continuum in multiple tumor types. Sean's commitment to improving the quality of healthcare through unique technology development is highlighted in his role as a board member of the Pittsburgh Technology Council and as board member of the Pittsburgh Regional Health Initiative. In addition, he serves as an overseer for the School of Engineering at the University of Pennsylvania.



Steven Nichtberger, M.D.

Dr. Nichtberger is a serial entrepreneur with 20 years of healthcare and industry experience focused on developing and

commercializing breakthrough medical advances. Introduced to ControlRad as a potential investor, his interest in the business opportunity led to his investing and becoming Chairman and CEO. He is also managing partner of GBF, LLC providing advisory services to healthcare companies, investors, and leading academic scientists to maximize the value of breakthrough advances. As a senior fellow and adjunct professor at the Wharton School, he leads the Vagelos Life Sciences & Management capstone course on healthcare company formation, financing, and leadership. From 2004-2011, he was the founding CEO of Tengion (TNGN), advancing novel regenerative medicine products from early stage research to late stage clinical trials. During his tenure, the company raised \$230MM (including an IPO) from leading public and venture investors, as well as strategic investments from

J&J and Medtronic. Novel regulatory approaches, manufacturing facilities, and clinical pathways were created with FDA under his leadership. Previously, Dr. Nichtberger held senior strategic and operating roles at Merck. As head of global marketing for the company, he was responsible for marketing strategy on all Merck brands globally.



H. Joseph Reiser, Ph.D.

Dr. Reiser received his Ph.D. in Physiology, Masters, and Bachelor of Science degree from Indiana University School of Medicine. Dr. Reiser has more than 32

years of pharmaceutical and biotech experience in both public and private companies. He served as President, Chief Executive Officer and a member of the Board of CureDM Inc., a privately held biopharmaceutical company focused on the discovery and development of new therapies that ameliorate or reverse diabetes. From 2003-2008, he was President and Chief Executive Officer and member of the Board of Locus Pharmaceuticals, a small molecule-oriented oncology company. From 1998 to 2002, Dr. Reiser served as President, Chief Executive Officer and member of the Board of Cytogen Corporation, a NASDAQ-traded product based Oncology Company. Prior to joining Cytogen, Dr. Reiser was Corporate Vice President, General Manager, Pharmaceuticals and member of the Board of directors for Berlex Laboratories, Inc., the U.S. subsidiary of Schering AG. During his 17-year tenure at Berlex, he held numerous senior leadership positions, including serving as the first President of Schering Berlin's Venture Corporation. He has served on numerous Boards and as Chairman of the New Jersey Biotechnology Council from 2001 to 2002.



Paul Touhey

As President/CEO and member of the Board of Directors of Fujirebio Diagnostics, Inc. (FDI), Paul Touhey leads the world's premier cancer diagnostics

company. Touhey brings more than 25 years of industry experience to the position, in which he is responsible for the company's growth in the

competitive in vitro diagnostics industry. Touhey is also a member of the Board of Directors of Fujirebio Inc., the Tokyo-based parent of FDI.

Touhey joined FDI, formerly Centocor Diagnostics, in 1985, where he has held a variety of positions including Senior Vice President of Operations. Prior to FDI and Centocor, Touhey worked for Johnson & Johnson in a variety of positions with increasing levels of responsibility and management. Touhey is past Chairman and current member of the Board of the Medical Device Manufacturers Association (MDMA), a national trade association representing the entrepreneurial sector of the medical device industry in the United States, and is a member of the FDA/Industry Grass Roots Task Force. Touhey established the Companies of Caring Campaign with the Community Volunteers in Medicine, a Chester County charity focusing on providing medical care to the uninsured, and is a member of the Freedom Valley YMCA Board of Directors.



Christopher Yochim

Chris has global responsibility for External Relations to drive awareness of AstraZeneca's areas of partnering interest. The goal is to establish AstraZeneca as a Preferred

Partner within the biotechnology sector, venture capital & academic community. GPPS is leading the delivery of one of AstraZeneca's business priorities, Externalization, to improve growth prospects by accessing external opportunities. The function is globally integrated across the business and has established a leading edge capability in Licensing, Mergers & Acquisition, and strategic collaboration. Chris has 18 years experience leading technology transfer and academic relations at the North America Headquarters in Wilmington, Delaware. Chris is a founding member and Chairman of the Board of the Delaware Bioscience Association. He is a former member of the Executive Committee of the Board of Trustees of the Association of University Technology Managers (AUTM), and served as Vice President for Eastern US Region (2006-2007). As an active volunteer in AUTM, Chris founded and chairs the AUTM Sponsorship Committee for the past 8 years. Locally, Chris serves on The Japan America Society of Greater Philadelphia. 

Membership News

Pittsburgh-Based Start-Up Receives National Exposure

Jamie Quintero is one of three 20-something Carnegie Mellon University graduates who co-founded Pittsburgh-based PECA Labs. The team has developed a pediatric heart valve that would help an estimated 3,200 children born annually with a specific birth defect to avoid multiple open heart surgeries.

The MASA Valve is a synthetic valved conduit for pediatric RVOT reconstruction. The device utilizes the material properties of ePTFE and an RVOT-specific valve design to alleviate the problems with currently available conduits.

In his quote to the Pittsburgh Post-Gazette, which ultimately went viral and lead to a coveted segment on Fox Business Network, Quintero perfectly captures the spirit of entrepreneurship. “No matter what froufrou titles we have, we still take turns cleaning the bathroom.”

According to a feature about the company in the Pittsburgh Post-Gazette, the PECA Labs entrepreneurs often work seven days a week amid bare furnishings, eating at their desks (one of them occasionally naps on a pullout sofa bed after an all-night work session), while earning what one described as “survival wages.”

It may seem an improbable scenario for advancing the complex world of medical devices. But in three short years, the young men -- CEO Doug Bernstein, 23, from Los Angeles; COO Jamie Quintero, also 23, of New York City; and Arush Kalra, 26, a pediatric urology resident surgeon in New Delhi, India, before enrolling at CMU -- have assembled an impressive army of supporters.

In July, the tech startup booster Innovation Works committed \$250,000 to PECA Labs, and it has connected them with mentors to help them navigate regulatory and fundraising waters.

The story caught the attention of Fox Business Network, and Doug Bernstein was featured on the program “Markets Now” in late August.

Bernstein shared the three aspects that make PECA Labs a success. The first is the company’s lean, agile business model; second, they have utilized recent changes to the FDA’s Humanitarian Device Exemption Program, which provides an expedited regulatory pathway to approval for pediatric humanitarian use devices; and third, they aren’t inventing devices from scratch.

“We’re translating surgeon-created devices,” said Bernstein. “Because of the nature of working with rare pediatric diseases, there usually aren’t sufficient solutions available to treat these patients. Doctors have to innovate in the clinic, and we’re working with them to bring those solutions out to the market.”

According to Bernstein, each MASA Valve can be produced for about \$1,000 and the retail price is expected to be about \$10,000. Since appearing on Fox Business, PECA Labs has seen an uptick in website traffic and received multiple inquiries from prospective investors. ☐

Sources: <http://www.post-gazette.com/stories/business/news/three-young-entrepreneurs-are-working-to-develop-a-heart-valve-for-children-698235/>; <http://pecalabs.com/#everyone-section2>; http://video.foxbusiness.com/v/2636904443001/students-design-heart-valve-for-children/?playlist_id=937116503001

*“No matter what
froufrou titles
we have, we still
take turns cleaning
the bathroom.”
– Jamie Quintero*

Saladax and Iroko Establish Commitment to Pennsylvania Life Sciences Community

Companies upgrade to Pennsylvania Bio Leadership Level Membership

Bethlehem-based Saladax Biomedical and Philadelphia-based Iroko Pharmaceuticals recently upgraded to Pennsylvania Bio's Leadership member status.

PA Bio's Leadership Level Members are companies that demonstrate interest in fostering the growth of the life sciences in Pennsylvania along the entire spectrum of activities supported by the Association. To create a cohesive life sciences community in the Commonwealth, Leadership Level Members help unify the strengths in biotech, pharma, diagnostics, devices, research and finance, while making Pennsylvania the most attractive location in the United States to open and operate a life sciences company. PA Bio needs the financial support to execute its two core accountabilities of policy advocacy (lobbying in Harrisburg and Washington, DC) and facilitating strategic connections between members and with group purchasing programs.

"Charting a course through today's complex healthcare environment cannot be done in a vacuum," said Kevin M. Harter, President and CEO, Saladax Biomedical, Inc. "Collaboration, advocacy, and communication are essential in developing a solid strategy for Saladax. PA Bio helps facilitate our involvement in all three of these areas."

Saladax is a leader in the development and deployment of high quality diagnostic services and products, delivering actionable data to help physicians select and optimize the use of current and new pharmaceutical products, with the goals of improving health and



positively impacting the economics of care. Saladax also serves as a valuable collaborator for pharmaceutical and biotechnology companies in the development of companion diagnostics (CDx), addressing multiple risks and challenges encountered in drug development.

Iroko is a global specialty pharmaceutical company dedicated to scientific advancements in analgesia. The company acquires, develops and globally commercializes currently marketed products. In addition to the Iroko products that are marketed worldwide, the company has a robust pipeline of late-stage submicron NSAID product candidates using the proprietary SoluMatrix™ platform. These submicron NSAIDs are being developed using iCeutica Pty Ltd's SoluMatrix™ technology, licensed to Iroko for exclusive use in NSAIDs. [O](#)

Special Welcome to Our Q3 New Members

ATHS, Inc.

AUM Life Tech

Avidas Pharmaceuticals

BioEntrep

Biomedical Systems

Cerecor, Inc.

Decon Laboratories

Drinker Biddle & Reath LLP

Fidato Partners, LLC

Graphene Frontiers LLC

InteguRx Therapeutics

Iroko Pharmaceuticals

Mid Atlantic Employers' Association

NorthPoint

Organogenesis Inc.

Packaging Coordinators

PDS Biotechnology Corp

PMV Pharma

The Patient Experience Project

The STEM Academy

Veeva Systems

Auxilium Hosts French Delegation, Promotes Pennsylvania as Ideal Location to Establish and Expand Operations

Auxilium Pharmaceuticals hosted the Rhône-Alpes Regional Council at their U.S. headquarters in Chesterbrook on July 18, 2013. An impressive representation of elected officials, educators, company executives and economic development representatives convened to encourage Pennsylvania as the premier location to establish or expand international operations.

The visiting delegation was led by Jean-Jack Queyranne, President of the Rhône-Alpes Regional Council. Rhône-Alpes is one of France's 22 administrative regions, similar to states in the U.S.

Adrian Adams, President and CEO of Auxilium, welcomed the delegation and served as the representative of the life sciences industry in Pennsylvania.

"I was pleased to welcome the Rhône-Alpes Regional Council to our headquarters in Chester County," said Adams. "This area is a wonderful place to live and work, and we encourage companies from around the world to consider Pennsylvania when expanding operations."

Natalia Dominguez Buckley of the Pennsylvania Department of Community & Economic Development shared an overview of Pennsylvania's International Business perspective.

"Currently, Pennsylvania is third in the northeastern U.S. and ninth out of all U.S. states in the total number of foreign-owned firms," said Dominguez Buckley. "More than 1,400 foreign-owned firms operate in Pennsylvania. These firms employ more than 249,400 individuals, comprising nearly 5 percent of the state's private sector workforce."



Mary Frances McGarrity, Director of Business Development for the Chester County Economic Development Council (CCEDC) addressed the delegation regarding the region's strengths and opportunities.

"Our region serves as a hub for life sciences companies. The diversity of businesses coupled with the support of the area's colleges and universities have created a confluence of activity and employment," said McGarrity. "This environment heralds the potential to create a more vigorous pipeline for new products and a qualified workforce."

Representative Warren Kampf (R-157), Life Science Caucus Co-Chair,

emphasized the importance of the industry. The life science industry in Pennsylvania directly employs nearly 80,000, with total employment impact of nearly a half of a million jobs and economic impact from wages alone totaling \$8.15 billion.

Pennsylvania offers a variety of business incentives, including job training grants, low interest loans, tax credits and abatements and venture capital. The state has invested \$120 million to support life sciences activity, leveraging an additional \$3.2 billion of private investment.

"As a co-chair of the Life Science Caucus,

I continue advocating for tax policy and initiatives that advance research and development within the life sciences economy here in the Commonwealth," said Kampf. "Innovation here helps my constituents, promotes entrepreneurial activity across the state, and can make great strides in the treatment and toward the cure of some of our most lethal diseases."

Pennsylvania is uniquely positioned to offer the entire bioscience ecosystem in one location through seed capital, discovery research, emerging industry, contract laboratory organizations, medical devices and diagnostics companies, mature biopharmaceutical industry and global pharmaceuticals. 

Drexel University supports Pennsylvania's Innovation Economy with Plans to Transform the Modern Urban University

Positioned to be the preeminent university located at a major national transportation hub, Drexel University seeks to become one of the country's most dynamic and inviting urban universities – an essential civic, intellectual, and business partner, and a welcoming physical gateway to Philadelphia. The university outlines its roadmap for “Transforming the Modern Urban University” in its 2012-2017 Strategic Plan, and has already made significant progress to deepen its innovation culture.



In a mixed-use setting that brings robust education and research institutions together with the commercial sector, Drexel aims to anchor a vibrant Innovation Neighborhood in University City.

“In the University’s Strategic Plan,” Drexel states, “We will continue to work with citizens, businesses, entrepreneurs, and government leaders to become a centerpiece of innovation, technology, globalization, and economic development. Our first step will be to create an attractive and exciting front door to Drexel’s University City Campus at Philadelphia’s 30th Street Station – one of the United States’ most important train stations, connecting New York, Washington, and the entire East Coast.”

Drexel has already made significant strides toward becoming a hub for innovation and job creation. In July, the university launched Drexel Ventures – an organization dedicated to supporting Drexel faculty, students, alumni, and regional entrepreneurs seeking to start new companies and fostering economic growth and development in the Greater Philadelphia region.

Drexel Ventures provides funding and expertise to manage the invention disclosure process, determine patent and market viability, accelerate translational research, provide entrepreneurial co-ops, support and partner with area incubators and accelerators, provide seed funding to start-up organizations,

expedite licensing for small businesses, and facilitate the ability of Drexel faculty to compete for and undertake contract propriety research.

The Charles D. Close School of Entrepreneurship marks an additional advancement toward Drexel’s innovation initiative. Established in January through a \$12.5 million gift from the Charles and Barbara Close Foundation, the Close School will help drive the expanded culture of entrepreneurship envisioned in the Strategic

Plan. As the only freestanding school of entrepreneurship in Philadelphia, the Close School will be the gateway through which student entrepreneurs begin their journeys to becoming leaders in the 21st century innovation economy.

In fall 2013, the Charles D. Close School will establish its presence with programs including an “Entrepreneurship Living-Learning Community,” where like-minded students will live in a residential environment dedicated to entrepreneurship programming; “Entrepreneurship Co-ops,” offering mentoring and financial support to students who spend a co-op period developing their own business idea; and a “Launch It” course that provides students with guidance and seed money to “de-risk” their own business models.

Over the next few years, Drexel will continue building on the successes of its Innovation Neighborhood – solidifying the region as an anchor of company formation and job creation. ◻

Source: Drexel University Strategic Plan (http://www.drexel.edu/ia/roundtables/doc/strategic_plan.pdf) and Drexel News (<http://drexel.edu/now/news-media/releases/archive/2013/January/Close-School-of-Entrepreneurship/>)

ChemoFx[®] Test Identifies Platinum-Resistance in Primary Ovarian Cancer Patients

New research shows Precision Therapeutics' ChemoFx[®] could provide clinically valuable information about an individual patient's prognosis.

Research led by Thomas C. Krivak, M.D., Assistant Director of Gynecologic Oncology and Director of Clinical Research in Gynecologic Oncology at West Penn Allegheny Health System, supported Precision Therapeutics' ChemoFx[®] as a tool to aid in the identification of platinum resistance in primary ovarian cancer.

Platinum-based combination therapy is the standard of care in treating women with primary ovarian cancer. While most women will initially respond to first-line treatment, the vast majority will eventually relapse. Platinum status is classified at the time of relapse and aids in determining future prognosis and subsequent treatment strategies.

ChemoFx[®] is a drug response marker that quantifies an individual gynecologic cancer patient's probable tumor response to various chemotherapeutic and biologic agents—providing both sensitivity and resistance information. While not intended to replace standard of care therapy, ChemoFx[®] provides valuable insights that help guide physicians' treatment decisions and give both physicians and patients an edge against gynecologic cancer.

In Krivak's observational, multi-site study, 276 women with ovarian cancer were treated with carboplatin/paclitaxel, following cytoreductive surgery, and association of progression-free survival with ChemoFx[®] assay results for carboplatin or paclitaxel was analyzed individually and jointly. Tumors that were resistant to carboplatin in vitro were associated with an increased risk of disease progression compared to those that were sensitive (HR=1.87, p=0.0009). This finding was independent of other clinical covariates in multivariate analysis (HR=1.71, p=0.013). A similar trend was also observed in patients that showed in vitro



Precision Therapeutics[®]
The Science of Individualizing Cancer Therapy

resistance to both carboplatin and paclitaxel (HR=1.66, p=0.017). Knowing which patients are more likely to experience early recurrence on platinum-based therapy prior to treatment can help physicians with developing effective treatment plans.

“Each and every patient's cancer is unique. We believe in ensuring every patient receives treatment that is customized to his or her individual needs,” said Sean McDonald, President and CEO of Precision Therapeutics, Inc. “We aim to support physicians in their treatment decisions and improve the chances for a better quality of life for those living with cancer.”

Precision Therapeutics, a leading life sciences company in Pittsburgh, is dedicated to utilizing precision medicine for personalized cancer care. Precision offers a portfolio of products developed to help guide physicians and patients with difficult clinical decisions throughout the cancer care continuum. 

Source: <http://www.bizjournals.com/pittsburgh/news/2013/07/11/value-of-precisions-test-shown.html?page=all>, <http://www.wpahs.org/news/7-11-2013/research-allegheeny-health-network-physician-finds-test-developed-locally-accurately-p>, <http://www.chemofx.com/>

Ursinus College hosts Executive Director of Institute on Science for Global Policy

Ursinus College's Center for Science and the Common Good hosted Dr. George Atkinson on September 16, 2013 at Ursinus' campus. Dr. Atkinson is the Executive Director of The Institute on Science for Global Policy (ISGP) and former Science and Technology Advisor to U.S. Secretaries of State Colin Powell and Condoleezza Rice. Dr. Atkinson shared his knowledge on bridging the gap between science and public policy.

Dr. Atkinson has pioneered a format for international conferences in which distinguished scientists present policy makers a range of options available for addressing a major geopolitical or security issue. In his format, the scientist fields questions from legislators, business leaders, and NGO executives in attendance. After participants find common ground from understanding and action, deliberations and action plans are released for public consideration. These critical debates are believed to be essential to formulating and implementing effective public policy.

The ISGP was founded in 2008 by Dr. Atkinson and focuses on balancing the urgency of addressing immediate science and technology challenges with the patience to accurately incorporate emerging and "at-the-horizon" science and technology advances into longer-term policies. More specifically, Dr. Atkinson believes that by involving students in these debates, the ISGP exposes them to the often challenging processes that underlie the decision involving science and technology.

Dr. Atkinson hopes to create conferences organized by undergraduate students, which will bring together policy makers and scientists. An upcoming conference is scheduled for April 11-12, 2014, and the topic will be infectious disease preparation in the Delaware Valley. ◊

CIMA Technology, Inc. Moves to Larger Facility in Pittsburgh

CIMA Technology, Inc. recently expanded into a larger facility in Pittsburgh. The company manufactures and distributes ophthalmic products for the international market. CIMA designs, manufactures, and distributes intraocular lenses, visco-surgical devices, and ophthalmic solutions for patients with cataracts or retinal diseases. The manufacturing and technical teams are dedicated to bringing innovative products to ophthalmologists worldwide. In addition to the company's own product line, they offer development and manufacturing opportunities under OEM arrangements. ◊

Source: <http://www.cimatechinc.com>



Onconova Therapeutics Completes Initial Public Offering

Onconova Therapies Inc., a biotechnology company that is developing new cancer therapies, closed its initial public offering in late July. The net proceeds from the IPO totaled \$79.6 million.

They sold slightly more than 5.94 million shares of common stock at \$15 a share. This also included 775,000 shares for overallotments.

Onconova is known for its development in small molecule drug candidates to treat cancer.



The company is currently developing rigosertib, an inhibitor for P13K and PLK pathways, and it has been successful in several indications. This late-stage cancer drug is continuing to be tested in Phase II and Phase III clinical trials. With 270 patients in the lead trial that took place in May 2013, they expect to report high survival rates in the first quarter of 2014. In MDS patients for the Phase I/II study, there were 12 objective responses took place out of 30 participants, which were bone marrow responses. ◊

Source: <http://www.bizjournals.com/philadelphia/blog/craig-ey/2013/07/biopharm-company-completes-ipo.html>

Penn State Hershey Champions Innovation with Groundbreaking Research and Life-Saving Discoveries

Penn State Hershey College of Medicine has recently made headway towards becoming a national leader in pursuing scientific investigation and developing programs to advance medical and scientific knowledge. The Central PA-based research institution developed a cancer therapy that removes malignant cells from a patient's cerebrospinal fluid, which may soon be available to prevent metastases and decrease complications of cancers involving the brain.

Many cancer types metastasize to the brain -- including breast cancer, pancreatic cancer, prostate cancer and leukemia -- but by filtering these malignant cells out of the cerebrospinal fluid (CSF), the researchers hope to decrease the chance of cancer spreading toward and away from the brain.

Penn State researchers collaborated with Wafik S. El-Deiry, American Cancer Society Research Professor; Rose Dunlap, Professor, Chief of the Hematology/Oncology Division and Associate Director for Translational Research, Cancer Institute; and Michael J. Glantz, Professor of Neurosurgery, Medicine and Neurology.

The National Institutes of Health, the American Cancer Society and start-up funds from the Penn State Hershey Cancer Institute laboratory supported this work.

Penn State's Office of Technology Development works with Penn State College of Medicine and Penn State Milton S. Hershey Medical Center to facilitate translation of such life-saving discoveries to market.

"Any discovery that can provide better treatment or prevention of disease is always exciting," said Keith Marmer, Associate Dean for Research Innovation, Penn State College of Medicine. "Penn State Hershey performs groundbreaking research which can take years before reaching patients. While some discoveries

won't make it to market successfully, we evaluate every invention and work hard to support their commercialization in a myriad of ways."

Penn State Hershey supports development of life-saving therapies in three key ways. First, every invention is rigorously analyzed as to if and how it can be further developed into a commercial product or service. This includes analysis by business experts, scientists, intellectual property attorneys and investors. This analysis is conducted both on an individual basis and by an external advisory board.



Second, Penn State works with faculty, staff and students to help them understand and navigate the complexities of moving a discovery from the lab to the patient bedside. The college provides a number of education, training and mentoring programs.

And third, Penn State Hershey collaborates very closely with industry partners to transfer technologies from the university to the commercial realm. This includes licensing a discovery as well as forming a new company that can attract further investment to bring a discovery to market. 

Sources: <http://news.psu.edu/story/282970/2013/07/30/research/technique-filters-cancer-where-chemo-cant-reach>

Regional Events: Anniversaries Abound

Three major organizations advancing technology innovation in Pennsylvania celebrate important milestones this year. The Ben Franklin Technology Partners, University City Science Center, and Safeguard Scientifics are dedicated to fostering Pennsylvania's innovation economy.

Safeguard Scientifics Celebrates 60 Years

For 60 years, Safeguard has been synonymous with entrepreneurship and innovation. Founded in 1953, Safeguard has a distinguished record of building market leaders by providing capital and operational support to entrepreneurs across an evolving and innovative spectrum of industries.



When choosing companies to partner with, Safeguard picks entrepreneurs and visionaries who are pushing the boundaries for innovation. Safeguard's current management team has deployed more than \$351M of capital in its partner companies since January 2006. Throughout its 60 year history, Safeguard has successfully completed more than 100 M&A transactions and more than 20 IPOs. Safeguard continues to build value in tomorrow's market leaders. ◻

The University City Science Center Celebrates 50 Years



The oldest and largest urban research park celebrated with several highlights including a new 50th anniversary logo, hosting of the Association of University Research Parks (AURP) International Conference in September, a call for nominations for a regional Innovators Walk of Fame, and a 50th anniversary celebration set for October 17, 2013.

"As we embark on our 50th anniversary, we have two goals," says Science Center President and CEO Stephen S. Tang, Ph.D., MBA. "Not only do we want to honor our past, and the scores of innovators who have walked our halls and toiled in our labs, but we want to look ahead to the future of innovation in our great region."

The Science Center pioneered the concept of business incubation. Graduate organizations and current residents of the University City Science Center's Port business incubators have created more than 15,000 jobs that remain in the Greater Philadelphia region today and contribute more than \$9 billion to the regional economy annually. ◻

Ben Franklin Technology Partners Celebrates 30 Years

To help commemorate this milestone, Ben Franklin Technology Partners hosted a celebration at the Harrisburg Institute of Science and Technology. Governor Tom Corbett and former Governors Dick Thornburgh and Tom Ridge made opening remarks.

"Ben Franklin Technology Partners (BFTP) is a leading example of the benefits of technology-based economic development, illustrating the positive impact government investment in innovation can have on entrepreneurship and economic growth," notes Robert Atkinson, President of the Information Technology and Innovation Foundation (ITIF) "Over its thirty year history, BFTP has been a major catalyst in the development of the modern high-tech economy and I am confident they will continue to play a major role in the development of next generation technologies, businesses and industries."

BFTP has played a central role in Pennsylvania's transition to a globally competitive knowledge economy. The success of BFTP's portfolio clients ripples throughout Pennsylvania's economy, contributing to new jobs, new growth, new investments and higher Gross State Product. ◻

Sources: <http://benfranklin.org/>, <https://www.sciencecenter.org/>, <http://www.safeguard.com/>



Advocacy Update

We Work for Health Hosts Co-Chair Summit in Washington D.C.

We Work for Health (WWFH) hosted its co-chair summit July 17-18 at the Liason Hotel in Washington, D.C. We Work for Health seeks to educate elected officials, members of the media and the communities they serve about the regional economic impact of biopharmaceutical companies and their employees.

This two-day event was held to discuss life science industry priorities with members of Congress. The summit included productive meetings and informative sessions with co-chairs from across the country, and was the first time all We Work for Health states were able to come together for discussion.

On July 17, the summit hosted high level speakers, including Robert Hugin, Chairman of the Board of Directors at PhRMA and CEO of Celgene, and John Castellani, President and CEO of PhRMA. Discussions featuring expert panelists focused on two topics of interest: “The Federal Landscape: An Industry Perspective” and “Medical Innovation Landscape: A Hill Perspective.” Christopher Gahan, Senator Toomey’s Chief of Staff, offered inside-the-Capitol perspective as a participant on the medical innovation panel.

The second day gave the state co-chairs time to meet with elected officials to discuss key policy items impacting the industry, including Medicare Part D Rebates, Medicare Part B Reimbursements, IP Protections for International Trade Agreements and IPAB Repeal.

Christopher P. Molineaux serves as Pennsylvania Co-Chair of We Work for Health with Gene Barr, President & CEO of the Pennsylvania Chamber. ◊

Despite Gridlock in D.C. Life Sciences Remain a Priority

Casey, Patients and Researchers Push to Restore Job-Creating NIH Funds Gutted by Sequester

In August, U.S. Senator Bob Casey (D-PA) pushed to restore job-creating NIH funding that was gutted by the sequester. At the American Cancer Society Cancer Action Network in Philadelphia, Casey detailed the impact that these cuts have on patients and the region’s economy.

“There are many reasons to invest in medical research, but the two most important reasons are: it saves lives, and it creates jobs,” said Senator Casey. “We simply cannot afford, from a public health or an economic standpoint, to ignore medical research.”

The NIH is our country’s premier institution for medical research. NIH research has a significant economic impact, directly supporting hundreds of thousands of researchers, assistants and other lab and administrative staff, while indirectly supporting even more jobs in the fields of pharmaceutical and medical device research, development and manufacturing.

In 2012, Pennsylvania researchers received \$1,431,589,539 (\$1.4 billion) in grants from the National Institutes of Health; the state is ranked 4th in the nation for the number of grants awarded. This funding supported over 3,400 competitive grants to almost 100 Pennsylvania companies or universities; in turn, these grants supported thousands of jobs across the state – an estimated 2,500 in-state jobs and total employment of more than 24,000 jobs. ◊

Source: <http://www.casey.senate.gov/newsroom/releases/casey-patients-and-researchers-push-to-restore-job-creating-nih-funds-gutted-by-sequester>

Senator Casey, PA Bio Assemble Life Science Executives to Discuss State of the Industry



Senator Casey discusses the state of the life sciences with Mel Billingsley (left) and Maxine Gowen (center)

As the statewide trade association dedicated to promoting strategic engagement between the Pennsylvania life sciences industry and key stakeholders, Pennsylvania Bio hosted a roundtable discussion in July with U.S. Senator Bob Casey (D-PA) and a representative cross-section of executives from member organizations.

Sen. Casey asked PA Bio to convene the group to discuss the state of the industry and priority issues to generate a favorable

landscape for the life sciences industry to create jobs and advance research.

The group discussed the following issues influencing the life sciences industry:

- Medical Device User Fee Amendments of 2012 (MDUFA III) – The FDA is authorized to collect user fees from medical device companies that will total approximately \$595 million over five years. With this additional funding, the FDA had intended to hire more than 200 full-time-equivalent workers. However, as a result of sequestration, companies are still paying the fees, but are not seeing the efficiency in responses as the agency experiences cutbacks.
- Acceleration of the Orphan Drug approval pathway and opportunities for connecting shelved assets of large pharmaceutical companies with smaller research companies – This area presents a real opportunity in Pennsylvania to create jobs and deliver breakthrough therapies to patients.
- FDA reauthorization - In 2012, the fifth authorization of the Prescription Drug User Fee Act (PDUFA V) occurred. This provided the FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biological products. Highlights include enhanced benefit-risk assessment and more transparent communication between the FDA and sponsors.

- The JOBS Act - This helps emerging growth companies as they seek entrance to the public market by allowing them five years to invest in research efforts prior to undertaking the costly compliance measures associated with Sarbanes-Oxley.

Sen. Casey has been a leading supporter of National Institutes of Health (NIH) funding, leveraging his position on the Committee on Health, Education, Labor and Pensions (HELP Committee) to champion innovation in the industry. He is a co-sponsor of the Medical Device Access and Innovation Protection Act that seeks to repeal the 2.3% medical device excise tax.

The life sciences community will continue to work with Sen. Casey toward a shared goal – ensuring Pennsylvania is a global leader in the life sciences. ◊

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Senators Toomey & Casey, Representative Gerlach: Ensure Development Of Treatments For Rare Diseases

U.S. Senator Bob Casey (D-Pa.) joined Senator Pat Toomey (R-Pa.) in introducing legislation to ensure the development of treatments for rare diseases is not jeopardized. Representatives Jim Gerlach (R-Pa.) and Richard Neal (D-Mass.) sponsored the companion measure in the House.

The bipartisan Preserving Access to Orphan Drugs Act of 2013 eliminates unnecessary regulatory hurdles placed on the development of innovative new therapies for rare diseases and conditions.

“With 30 million Americans suffering from a rare disease, it is important to ensure that the development of treatments and cures for these diseases is not inhibited,” Senator Casey said. “This is a responsible step to make certain that current law won’t threaten development of treatment or jeopardize care.”

“The government should be encouraging the development of treatments for rare diseases, not imposing additional fees on those badly needed medicines,” Sen. Toomey said. “In Pennsylvania, many of our life sciences companies are working on developing orphan drugs, but due to a narrow provision in the president’s health care law, some will be hit with additional fees. Our bipartisan legislation will rectify this problem, and we hope it will lead to the development of many new treatments and save lives.”

“The goal here is to make sure patients with rare diseases have access to the treatments with the amazing potential to extend and improve their lives,” Rep. Gerlach said. “In addition, the legislation would allow our life sciences companies to continue investing in the development of groundbreaking

research that will hopefully lead to new, innovative treatments. That’s important to preserving existing jobs in our Commonwealth and creating new ones.”

The president’s health care law created a fee on the sales of brand name drugs. While the legislation intended to exempt drugs targeting rare diseases, or orphan drugs, the Treasury Department issued a narrow interpretation that left some orphan drugs susceptible to the fee. The Preserving Access to Orphan Drugs Act of 2013 corrects this inequity and would exempt orphan drugs from the pharmaceutical fee if they have received an FDA indication solely for one or more rare diseases. ◊

Source: http://www.toomey.senate.gov/?p=press_release&id=1065

“Innovate in PA” to Provide Funding for Emerging and Early-Stage Companies

The “Innovate in PA” initiative was signed by Governor Corbett in July and will support company formation and retention in the Commonwealth. Led by the collaboration between the Ben Franklin Technology Partners of Southeastern PA and the Greater Philadelphia Alliance for Capital and Technologies (PACT), the initiative’s goal is to increase investment capital for emerging and early stage technology enterprises.

The Innovate in PA tax credit program provides tax credits for insurance companies whose bids for those credits are expected to net at least \$75 million to address the seed capital needs of start-up companies and small businesses that are growing and expanding in Pennsylvania, and will

facilitate job growth, new patents and products, and increased tax revenues for the Commonwealth. The proceeds from the sale of the credits will be distributed through the Ben Franklin Technology Partners, the Ben Franklin Technology Development Authority’s Venture Investment Program and the Life Sciences Greenhouses.

Thank you to sponsors Representative Warren Kampf, Representative Joe Hackett, and Senator John Blake. ◊

Source: <http://www.sep.benfranklin.org/innovate-in-pa-tax-credit-program-will-propel-pennsylvanias-innovation-economy/>

Pennsylvania Bio Weighs In Regarding Proposed Revisions to CMS Hospital Outpatient Prospective Payment System (HOPPS)

Pennsylvania Bio weighed in on a proposed rule issued by the Centers for Medicare & Medicaid Services (CMS) that contains its annual proposed revisions to payment policies under the Hospital Outpatient Prospective Payment System (HOPPS). The particular area of concern was CMS' plan to bundle a diverse group of wound care products as "skin substitutes" for reimbursement purposes, regardless of their efficacy or regulatory approvals.

Under the proposed rule, several healing products used to treat patients would now be reimbursed as mere "supplies," contrary to CMS precedent with other therapeutics. This proposed payment structure would restrict patient access to cutting-edge healthcare by incentivizing hospitals to use less costly – and less effective – wound coverings instead of therapeutic products that have been proven under an FDA pre-market approval pathway. Under such a "bundled" arrangement, patient treatment options could become significantly limited, putting "practical matters" ahead of good medicine. The rule could result in longer hospital stays and increased healing time for patients.

This proposed HOPPS rule also would undermine the incentive to innovate and bring to market the kind of new medical products that require millions of dollars of research and development and lengthy FDA approval processes. Biotechnology sector jobs and venture capital investment might be negatively affected by such a revision, which essentially signals that CMS is implementing reimbursement policies that do not reimburse novel products.

Pennsylvania Bio wrote a letter to the Pennsylvania Delegation encouraging the members to take action and contact senior officials at HHS and CMS urging they have discussions with stakeholders. Pennsylvania Bio seeks to ensure that cost savings within the government do not come at a cost to patient care.

Biopharmaceutical and Medical Device Associations Strongly Support Senate Bill to Exempt FDA User Fees from Sequestration

In August, Sen. Mark Pryor (D-AR), chairman of the Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration and Related Agencies, and Sens. Roy Blunt, (R-MO), Daniel Coats (R-IN), Al Franken (D-MN), and Jerry Moran (R-KS) introduced S. 1413 to exempt future Food and Drug Administration (FDA) user fees from sequestration. A similar bill, H.R. 2725, was introduced in the U.S. House of Representatives earlier this month by Representatives Leonard Lance (R-NJ), Anna Eshoo (D-CA),

Mike Rogers (R-MI) and Doris Matsui (D-CA).

Pennsylvania Bio joined The Advanced Medical Technology Association (AdvaMed), Biotechnology Industry Organization (BIO), Generic Pharmaceutical Association (GPhA), Medical Imaging & Technology Alliance (MITA) and Pharmaceutical Research and Manufacturers of America (PhRMA) in praising Sens. Pryor, Blunt, Coats, Franken, and Moran for their efforts to prevent the sequestration of future FDA user fees and urged Congress to find a bipartisan solution for releasing sequestered FY13 user fees as Congress continues its work on the FY14 appropriations process.

Pennsylvania Bio, with elected officials in Washington, has expressed the industry concern regarding user fees. While the life sciences community has agreed to these increased fees under the promise of improving the FDA review process, under sequestration the fees are being paid but the promise has not been fulfilled.

PhRMA issued the following statement:

"Last year, Congress passed the FDA Safety and Innovation Act (FDASIA), which reauthorized the Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee Act (MDUFA), and created the Generic Drug User Fee Act (GDUFA) and Biosimilar User Fee Act (BsUFA). User fee levels were increased to provide much-needed improvements to the regulatory review processes at FDA in order to facilitate timely patient access to safe and effective new and generic medicines, medical devices and diagnostics.

"However, sequestration is preventing FDA from accessing nearly \$83 million in industry-paid user fees in the current fiscal year. These user fees cannot, by law, be used for any other purpose and their sequestration does not decrease the nation's deficit. Preventing FDA from fully accessing these user fees only serves to exacerbate the severe budgetary constraints of a historically underfunded agency, to the detriment of patients and public health.

"We call on the Congress to quickly consider and pass this important legislation and to continue to work to release the user fees from FY2013 which have been sequestered. ◊

<http://phrma.org/phrmapedia/press-room/biopharmaceutical-medical-device-associations-support-senate-bill-exempt-fda-user-fees-sequestration#sthash.bEzkDrqu.dpuf>

Programs

Preparing for the Sunshine Act: Program Helps Industry Leaders Strategize

PA Bio hosted a Special Interest Group Program on June 27th at Audubon-based BioClinica, a global provider of integrated, technology-enhanced clinical trial management services. Sponsored by Compliance Implementation Services (CIS), the event offered insights and best practices from compliance experts who are in the process of implementing a federal and state compliance and reporting program.

In February 2013, the Centers for Medicare & Medicaid Services (CMS) issued long-awaited final regulations relevant to Section 6002 of the Patient Protection and Affordable Care Act, also known as the “Physician Payment Sunshine Act.” The Physician Payment Sunshine Act requires applicable manufacturers of a covered drug, device, biological, or medical supply to report certain information annually to CMS regarding payments and other transfers of value provided to covered recipients. In addition, applicable manufacturers and group purchasing organizations (GPOs) are also required to report certain information annually to CMS regarding ownership or investment interests held by physicians and their immediate family members.

CMS provided a preparation period to applicable manufacturers and GPOs to implement the final regulations and begin collecting data. Applicable manufacturers and GPOs were required to begin data collection on August 1, 2013, and the first report is due to CMS by March 31, 2014. CMS plans to release the data on a public website by September 30, 2014.

In the weeks leading up to the August 1 data tracking deadline, PA Bio hosted a Special Interest Group program to help members develop successful strategies for accurate and compliant data collection and reporting.

Sponsored by Compliance Implementation Services (CIS), the program featured the following:

- **Key Data Requirements and Operational Challenges** – Identified gaps and remediated concerns for successful implementation



- **Ensure Compliance, Minimize Impact** – Align compliance program to the state mandates and ensure the reporting requirements are met with consideration to the exposure on the program
- **Cangene’s Journey to Compliance** – A manufacturer’s perspective on compliance requirements including a timeline on when to engage experts and resources
- **Panelist Roundtable and Audience Q&A** – Discussed the challenges and lessons learned in complying with regulations

Program speakers addressed Sunshine’s impact on the life sciences industry, providing practical solutions to the predominant issues and challenges that manufacturers face daily. Featured speakers included:

- Clarissa Crain, Vice President, Strategic Consulting, CIS
- Judy Fox, Director, Transparency Compliance, CIS
- Stephanie Kupski, Manager, Commercial Compliance, Cangene BioPharma

As a consulting firm focused on helping life sciences clients proactively manage complex compliance requirements, CIS offers a broad portfolio of services and solutions that expand deep into the clinical, manufacturing and commercial disciplines, and that align with clients’ strategic priorities and business operations. CIS continually provides leadership, global regulatory knowledge, industry experience and a problem-solving culture that responds to today’s compliance and commercial challenges.

CIS’ Emergent BioPharma Insights™ is a program for emerging companies that provides valuable training, up-to-date regulatory guidance, insights and best practices at each stage in the product lifecycle, from pre-launch through launch and commercialization. The program is designed to help companies achieve successful commercialization by educating executives on the processes needed for a compliant business and on the options available for commercial success. ◻

Source: http://www.ebglaw.com/files/55081_IHAIR_CMS-Issues-Final-Rules-on-Federal-Sunshine-Law.pdf



Christopher P. Molineaux, President & CEO of Pennsylvania Bio, addresses attendees at the Supply Chain Summit

PA Bio Collaborates with Delaware Bio to Present Supply Chain Summit

Pennsylvania Bio and Delaware Bio hosted the second annual Supply Chain Summit on September 10, 2013 at the Airport Hilton in Philadelphia. The summit featured panel discussions and speakers to highlight current supply chain challenges in the life sciences arena. In addition to the insights gained from the speakers, members of APICS (The Association for Operations Management) who are CPIM or CSCP Certified received 6 points towards their re-certification by attending this event.

Following introductory remarks by PA Bio President & CEO, Chris Molineaux, and Delaware Bio President Bob Dayton, Robin Hooker, Director, Global Healthcare Logistics Strategy, UPS, opened the day's presentations with "Pain in the Chain" - Trends in the Healthcare Supply Chain. Supply chain experts followed with three panel discussions, covering Technology and Systems, Sales and Operational Planning, and Risk Mitigation.

Denise Hudson, Former EVP, Enterprise Quality and Supply Chain of Endo Health Solutions, served as the keynote speaker.

Hudson talked about her experiences leading and implementing transformational change in a pharmaceutical supply chain, identifying some of the pitfalls and what can be done to ensure success.

Following the luncheon keynote address, attendees had the opportunity to tour the UPS East Coast Central Regional Air Hub, the second largest domestic air hub in the UPS network. This 1,000,000+ square foot facility turns 35 aircraft daily and is capable of sorting up to 120,000 packages per hour. It also supports the UPS' Customs Brokerage operations for both international imports and exports.

Attendees at the sold-out event included Vice Presidents, Managers and others who work in fields related to supply chain, procurement, transportation and logistics. The Supply Chain Summit was made possible by founding sponsor UPS, with co-sponsors VWR, Fisher Scientific, and APICS. ◊

BioBasics Course Seeks to Educate the Non-Scientist

Pennsylvania Bio hosted its fifth offering of the popular class on July 25-26th to familiarize non-scientists working in the life sciences industry about basic biotech terminology and principles.

This in-depth, two-day course for the non-scientist highlighted science and technology concepts, in easy-to-understand language, that are the basis of the biotechnology industry. Attendees learned about the science and technology driving the biotech and pharmaceutical industries, who the main industry players are, and how they interact.

The course was led by a credentialed BioTech Primer instructor equipped with the skills and experience to teach those with a wide variety of non-science backgrounds in an engaging environment. ◊

"Class material and instructor were very relevant to our CRO business. It opened my understanding of the pharma industry to a different level and the business opportunities that are there. This gives me more ammunition in my marketing endeavors of our company comprehensive services."

– S.K., President and CEO of a CRO

Q&A with Jim Greenwood, President & CEO of BIO

James C. Greenwood is President and CEO of the Biotechnology Industry Organization (BIO) in Washington, D.C., which represents more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO produces the annual BIO International Convention, the world's largest gathering of the biotechnology industry, along with industry-leading investor and partnering meetings held around the world.

In 2015, Philadelphia will host the BIO International Convention. Jim took time to answer our members' questions about the BIO 2015 planning process.



Jim Greenwood

What's going on with planning for BIO 2015?

I am very pleased the BIO International Convention will be returning to Philadelphia in two years. It's both my hometown and an important hub of America's bioscience industry. As part of our ongoing effort to ensure our convention continues to meet the evolving needs of the scientists and entrepreneurs we serve, I have recently implemented several strategic changes.

Foremost among these changes, BIO's Chief Operating Officer, Scott Whitaker, has assumed the added role of President of the BIO International Convention. We have conducted extensive opinion research and found that our members, attendees, exhibitors, and sponsors have new wants and needs. With Scott's help, we will be able to implement exciting changes within the Convention that will better deliver the experience they seek.

While our main focus is now on next year's BIO International Convention in San Diego (June 23-26), we are already working to bring together the key policymakers, scientists, CEOs, and celebrities that help make this the world's premiere biotechnology event, and the industry's largest and most diverse meeting.

We look forward to starting the planning process for BIO 2015 in Philadelphia before the San Diego convention concludes. An early start to the planning process will allow the local leadership

team from the Greater Philadelphia region to attend the San Diego meeting to gain an important perspective on how local community support is an essential element to the ultimate success of our convention.

How has the Convention changed since 2005, when it was last in Philadelphia?

The Convention has evolved in a number of positive ways over the years. Our team has worked hard to engage the interests of attendees from all areas of our industry. We have been pleased with the rapid increase in international attendance in recent years, reflecting the global growth of our industry.

One of the most visible changes at the Convention has been the dramatic growth of our one-on-one partnering sessions, which has more than doubled since 2005. Last year, companies held over 25,500 individual partnering sessions. These one-on-one meetings enable companies of all shapes and sizes to have better and more meaningful access to potential partners from all over the globe.

One of our newest additions is the BIO Buzz Center, which is the go-to news source for attendees to find out what's happening at the Convention. At last year's Convention, we video podcasted more than 40 industry leaders and three state Governors to get their thoughts on trends and issues affecting the industry.

What will the role of PA Bio be at the BIO International Convention 2015?

Pennsylvania Bio is an indispensable partner in our shared objective of promoting public understanding and advocating for public policies that support the continued development of our industry.

PA Bio will once again play a critical role in helping ensure the Philadelphia event exceeds the expectation of all attendees and exhibitors. As a member of the Convention steering committee, PA Bio will play a pivotal role in planning, directing and engaging the support of the local biotech industry.

Is there a local perspective?

It is important that we showcase Pennsylvania's life sciences industry, both during and leading up to the Convention. We will look to PA Bio to ensure we are engaging all the appropriate local organizations. It is also important to note that planning this convention will truly be a regional effort between Pennsylvania, New Jersey and Delaware. We look forward to working with our three strong partners, Pennsylvania Bio, BioNJ and Delaware Bio, to showcase to the world the key scientific advances and business opportunities that our region offers the global biotech industry.

We have a lot to be proud of, and this event truly puts our local industry in the spotlight among key thought leaders, academics, scientists and international dignitaries.

What will the economic impact of the Convention be on our local economy – specifically restaurants, hotels and local attractions?

Reflecting the large number of attendees and the high level of activity, the BIO

International Convention typically brings more than \$30 million in economic impact to the host city, including direct spending, tax revenue and hotel rooms.

What do you see as the biggest advantage to having BIO 2015 in Philadelphia?

Biotech is an important industry all across Pennsylvania, providing over 80,000 direct jobs. Aside from being a key hub for the biopharma industry, Philadelphia is

geographically situated near the center of the Northeast’s biotechnology corridor. This certainly factored in our decision to bring the Convention back in 2015.

You want your cheesesteak wit’ or wit’out?

Absolutely wit! ◊

Continued from page 1

Corbett visited Merck, GlaxoSmithKline, CSL Behring and ViroPharma. He held town hall meetings with employees and conducted question-and-answer sessions on a wide range of issues impacting the industry. He fielded questions about the 2013-2014 budget and his policies to grow and maintain the life sciences industry in Pennsylvania.

“Pennsylvania is fortunate to have a pro-active Governor who takes an interest and understands the importance of our industry,” said Charles Grezlak, Ph.D., Vice President, Merck State Government Affairs & Policy and member of the PA Bio Board of Directors. “The life sciences continue to be a significant economic driver for the Commonwealth with continued support from Governor Corbett and his administration.”

ViroPharma is an international biopharmaceutical company committed to developing and commercializing innovative products that address unmet medical needs. The company was founded by a small group of entrepreneurs in Downingtown nearly 20 years ago and currently has more than 200 Pennsylvania employees.

Corbett last year announced ViroPharma planned to double its space and hire an additional 151 employees. The expansion project was coordinated by the Governor’s Action Team and the Chester County Economic Development Council.

“ViroPharma is a true Pennsylvania success that continues to grow and create jobs in the region,” Corbett said. “The investments we make today to help our companies grow and create jobs for all Pennsylvanians will lead to a more stable and thriving Commonwealth for generations to come.”



Vin Milano, President & CEO of ViroPharma (center), hosts Governor Corbett at the company’s headquarters in Exton.

In addition to ViroPharma, Corbett praised the economic impact of companies like Merck, GlaxoSmithKline and CSL Behring. Headquartered in King of Prussia, CSL Behring is a leader in the plasma protein therapeutics industry and is committed to saving lives and improving the quality of life for people with rare and serious diseases. The company manufactures and markets a range of plasma-derived and recombinant therapies worldwide. CSL Behring currently houses 398 full-time employees.

“The life sciences industry is a cornerstone of our economy, and successful companies like CSL Behring are an important reason why manufacturing jobs in Pennsylvania have grown,” Corbett said. ◊

Source: <http://www.newpa.com/newsroom/governor-corbett-visits-life-science-employers-southeast-holds-town-hall-employees>

Showcasing Pennsylvania's Strengths at AdvaMed 2013: The MedTech Conference

AdvaMed, the leading MedTech Conference in North America, took place September 23-25 at the Walter E. Washington Convention Center in Washington, D.C. Representatives from Pennsylvania's life sciences industry attended the conference to showcase the state's resources for medical device companies.

The conference brought more than 1,000 companies together to learn about business development, capital formation, innovative technology, world-class educational opportunities, and networking. Over the course of the three-day event, there were more than 40 education panels organized into 11 different tracks including key health policies, legal, and compliance best practices.

CEOs took the stage to discuss the industry's most crucial issues by drawing on their personal observations and experiences. These unplugged sessions gave participants a chance to gain an understanding of the industry's biggest challenges and opportunities.

Along with the panels and CEO series, there were several special programs offered to niche markets. These programs included MedDevice Development, Entrepreneurship Boot Camp, MedTech Veteran Program (MVP), and Scientist Mentoring & Diversity Program. ◊



"AdvaMed 2013 in Washington DC was a great opportunity to meet with the MedTech industry leadership and understand major trends in public affairs, regulatory and compliance areas. Cerora was very pleased with the Featured Company presentation response we received from many in attendance and look forward to next year's meeting. PA Bio did a great job keeping us well informed."

– Adam Simon, President & CEO, Cerora, Inc

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he oversaw the commercialization and development of prescription pharmaceutical products and led the company through a strategic acquisition by global pharmaceutical leader Merck & Co., Inc. in May 2011.

Adams has extensive international and national experience and has been instrumental in launching major global brands, in addition to driving successful corporate development activities encapsulating financing, product and company acquisitions, in-licensing and company M&A activities. Adams serves as Chairman of the Board of AcelRx Pharmaceuticals and recently served as a director of Amylin Pharmaceuticals.

When asked about the behind-the-scenes aspect of a deal, McDonald emphasized the importance of personal connections and alignment.

"The stuff your mom taught you actually matters," said McDonald. "People always underestimate the personal factors involved in a deal. It's not all about economics; it's about people. They're proud of what they've built and want to find it a good home."

McDonald has dedicated the past decade to developing innovative technology with the goal of improving outcomes for cancer patients. ◊



President's Column

Building momentum toward 2015: Acquisitions, Expansion and Growth in Pennsylvania

As we review the accomplishments of our industry each quarter, I am continually impressed by the progress we've made toward our goal of ensuring Pennsylvania is the global leader in the life sciences.

The Commonwealth is home to a cohesive community working to ensure the success and advancement of the life sciences industry. Our strengths span a thriving entrepreneur community, leading research institutions, proactive economic development organizations, supportive policy makers and anchor tenants driving growth.

Pennsylvania is only beginning to receive the recognition and attention it deserves. Earlier this quarter, Business Facilities Magazine ranked Pennsylvania third in the nation in two key measures of Biotechnology Strength in its annual report. Pennsylvania was ranked sixth in the Business Facilities report two years ago, and while we are proud of our progress, we continue to strive for the #1 position.

In less than two years, Philadelphia will host the BIO 2015 International Convention, where our life sciences community will be showcased on a global stage. Our industry has achieved many accomplishments during the past twelve months that help us build momentum toward 2015. We've seen significant deals, acquisitions, expansions, discoveries and partnerships that contribute to Pennsylvania's position as a global industry powerhouse.

Our state's anchor tenants are consistently driving this industry growth. Auxilium expanded in Chesterbrook and acquired Actient Holdings LLC, creating a leading urology franchise with a diversified product portfolio and strong growth profile. BTG, a growing international specialist healthcare company with U.S. operations based in Conshohocken, announced back-to-back acquisitions of TheraSphere and EKOS in July. Endo Health Solutions acquired specialty generics company Boca Pharmacal, a move that is consistent with Endo's strategic transformation into a leading specialty healthcare company.

The list goes on, each accomplishment bringing us a step closer to achieving our goal. We will continue to build momentum toward 2015 and look forward to celebrating with you each success along the way.

Thank you for your continued support.

Christopher P. Molineaux
President & CEO, Pennsylvania Bio 

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