

NEWSLETTER







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President's Message: Like eating a bowl of Häagen-Dazs Pineapple-Coconut ice cream...

Dear Fellow Members

This is my last letter as your President as elections are coming up soon and there will be a new President by September. Like eating a bowl of Häagen-Dazs Pineapple Coconut ice cream (my favorite), it has been fantastic but when you get to the end you realize it is best if it does not continue forever. We did a lot of things I am pretty proud of, so allow me to brag for a moment.



We were more adventurous in our educational programming this year. We changed the content to include programs about the business side of working in the pharmaceutical industry

(Partnering with Outside Contractors, Leadership). In light of the economy we tried to focus on venues that were free to us so we could charge less and located them closer to you so you could attend without traffic or parking concerns. When we had to use more expensive venues we subsidized the programs. We had programs given by MIT and Tufts professors for the first time ever.

I think we were very successful at working with other groups. The Product Show now includes a GAMP meeting and participation from the ASME BPE. Shire asked for training of their newer employees on biotech and GMP basics and we did that with help from ISPE headquarters. We organized a dinner with the officers from other Chapters all over the country at the meeting in DC and got plenty of new ideas for next year.

We tried other ways to benefit our members as well. We bought custom Web site programming so now you can register on-line and pay with a credit card for all our events (and without using PayPal like some other Chapters do). Our Membership Services Committee had a "Marketing Yourself" event to help people find a new job, which they may find on our new local Career Exchange Web site. We are starting a CPIPTM (Certified Pharmaceutical Industry ProfessionalTM) Study Group later this year so that Members can get free training they need for the exam. We reached out through the Young Professionals Initiative to get more participation from an age group that has not been well represented in the past.

One of the biggest benefits of ISPE membership is one that too few receive - meeting other Members face to face, exchanging ideas and having fun. That benefit only accrues to those Members who go to events, which apart from the Product Show only applies to about 25 percent of you. Consider coming to an event next year and see what you're missing!

As my term ends, I can feel good about leaving the Chapter in capable hands. Sylvia Beaulieu has been nominated to be President and should she be elected I know we will be well-served by her energy, organizational ability and commitment to continuous improvement. It should be another "fun" year for ISPE Boston Chapter!

Thank you for the honor of serving as your President this past year.

Doyle Johnson

President, ISPE Boston Area Chapter

Golf Tournament Raffle Prizes Needed

The Chapter is looking for donations of raffle prizes for the 2009 Golf Outing on August 17th.

Tickets to sporting events, restaurant gift certificates, golf clubs, golf balls, shirts, jackets, wine and liquor, store gift cards, etc. are all popular items.

Companies donating raffle items will be listed in the event brochure, on posters at the event and in the Chapter newsletter and Web site.





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Please contact Chris Opolski at (401) 233-1200 or <u>copolski@aol.com</u>; or Sylvia Beaulieu at (978) 222-9584 or <u>sbeaulieu@columbiacc.com</u>

Upcoming Chapter Events - Mark Your Calendar

Monday, August 17, 2009 7th Annual Golf Tournament

Purchase a Foursome now! There aren't many left.

Ferncroft Country Club, Middleton, Massachusetts

Click Here for a REGISTRATION FORM

Monday, September 14, 2009 Educational Program

Process Analytical Technology (PAT) / Quality by Design (QbD): Integrated Systems in the Future Pharma Business Landscape

Save the Date! Registion Will Open Soon at <u>www.ispeboston.org/events</u>

Wednesday, October 7, 2009

Annual Product Show

Gillette Stadium Clubhouse, Foxborough, Massachusetts

Click Here: <u>REGISTRATION IS OPEN FOR EXHIBITOR</u> <u>REGISTRATION</u>

Student Poster Contest Winners Selected

text and photos by Rick Pierro, Superior Controls

The ISPE Boston Area Chapter held their annual Student Poster contest at Northeastern University on May 8th and the competition was fierce. Ambitious students from six ISPE Student Chapters across Massachusetts and New Hampshire are encouraged each year to compete for the coveted spot representing the Boston Area Chapter at the November ISPE Annual Meeting. This year the all expenses paid trip is being held in beautiful San Diego, California. Judging from the competition, many students wanted to win that trip out west.

Six wise ISPE judges were recruited, all with many distinguished years of studying posters. These noble judges and volunteers were Henry Brush of Alkermes, David Novak of AMEC, Mike Denault of Denault Associates, Doyle Johnson of MassBioLogics, Professor Carolyn Lee-Parsons of Northeastern University, and Rick Pierro of Superior Controls.



Each of the 24 students was allowed a concise five-minute period to

Poster Contest winners Lara Scheherazade Milane and Jason Crater surrounded by judges (I to r) Carolyn Lee-Parsons, Doyle Johnson, Mike Denault, Henry Brush, Dave Novak and Rick Pierro.

explain their research and poster and then five minutes to answer rapid fire questions about their work. The students were rated on both their presentation (poise, clarity, confidence, knowledge of the subject matter) and their poster quality (layout, color, readability).

The research being carried out by these students, both graduate and undergraduate, can truly cause shock and awe. It was amazing to see the research into cancers and the testing of therapeutics that might cure some of our most common diseases. Some of the presentations and research is so compelling that some judges asked to be allowed to invest, forgetting for the moment that these weren't yet business propositions and only student research.

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Northeastern University provides an impressive backdrop for the group of Poster Contest entrants and judges.

By the end of the night two winners stood out and were announced.

* Undergraduate Winner: Jason Crater, a Northeastern University Chemical Engineering student with his poster entitled "Examining the Barrier Properties of Gastrointestinal Mucus to Nanoparticle Transport Using Multiple Particle Tracking"

* Graduate winner: Lara Scheherazade Milane, a Northeastern University PhD candidate with her poster entitled "Polymer Blend Nanoparticulate Carriers for Combination Paclitaxel/Lonidamine Therapy in Overcoming Multidrug Resistance in Breast and Ovarian Cancer via Exploitation of the Warburg Effect"

Didn't I tell you this was compelling? Both Jason Crater and Laura Scheherazade Milane will represent the Boston Area Chapter when they travel to the ISPE Annual Meeting in San Diego this November to compete with students from all over North America. Boston is becoming known throughout the world in ISPE circles for their sharp, articulate and fiercely competitive Student Poster Contest winners and we're certainly proud to send our winners again this year.

A special thanks to our generous hosts, Northeastern University, Professor Carol Lee-Parsons, and the Northeastern University ISPE Student Chapter, for arranging the contest. And best of luck to Jason and Lara at the international competition in November!

Abbott Bioresearch Center Hosts Engineering Leadership Panel Discussion

by Janet Tice, GMP Piping, with photo by Doyle Johnson

On Tuesday, May 19th Boston Area Chapter members had the privilege of attending an educational program and panel discussion hosted by Abbott Bioresearch at their impressive hilltop campus in Worcester. The focus of the session was two-fold: "Organizational Leadership: Getting Things Done in White Water" and "Building Leadership Skills: How to Influence Without Authority." The program was specifically designed for young engineering professionals in the early stages of their careers but a healthy turnout of members in all age groups attested to the topics' wide appeal.

The evening opened with formal presentations by industry veterans Dr. Sam Liggero and Dr. Mary Viola, both of the Gordon Institute of Engineering Management at Tufts University. The program then transitioned to a panel discussion featuring a group of young professionals who discussed their real-world experiences and "lessons learned" during the early years of their careers.

First up, Dr. Liggero described "Getting Things Done in White Water" during a tumultuous period when downsizing and restructuring had led to an epidemic of poor morale, high turnover and low productivity at Polaroid. Using this "worst case scenario" as an



Presenter Sam Liggero and Meeting Manager Mukesh Yadav get acquainted during the networking reception.

example, Dr Liggero described in detail the steps he followed to reduce turnover and improve morale within the Media R&D group while simultaneously delivering on three ambitious R&D projects. Any manager facing their own company's version of "white water" could apply his managerial "keys to success" and personal

behavior tips. Among these were regular, informal meetings between him and all levels of staff to discuss topics of concern to them, and solicitation of ideas from the general population for new products and strategies.

Next up was Dr. Viola who tackled a subject near and dear to the hearts of individual contributors everywhere: "How to Influence Without Authority." With a series of witty, animated overheads and a high-energy presentation style, Dr. Viola kept the audience fully engaged during her discussion of "soft" tactics that often work when facts, data, logical arguments and "hard" tactics don't. Borrowing from the social sciences, she described the concepts of "currencies" and "exchanges" or "getting what you want while giving others what they need." These tactics can be used in the short term, during individual negotiations, or in the long term, to build reciprocal relationships and networks of allies that can be called upon in the future as the need arises.

Last, but by no means least, were panelists Mike Doucette (Abbott Bioresearch Center), Amanda Ashcraft (Genzyme Corp), Michael Long (Cooper Surgical) and Lisa Wyman (Boston Scientific), all young professionals in engineering roles, who shared experiences that helped to illustrate the concepts introduced by the speakers. Their personal stories were a perfect way to conclude the evening, bringing the conversation down to a very practical level that struck a chord with everyone in the audience.

Many thanks to the presenters and panelists, Meeting Managers Joyce Chiu (Perceptive Informatics, PAREXEL) and Mukesh Yadav (MassBioLogics) and the Boston Area Chapter Educational Program Committee for an extremely interesting and thought-provoking evening and to Abbott Bioresearch Center for graciously hosting the event.

"Forefronts in Bioengineering" Program Provides a Fascinating Look into the Future

by Anna Vogel, Rose-Hulman Institute of Technology, Biomedical Engineering Class of 2012, with photos by Joyce Chiu, Perceptive Informatics, PAREXEL

On June 16th the Boston Area Chapter traveled to the Tufts Gordon Institute in Medford for a presentation by David Kaplan, professor and chair of the Department of Biomedical Engineering at Tufts. Dr. Kaplan's presentation included a description and developmental study of bioengineered fibrous proteins which have promising potential for use in medical diagnosis and other treatment. The three-part presentation focused on the following research topics: stem cells, soft body robots and biophotonics. Following the presentation, attendees toured the labs where the research is being conducted.

Before the presentation, attendees enjoyed a networking reception with great food and conversation, then proceeded to the presentation room where Chapter President Doyle Johnson welcomed the attendees and Meeting Manager Joyce Chiu introduced Dr. Kaplan.



Chapter Past President Rick Pierro with Tufts undergrads (I to r) Calvin Kwon, Jessica Sites, Raeann Bourscheid, Sterling Wall & Melissa Myint.









Cambridge, MA 02139



Keeping our eye on the valve





Previous Issues

July 2009. Volume XIX.... (11) May 2009. Volume XIX.... (9) April 2009. Volume... (11) February 2009. Volume... (10) December 2008. Volume... (13) October 2008. Volume... (10) June 2008. Volume... (11) April 2008. Volume... (10) February 2008. Volume... (10) December 2007. Volume... (13) October 2007. Volume... (10) The presentation covered three different areas that Dr. Kaplan and his team have been working on at Tufts and began with a brief introduction to the basic biological and chemical aspects of cell growth and how stem cells can be grown in their respective environments. This led to a discussion about collagens and silks, both of which are polymers that can be used to provide structure and self-assembly for cell growth and regeneration, and the three factors that contribute to the growth and development of stem cells. They are

- the source of the cells: adipose, bone marrow and soft tissue;
- · the scaffold on which the cells grow: collagens or silks; and
- the environment: signaling factors or mechanical forces will define the final cell type that develops from the stem cells.

Once the specific cells are produced, they can be placed into an organism to repair or replace existing tissues.

Dr. Kaplan used a "humanized" mouse model to describe the tissue engineering process. The silk and collagen scaffolds were used to introduce a human bone implant containing metastasizing breast cancer cells into a mouse. (It was noted that many forms of breast cancer spread to the bones.) The mouse then developed the "human" cancer, producing an excellent model for use in drug screening. Optical imaging can be used to track the disease process and its response to different drugs or drug variations.

The audience was intrigued by the first part of the presentation but the second part was even more exciting. Dr. Kaplan opened with a video clip of a how a soft robot can be made to match the physical characteristics of a caterpillar. Characteristics of a caterpillar that are mimicked by the soft body robot include the following: the robot should not be heavy nor energy-intensive and must be able to climb and navigate just like a caterpillar found in anyone's backyard. Dr. Kaplan explained that the robot was built of many hollow, silicone, elastomeric shells that were pressurized cavities containing Nitinal actuators, and its shape was temperature-dependent. The building blocks for the modules were resilin, a controllable, elastomeric, energy-storage material; elastin, an elastomeric, inverselytemperature-controlled material; and silk, a tough, cross-linked material.

A second video showed a mucoadhesive being applied underwater and holding for a couple of seconds before falling to the bottom of the tank. The adhesive would be applied to the ends of the limbs of the soft body robot and was required to temporarily stick, but not permanently become stuck, just like a normal caterpillar climbing a tree.

The final part of the presentation covered the optics and biophotonic capabilities of silk. The silk cocoon is put into a 0.02M solution of bisodium carbonate and boiling water, with the addition of air-dried fibroin, in order make a silk solution. This silk solution is made of 100 percent natural and raw materials and its biodegradability can be varied. The silk solution is then cast into a film on various flat or



Father & daughter attendees, Jim & Anna Vogel.

patterned surfaces. The pattern determines how light photons hit the material and produce an output.

Depending on the pattern, these silk films could be produced to have nanopatterned diffractive or refractive optical characteristics and to be carriers for biological material. Dr. Kaplan demonstrated using a small credit card size film for the audience, shining his red LED pointer light on the lenses encoding an assortment of holograms on the whiteboard behind him.

Following Dr. Kaplan's presentation, tours were given of the Tufts University labs. One of the labs was classified as a Class 1000 cleanroom. Another was the lab where all the silk was produced with silk-weaving machines that dated back to the industrial revolution. In the characterization lab, a grad student described his research on the caterpillar gut. He was studying the gut because research and motion analysis of caterpillars indicated that the gut acted as a key component in their movement and locomotion.

The evening was a great success and opened many eyes to the fascinating research that is being conducted at the "forefront of bioengineering" at Tufts and elsewhere. Attendees were fascinated by the information presented and left still pondering the exciting possibilities the future holds.

More information on soft body robots is available at the link: http://engineering.tufts.edu/1181647322330/Engineering-Page-eng2w 1181647323398.html

More information on bio-optics is available at the link: http://tuftsjournal.tufts.edu/2008/09/features/04/

Members Enjoy Fun in the "Sun" at the Annual Summer Social

by Chris Opolski, Alexion Pharmaceuticals, with photos by Chris Ciampa, Thermo Fischer Scientific

Thank you to our Volunteers! Communications Janet Tice On June 23rd, the Boston Globe reported that June had been 4.3 degrees below normal for the month and had made summer feel more like early spring. On June 11th, the sun was obscured by an

Pietro Perrone Patti Charek Christopher Ciampa Deepen Joshi Paul Kohler

Educational Programs

Lee Ward Jovce Chiu Rami Mitri Chuck Gillingham John Sheridan Wentao Wang Arkady Mayblyum Debbie Crooke Jav Zaino Steve Kennedy Mukesh Yadav

Member Services

Monique Sprueill Leena Asplund James Mirisola Bob Urbanowski Ron Belling Steven Kennedy Ted Haley Ric Feldt Bryan Gubbins

Product Show

Brian Hagopian Mark Sitcoske Svlvia Beaulieu Deborah Botham Tim Crowlev Mike Denault lim Desrosiers Joe Durning Ted Haley Doyle Johnson Steven Kennedy Mike Matton Carolyn Morgan **Rick Pierro**

Social

Chris Opolski Svlvia Beauliue Gene Dennen

Student Affairs

Kevin Brush Jim Blackwell Lesley Woods Dave Novak Doyle Johnson Kevin Lynch Rob Mitchell Aaron Conant Dr. P. T. Vasudevan Dr. Carolyn Lee Parsons

Training Initiative

Dan Paquette Kevin Lynch lim Grunwald Sylvia Beaulieu Pietro Perrone Mike Denault

Young Professionals Dan Ramsey

impenetrable pall of cement-colored clouds yet there was one bright spot to be found in the city - the Boston Area Chapter's Summer Social and Volunteer Appreciation Night held at the Beer Works on Canal Street with almost 100 Chapter members and their friends attending.



Members Jay Zaino and Ric Feldt share a hand-crafted Boston brew.

artichoke dip, Buffalo wings, chicken tenders, and spring rolls to a full dinner buffet of steak tips, salmon, stuffed chicken, pasta and all the sides,

of home brew like beer made by the Beer Works.

For those beer lovers who missed out, Beer Works offers 12 to 16 hand-crafted beers every day, from the lightlyflavored Havmarket Hefe-Weizen to a more robust Back Bay I.P.A and, for the not so faint of heart, Curley's Irish Stout. A big hit of the night was the Bunker Hill Blueberry ale. One attendee commented on how healthy it was because they could drink the beer and get their daily serving of fruit and antioxidants at the same time! For an even fruitier treat, members could partake in a Watermelon Ale, Castle Rock Raspberry Ale or the famous Cherry Bomb, a Belgian Ale fermented with sour cherries.

Doyle and Sylvia did their best Abbot and Costello impersonation finishing off the night by drawing for raffle prizes. The prizes were sponsored by Hart Design Company, FW Webb, Columbia Construction and the Boston Area Chapter. The giveaways were highlighted by the grand prize of a bottle of fine single malt scotch won by member Joyce Chiu. Other prizes included beach blankets, margarita and mojito mixes, oil changes, gift cards, and a selection of fine liquors.



Joyce Chiu and Anthony Giragosian embody the "summer party" theme.

this another memorable Chapter event!

We look forward to seeing you at future social events like the golf tournament in August, the holiday social in January 2010 or the ski trip in March 2010.



The theme of the social was a summer party and that it was. The fun started with brightly colored beads and leis given to each attendee as they entered the summer oasis. Beach balls and sand pails decorated the second floor function room. The gathering was designed to allow vendors and customers to join together in a relaxed setting to network and socialize, enjoy the food and good company and, especially, stay out of the rain!

A consensus among the party goers was that the food was outstanding and there was plenty of it. There wasn't an empty stomach after dinner. From the finger food appetizers including spinach and

people ate well. Additionally everyone's taste buds were delighted by the fine selection



Enjoying the food, drink and

volunteer who lent a hand to the Chapter during the last year and to thank them personally for their help. Each volunteer received a personalized letter from the chapter. As a token of thanks, the letter acts as a free ticket to attend an educational event during the upcoming year.

The rain and grey skies didn't damper members' spirits and the Summer Social was a huge success. Many thanks to Amy Poole, Doyle Johnson and Svlvia Beaulieu and the entire Chapter Board of Directors for making

Tech Talk: What's So Special About Specialty Gases?

by Mike Lee, Middlesex Gases & Technologies

Lab gases will always play a significant role in the everyday life of those in labs across the country and worldwide. A gas chromatograph (GC) or a mass spectrometer (MS) is just a sizable paperweight without gases. There are a myriad of gases and gas grades to choose from and the gas company representatives are not always up to speed with the upper end of the Specialty Gas spectrum.

First things first. What makes a Specialty Gas special? Standard, everyday gases used in industrial processes such as welding or metal cutting are called Industrial Gases. The tanks are filled with the gas of choice for the application and shipped to the customer. When the tank comes back empty it is simply re-filled and out the door it goes again.

Such is not the case with Specialty Gases. A Specialty Gas must meet or exceed a particular set of specifications and should never be allowed to leave the gas company's Gas Lab until the gas cylinder in question has proven its worth under great scrutiny.

Using Ultra High Purity (UHP) Helium as an example, let's walk through the process that results in the coveted "Ultra High Purity" status. First, the cylinder is fitted with a positive open/close valve which will ensure a high level of leak integrity. Second, the cylinder is placed in an oven and baked for eight hours at 140°F to remove any contaminants from the inside of the cylinder walls.

During the baking process the tank is purged with an inert Ultra High Purity gas and then quickly placed under vacuum. This purge/vacuum sequence is repeated seven times during the eight-hour baking period. The intent with this process is to break the polar bond of any existing moisture molecules that have affixed themselves to the inside of the cylinder walls. Trapped within these moisture molecules are other harmful contaminants such as hydrocarbons, particulates etc. This thermal energy transfer frees the molecules from the cylinder walls and the purge/vacuum process removes the moisture molecules and entrapped contaminants from the tank.

When the baking process is complete, the cylinder is clean enough on the inside to accept and maintain the integrity of an Ultra High Purity gas. Once the cylinder is filled, it goes to the lab where our chemists will put the cylinder through a battery of tests, checking for contaminants such as moisture, total hydrocarbons and oxygen. Should a cylinder be "rejected" at this point, it is purged and returned for a repeat of the baking process. Cylinders that "pass" the first round of testing proceed to the GC for verification of the initial results. Passing the GC analysis earns the tank a shrink-wrapped valve and a place among the "Specialty Gas" family.

Our Ultra High Purity Helium must meet the following specifications:

Moisture (H₂O).....<1.0 ppm Total Hydrocarbons (THC)......<0.5 ppm Oxygen<1.0 ppm

By contrast, Industrial Grade Helium may have many hundreds or even thousands of ppm of each contaminant.

Saving a few dollars on gas purchases might seem like a wise decision but replacing a Specialty Gas with an Industrial Gas in order to save a few dollars upfront may end up costing the user more money downstream. To continue with our helium example, using Industrial Grade Helium in a GC can jam the columns with moisture in the hundreds or thousands of parts per million and render the test results useless. Hydrocarbon contamination in excess of Ultra High Purity levels may cause additional problems. This scenario may necessitate any or all of the following: a repeat of the failed GC analysis, repeat processes and repair work on the GC, along with replacement of the gas cylinder and a considerable dose of aggravation for the end user.

So we now have the right Ultra High Purity Helium in our lab and we are ready to deliver it to our process. What about the pressure regulator that goes on the tank? Industrial Grade regulators commonly use neoprene diaphragms that can contribute hydrocarbon contamination. They also have very low leak integrity and can draw atmospheric moisture and oxygen into the gas stream.

A good choice for our UHP Helium is a pressure regulator that has a leak integrity of

1 x 10⁻⁹. It will also have stainless steel diaphragms and Teflon and Tefzel seats and seals. This regulator will maintain the integrity of the UHP Helium and deliver it to the process without a degradation in quality. Lastly, don't forget the process line. For our UHP Helium we would require a stainless steel-cored, stainless steel hose. A standard stainless steel pigtail is commonly Teflon-lined and our very fine helium molecules will find their way right through the Teflon.

In summary, the following table presents a quick comparison of Specialty and Industrial Gases:

	Specialty Gas	Industrial Gas
Contaminants	Moisture <1.0 ppm THCs <0.5 ppm Oxygen <0.5 ppm	no specifications; moisture, THCs & oxygen levels vary widely
Cylinder Prep	eight-hour bake and purge process with final high vacuum	none
Regulator	machined & polished body, stainless steel diaphragms, Teflon & Tefzel seats and seals; 1 x 10 ⁻⁹ helium leak integrity	forged brass body, neoprene diaphragms, rubber seats and seals; bubble-tight leak integrity
Process Line	stainless steel or appropriate grade of	rubber hose

Now, you have the right grade of gas, the right regulator and the right hose to deliver the gas to the process. What's left to do? Partner your business with a gas company that has the answers to your questions and people in the field with a broad knowledge base regarding the products they sell and the equipment you use; and be sure there is an elevated level of service that goes along with your gas purchases.

##

Mike Lee is a 25-year employee with Middlesex Gases & Technologies (MG&T) and has held the title of Specialty Gas Manager since 1997. Middlesex Gases & Technologies is a premier supplier of Specialty Gases, Industrial Gases, Cryogenics and all related equipment serving Massachusetts, Southern New Hampshire and Rhode Island. In business since 1949, MG&T focuses on Life Science, Medical Device and Defense Contractors. In addition to his sales duties at MG&T, Mike is also a professional writer, trainer and has traveled nationally to address audiences regarding Specialty Gases.

Industry News In Brief

by Patti Charek, Linbeck

Growth In Drug Sales of the Top 10 Pharmas at Lowest Level in Years

Decision Resources, one of the world's leading research and advisory firms focusing on pharmaceutical and healthcare issues, finds that the growth in drug sales of the top 10 pharmaceutical companies slowed to its lowest level in years in 2008 - growing just 3.7 percent compared to 7.9 percent the year before. The performance of the top 10 companies in the US market, the world's largest, was particularly poor, with sales down 3.5 percent year-over-year.

"This trend is expected to continue in the US with growth in the top 10 companies forecasted to remain flat out to 2015 despite the contribution of recently seen large-scale acquisitions by Pfizer, Roche and Merck & Co.," said Stephan Gauldie Ph.D., Director at Decision Resources. "Of the top 10 pharma companies, only Roche is expected to post a compound annual growth rate above the 3 percent..." (Source: Decision Resources Website, 12 May, 2009)

Demand For Biotech Space Still High

To commercial real estate experts, it looks as if the biotechnology sector, and specifically the biggest players in it, will carry Massachusetts through the current recession. In the six months ended March 31, tenants took up 673,000 square feet of laboratory space in Greater Boston, lowering vacancy from 14 percent to 9.7 percent, according to a market report from Boston-based commercial real estate firm Richards, Barry, Joyce & Partners.

Large biotech companies like Genzyme, Novartis and Abbott have maintained decent cash positions, are attracted to the "robust offering of appropriately skilled labor" in Massachusetts and have helped offset some of the crushing downward pressure the economy has put on the state as a whole.

Brendan Carroll, vice president of research at RBJ, said his firm expects a positive demand trend, especially in continued biotech hotspots like Cambridge. However, while tenancy by large, rich biotech companies may stave off widespread vacancy and job loss, recruiting employees needed for further expansion may become difficult. And for the smaller, younger biotech companies scattered across the suburbs, being acquired may become the best way to stay alive.

According to RBJ, recruiting has become "strained." Many potential employees are trapped in homes they can't sell for anywhere near what they paid for them and the prospect of moving to one of the most expensive areas of the country is proving too daunting for many.

Unable to get new facilities built, Carroll said biotech companies "that really need the space are doing it in-house" simply by adding to existing campuses. Carroll said Genzyme's facility on New York Avenue in Framingham is a good example. The Cambridge-based company has been gobbling up real estate around its Framingham campus since last year. "If they had been interested in looking around and seeing other options, there weren't any," Carroll said.

Carroll said availability is on the increase in the suburbs, but not in a way that is particularly attractive to larger companies. All of this may have biotech companies and developers looking for the next best thing in areas of the state where land is relatively inexpensive and the workforce, while perhaps not ultra-educated like it is in Cambridge, is highly skilled nonetheless.

Two areas that fit that bill are Devens and Worcester's biotech park, Carroll said. Even though Cambridge is the nucleus of biotech research, Devens and Worcester could become the nuclei of biotech production, especially with the addition of state and federal funding, which tends to be spread around more than venture funding, which results in concentrations like Cambridge. (Source: Matthew L. Brown, Worcester Business Journal)

Exact Sciences To Leave Marlborough For Wisconsin

Marlborough-based Exact Sciences Corp. has received a \$1 million loan from the Wisconsin Department of Commerce to relocate its headquarters and operations to Madison. The company expects to make a significant investment in its relocated operations, creating as many as 150 jobs over five years, as it achieves its commercial milestones, according to an official press release from the state of Wisconsin. The company will use its loan for

equipment and working capital related to the relocation.

Exact Sciences is a molecular diagnostics company focused on colorectal cancer with headquarters at 100 Campus Drive in Marlborough in one of several buildings that the Marlborough-based switchmaker 3Com originally built.

Last week Exact Sciences Corp. closed a deal to privately place \$8.2 million worth of its common stock and struck a deal with the Mayo Clinic in Rochester, Minn., to develop noninvasive diagnostics for colorectal cancer under a new licensing and collaboration agreement. (Source: Eileen Kennedy, Worcester Business Journal, 18 June, 2009)

West Coast-based Volcano opens East Coast HQ in Billerica

San Diego-based medical software and imaging systems maker Volcano Corp. sees the Bay State as a promising place to do business and will be expanding its research and manufacturing footprint in Massachusetts, as it makes the Bay State its East Coast headquarters.

In December, Volcano bought out 90-strong Axsun Inc. of Billerica. Privately held Axsun primarily made systems to monitor signal quality for the telecommunications industry. However, its portfolio also included medical lasers and optical engines that relied on optical coherence tomography. Volcano already made an ultrasound catheter that could be inserted into the heart to assess heart disease, said Joe Burnett, Volcano's vice president of marketing. Axsun, in turn, had technology that was capable of doing similar diagnostic work, except it was using light. These devices are connected via interface modules with a catheter to create heart images. The company declined to comment if the components would remain separate or be merged into a single integrated system. That deal followed Volcano's May 2008 acquisition of Methuen-based Novelis Inc., a privately-held maker of ultrasonic visualization technology.

Since the Axsun buyout, Volcano has been evaluating both firms and seeing how they fit in with the company's overall evolution, said Burnett. The news is good for Axsun's employees. "We've decided to make Billerica a focus of our East Coast efforts," he said. This includes hiring more engineers with medical device experience into the Axsun group.

While he acknowledged both San Diego and San Francisco are also strong contenders in biotech and medical devices, Boston can provide full services to develop the Volcano portfolio, he said. "The fact of the matter is, our systems are so complex, involving business consoles, software development, hardware, cabling and interfaces with X-ray machines, the type of engineering required is diverse," said Burnett. "We've found few places like Boston to serve that entire package." Moreover, while Research Triangle Park in North Carolina is a potential East Coast biotech-and-med device manufacturing contender, it still lacked access to the necessary labs and other resources for rapid clinical studies, said Burnett.

Volcano plans to expand the engineering facility. It will include open lab space, and allow work for a wide array of new technologies, including lasers, micro-machined manufacturing systems and other research tools. The company will also keep Axsun's two core telecommunications units operating, as well, said Burnett.

Additionally, using the Axsun technology, Volcano hopes to branch out to treat eye ailments and diagnose cancer, potentially without having to do an invasive procedure like a biopsy. There are also potential dental applications for identifying cavities. However, these aren't necessarily within Volcano's core competencies, and the company may partner with companies that are already established in these fields, said Burnett. (Source: Marc Songini, Mass High Tech, 12 June 2009)

Franklin's Echo Therapeutics Licenses Key Product to Brit Firm

Franklin-based medical device maker Echo Therapeutics has signed a multi-million dollar license agreement with an English company that plans to develop, market, sell and distribute one of its key products. Under the agreement, Ferndale Pharma Group of the UK will use Echo's Prelude SkinPrep system to expand its presence in the topical dermal anesthesia market in hospitals, clinics and with plastic surgeons and dermatologists. Ferndale will pay Echo an up-front licensing fee of \$750,000 and another \$750,000 once the SkinPrep system is cleared by the FDA. Echo said it stands to receive minimum guaranteed royalties of \$12.6 million.

SkinPrep prepares the skin prior to certain medical procedures and allows for the quick removal of the outermost layer of the skin to facilitate drug delivery and glucose measurement. (Source: Matthew L. Brown, Worcester Business Journal, 28 May 2009)

Genzyme Closes Drug Deal With Bayer

Genzyme has completed its acquisition of a multiple sclerosis therapy and two cancer drugs from Bayer HealthCare. The multiple sclerosis drug, branded as Campath, is currently in phase III clinical trials. The cancer drugs are known as Fludara and Leukine. Genzyme has acquired the worldwide marketing and distribution rights for the two drugs. Genzyme will make no upfront payments to Bayer. In exchange for the rights to the drugs, Genzyme will make payments based on revenues. Genzyme will also acquire a new Leukine manufacturing facility upon FDA approval of the plant, which is expected in 2010. (Source: Christina H. Davis, Worcester Business Journal, 2 June 2009)

Drug Giants Pump \$40M into Aileron

Four global pharmaceutical companies have joined in a consortium to provide \$40 million in financing to Aileron Therapeutics, a Cambridge biotech start-up that is developing a novel approach to treating cancer and other diseases.

Aileron's technology, "stapled peptides," combines molecular devices called staples with fragments of proteins called peptides, enabling them to remain in the human body long enough to be effective. Most peptides are prone to

breaking up in the bloodstream within minutes.

"The pharmaceutical industry is looking for new growth avenues," Joseph A. Yanchik III, the president and chief executive of four-year-old Aileron, said. "If it plays out, this opens up a new playing field, and that is what they're starving for." Yanchik said Aileron envisions stapled peptides as a "technology platform," a third tool, beyond small molecules and biologics, for fighting cancer, metabolic diseases, and other ailments. He said the company will use its funding round to speed up research, search for new applications, advance into human trials, and expand its workforce from 23 to between 35 and 40 employees this year.

The venture round was co-led by SR One Ltd., the corporate venture fund of GlaxoSmithKline and Excel Medical Fund. Also investing in the Series D round were Apple Tree Partners, the founding investor of Aileron, and Novartis Venture Funds, another early investor. Two other pharmaceutical venture funds, Lilly Ventures and Roche Venture Fund, also took part.

While drug companies often make strategic investments in biotechs as a prelude to a business alliance, it's rare that more than one company - let alone four - would invest in the same deal, said Steve Burrill, the founder and chief executive of Burrill & Co., a life sciences merchant bank in San Francisco. "This could be a critical platform technology for a lot of companies, and they all want a place at the table," Burrill said. "It's very unusual to see four pharmas get to the goal line with the same company at the same time. This is probably the first time I've seen it."

Aileron's funding round, coming as venture capital has dried up for many smaller life sciences businesses, marks the second large biotech funding round this year for a Massachusetts company. BioVex Group of Woburn, which develops vaccines for cancer and chronic infectious diseases, raised just over \$40 million in March. (Source: Robert Weisman, The Boston Globe, 9 June 2009)

Novartis Produces First Batch of H1N1 Vaccine

Swiss pharmaceuticals company Novartis AG said it has successfully produced a first batch of swine flu vaccine weeks ahead of expectations. The vaccine was made in cells, rather than grown in eggs as is usually the case with vaccines. The announcement came a day after the World Health Organization declared swine flu a pandemic. The move indicates that a global outbreak is under way. WHO says drugmakers will likely have vaccines approved and ready for sale after September.

Novartis said it would use the first batch of vaccine for pre-clinical evaluation and testing. It is also being considered for clinical trials. The vaccine was produced at a Novartis plant in Marburg, Germany. Novartis said the facility could potentially produce millions of doses of vaccine a week. A second plant is being built in Holly Springs, NC.

Novartis said more than 30 governments have requested vaccine supplies, including the US Department of Health and Human Service, which placed a \$289 million order in May. (Source: Yahoo! News, 12 June 2009)

Third Acceleron Facility Expansion to Prompt Job Growth

Just as Acceleron Pharma was celebrating the completion of the company's new Cambridge headquarters and a second GMP protein manufacturing site, Acceleron officials also announced the signing of a lease for a third facility in the city. The additional 19,700 square feet of laboratory and office space means an expected 50 percent increase in workforce, particularly in research and development and manufacturing jobs, this year, the company said.

Founded in 2004, Acceleron has shown 50 percent growth every year, CEO John Knopf said in a statement. Last June, the company pointed to an October 2007 completion of a \$31 million Series C round of financing, which triggered the ensuing job and facility growth. Acceleron develops preclinical protein treatments to combat bone loss, grow blood vessels and block fat growth. (Source: Mass High Tech, 1 May 2009)

Massachusetts Life Sciences Center Approves Loans for Early-Stage Companies

The Massachusetts Life Sciences Center, a quasi-public agency tasked with implementing the State's \$1 billion Life Sciences Initiative, announced the awarding of \$3.4 million in loans to seven early-stage life sciences companies in Massachusetts. The Center's Accelerator Program provides loans of up to \$500,000 to early-stage companies engaged in life sciences research and development, commercialization and manufacturing. The Center's Board of Directors approved the first-ever round of Accelerator loans. Seven companies will receive loans out of a total of eighty-eight applications that were submitted to the Center for consideration.

The Accelerator Program, the Center's flagship investment program for companies, supports and "de-risks" earlystage companies by providing loans that will match grants and investments from the federal government, foundations, non-profit agencies, institutional investors, and other sources of capital. By leveraging other sources of capital, the Accelerator Program will provide support to companies at the most critical stages of their development cycle, enabling them to conduct vital research and proof of concept studies, and attract subsequent investment, and improving the odds of bringing cutting edge innovation to the marketplace.

Support for the Accelerator Program is augmented by the Center's Corporate Consortium Program, which provides matching funds for MLSC's investment activities. Corporate charter member Johnson & Johnson will contribute \$500,000 over two years to the Corporate Consortium and MLSC intends to add additional members over time.

Applicants for the Accelerator Program are generally early-stage life sciences companies with a high potential for technology commercialization, rapid growth, and downstream private equity financing. The loans are designed to address the need for capital investment associated with the long life sciences R&D cycle and the high cost of translating research into a commercially viable product. The seven companies that will receive loans from the Accelerator Program are:

Eutropics Pharmaceuticals (Dorchester/Boston) - Eutropics Pharmaceuticals, an oncology drug company,

headed by the co-founder of Merrimack Pharmaceuticals, develops drugs for treating aggressive forms of myeloma, lymphoma, leukemia, and other cancers. The company's initial target is Myeloid cell leukemia-1 (Mcl-1), a key member of the Bcl-2 family of proteins which are thought to be involved in resistance to conventional forms of cancer treatment. Eutropics has identified an exciting early lead compound that selectively inhibits the activity of Mcl-1 and is effective in a B-cell lymphoma mouse model.

Good Start Genetics (Boston) - Good Start Genetics, a molecular diagnostics company utilizing a proprietary process developed by team members from Dr. George Church's Laboratory at Harvard Medical School, is working to develop a low-cost, pre-pregnancy test for 50 genetic disorders that will replace single-disorder tests currently on the market. GSG aims to offer a sequencing-based test that is more accurate, more comprehensible, and more affordable than today's standard of care.

InVivo Therapeutics (Cambridge) - InVivo Therapeutics, a medical device company, is targeting the traumatic spinal cord injury market based on research by Robert Langer, PhD of the Massachusetts Institute of Technology and Jay Vacanti, MD of the Massachusetts General and Children's Hospitals in Boston. The company is developing technology to treat traumatic spinal cord injury by utilizing biomaterials with combinations of drugs and cells. InVivo Therapeutics is currently conducting a second round of non-human primate trials and has requested FDA permission to embark on human trials within the year.

Pluromed (Woburn) - Pluromed is pioneering injectable plugs to improve outcomes in cardio-thoracic surgery. Pluromed received the prestigious 2008 European Association of Cardio-Thoracic Surgery (EACTS) Techno-College Innovation Award for the most important technological breakthrough in any area related to thoracic and cardiovascular surgery for its LeGoo Internal Vessel Occluder. Pluromed plugs are based on "reverse thermosensitive" polymers that are liquid at low temperatures and gel at body temperature; these plugs are completely reversible via cooling and completely dissolvable. When injected into the body, the plugs block off blood flow to provide surgeons with a bloodless field. When cooled, the plugs liquefy and dissolve into the bloodstream. Unlike competing technologies, Pluromed's plugs allow surgeons to remove a tumor while normal blood flow is maintained in the rest of the organ.

Spectra Analysis (Marlborough) - Spectra Analysis is a leading supplier of molecular spectroscopy systems and applications for chromatography. Current products focus on real-time connection of Infrared Spectroscopy to Gas and Liquid Chromatography. The DiscovIR systems make it possible to collect full infrared spectra for each component in a separation, either as a standalone or in parallel with mass spectroscopy.

Wadsworth Technologies (Westborough) - Wadsworth Technologies is a medical device entity targeting the wound closure market. Wadsworth uses next generation adhesives combined with intelligent engineering to form a painless system which can be rapidly placed with optimal healing results. Its lead product, Dermaloc Wound Closure System, applies tension to skin wounds to close them without anesthesia or sutures resulting in a novel, painless, rapid, needleless and durable wound closure. The product is currently in clinical testing.

Wolfe Laboratories (Watertown) - Wolfe Laboratories provides quality assay development, formulation development, process development, and other services to the biotech and pharma industries. Wolfe Labs offers a variety of pre-clinical services, including pre- formulation and formulation development, analytical method development and characterization, PK and in vitro ADME bioanalytical development, dose formulation stability and uniformity assessment, lyophilization services, quality assay development, process development, and other services. Wolfe hopes to use the Accelerator loan to help build a new manufacturing facility focused on aseptic fill finish services and the manufacture of innovative biologic and cytotoxic drugs. Company founder, Janet Wolfe, was named Boston's Entrepreneur of the Year in 2008 by the Boston Chamber of Commerce.

"These initial investments in the Center's Accelerator portfolio reflect our commitment to early-stage companies working to produce therapies that will improve the human condition and address unmet medical needs," said MLSC President and CEO, Dr. Susan Windham-Bannister. "The Accelerator Program aligns with MLSC's mandate to ensure that Massachusetts maintains and strengthens its global leadership position in the life sciences sectors, spurring economic development, and creating new jobs." (Source: Angus McQuilken, Massachusetts Life Sciences Center, 29 April 2009)

Virus Shuts Down Genzyme Facility

Genzyme has temporarily halted production at its Allston Landing production facility after a virus that impairs cell growth was detected in one of six bioreactors there. The company, which has significant operations in Framingham and elsewhere in Central Massachusetts, said it expects the Allston facility to be operational again by the end of July.

The virus detected at the facility is known as Vesivirus 2117 and while it is known to interfere with the growth of certain cells used to produce biologic drugs, it has not been shown to cause human infection. The company said the virus was likely introduced to the facility through a nutrient used in the drug manufacturing process. The company said the drugs Cerezyme and Fabrazyme are produced at the Allston facility. (Source: Matthew L. Brown, Worcester Business Journal, 16 June 2009)

AstraZeneca and Merck Collaborate to Investigate Novel Anticancer Regimen

AstraZeneca and Merck announced a collaboration to research a novel combination anticancer regimen composed of two investigational compounds, MK-2206 from Merck and AZD6244 from AstraZeneca. This is the first time that two large pharmaceutical companies have established a collaboration to evaluate the potential for combining candidate molecules at such an early stage of development. The collaboration will more quickly advance a potentially promising anticancer treatment.

Under the terms of the agreement, AstraZeneca and Merck will work together to evaluate co-administration of the compounds in a Phase I clinical trial for the treatment of solid cancer tumors. All development costs will be shared jointly. Following the Phase I trial, the companies will consider opportunities for further clinical development.

Advances in cancer research have led to a new generation of drugs designed to precisely target features specific to cancer cells while minimizing the effect on healthy cells. Several of these drugs provide patient benefit as monotherapy, but increasingly the ability of cancer cells to adapt and develop resistance has become apparent. Research suggests that combination therapies that include drugs with different mechanisms of action impacting cancer cells in multiple ways may provide an improved anticancer benefit and decrease the risk of relapse. Usually, combinations of novel anticancer agents would only be studied in clinical trials when one component of the regimen is at a late stage of development or when one compound has received marketing approval. (Source: Merck Research and Development)

GSK and Concert Pharmaceuticals Form Alliance to Develop Novel Deuterium-Modified Drugs

GlaxoSmithKline and Lexington-based Concert Pharmaceuticals have announced that they will collaborate to develop and commercialize deuterium-containing medicines. The deal includes three of Concert's R&D programs; namely, CTP-518, a protease inhibitor for the treatment of HIV expected to enter Phase I clinical trials in the second half of 2009, a preclinical compound for chronic renal disease, and a third research product in Concert's pipeline. Concert will also provide GSK with deuterium-modified versions of three GSK pipeline compounds for GSK to develop.

Concert Pharmaceuticals is a clinical stage biotechnology company focused on the application of deuterium chemistry to create novel small molecule drugs. Concert's approach leverages known activity and safety of existing drugs to reduce time, risk and expense of drug research and development. The company has a broad research pipeline encompassing many therapeutic areas including renal disease, infectious disease, and cardiovascular disease, among others. CTP-518 is its lead development candidate.

CTP-518 is a novel HIV protease inhibitor developed from Concert's deuterium chemistry platform by replacing certain key hydrogen atoms of atazanavir with deuterium. Concert has demonstrated in pre-clinical studies that selective deuterium modification of atazanavir fully retains its antiviral potency but can markedly slow hepatic metabolism, thereby increasing half life and plasma trough levels. As a result, CTP-518 could potentially avoid the need to use a protease inhibitor boosting agent such as ritonavir.

Current standard of care is to co-administer HIV protease inhibitors with ritonavir. However, significant complications are associated with ritonavir. Importantly, because the relationship between atazanavir trough plasma levels and clinical virological response is well-established, Phase 1 testing is expected to provide clinical validation of CTP-518. CTP-518 has the potential to be the first HIV protease inhibitor to eliminate the need to co-dose with a boosting agent.

Under the terms of the agreement, Concert will receive \$35 million in upfront payments, including a \$16.7 million equity investment by GSK. Concert is eligible to receive milestones and tiered, double-digit royalties based on deuterium-containing products arising from the Concert pipeline programs. In addition, Concert is eligible to receive milestones as well as royalties on the sales of deuterium-containing products arising from the GSK pipeline compounds. Overall, Concert has the potential to receive in excess of \$1 billion in total milestone and upfront payments from GSK spread across all programs.

For each Concert pipeline program, Concert will have responsibility for R&D activities through completion of preagreed clinical trials. After the completion of such clinical trials for each program, or earlier if it chooses, GSK may elect to obtain an exclusive, worldwide license to product candidates within the program. At such time, GSK will assume responsibility for development and commercialization. Concert will retain full rights to further develop and commercialize its product candidates in any program GSK chooses not to license. (Source: GlaxoSmithKline Website, 2 June, 2009)

GSK Announces Alliance to Further Accelerate Sales Growth in Emerging Markets

GlaxoSmithKline has announced an agreement with Dr. Reddy's Laboratories to develop and market selected products across an extensive number of emerging markets, excluding India. Established in 1984, Dr. Reddy's is an emerging global pharmaceutical company consisting of three core businesses: Pharmaceutical Services and Active Ingredients, Global Generics and Proprietary Products. Their products are marketed globally, with a focus on India, US, UK, Germany and Russia.

Abbas Hussain, President Emerging Markets, GlaxoSmithKline said: "This is another significant step forward in our strategy to grow and diversify GSK's business in emerging markets. Growth in both population and economic prosperity is leading to increased demand for branded pharmaceuticals. This new alliance will combine Dr. Reddy's portfolio of quality branded pharmaceuticals together with GSK's extensive sales and marketing capabilities. Together we will be able to deliver more medicines of value to more patients in these countries."

Under the terms of the agreement, GSK will gain exclusive access to Dr. Reddy's rich and diverse portfolio and future pipeline of more than 100 branded pharmaceuticals in fast growing therapeutic segments such as cardiovascular, diabetes, oncology, gastroenterology and pain management. The products will be manufactured by Dr. Reddy's, and licensed and supplied by GSK in various countries in Africa, the Middle East, Asia Pacific and Latin America. In certain markets, products will be co-marketed by the GSK and Dr. Reddy's. Under the terms of the agreement, revenues will be reported by GSK and shared with Dr. Reddy's as per the agreed terms. (Source: GlaxoSmithKline Website, 15 June, 2009)

Regulatory & Legislative Highlights

by Deepen Joshi, Sepracor

FDA Approves New Influenza Vaccine Production Facility

The FDA has approved a new manufacturing facility used to produce influenza virus vaccines. The facility is approved for seasonal influenza vaccine production and could be used for the production of vaccine against the new 2009 H1N1 influenza strain. The facility, located in the US, is owned and operated by Sanofi Pasteur, the vaccines division of Sanofi-Aventis, which manufactures Fluzone Influenza Virus Vaccine. This new facility will greatly increase Sanofi Pasteur's production capability.

As part of its overall pandemic influenza preparedness efforts, the FDA meets with vaccine manufacturers to guide the efficient establishment of influenza vaccine facilities that comply with agency requirements. The agency promptly reviews applications and manufacturing supplements that could increase both the number of manufacturers and the overall supply of vaccine.

The FDA has interacted with the company throughout the regulatory process to help ensure compliance with applicable requirements. The bulk manufacturing facility will be used for the production of Fluzone, Sanofi Pasteur's egg-based influenza vaccine. Sanofi Pasteur is located in Swiftwater, Pa. (Source: FDA Website, 6 May, 2009)

FDA 2010 Budget Increased by 19 Percent

The FDA is requesting a budget of \$3.2 billion to protect and promote the public health as part of the President's fiscal year (FY) 2010 budget - a 19 percent increase over the current FDA fiscal year budget.

The FY 2010 request, which covers the period of Oct. 1, 2009, through Sept. 30, 2010, includes increases of \$295.2 million in budget authority and \$215.4 million in industry user fees. The FDA budget proposes two major initiatives for FY 2010: Protecting America's Food Supply and Safer Medical Products. It also includes increases for current law user fees and for infrastructure to support critical agency operations. The FDA is also proposing four new user fees to facilitate review of generic drugs, register and inspect food manufacturing and processing facilities, reinspect facilities that fail to meet Good Manufacturing Practices and other safety requirements, and issue export certifications for food and feed.

The following are the FDA's key proposed budget increases:

- Protecting America's Food Supply \$259.3 million
- Safer Medical Products \$166.4 million
- Current Law User Fees \$74.4 million
- Follow-on Biologics & Drug Importation \$5 million

(Source: FDA Website7 May, 2009)

FDA Approves Drug for Treatment of Aggressive Brain Cancer

The FDA has approved Genentech's Avastin (bevacizumab) to treat patients with glioblastoma multiforme (GBM) when this form of brain cancer continues to progress following standard therapy. GBM is a rapidly progressing cancer that invades brain tissue and can impact physical activities and mental abilities. It affects about 6,700 persons in the US every year. Following initial treatment with surgery, radiation, and/or chemotherapy, the cancer nearly always returns.

Avastin is a monoclonal antibody that mimics the antibodies produced by the body's immune system to defend against harmful substances. The medication inhibits the action of vascular endothelial growth factor that helps form new blood vessels. These vessels can feed a tumor, helping it to grow and can also provide a pathway for cancer cells to circulate in the body. The drug was first approved in 2004 to treat metastatic cancer of the colon or rectum and has since been approved for treatment of non-squamous, non-small cell lung cancer and metastatic breast cancer. (Source: FDA Website, 8 May, 2009)

FDA Forms Transparency Task Force

The FDA announced the formation of a task force to develop recommendations for enhancing the transparency of the agency's operations and decision-making process. To support the efforts of the task force, the FDA issued a Federal Register notice announcing a public meeting to solicit recommendations on how the agency can make more available, useful and understandable information on its activities and decisions.

The task force will be chaired by Principal Deputy Commissioner Joshua Sharfstein, MD, and will include center directors, the associate commissioner for regulatory affairs, chief scientist, and the chief counsel. The Transparency Task Force will amongst other things:

- · Seek public input on issues related to transparency;
- Recommend ways that the agency can better explain its operations compatible with the appropriate protection of confidential information;
- Identify information the FDA should provide about specific agency operations and activities, including enforcement actions and product approvals;
- Identify problems and barriers, both internal and external, to providing useful and understandable information about FDA activities and decision-making to the public;
- Identify appropriate tools and new technologies for informing the public;

The establishment of the task force follows President Obama's January 21, 2009 memorandum directing executive agencies to find new ways of making information available to the public rapidly and in a form that is easily

FDA: First Drug to Treat Cancer in Dogs Approved

The FDA announced the approval of Palladia (toceranib phosphate), manufactured by Pfizer Animal Health, the first drug developed specifically for the treatment of cancer in dogs. Palladia is approved to treat canine cutaneous (skinbased) mast cell tumors, a type of cancer responsible for about 1 out of 5 cases of canine skin tumors. The drug is approved to treat the tumors with or without regional lymph node involvement.

Palladia is a tyrosine kinase inhibitor and works in two ways: by killing tumor cells and by cutting off the blood supply to the tumor. In a clinical trial, Palladia showed a statistically significant difference in tumor shrinkage when compared with an inactive substance (placebo).

All cancer drugs now used in veterinary medicine originally were developed for use in humans and are not approved for use in animals. Cancer treatments used in animals are used in an "extra-label" manner as allowed by the Animal Medicinal Drug Use Clarification Act of 1994.

While canine mast cell tumors often appear small and insignificant, they can be a very serious form of cancer in dogs. Some mast cell tumors are easily removed without the development of any further problems, while others can lead to life threatening disease. (Source: FDA Website, 3 June, 2009)

FDA Approves Injectable Form of Ibuprofen

The FDA approved Caldolor, manufactured by Cumberland Pharmaceuticals of Nashville, TN, the first injectable dosage form of the common pain medication ibuprofen, to treat pain and fever. Caldolor will be available for hospital use only. It is approved to be administered in 400 mg to 800 mg doses, over 30 minutes, every 6 hours for acute pain. To treat fever, the drug is approved in a 400 mg dose administered over 30 minutes, followed by 400 mg every 4 to 6 hours, or 100-200 mg every 4 hours, as necessary.

Caldolor should be used with caution in patients with congestive heart failure, kidney impairment, at risk of blood clots and those who have a prior history of ulcers or gastrointestinal bleeding. When used in such patients, attention to using the lowest effective dose for the shortest time period is important to reduce the risk of serious adverse events. The drug has also been associated with high blood pressure, serious skin reactions, and serious allergic reactions. (Source: FDA Website, 11 June, 2009)

FDA Warns Web Sites against Marketing Fraudulent H1N1 Flu Virus Claims

On May 1, 2009, the FDA warned consumers regarding products related to the 2009 H1N1 flu virus offered on the Internet. The products involved are those that are promoted and marketed to diagnose, mitigate, prevent, treat, or cure the 2009 H1N1 flu virus but are not approved, cleared, or authorized by the FDA. The agency advised operators of offending Web sites that they must take immediate action to ensure that they are not marketing products intended to diagnose, mitigate, prevent, treat, or cure the 2009 H1N1 flu virus that have not been cleared, approved, or authorized by the FDA.

Since then, the FDA has issued more than 50 warning letters to offending Web sites and as a result, more than 66 percent of these Web sites have removed the offending claims and/or products. Examples of unapproved, uncleared, or unauthorized products targeted by the FDA include a shampoo that claimed to protect against the H1N1 flu virus and a dietary supplement that claimed to protect infants and young children from contracting the H1N1 flu virus.

The FDA's warning letters are consistent with an aggressive strategy the agency put into place to protect consumers from individuals or businesses that promote fraudulent claims for products in an attempt to take advantage of the public's concerns about the 2009 H1N1 flu virus. (Source: FDA Website, 15 June, 2009)

FDA Approves Novel Novartis Drug

The FDA has approved Novartis AG's Ilaris (canakinumab) for the treatment of children and adults with cryopyrinassociated periodic syndrome (CAPS), which includes a number of rare but life-long auto-inflammatory disorders with debilitating symptoms and limited treatment options. The FDA granted priority review to Ilaris based on its potential to meet an important clinical need for patients with CAPS.

CAPS is caused by a single gene mutation that leads to overproduction of interleukin-1 beta (IL-1ß), which causes sustained inflammation and tissue damage. Symptoms, such as debilitating fatigue, rash, fever, headaches, joint pain and conjunctivitis, can be present from birth or infancy, and can occur daily throughout patients' lives. Long-term consequences may be serious and potentially fatal, including deafness, bone and joint deformities, central nervous system damage leading to visual loss, and amyloidosis resulting in renal failure and early death.

Ilaris, previously known as ACZ885, is a fully human monoclonal antibody that rapidly and selectively blocks IL-1ß. "Until now, treatments for CAPS patients have been limited to traditional inflammatory-disease medications that work by suppressing the entire immune system, and newer therapies that control the disease better but require more frequent injections," said Hal Hoffman, MD, Associate Professor of Pediatrics and Medicine at University of California, San Diego.

CAPS comprises three disorders of increasing severity: FCAS, MWS and neonatal-onset multisystem inflammatory disease (NOMID). There are believed to be approximately 300 cases in the US, but many patients may remain undiagnosed due to poor disease recognition. A clinical study is ongoing to evaluate the potential of Ilaris to treat patients with NOMID. There are currently no approved therapies for the treatment of NOMID. (Source: Novartis Website, 18 June, 2009)

New Members

Ms. Sarah A. Anderson, Sr Key Account Manager NE, Charter Medical Ltd Mr. Paul A. Bellville, President, Solutions-North East Mr. Peter F. Burke, Validation Engineer, Tufts University Mr. Paulo J. Carvalho, Manufacturing Supervisor, Shire Linda Christle, Compliance Analyst, Vertex Pharmaceuticals Mrs. Anabelle Delgado, Lead QA Specialist, Vertex Pharmaceuticals Mr. Stephen J. DePaulo, Assistant Director Vaccines, University of Massachusetts Biologic Labs Mr. Shane A. DuPont, Manufacturing Manager, University of Massachusetts Biologic Labs Mr. Tony Favaloro, President, American Plant Maintenance, Inc. Kevin Gillespie, Sr. Laboratory Systems Administrator, Momenta Pharmaceuticals Karen Holland, Control System Engineer, Shire HGT Dr. Christina Kriegel, Postdoctoral Research Associate, Northeastern University Ms. Eydis Lima, Student, University of Massachusetts Amherst Ned Lomigora, VP Corporate Development, DECCO Process Solutions, Inc. Kenneth Micciche, Area Business Development Manager - East Coast, Cole-Parmer Instruments Mr. Andrew Santella, Vice President, Alfieri Proctor Associates Ms. Laura B. Silverman, Student, University of Massachusetts Amherst Mr. David J. Stack, Territory Manager, Parker Hannifin Mr. Paul D. Sullivan, President, RW Sullivan Engineering Ms. Lesa Valentine, Director Quality Assurance, Novartis V & D Mr. Joseph G. Welch, Manufacturing Manager I, University of Massachusetts Biologic Labs Back

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