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NEWSLETTER

January 2011, Volume XXI No. 1

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Presidents Message: Thank You to Our Many, Loyal Chapter Members for Another Great Year!



Dear Friends,

Another year is in the books. We have done our reflection on 2010 and we are moving - full speed ahead - into 2011. On behalf of the Board of Directors of the Boston Area Chapter of ISPE, thank you for being a member of our Chapter.

2010 was a challenging year for many of our members and their organizations. We are proud to say that for our Chapter 2010 was not without its highlights. Our planning and efforts paid off as our Chapter was recognized with the award of three prestigious citations from the ISPE. These awards included:

- Platinum Grand Award for Excellence and Innovation, also known as the "Chapter of the Year" Award.
- Award for Innovation in Member Services which stressed our efforts to provide a wide diversity of events and programs throughout the year.
- Award for Innovation in Special Events, which highlighted the CPIP™ Study Group led by Past President Doyle Johnson, another innovative and valuable service to Members.

This is a reflection on the dedication and hard work of our many volunteers and, of course, the robust attendance that you, our membership provide. So thank you for helping make 2010 a great success for the Boston Area Chapter.

For 2011, your Board and all of our Committee volunteers have already planned a great slate of programs and socials. What makes all this possible is the incredible level of volunteerism we have here in our Chapter, truly one of our strategic advantages.

There are several new initiatives we are rolling out in 2011, so please watch for announcements regarding the following:

- Our first-ever Scholarship Program.
- Our Sponsorship Program, which will provide a vehicle for Vendors to sponsor a variety of programs and activities at different levels.
- The Student Leadership Forum, which the Boston Area Chapter will host for the first time in cooperation with the Delaware Valley, New Jersey and New England Chapters. This is an all-day event for members of ISPE Student Chapters. Locally we enjoy great relationships with Northeastern, UMass Amherst, UMass Lowell, Tufts and UNH. And we hope to formally welcome WPI in January of 2011. We expect Student Member attendees from the NY/NJ/PA areas to attend as well.
- Our first-ever "Dual Track" Educational Program on January 20th, which will feature two simultaneous presentations on the topic of automation, one designed for Young Professionals and the other for seasoned industry veterans.

So, as you can see our commitment to turn over rocks in our attempts to provide you with more value for your membership commitment.

With all of our activities we always welcome new volunteers. After all, volunteers are the grist that feeds the ISPE mill! The Board of Directors will be in attendance at our post Holiday Social on January 13th at Flat Top Johnny's. So join us to help kick off the year and be sure to let us know if you'd like to support the Chapter's efforts by volunteering. Whether you have lots of time to devote, or only a little, we have a job for you!

As always, please send us your ideas, questions and concerns to ispe@camihq.com - or you can reach me at 617-869-8287. I look forward to a year of great dialog with many successful programs and events and hope to see you at an event in 2011.

Thank you,



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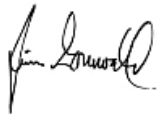
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Jim Grunwald
President, ISPE Boston Area Chapter

Upcoming Chapter Events - Mark Your Calendar

New Year's Social

Thursday, January 13, 2011
Flat Top Johnny's Billiards, One Kendall Sq., Cambridge, MA
6:00 pm to 10:00 pm

Bringing in the New Year! Socialize and network with your fellow members and colleagues and enjoy a game of pool at Flat Top Johnny's.

Join ISPE Boston Area Chapter in making a difference: **"Adopt-A-Box"** for a Massachusetts Soldier fighting for your Country. Helping Our Troops (H.O.T.) is a non-profit 501(c)3 public charity based in Stoneham, MA providing care packages to our local soldiers. With a small donation of just \$12.00 you can send a soldier a care package that will brighten up his/her day!

What is a Care Package? A wish list of items the soldiers have requested throughout the year, that could include a bar of soap, beef jerky, Tylenol, mini first aid kits, sox, disposable cameras, note pads, pen, pencils, playing cards, balls, Frisbees, holiday items (santa hats or Halloween items), the list is endless, however the items are small.

We are requesting you **"Adopt-A-Box"**, and **NOT** bring specific items. This will allow the H.O.T. organization to fill the boxes with items they have collected and also ship boxes to soldiers who requested specific items.

Do you have a friend or relative from Massachusetts currently serving in Iraq or Afghanistan that you would like to send a care package to? The H.O.T. organization has provided us with a Care Package Registration Form. See attached! If you have a specific request, complete this form and provide it to a CAMI Staff member upon registration. Once received your soldiers information will then be registered into the H.O.T. Program for future care package deliveries.

ISPE Boston Area Chapter's GOAL is to have **200** boxes adopted by the end of the night – so HELP us reach our goal by Adopting 2 boxes each!

Thank you for your Support! The ISPE Boston Area Chapter has a long history of helping the less fortunate with recent charitable donations to Toys for Tots, Backpacks for Kids, and Project Place.
Purchase one Box for \$12 and receive one raffle ticket!
Purchase two Boxes for \$24 and receive one raffle ticket and one drink ticket!

Click here to register online: [New Year's Social](#)
Click here for the Care Package Form and Social flyer: [Care Package and Social Flyer](#)

Dual-track Seminar on Process Automation & Control

Track 1: Introduction to Automation in Life Sciences



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Track 2: Advanced Process Control for Greater Profitability

Thursday, January 20, 2011
Hyatt, Cambridge, MA

Track 1: Introduction to Automation The field of automation is loaded with buzzwords and acronyms like I/O, PLC, HMI, DDS, BMS, PID loops, busses, etc., which are widely used in the industry, but can create confusion. You may think that automation matters little to you in your job, but you would be surprised at how much of a role it plays in your daily life. Regardless of whether you are involved in an entry level automation position or just want to understand the topic better, this session will give you the core knowledge that you need to understand automation. Attendees will learn that all systems, regardless of how complicated or proprietary they are, utilize the same basic building blocks. Control concepts such as PID loops, open and closed loop control, automation terminology, communication architecture, and process monitoring and control functions will be covered. The audience may also have the opportunity to see some of the hardware involved with some control functions and processes.

SPEAKER:
Tim Alosi, VP of Operations Management & Intelligence, New England Controls, Inc.

Track 2: Advanced Process Control for Greater Profitability

Advanced control systems have been utilized in refineries, pulp and paper factories, and chemical plants to reduce variability, streamline processing, minimize waste, and increase profits. However, our industry has some unique requirements and standard modeling does not always yield the desired results. Advanced control systems such as Neural Networks, fuzzy logic, etc. are gaining success in demanding applications at local biotech facilities. Leading companies in the area have optimized some of their most complex applications with the use these of advanced control systems.

Attend this advanced session to learn why alternative advanced controls systems were sought, their potential applications, how they were integrated into existing control systems, their impact on documentation and validation, the return on investment, and more during this lively discussion.

SPEAKERS:
Joe Kauten, Lonza Biologics Inc.
James Heimbach, Lonza Biologics Inc.

Click here to: [Register Online](#)
Click here for the: [Meeting Flyer](#)

Save These Dates!

February 9, 2011
Career Transformations: Capitalizing on Your Transferrable Skills

February 17, 2011
Risk-Based C&Q Case Studies: A Panel Discussion

March 17, 2011
Shire Tour and Educational Program

Members Gather to Celebrate "Chapter of the Year" Repeat Win

by Janet Tice, GMP Piping, with photos by Joyce Chiu, CPIP, Honeywell Safety Products

In a repeat of last year's festivities, the Boston Area Chapter again gathered at the Sonesta in Cambridge to celebrate its big win at Annual Meeting. This time, the Chapter won the coveted Platinum Grand Award for Excellence and Innovation - for the second year in a row! In addition, the Chapter was honored with two additional awards: the Grand Award for Innovation in Member Services and the Grand Award for Innovation in Programs and Events. Finally, the International Student Poster Competition Award in the Graduate Category went to Sheba Goklany of Northeastern University, a Boston Area Chapter student member.



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Chapter Vice President Brian Hagopian and Product Show Committee Co-Chair Laurie Masiello helped the Chapter celebrate success.

Chapter Past-Presidents Sylvia Beaulieu (2010) and Doyle Johnson (2009) earned Chapter of the Year Awards two years in a row.

What better reason for a celebration to sing the Chapter's praises and thank the many volunteers who made this exciting win possible? And celebrate we did - with drinks, hors d'oeuvres, a cake with icing proclaiming our win, and a thank you to Chapter volunteers and Members from 2010 Chapter President Sylvia Beaulieu, whose energy and creative vision helped cement our triple win. As the evening drew to a close, and with the new year fast approaching, current President Jim Grunwald took the floor and encouraged the crowd to work hard for another win in 2011. After all, three's a charm!

The Innovation in Member Services Award and the Member Services Committee whose efforts helped earn it: (l to r) Ric Feldt, Joyce Chiu, Chair Bob Urbanowski, Ann Engelkemeir and Barry Potts.

Boston Area Chapter Hosts Japan Affiliate

by H. Steven Kennedy with photos by Shigeru Nakamura, Head of Secretariat, Japanese Affiliate

On November 1st, the Boston Area Chapter welcomed a group of 20 delegates from the Japan Affiliate to Boston as they passed through on their way to the ISPE Annual Meeting in Orlando. The Chapter's Board of Directors hosted a reception and dinner for the visitors at Legal Seafood in Cambridge. The event was co-coordinated between Shigeru Nakamura, Head of Secretariat for the Japanese Affiliate and myself on behalf of the Board of Directors.

<http://www.ispeboston.org/newsletter/index.php?id=31&do=cat&showAll=1>[3/7/2011 7:55:42 AM]



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Past President Sylvia Beaulieu and Japan Affiliate Member Masayuki Akutagawa enjoyed comparing notes over dinner.

The evening opened with the traditional Japanese toast - Kampai - followed by a presentation on the Chapter and its activities that I had prepared especially for this event. Nakamura-san followed with a reciprocal presentation about the Japan Affiliate. Nakamura-san concluded his presentation with an invitation to the Board to travel to Japan in the spring to help the Japanese affiliate celebrate their tenth anniversary. Discussions followed, exploring how the Boston Area Chapter can help support initiatives by the Japan Affiliate to expand their educational offerings in the area of biomanufacturing.

To bring the evening to a lively close, Nakamura-san led the new group of friends in Tejime - a Japanese custom of ceremonial rhythmic hand clapping performed at the end of a special event. The Japan Affiliate was invited to attend the Boston Area Chapter reception at the ISPE Annual Meeting and a few days later the group reconvened in Orlando, where the friendships forged over food and drink in Boston were strengthened further at (Boston's own) Todd English's restaurant, Blue Zoo.

ISPE Annual Meeting & Student Poster Contest - A Winning Combination

by Sheba Goklany, PhD Candidate, Northeastern University with photos by Teo Zi Qiang, PhD Candidate, Nanyang Technological University

With its beautiful tropical weather and Disney's largest creation, Orlando was the perfect getaway destination from Boston. My friend and I, representing Northeastern University, were headed there for the ISPE Annual Meeting and Student Poster Contest. We arrived in Orlando on Saturday. We were staying at the Disney Swan and Dolphin Resort, which was also the venue for the meeting. During our stay there, we got an opportunity to wander around the world-famous Disney World. We also had the chance to explore Epcot, showcasing different parts of the world such as Canada, United Kingdom, and China, and Disney's Hollywood Studios, presenting the "Spectacle of Dancing Lights." The atmosphere in Orlando was one of sheer magic.



Proud winner Sheba Goklany (center, front) of Northeastern University with fellow students following the Awards Luncheon at the ISPE Annual Meeting in Orlando.

For us, the Annual Meeting kicked off on Sunday with a luncheon hosted by the Young Professionals. This was a networking event to gather the undergraduate and graduate students from all over the world participating in the Poster Contest, including those from Singapore and Turkey. This event also focused on connecting with young professionals in the biotech industry who were more than happy to mentor us and encouraged us to provide feedback to help make ISPE more beneficial for its young members. Never before have I seen such involvement and commitment on the part of members of a professional organization in an effort to help students by sharing their experiences, knowledge, and support and by guiding them through their academic and professional careers.

Besides learning about the different aspects of the biotech industry, the ISPE meeting was a great place to meet,



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network, and make new friends. Events included keynote sessions, presentations from several industry leaders, product exhibits, networking breakfasts/dinners, and even a 5K walk/run for the fitness-conscious. In addition, each local Chapter had organized an exclusive social event for its members. The Boston Area Chapter had arranged cocktails and dessert on Sunday night giving all of us the opportunity to mingle with the locals in the Boston area biotech industry.

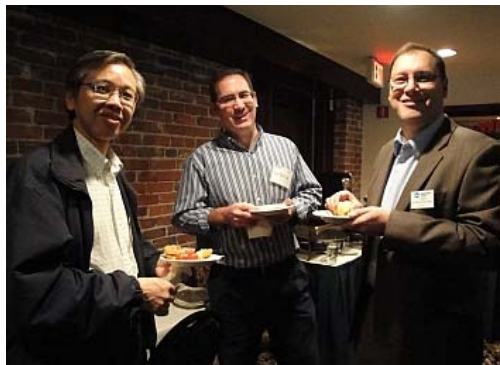
The Poster Contest was on Monday afternoon. I remember practicing my talk just prior to the competition. I think the biggest challenge for me was to fit my presentation into the five-minutes allotted to each presenter. Even though I was nervous, I was happy that I had the opportunity to compete at the international level and also to interact with and learn from so many ISPE members. At the awards ceremony I was surprised and overjoyed when my name was called out as the winner of the graduate-level competition. To receive the award in front of thousands of leaders from the industry was truly a humbling experience and a privilege.

This was my first time at the ISPE Annual Meeting and it was a great experience. My special thanks to Rick Pierro (President of Superior Controls), Kevin Lynch (Director of Manufacturing at Shire), Dr. Carolyn Lee-Parsons (my advisor at Northeastern University), and Hong Long (President of the ISPE Student Chapter at Northeastern University) for providing me with valuable feedback on my poster and for helping me prepare for this event. I am also grateful to the ISPE Boston Area Chapter for sponsoring our trip to Orlando and giving us this valuable opportunity to showcase our research and connect with people from the pharmaceutical industry worldwide. For those of you who ever get the chance of attending one of these ISPE meetings, I would say, "Go for it, it will be an event to remember and cherish for a long time to come".

"Negotiation for Success" Workshop Provides Useful Insights

by Barry Potts, AutomaTech with photos by Joyce Chiu, CPIP, Honeywell Safety Products

Have you ever hoped to better understand and practice negotiation skills and principles that would help in your business and personal lives, in your daily interactions with clients, co-workers, family members, friends and neighbors? Learning how to uncover underlying interests and mutually beneficial opportunities to create win-win solutions in even the toughest negotiating situations was the subject of the workshop presented by the Member Services Committee, on the evening of November the 3rd at the Elephant & Castle Pub and Restaurant in Boston.



Chapter Board Member Steven Kennedy (far r) chats with workshop participants (l to r) Dan Gee and Robert Fortier.

made for a relaxed atmosphere where ISPE members as well as non-members were able to meet with friends and foster new relationships while learning new skills or polishing an existing skill-set.

The instructor for this session was D. Mark Fourman of Unify Consulting, a respected consultant specializing in conflict resolution and alliance management. Since 1992 Mark has trained and coached staff from the boardroom to the bench in leading biopharmaceutical companies such as GlaxoSmithKline, Roche and Genentech as well as many smaller biotechs.

This highly interactive workshop involved role playing activities of 5 to 15 minutes each in a fun and engaging environment with four small breakout groups, each with their own whiteboard, all trying to brainstorm and figure out compromises, solutions, etc. based on a scenario that needed to be negotiated. Case studies and workshop exercises ran the gamut, ranging from a business situation involving two companies negotiating to support a new product launch in a threatened economy, to everyday situations that can occur in one's own neighborhood. This all



Role playing activities in small breakout groups resulted in immediate camaraderie among participants. Pictured: John Vital, Chris Coughlin, Julieann Dickerman and Karen Snyder.

Mark pointed out that these principles - uncovering underlying interests and mutually beneficial opportunities to create win-win solutions - have even been applied to resolve situations involving international political relationships. While most of us won't be negotiating on such a grand scale, learning and understanding the steps behind successful preparation and negotiation can be very helpful. In fact, a couple of workshop attendees reported back that they were able to make use of what they had learned the very next day!

EMD Serono Hosts Facility Tour & High Purity Water Panel Discussion

by Sean Brown, Lantheus Medical Imaging, and Brian Hagopian, Mar Cor Purification, with photos by Joyce Chiu, CPIP, Honeywell Safety Products

The Boston Area Chapter participated in an exciting tour of EMD Serono's Project Unity in Billerica on December 9th. It was clear from the start that this was an extraordinary location for the Hot Topics in High Purity Water discussion that followed the tour. The event began in the early evening on a bitterly cold New England day, with flurries possibly giving way to winter weather. Although this might have meant a dropoff in attendance, the weather was not a factor for this sold-out educational event due to the spectacular venue and intriguing presentation.

The audience was filled with people from across New England who traveled to see this magnificent project. The event started out with a networking social sponsored by Jones Lang LaSalle prior to the departure of several "flights" piloted by a team of tour guides from the Facilities Management group. The venue provided insights into the cutting edge technologies utilized throughout the project to create an energy efficient and sustainable facility to support EMD Serono's quest to address "unmet" medical needs.



[Lucky Members get a behind-the-scenes look at EMD Serono's newly completed research center.](#)

Tony Meenaghan, EMD Serono Senior Director of Facilities Management and Engineering, EHS, followed with an informative overview of Project Unity, the culmination of the strategy to create a global research presence in the US. Project Unity creates a modern, collaborative environment by bringing Technical Operations and Research together under one roof - a 140,000 square foot research facility that will ultimately achieve LEED gold certification. Coincidentally, the date of our visit was also the official Project Unity completion date!

Tony provided a colorful overview of the project from inception to occupancy, as well as a passionate description of the value this investment will provide to the healthcare and patient community. He then passed the baton to Alan Ames, President at BR+A who provided a deep dive into the project programming and the significant features of this

unique facility, including the sustainable energy savings infrastructure, that will position EMD Serono to reap its benefits well into the future.

The tour and Project Unity presentations were followed by a standing room only discussion on Hot Topics in High Purity Water which was moderated by Boston Area Chapter Vice President, Brian Hagopian of Mar Cor Purification. The panelists were a mix of suppliers and end users with local, national and international experience, and represented yet another example of the quality of speakers the Chapter is able to attract. At the beginning of the session, attendees were encouraged to join the ISPE critical utilities community of practice (COP) to keep up to date on the topic of high purity water.



[Attendees included Student Members from the Student Chapter soon to be formed at WPI.](#)

The panelists demonstrated their thorough knowledge of the subject matter and responded to a wide range of complex questions posed by the audience during the lively and interactive session that followed. Audience questions covered a broad spectrum of topics, including the effect of water supplies on water treatment processes, water treatment performed by municipalities (particularly the MWRA) before the water even reaches our buildings, and effective methods of chlorine/chloramine removal along with symptoms and corrective actions associated with ammonia. A few audience members volunteered their experiences by offering suggestions on treatment, detection, and monitoring techniques they have used successfully.

Attention next turned to the subject of biofilm, where the panelists drew distinctions between biofilm (and the bacteria that create biofilm) upstream and downstream of a reverse osmosis (RO)

system. And what would a pure water session be without discussion on the topics of validation and rouge? Panelists shared their experiences on "breaking into" a validated system to extend piping loops to new areas and the validation impact of such changes.

As for rouge, many of you know rouge is prevalent in heated WFI and some USP systems and it was postulated that the presence of carbon dioxide may accelerate rouge formation. Panelists discussed the different types of rouge along with detection methods and how to determine when to plan a shutdown to remove rouge. The pros and cons of risk-based approaches were examined and compared against planned shutdowns where multiple activities such as calibrations, gasket changes, etc. could be combined for cost effectiveness.



Moderator Brian Hagopian (center) with "high purity water" panelists (l to r) Christopher Corsetti, Bob Livingston, Anthony Bevilacqua, Rick Kotosky.

There was such a high level of interest in the topic of rouge that we have planned a follow up technical article in an upcoming issue of this newsletter. And because of the importance of pure water to our industry as demonstrated by the turnout and lively discussion at this event, members can expect to see more coverage of water purification topics in future newsletters and educational programs.

This expert panel provided great insight and practical knowledge during the panel discussion. Our sincere thanks go to Anthony Bevilacqua (Mettler-Toledo Thornton), Christopher Corsetti (Genzyme), Bob Livingston (Arion Water) and Rich Kotosky (Organogenesis) for their time and valuable contributions to the success of this event.

Young Professionals Brave Cold to Attend Winter Social

by Marjorie Bruce, Capaccio Environmental Engineering

On the first Tuesday of December the Boston Area Young Professionals held a Winter Social at Flat Top Johnny's in Kendall Square to kick off the holidays. Many young professionals braved the first real cold snap of winter to play pool, eat good food, and network. The goal of this event was to bring new faces out to ISPE and show them some of the benefits of the YP group and it definitely accomplished its goal.

The Winter Social began at 7pm and the pool tables served as an excellent ice breaker to begin conversations. By the end of the night, everyone was deep in discussion with pool forgotten, as people exchanged business cards and ideas. All the attendees were able to mingle and talk with members of the YP committee to learn about our goals for the upcoming year as well as events taking place in the near future. Several attendees expressed interest in joining the YP committee, which is always in need of volunteers.

Keep your eyes open for announcements about our next social in early February - details to be announced. We are particularly interested in reaching out more effectively to area students and plan to hold an event especially for them in the near future as well. We welcome any ideas and suggestions for future events! If you have any ideas or feedback, please don't hesitate to email us at ispe@camihq.com. We look forward to hearing from you!

YP Educational Event on Chromatography and Project Management a Hit

by Jillian Willard, Genzyme, with photos by Aarash Navabi, Genzyme

On November 17th, young and seasoned professionals alike came out to Genzyme Center in Kendall Square to attend an educational event on Chromatography and Project Management. Angela Lewandowski, PhD, from Genzyme's Purification Development group started the night off with a presentation on Chromatographic Protein Purification. She discussed the basics of chromatography, possible issues seen in scale-up of chromatographic processes and the major factors to consider when developing chromatography steps. Former Boston Area Chapter President Niall Johnson followed with a Crash Course on Project Management. With only 60 minutes to present, Niall was able to squeeze in an overview of the basics of project management, the main causes of project failures, what makes a great project manager, the major challenges faced by project managers, the elements of a successful project and the pitfalls to avoid.



Niall Johnson describes the trials & tribulations of Project Management to a rapt audience of young professionals at Genzyme Center in Cambridge.

The event had record attendance for a YP educational event, with more than 75 people packed into the lecture hall at Genzyme Center to hear two excellent presentations from experts in their respective fields. Keep your eyes open for announcements of our educational event in January on the topic of automation. This will be a good first look into what automation is and how it is influencing our industry. Hope to see you all then!

Industry News in Brief

RXi, ACT Land Nearly \$1M Each in Federal Research Grants

Worcester-based RXi Pharmaceuticals and Advanced Cell Technology (ACT) have each received four tax exempt grants totaling nearly \$1 million from the Internal Revenue Service as part of the Patient Protection and Affordable Care Act of 2010. The program provides financial support for biotech research aimed at making clinical breakthroughs. RXi said it plans to use the money in the development of RNAi drugs in a number of disease areas. ACT is developing stem cell-based treatments for regenerative diseases. The program's grant applications were reviewed by the IRS and the US Department of Health and Human Services. Of the total grant amount, about \$800,000 is expected to be received by the end of the year and the remainder will be received in January. (Source: Matthew L. Brown, Worcester Business Journal, 2 November 2010)

ACT Gets OK for Clinical Studies on Drug for Stargardt's Macular Dystrophy

Advanced Cell Technology (ACT) has received government approval to move forward on clinical testing for an eye disorder treatment using stem cells. ACT is developing a drug for Stargardt's Macular Dystrophy, which causes vision problems and can lead to blindness in children. The company will test its stem-cell based treatment on 12 patients across the country. One of the test sites could include UMass Memorial Medical Center in Worcester. Macular degeneration, which Stargardt's is classified as, impacts more than 30 million people in the US and Europe, according to ACT. (Source: Brandon Butler, Worcester Business Journal, 22 November 2010)

ACT Seeks FDA Approval For Studies on Treatment for Macular Degeneration

Advanced Cell Technology has filed an application with the FDA seeking permission to begin the first phases of studies into a stem cell-based treatment for macular degeneration, an eye disorder that can cause blindness. The company said macular degeneration represents a \$25-billion to \$30-billion market opportunity and that there are currently no FDA-approved treatments for the most common, "dry" form of macular degeneration. In its studies, ACT will transplant retinal pigment epithelial cells derived from human embryonic stem cells into patients with dry age-related macular degeneration. The company has already received approval from the FDA for a similar process for treating juvenile macular degeneration. (Source: Matthew L. Brown, Worcester Business Journal, 30 November 2010)

GlycoSolutions Moving to Marlborough

Elizabeth Higgins, founder of GlycoSolutions of Worcester, plans to open up shop in Marlborough in early 2011. According to Higgins, now is "a great time to be looking for real estate." GlycoSolutions will be moving from its 1,800 sqft lab at the Massachusetts Biotechnology Initiative's incubator space on Innovation Drive in Worcester to more than 5,000 square feet of lab space in Marlborough. The company, which does quality control testing for pharmaceutical companies, will have new offices at 33 Locke Drive, a three-story, 60,000 sqft building just off of Interstate 495. Sunovion Pharmaceuticals (formerly known as Sepracor) previously occupied the entire building at 33 Lock Drive, but vacated the space when its new headquarters was built off of Interstate 290.

"It can be very difficult for companies to find small lab space, especially smaller than 10,000 square feet," said William Sullivan, a vice president with Wayland-based real estate company RW Holmes, which brokered the GlycoSolutions lease on behalf of WRT Management. "But right now is still a tenant's market, so you can find some good deals."

As for the GlycoSolutions' business, work has been steady during the past few years, although Higgins would not release financial information about the company. She said more companies are outsourcing the type of quality control work that GlycoSolutions does in an effort to create cost savings. (Source: Brandon Butler, Worcester Business Journal, 2 November 2010)

Boston Scientific to Sell Neurovascular Unit to Stryker for \$1.5B

Natick-based Boston Scientific has signed an agreement to sell its neurovascular business to Stryker Corp. for \$1.5 billion in cash. Boston Scientific's neurovascular division is located in Fremont, CA and employs about 1,150 people. It reported revenue of \$348 million last year. The division develops less-invasive technologies used to treat brain aneurysms and other types of cerebrovascular diseases. Stryker has facilities in Cambridge and Hopkinton and is based in Michigan.

The sale agreement calls for Stryker to pay \$1.4 billion to close the deal, and \$100 million once certain products being developed by the neurovascular division are brought to market and other requirements are met. Boston Scientific said it expects total after-tax proceeds of about \$1.2 billion, which it will use to make acquisitions and pay off debt. The deal is expected to close before the end of 2010. (Source: Matthew L. Brown, Worcester Business Journal, 28 October 2010)

Boston Scientific Gets European Stent Approval

A stent produced by Natick-based medical device manufacturer Boston Scientific has met European Union quality standards. The WallFlex Biliary RX Fully Covered Stent is made of braided wire, which helps hold its form, but is also flexible to conform to a patient's need. It also maximizes visibility to help doctors check up on the stent. The product has not yet been approved for use in the U.S. The company will be showcasing the product at a gastroenterology conference in Spain. (Source: Brandon Butler, Worcester Business Journal, 22 October 2010)

Boston Scientific Gains Two Approvals for Plastic Stent System

Natick-based medical device maker Boston Scientific said it has received clearance from the FDA and CE Mark

approval for a plastic stent system. The system is already available in Europe and other markets. The company intends to offer it in the U.S. beginning this quarter. The CE Mark is a European health and safety designation. The stent is designed for the treatment of biliary strictures, a narrowing of the bile duct between the liver and the small intestine. The system can be implanted by an endoscopic procedure rather than invasive surgery. (Source: Matthew L. Brown, Worcester Business Journal, 21 October 2010)

Biogen Idec to Cut 650 Jobs, Including 86 in Massachusetts

Biogen Idec has said it will reduce its workforce by 13 percent, or 650 jobs, as part of cost-cutting efforts that aim to realize annual savings of \$300 million. The workforce in Massachusetts will be pared by 86 jobs to 1,900, a roughly 4 percent cut to the company's Bay State workforce. The cuts will come from all four of the company's current sites: Weston, Cambridge, Waltham, and Wellesley. Plans call for closing of offices in Waltham and Wellesley, with some administrative employees from Waltham and Wellesley to be moved to corporate headquarters in Weston.

Taking the biggest hit will be the former Idec Pharmaceuticals oncology research site in San Diego, which employs 327 workers. Biogen, then based in Cambridge, purchased Idec in 2003. Another 123 jobs will be eliminated across the country as Biogen Idec shifts the US sales and marketing of its Rituxan cancer drug to its partner, the Genentech division of Swiss drugmaker Roche Holding AG, which markets the drug in Europe. Forty jobs will be eliminated outside the US and six at Biogen Idec's operation at Research Triangle Park in North Carolina. When workforce reductions are completed, the company said it will have approximately 4,275 employees worldwide.

"The company will terminate its efforts in cardiovascular medicine and seek to spin out or outlicense its oncology assets" as part of a strategy to focus on its core business, Biogen Idec said in a press release. The company said it now looks to focus on neurology and to leverage its strengths in biologics R&D and manufacturing as it seeks to pursue select, high-impact biological therapies.

Biogen Idec chief executive George Scangos said in a statement: "Biogen Idec will be better off as a result of these actions. First, we will have increased focus. We have been operating in too many therapeutic areas and haven't maximized our opportunities. We will now focus on a few areas where we can be among the best, and this starts with neurology. We have excellent R&D and commercial capabilities in neurology, and we will build from that strength. We also have expertise and some excellent programs in hemophilia and immunology and will pursue select projects in those therapeutic areas as well. We will leverage our strengths in biologics manufacturing to bring forward our own projects as well as aggressively in-license projects in our target areas. Second, as a result of these actions, Biogen Idec will be leaner, more nimble and more decisive. Importantly, the initiatives will save more than \$300 million annually and will position Biogen Idec to accomplish great things in the future." Scangos took over as company chief executive earlier this year. (Source: Robert Weisman and Chris Reidy, Boston Globe, 3 November 2010)

Novartis Discontinues Clinical Trial Program for Cancer Treatment ASA404

Novartis has announced that the clinical trial program for the investigational cancer treatment ASA404 (vadimezan) will be discontinued and resources will be reallocated to other compounds in the oncology pipeline. The decision was made after interim results from a Phase III trial showed that ASA404 would not likely meet the primary endpoint of significantly extending overall survival when used in combination with chemotherapy for the second-line treatment of patients with advanced non-small cell lung cancer (NSCLC).

The study, called ATTRACT-2 (Antivascular Targeted Therapy: Researching ASA404 in Cancer Treatment), included patients with advanced (stage IIb/IV) NSCLC of squamous or nonsquamous histology who experienced disease progression on or following an initial chemotherapy regimen. The trial has been stopped early based on a recommendation from an independent data monitoring committee. Investigators involved in the study and regulatory agencies have been notified of the decision to stop the trial. Novartis does not plan to proceed with regulatory filings based on these data. (Source: Novartis Website, 11 November 2010)

Alnylam Licenses Ebola treatment

Alnylam Pharmaceuticals said it has licensed a potential treatment for Ebola virus to Tekmira Pharmaceuticals. The company granted Tekmira a license for a target-specific InterfeRx, which uses gene-silencing technology. Detailed financial terms were not disclosed, but include royalties on sales of any resulting product under the licensing agreement.

"We now have broad access to Alnylam's leading intellectual property for the development of eight RNAi therapeutic products, including TKM-Ebola. We are encouraged by the strong preclinical data supporting the development of TKM-Ebola and look forward to filing an IND in the second half of 2011," said Mark J. Murray, Tekmira president and chief executive. "The TKM-Ebola program is fully funded under a \$140 million contract Tekmira signed with the US government earlier this year." To date, Alnylam has granted InterfeRx licenses to a total of six companies, including Tekmira. (Source: Boston Globe, 5 November 2010)

GlaxoSmithKline Nears Deal to Acquire China's Nanjing MeiRui Pharma

UK-based drug maker GlaxoSmithKline plc is nearing a deal to buy Chinese drug maker Nanjing MeiRui Pharma, according to media reports. The deal, which is likely to be valued in the low hundreds of millions of dollars, would enable the company to boost its presence in the fast-growing Chinese market.

Hurt by lower sales due to generic competition and negative sales trends in the U.S. and Europe, drug makers like GlaxoSmithKline are seeking to enhance their presence in the fast growing emerging markets. Glaxo had about \$10 billion of cash on its balance sheet at the end of the recent third quarter. The company has stated that it intends to use a portion of the cash to fund acquisitions.

Nanjing MeiRui's presence in the urology market in China is seen as a key attraction for Glaxo, which sells the urology drug Avodart. MeiRui's relations with Chinese urologists could help Glaxo build awareness for Avodart, which treats benign prostatic hyperplasia, the ailment commonly known as an enlarged prostate.

MeiRui is owned by Pagoda Pharma Group, a British Virgin Islands-based holding company that established MeiRui in

1996. MeiRui competes in the \$30 billion Chinese hospital pharmaceutical market and the medical diagnostic market. According to the company, the pharmaceutical market in China has grown at 27 percent per year over the last five years. MeiRui's products address both the urology market and the allergy segment of these markets.

In mid-October, GlaxoSmithKline reported a lower profit for the third quarter, hurt by higher restructuring costs and charges related to its diabetes drug Avandia. The company also witnessed sales declines in its pharmaceuticals business. (Source: RTT News, 1 December 2010)

Merck Agrees to Buy Biotech Firm SmartCells

Merck has announced a definitive agreement to acquire privately held SmartCells, which is developing a diabetes treatment, for potential aggregate payments in excess of \$500 million. Merck said SmartCells shareholders will receive an upfront cash payment and be eligible to receive clinical development and regulatory milestones for products resulting from the transaction. The company added that it will make sales-based payments for products resulting from the transaction. The deal has been unanimously approved by SmartCells' board of directors.

SmartCells is focused on developing glucose-regulated SmartInsulin products for the treatment of diabetes. The company's core technology was originally developed by its president, co-founder and chief executive officer Dr. Todd Zion.

Nancy Thornberry, senior vice president and head, diabetes and obesity franchise, Merck Research Laboratories stated that SmartCells' innovative technology would enable the company to develop glucose-responsive insulins. "If this investigational technology is ultimately approved for use with patients, it could provide an important new therapy for the treatment of diabetes. This holds the potential to significantly impact the treatment of this disease," Thornberry added. Zion said, "This acquisition positions our novel technology for success in the hands of a leading pharmaceutical company with proven expertise and exceptional resources to deliver breakthrough diabetes products to patients." (Source: RTT News, 2 December 2010)

Pfizer Withdraws Drug for High Blood Pressure

Pfizer has said it is pulling its blood pressure drug Thelin off the market and stopping all trials because the drug can cause fatal liver damage. Thelin is sold in the European Union, Canada, and Australia as an oral treatment for severe pulmonary arterial hypertension, or high blood pressure in the pulmonary artery. Pfizer said two patients who were taking Thelin died during a clinical trial, and a review of data from clinical studies and postmarketing reports showed a new link to liver injury. Liver damage was a known side effect of Thelin and similar drugs, the company said, but the review uncovered a link to liver damage that was not tied to identifiable risk factors. Pfizer said the withdrawal was voluntary and added that it has withdrawn its filing for marketing approval in the US. (Source: Boston Globe, 11 December 2010)

FDA Panel Backs New Weight-Loss Pill

Orexigen Therapeutics Inc. won a FDA panel's backing for Contrave, a new diet pill that may be the first prescription weight-loss drug approved in more than a decade. Contrave's benefits in helping obese people lose weight are greater than the drug's potential long-term risks, outside advisers to the FDA said in a 13-7 vote. The panel earlier said a study of Contrave's heart risks should be done after approval. The FDA usually follows its advisers' recommendations and is scheduled to make a decision on approval by January 31st.

Orexigen and partner Takeda Pharmaceutical avoided safety concerns that delayed competing products from Arena Pharmaceuticals and Vivus in October. About 68 percent of American adults are overweight. The FDA hasn't approved a prescription weight-loss drug since Roche Holding AG's Xenical in 1999. The drug is now the only long-term option for treating obesity.

Contrave is a combination of two approved drugs that target different parts of the brain that influence appetite and cravings. The pill contains bupropion, an antidepressant also used to quit smoking, and naltrexone, a treatment for alcohol and painkiller addiction. Takeda paid \$50 million upfront for co-promotional rights to Contrave in the U.S. and exclusive rights in Canada and Mexico. (Source: Catherine Larkin, Bloomberg News, 8 December 2010)

J&J Sets Dutch Deal; Leaves Option Open

Johnson & Johnson said it plans to proceed with its agreed \$2.27 billion cash takeover offer for Dutch biotechnology company Crucell NV. However, J&J left open the option to change the terms if problems at Crucell's manufacturing plant in South Korea prove worse than thought.

Crucell in late October abandoned its full-year earnings targets after suspending operations at its Shingal facility in South Korea and temporarily halting shipments of two vaccines because of sterility issues at the plant. The companies said they expect the facility to resume manufacturing in February 2011.

J&J said in a statement that the two companies have agreed to go ahead with the deal. But J&J added that while the impact of the Korean manufacturing issues, as described in Crucell's financial results for the third quarter, wouldn't alone constitute a material adverse effect, "all effects relating to the Korea manufacturing issues, including those related to the period prior to commencement of the offer," may be taken into account in combination with further developments that might become known to J&J. The Dutch market regulator, Autoriteit Financiële Markten, said that once it has approved a merger, the rules to amend the offer are very strict, making it difficult to adjust the bid.

In early October, Crucell and J&J said they had reached an agreement on J&J's cash offer for the portion of the Dutch vaccine maker it doesn't already own. J&J holds about 17.9 percent of Crucell shares, and the offer is for the shares outstanding. In its statement, J&J said it expects to get final approval for the offer from the Dutch regulator before Crucell's general shareholder meeting. (Source: Anna Marig van der Meulen, Wall Street Journal, 2 December 2010)

Glaxo Halts Development of Sirtris's Resveratrol

GlaxoSmithKline stopped development of SRT501, a drug designed to mimic the benefits of red wine, saying the

medication didn't work well enough in cancer patients and could worsen kidney damage.

A clinical trial of the compound was halted this year after kidney damage developed in some patients, the company said in May. After reviewing results of the study in multiple myeloma patients, the company dropped the compound, which is also known as resveratrol, said Claire Brough, a Glaxo spokeswoman. "These data suggested this formulation of resveratrol may only offer minimal efficacy while having a potential to indirectly exacerbate a renal complication common in this patient population," she said.

The decision means Glaxo has given up on the leading drug candidate from Cambridge-based Sirtris Pharmaceuticals, which Glaxo acquired for \$720 million in 2008. Another drug, SRT2104, is being tested in "a number of" midstage clinical trials for use against Type 2 diabetes and psoriasis, among other illnesses, Brough said. An early-stage trial was recently completed on a third compound, SRT2379, she said.

Resveratrol, a compound found in red wine, switches on a class of proteins called sirtuins that may prevent gene mutations and repair DNA damage, potentially slowing the aging process. (Source: Albertina Torsoli, Bloomberg News, 2 December 2010)

Genzyme to Sell Diagnostics Unit for \$265M to Japan's Sekisui Chemical

Genzyme's sales of non-core businesses continues. The company said that it has agreed to sell its diagnostic products business to Japan's Sekisui Chemical for \$265 million in cash. The deal takes Genzyme, the world's largest provider of drugs for rare genetic diseases, a step further in sharpening its focus as it fights off an unsolicited takeover bid from the French drug giant Sanofi-Aventis.

Sekisui, which is expected to close on its purchase by the end of 2010, is offering jobs to the some 575 employees of the Genzyme diagnostics business, which has operations in Framingham, San Diego and at least four other locations, according to Sekisui. The diagnostics business, which brought in \$167 million in 2009 revenue, sells raw materials and other products for the cardiovascular, diabetes, infectious disease and renal health markets.

Genzyme announced in May that it planned to sell off its diagnostics business and two others as part of a plan to raise shareholder value. In September, the 29-year-old company sold its genetic testing business to Burlington, NC-based Laboratory Corporation of America for \$925 million. Genzyme still has one of the three businesses, its pharmaceutical ingredients unit, on the block. The company says it might use proceeds from these transactions to finance the second half of its \$2 billion stock buyback, which was also announced in May. (Source: Ryan McBride, Xconomy, 18 November 2010)

Eli Lilly to buy Avid Radiopharmaceuticals for \$300M Plus

Philadelphia-based Avid Radiopharmaceuticals has agreed to be acquired by Eli Lilly for \$300 million up front and up to \$500 million in additional payments. The additional money is contingent on regulatory and commercial milestones for florbetapir, a molecular imaging agent Avid is developing to detect a type of plaque in the brain that signals Alzheimer's disease.

Avid was spun out of the University of Pennsylvania and develops molecular imaging products to enable early detection of pathology associated with neurodegenerative diseases. It will continue to be based in Philadelphia after the closing of the deal, which must be approved by antitrust regulators.

Pennsylvania-based Safeguard Scientifics owns 13 percent of Avid, which it has invested \$12 million in since May 2007. Safeguard said it expects to receive at least \$36 million from the sale, with the possibility of getting much more if Avid meets performance milestones. Safeguard said it will offset the taxable gain on the deal with part of its \$355 million in tax-loss carryforwards.

Safeguard invests in life-sciences and information-technology companies. Another life-sciences company in its portfolio agreed to be acquired last month. Clariant agreed to be bought by the GE's healthcare unit in a deal that Safeguard said will net it \$145 million. (Source: Peter Key, Philadelphia Business Journal, 8 December 2010)

FDA Clears BG Medicine's Heart-Failure Test

BG Medicine, a Waltham diagnostics company, has received FDA clearance for its lead product in development, the Galectin-3 test to measure the progress of patients with chronic heart failure. Galectin-3 is a protein associated with progressive fibrosis, or stiffening, of the heart muscle that makes it more difficult to pump blood, BG said. The protein marker is found in about 30 percent of heart failure patients.

In January, BG said it hoped to raise as much as \$86 million through an initial public offering, but it has not updated its plan with details on the share price or number of shares it plans to sell.

While an FDA approval is always good news for a start-up, BG cautioned in its investor prospectus against expecting too much in the way of sales. The company won approval in Europe in October 2009 for a similar, manual version of the Galectin-3 test, but has generated "only a limited amount of product revenue," according to the prospectus.

Future success will depend on BG's ability to commercialize a more automated test, the company said in documents filed with the Securities and Exchange Commission. "Although our manual BGM Galectin-3 test is an important element of our commercialization strategy, we believe that automated instrument versions of our test will be required for us to achieve broad customer acceptance and clinical adoption," BG said. (Source: Luke Timmerman, Xconomy.Com, 29 November 2010)

Regulatory & Legislative Highlights

By Deepen Joshi, Sunovion Pharmaceuticals

FDA Approves Additional Medical Indication for Bristol-Myers Squibb Sprycel

The FDA has approved a new indication for Sprycel (dasatinib) for the treatment of a rare blood cancer when it is first diagnosed. The cancer, called Philadelphia chromosome positive chronic phase chronic myeloid leukemia (Ph+ CP-CML), is a slowly progressing blood and bone marrow disease linked to a genetic abnormality. Sprycel, an oral kinase inhibitor, is believed to inhibit the activity of certain proteins responsible for the growth of cancer cells. The action allows bone marrow to begin reproducing normal red and white blood cells.

The FDA granted Sprycel a priority review for Ph+ CP-CML. Sprycel is the third drug approved for Ph+ CP-CML under accelerated approval, a process allowing the FDA to approve a drug to treat a serious disease with an unmet medical need based on an endpoint thought to reasonably predict clinical benefit. Other FDA-approved drugs to treat various forms of CML include Gleevec, approved in May 2001, and Tasigna (nilotinib), approved in October 2007. Sprycel is marketed by Bristol-Myers Squibb. Tasigna and Gleevec are marketed by Novartis. (Source: FDA Website, 28 October, 2010)

FDA Approves Sunovion Pharmaceuticals Latuda to Treat Schizophrenia in Adults

The FDA has approved Latuda (lurasidone HCl) tablets for the treatment of adults with schizophrenia. Schizophrenia affects about 1 percent of the U.S. population, ages 18 years and older, in a given year. The most prominent symptoms include hallucinations, delusions, disordered thinking and behavior, and suspiciousness. Hearing voices that other people don't hear is the most common type of hallucination. These experiences can make people with the disorder fearful and withdrawn.

Latuda is included in the atypical antipsychotic class of drugs. All atypical antipsychotics contain a boxed warning alerting prescribers to an increased risk of death associated with off-label use of these drugs to treat behavioral problems in older people with dementia-related psychosis. No drug in this class is approved to treat patients with dementia-related psychosis. Latuda is manufactured by Sunovion Pharmaceuticals of Fort Lee, NJ. (Source: FDA Website, 28 October, 2010)

FDA Approves Forest Laboratories Teflaro for Bacterial Infections

The FDA has approved Teflaro (ceftaroline fosamil), an injectable antibiotic to treat adults with community acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI), including methicillin-resistant *Staphylococcus aureus* (MRSA). Teflaro is an antibacterial agent in a class of drugs known as cephalosporins, which act by interfering with the bacterial cell wall.

CABP is a bacterial infection that develops in the lungs of patients who are exposed to the bacteria in their normal environment, and not in the hospital. ABSSSI is a bacterial infection of skin and skin structures that requires antibiotic treatment and may require surgical treatment. Teflaro is marketed by New York City-based Forest Laboratories. (Source: FDA Website, 29 October, 2010)

FDA Approves New Indication for Novartis Afinitor

The FDA has approved Novartis' cancer drug Afinitor (everolimus) to treat patients with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS), a rare genetic disorder. This approval was for treatments of SEGA that can not be treated with surgery. Afinitor was first approved in March 2009 to treat kidney cancer after patients fail treatment with Sutent (sunitinib) or Nexavar (sorafenib).

TS causes benign (non-cancerous) tumors to grow in the brain and in other parts of the body including the eyes, lungs, liver, heart, skin and kidneys. TS occurs as a result of genetic mutations that lead to the development of tumors and results in a variety of possible symptoms including learning and developmental disabilities, skin abnormalities, seizures, and lung and kidney disease. The drug was approved under the FDA's accelerated approval program.

Everolimus is also approved under an alternative trade name, Zortress, for prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant. Zortress has a different safety profile in these patients. (Source: FDA Website, 1 November, 2010)

FDA & University of Rochester Announce Partnership for New Drug Products

The FDA has announced a partnership agreement with the University of Rochester to form the Analgesic Clinical Trial Innovations, Opportunities, and Networks (ACTION) Initiative. The initiative is aligned with the FDA's recently launched Initiative for the Advancement of Regulatory Science, and is designed to streamline the discovery and development process for new pain-reducing (analgesic) drug products. This multi-year, multi-phased initiative will address major gaps in scientific information that can slow down analgesic clinical trials and analgesic drug development.

Study results, best practices, and outcomes of the ACTION Initiative will be available at <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/PublicPrivatePartnershipProgram/ucm166082.htm> as they are developed. (Source: FDA Website, 1 November, 2010)

FDA Clears Eli Lilly's Cymbalta to Treat Chronic Musculoskeletal Pain

The FDA has approved Eli Lilly's Cymbalta (duloxetine hydrochloride) to treat chronic musculoskeletal pain, including discomfort from osteoarthritis and chronic lower back pain. Cymbalta was first used to treat major depressive disorder in 2004. Since its initial approval, about 30 million patients in the United States have used Cymbalta. It was approved for the treatment of diabetic peripheral neuropathy in 2004; generalized anxiety disorder and maintenance treatment of major depression in 2007; and fibromyalgia in 2008.

More than 29,000 patients have used Cymbalta in clinical trials, and more than 600 patients were studied in the clinical trials involving osteoarthritis and chronic low back pain. The safety evaluation for Cymbalta included review of data from the clinical trials as well as post-marketing data from the previously approved patient populations.

Consumers and health care professionals are encouraged to report adverse events to the FDA's MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/how.htm. (Source: FDA Website, November 4, 2010)

Most Drug and Biological Product Makers Meeting Postmarketing Obligations

Most makers of approved drug and biological products are meeting their regulatory obligations and meeting targets for postmarketing studies/clinical trials in a timely manner, according to a study recently released by the FDA.

The study, based on the second annual review of the status of 1,551 postmarketing studies/clinical trials, showed that 40 percent of the postmarketing studies/clinical trials had been closed (either fulfilled or released) by FDA. Of the remaining 60 percent, most were in progress and on schedule or the final report has been submitted for FDA review.

The review examined the backlog of industry postmarketing studies and clinical trials for FDA-approved drugs and biologics. The backlog was defined as all those postmarketing requirements (PMR) and postmarketing commitments (PMC) open when the Food and Drug Administration Amendments Act (FDAAA) was enacted on September 27, 2007.

Under the FDAAA, the agency must annually report the status of the backlog of PMR and PMC for all approved drug and biological products. In addition, manufacturers of drugs and biologics are required to report to the FDA in a timely manner any serious safety issues that are identified from studies or other sources. (Source: FDA Website, 9 November, 2010)

FDA Approves EMD Serono Egrifta to Treat Lipodystrophy in HIV patients

The FDA has approved Egrifta (tesamorelin) to treat HIV patients with lipodystrophy, a condition in which excess fat develops in different areas of the body, most notably around the liver, stomach, and other abdominal organs. The condition is associated with many antiretroviral drugs used to treat HIV. Egrifta, the first FDA-approved treatment for lipodystrophy, is a growth hormone releasing factor (GRF) drug that is administered in a once-daily injection. Egrifta was developed by Montreal-based Theratechnologies and is marketed in the US by EMD Serono. (Source: FDA Website, 10 November, 2010)

FDA Approves New Treatment Option from Eisai for Late-Stage Breast Cancer

The FDA has approved Eisai's Halaven (eribulin mesylate) to treat patients with metastatic breast cancer who have received at least two prior chemotherapy regimens for late-stage disease. Breast cancer is the second leading cause of cancer related death among women, according to the National Cancer Institute. This year, an estimated 207,090 women will be diagnosed with breast cancer, while 39,840 women will die from the disease.

Halaven is a synthetic form of a chemotherapeutically active compound derived from the sea sponge *Halichondria okadai*. This injectable therapy is a microtubule inhibitor, believed to work by inhibiting cancer cell growth. Before receiving Halaven, patients should have received prior anthracycline- and taxane-based chemotherapy for early or late-stage breast cancer. (Source: FDA Website, 15 November, 2010)

FDA Approves Amgen Drug Xgeva to Help Prevent Cancer-Related Bone Injury

The FDA has approved Xgeva (denosumab) to help prevent skeletal-related events (SREs) in patients with cancer that has spread (metastasized) and damaged the bone. Skeletal-related events include bone fractures from cancer and bone pain requiring radiation.

Xgeva is a monoclonal antibody that targets a protein involved in cancer-related bone destruction called human RANKL. Other FDA-approved drugs for similar conditions include Zometa (zoledronic acid) and Aredia (pamidronate disodium).

Xgeva is not approved for patients with multiple myeloma or other cancers of the blood. In patients with breast or prostate cancers, Xgeva was superior to Zometa in delaying SREs. In men with prostate cancer, the median time to an SRE was 21 months with Xgeva compared to 17 months with Zometa.

Denosumab was originally approved under another trade name, Prolia, in June 2010. Prolia is indicated to treat postmenopausal women with osteoporosis who are at high risk for bone fractures. Xgeva is administered using a higher dose and with more frequent dosing than Prolia. Denosumab has a different safety profile in patients with osteoporosis than in patients with cancer and bone metastases. (Source: FDA Website, 19 November, 2010)

Xanodyne Agrees to Withdraw Propoxyphene from the US Market

Xanodyne Pharmaceuticals, which makes Darvon and Darvocet, the brand version of the prescription pain medication propoxyphene, has agreed to withdraw the medication from the US market at the request of the FDA. The FDA has also informed the generic manufacturers of propoxyphene-containing products of Xanodyne's decision and requested that they voluntarily remove their products as well.

The FDA sought market withdrawal of propoxyphene after receiving new clinical data showing that the drug puts patients at risk of potentially serious or even fatal heart rhythm abnormalities. As a result of these data, combined with other information, including new epidemiological data, the agency concluded that the risks of the medication outweigh the benefits. (Source: FDA Website, 19 November, 2010)

FDA Begins Process to Remove Breast Cancer Indication from Avastin Label

The FDA has announced that the agency is recommending removing the breast cancer indication from the label for Avastin (bevacizumab) because the drug has not been shown to be safe and effective for that use.

Oncologists currently treating patients with Avastin for metastatic breast cancer should use their medical judgment when deciding whether a patient should continue treatment with the drug or consider other therapeutic options.

The agency has informed Genentech, Avastin's manufacturer, of its proposal to withdraw marketing approval of the drug for breast cancer. Genentech has not agreed to remove the breast cancer indication voluntarily, so the agency has issued a Notice of Opportunity for a Hearing, which permits Genentech to request a public hearing if it wishes to contest the agency's determination. The company has 15 days to request a hearing; if it does not do so, the hearing will be waived, and FDA will begin proceedings to remove the breast cancer indication.

FDA is open to working with Genentech on any proposals to conduct additional studies of Avastin in patients with

metastatic breast cancer designed to identify a population of patients in which the drug's benefits exceed the risks.
(Source: FDA Website, 16 December, 2010)

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- Ms. Elizabeth Bergeron
- Ms. Misty D. Carlisle, *Validation Assoc. Specialist*, Genzyme
- Mr. George Chalas, *Associate*, Camp, Dresser & McKee
- Robert E. Christman, *Global Reliability and Maintenance Engineering Coordinator*, Genzyme Corp
- Ms. Veronica A. Conuel, *QA, Validation & Documentation Specialist*, Pall Life Sciences
- Mr. William J. Culleton, *Director of Facilities*, Genzyme corp
- Mr. Philip K. Dollar, *Operations Manager*, Astro Pak Corporation
- Kevin F. Donahue, *Sales Engineer*, D&D Filtration Consultants and Suppliers
- Mr. Jason Dunklee, *Consultant*, Maxiom Group
- Mr. Kareem W. Francis, *Student*, Worcester Polytechnic Institute
- Mrs. Fiona Geiger, *Sr. Director PMG*, Cenduit
- Mrs. Amy E. Genest, *Associate Director*, Pfizer
- Mr. Richard A. Gregoire, *Engineer*, GxP Automation
- Ms. Jessica Hanafin, *Education Coordinator*, New England Controls Inc
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- Mr. Christopher M. Kwan, *Senior Process Engineer*, Pfizer
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- Scott Morris, *Associate Director Facility Operations*, Genzyme Corp
- Mr. William T. Myrich, *Facilities Operations Manager*, Genzyme Corp
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