
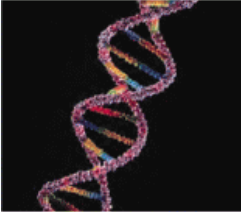


# Boston Area Chapter

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## NEWSLETTER

November 2010, Volume XX No. 6



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### President's Message: Chapter Wins Top Award at ISPE Annual Meeting



Dear Boston Area Chapter Members,

We did it! For the second year in a row, the Boston Area Chapter has been awarded the Platinum Award for Excellence and Innovation at the ISPE Annual Meeting. The Platinum Award is the top award recognizing overall excellence in Chapter management and services provided to Members. This year, we are sharing this top honor with the New Jersey Chapter. On top of this, our Chapter has won two additional awards, one for Innovation in Member Services, which stressed our efforts to provide a wide diversity of events and programs throughout the year including the introduction of career development and "soft skills" workshops; and the other for Innovation in Special Events, which highlighted the CPIP Study Group led by Past President Doyle Johnson, another innovative and valuable service to Members.

Needless to say, this triple win is a huge achievement for the Chapter. Kudos to Past President Sylvia Beaulieu, whose leadership and vision during 2010 was the motivation behind our success and to all our Board Members and Volunteers whose hard work turned vision into reality. And to all of our Members: by participating in our many activities during 2010 you ensured our success as a Chapter! And once again - just like last year - we will celebrate our success with a gala Award Celebration in December. We'll provide details on this upcoming event shortly...as soon as we climb down from Cloud Nine!

Even as we relish our success, with only a few months left in 2010 it is time to plan ahead for the challenges and opportunities that await us. With this in mind the Chapter is on track to finish the year strongly and make 2011 another great year. Consider some of our latest programs and I think it would be hard to duplicate the diversity of programming that we continue to offer. Our single biggest event of the year, our 19th Annual Product Show, was perhaps our best ever. We had an incredible opportunity to hear directly from the Shire HGT team regarding their strategic plan and how they are continuing to execute it at their Lexington campus. Thank you to Dr. Sylvie Gregoire, Bill Ciabrone, Dave Forney, Jerry Justin and Paul Slaman for providing such an informative presentation.

Thank you to all of our speakers and panelists who made this year's Product Show relevant educationally: Francis Boucher, Dr. Michael Druess, Dr. Carl Lawton, Paul Lukitsch, Theresa McCarthy, Kristin Murray, Charles Pappalardo, Randy Perez, Stephen Reich, Greg Ruklic, Dr. William Thomas, Dan Wall, Gregory Zarbis-Papistoitsis and Steve Zilonis. And a huge thank to every organization that supported the Product Show by being an exhibitor this year. We sincerely hope that our format provided you and your organization with great value and trust that you will join us again in October 2011.

So how do we do it? What makes the Boston Area Chapter viable and relevant? In my opinion, it is our volunteers. We currently enjoy the support of over 60 volunteers supporting 9 committees that will produce 33 distinct events by year end. Volunteerism is the core of what makes our organization run successfully. You too can become a volunteer. How much or how little time you invest is totally your call - it is very easy to make an impact.

Consider the following, if each of you take just a few moments and consider what you specifically want out of ISPE and the Boston Area Chapter and send us an email at [ispe@camihq.com](mailto:ispe@camihq.com) with your thoughts, it would be a voluntary action that will help your Chapter plan strategically. Your input is an incredibly important form of volunteerism, so please consider sharing your ideas with us.

I hope you enjoy this month's Newsletter. I thank you for your continued support for the Boston Area Chapter and I look forward to seeing you at an upcoming event.

Sincerely,

Jim Grunwald  
President, ISPE Boston Area Chapter

**Upcoming Chapter Events: Mark Your Calendar**

**Principles of Chromatographic Protein Separation and Project Management**

**Wednesday, November 17, 2010**

**Genzyme Center, Cambridge, MA**

**Registration and Reception: 6:00 pm; Presentations: 6:30 pm**

**Principles of Chromatographic Protein Separation**

The presentation will include a general overview of chromatographic principles and summarize the different types of chromatography and how they work, including HIC, IEX, SEC, and Affinity (including Protein A). In addition, more detailed information about the fluid dynamics theory (pore diffusion), binding capacity, column packing including HETP measurements, column pressure drop, and scale-up issues will be provided. The presentation will also include a discussion of several examples, during which the audience will be invited to participate.

**Project Management**

Ever wonder why some projects fail and others succeed, yet with very similar teams and constraints? Are you puzzled by how to prevent what happened on the last project from happening again? Come hear lessons learned on how to "design" a project and project team for success. This program will provide fundamental tools and techniques to help you work smarter, meet more schedule milestones, and gain more team collaboration.

Click here for more information: [Protein Purification and Project Management Flyer](#)

Click here to register online: [Online registration November 17th](#)

**Plant Tour: EMD Serono's Sustainable Facility and Panel Discussion: Hot Topics in High Purity Water**

**Thursday, December 9, 2010**

**EMD Serono, Billerica, MA**

**Tour Registration: 4:45 pm; General Registration & Panel: 6:15 pm**

PLEASE NOTE: The tour of EMD Serono is an ISPE MEMBERS ONLY tour. You must PRE-REGISTER to attend the tour. ISPE Members and non members are encouraged to participate in the networking reception and panel discussion following the facility tour.

**PLANT TOUR: EMD Serono "Sustainable Facility"** One of the finest examples of sustainability in biopharmaceutical research facilities has just been completed by EMD Serono Research Center, Inc. in Billerica, MA. EMD Serono is building a state-of-the-art research facility which will support the company's goal of developing innovative therapies in the areas of oncology, neurodegenerative diseases and fertility. ISPE invites you to join us for a presentation about the exemplary project management practices that EMD Serono used to execute this LEED registered project. This event will also include a tour of the sustainable mechanical, electrical and plumbing systems that have resulted in the organization registering with the certification goal of LEED gold.

**PANEL DISCUSSION: Hot Topics in High Purity Water** Regardless of whether you are involved in research, pilot production, clinical trials, or the manufacture of drugs, protein, or other products, pure water is a critical utility and is typically the single most important ingredient. Everyone has horror stories. Acknowledged industry experts have different opinions on how to consistently produce pure water. Who do you trust? How do you know your systems are under control? How do you control biofilm, bacteria? Can the costs of production, operation, and validation be controlled? Can expansion be done without re-validation? What about water conservation, recycling and green initiatives? What issues do you face? Come to learn, come to share, come to participate.

Bring your questions and experiences to share during this highly interactive program. We've assembled a panel of local experts with a wealth of practical operating and analytical testing and monitoring experience to answer your questions and open your eyes. Check out our panelists and sign up now for this enlightening, exciting, and lively session.

Click here for more information: [Tour and Panel Discussion Flyer](#)

Click here to register online: [Online registration December 9th](#)

**Save These Dates!**

January 20, 2011

Advanced Control for Greater Profitability, Hyatt, Cambridge, MA

February 9, 2011

Career Development: Roundtable with Hiring Managers

February 17, 2011

Educational Program

March 17, 2011

Educational Program

**Chapter Member Joyce Chiu Achieves CPIP Credential**

The Boston Area Chapter is proud to announce that Chapter Member Joyce Chiu has earned the Certified Pharmaceutical Industry Professional™ (CPIP™) credential from the ISPE Professional Certification Commission (PCC), an independent governing board within ISPE. To be eligible for

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CPIP certification, an applicant must hold a Bachelor's Degree in Science, Technology, Engineering, or Math (STEM), and 5 years of industry experience, or 10 years experience without a STEM degree. Applicants must also demonstrate professional experience and extensive pharmaceutical industry knowledge.

Joyce decided to pursue the CPIP credential when the Chapter announced it would sponsor a CPIP study group to help Members prepare, based on the success of a similar program in Denmark. Doyle Johnson, former President of the Boston Area Chapter and current ISPE International Board Member, provided able leadership for the group, while ISPE generously donated the study

materials. Genzyme provided a conference room at its Framingham campus and the Chapter provided light dinner at each session. "We are all very pleased to hear that Joyce passed the exam," said Doyle. "I was pretty sure that she would do well, since she came to each class well-prepared. Several others have applied for exam qualification and I expect that they will also become CPIPs in the not too distant future."

"When I began to prepare for my CPIP exam in June 2010, I didn't think too closely about the benefits of certification; I was mostly just curious about the program, and interested in learning something new," said Joyce. "Now that I've completed the process, I have a great sense of achievement. Overall, the program is very well designed and thought-out. Especially in the experience requirement leading to the eligibility test, the CPIP program espouses the leadership, change agent behavior that it strives for."

She continued, "Even though I transitioned to a position outside of the pharmaceutical industry while I was preparing to take the CPIP exam, I still find the concepts and principles I learned useful. I believe that CPIP is relevant to any industry spanning product development to manufacturing. Of course, it is most relevant to the biotech and pharmaceutical industries, but I find the fundamental principles of science-based approach, good engineering practice and rigorous quality standards to be universal for any manufacturing industry."

Joyce has over 20 years experience in a variety of industries, including six years in life sciences, and has held roles in process engineering, process development, product development, quality systems and project management. She holds a BS in Chemical Engineering from Cornell University and an MBA from Babson College, summa cum laude, with concentration in Entrepreneurship and Marketing. She has been an active Member of the Boston Area Chapter since 2007, serving on both the Education Program Committee and Member Services Committee where she has organized or collaborated on ten Chapter programs between 2008 and 2010.

### Chapter to Sponsor CPIP Study Group - Round Two

Chapter Member and CPIP study group participant John Spohn has expressed interest in leading the next study group. The group would likely begin weekly meetings in mid-December, with the March 7, 2011 CPIP exam as its goal. "If the interest is there, I'm in," he stated, adding that the study group was the most valuable benefit he has ever received from a professional organization.

Members interested in taking John up on his offer should contact the Chapter at [ispe@camihq.com](mailto:ispe@camihq.com) or (781) 647 4773. (More information on the CPIP program, including detailed eligibility requirements and an overview of the process, can be found at [www.ispe-pcc.org/index.cfm](http://www.ispe-pcc.org/index.cfm).)

### Crowds Brave Stormy Weather to Attend 19th Annual Product Show at Gillette

*by Brian Hagopian, Mar Cor Purification with photos by Kent Van Vliet Photography*

Neither rain, hail, snow or sleet....well, you know how the rest of it goes. Not even torrential rain could slow down the momentum of the Boston Area Chapter's Product Show. The Chapter once again attracted a huge crowd to Gillette Stadium for the 19th Annual Product Show. The biopharm industry has begun its rebound from the recent economic downturn and growth was in evidence at this year's Show. The Boston Area Chapter, with its hard working volunteers, great Chapter management, supportive Board and enthusiastic vendor community, pulled off another tremendous Product Show.





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Over 270 exhibits greeted the 1800 who attended in spite of the stormy weather

Thanks to the hard work of a group of dedicated Chapter volunteers, the number of exhibitors was increased by about 10 percent and the Show was sold out well in advance, proving that our industry is showing growth and progress in this economic climate. With over 270 vendors exhibiting and over 1750 attendees buying, networking, and learning, industry know-how was hard at work.

The Show's many featured activities helped draw attendees to Gillette, despite the inclement weather. Keynote speaker Dr. Sylvie Gregoire, president of Shire HGT, packed the house with her address describing Shire's products, technologies and plans for growth in Massachusetts. She was followed by a distinguished panel of Shire experts who provided in-depth, detailed answers to a number of wide-ranging questions posed by audience members. This industry-focused presentation with its unique local perspective proved to be winning formula that we hope to be able to repeat in upcoming years.



Keynote speaker Dr Sylvie Gregoire of Shire HGT with Chapter Vice President Brian Hagopian (l) and Product Show Committee Chair Mark Sitkoske (r)

The Chapter again worked with the GAMP Community of Practice (COP) team for the third consecutive year to offer presentations before and during the Show. Participants were able to attend these sessions at Gillette and experience the Product Show during one action-packed day. And again this year, the Product Show Committee worked closely with the Young Professionals (now an official Chapter committee), who organized and coordinated two of the seven educational sessions presented during the day and joined Chapter Student Members at their traditional evening reception held in one of Gillette's luxury suites.

For those who came to learn, in addition to the GAMP Forum and keynote address, the Show also hosted seven educational programs throughout the day. Many thanks to the presenters for the valuable information that they shared with attendees: Greg Ruklic, Theresa McCarthy from Pfizer, Kristin Murray from Pfizer, Randy Perez from Novartis, Stephen Reich from Pfizer, Dr. Carl Lawton from UMass Lowell, Dr. William Thomas from UMass Memorial Medical School, Dr. Michael Druess from Vascular Sciences, Gregory Zarbis-Papistoitsis from Percivia, Charles Pappalardo from Charles River Laboratories, Francis Boucher from National Grid, Paul Lukitsch from Millipore, Dan Wall from RDK Engineers and Steve Zilonis from Aricogen, Dresser-Rand.



Opportunities for impromptu meetings are a Product Show plus

For the second year running, the Chapter invited Karleen Kos, from the ISPE international headquarters in Tampa, to attend the Show, where she staffed the ISPE membership booth, enrolled new Members and attended the Student and Young Professionals reception. And again, she praised the size, quality and professionalism of the event and the enthusiasm of the exhibitors, attendees and Chapter volunteers who make it a success year after year.

This year, the Product Show featured its first-ever Silent Auction, the purpose of which was to raise seed money for the Joel Goldenberg Scholarship Fund under development by the Chapter. About 20 companies donated valuable items, which helped to raise almost \$1600 for the Fund, a great jumpstart for a worthy cause.

The Product Show is the one event that involves all of the Boston Area Chapter's volunteer committees. Its success is a compliment to those who work so hard to make it happen and a testament to the cohesive, get-it-done attitude that permeates The Chapter's energetic and enthusiastic group of volunteers. At times we want to pinch ourselves: is this really happening in our back yard - are we dreaming? No, its just great people doing a superlative job!

Every year, we hear stories about people who miss the Show because they could not get away from work or heard about the Show too late to register. This year the exhibitor booths sold out in July - the earliest ever - and we had a waiting list of exhibitors hoping for a cancellation. Please remember that the date has already been set for 2011: October 5th at Gillette Stadium. So mark your calendar now! And if you plan to exhibit, reserve your booth with a \$250 deposit.



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As always, the educational programs covered a wide variety of exciting topics

Visit the Product Show website at [www.ispeboston.org](http://www.ispeboston.org) or contact our management office (781-647-4773 or [ispe@camihq.com](mailto:ispe@camihq.com)) for updates and information or to reserve your exhibit space. 2011 will surely be another great year and we hope we see you there!

Shire HGT President Dr. Sylvie Gregoire Delivers Keynote to Overflow Crowd

by Brian Hagopian, Mar Cor Purification with photos by Kent Van Vliet Photography

The ISPE Boston Area Chapter Product Show featured Dr. Sylvie Gregoire, President of Shire HGT as this year's keynote speaker. The room was packed with over 270 guests who came to hear about Shire's products and their commitment to expansion in Massachusetts.



The overflow audience paid rapt attention as Dr Gregoire described Shire HGT and its commitment to expansion in Massachusetts

Dr. Gregoire began by introducing the audience to Shire HGT's purpose, which is to enable people with life altering conditions to lead better lives. She continued with a brief review of the products already developed and currently under development by Shire which address rare diseases affecting between 1,000 and 30,000 patients globally. Lastly, she focused on Shire's commitment to expansion in Massachusetts. Shire currently employs about 550 people, primarily in Cambridge, but recently made a major commitment to expansion in Lexington and a doubling of its workforce.

Dr. Gregoire touched on several critical factors that led Shire to adopt a "disposables" approach in their new production plant, including flexibility, time to market, automation, and validation. At the conclusion of Dr. Gregoire's talk, Shire's panel of experts were introduced (Paul Slaman, Dave Forney, Jerry Justin, and Bill Ciambrone) and a lively question and answer period followed covering a wide range of relevant topics including disposables, leachables, production flexibility, and much more.

The ISPE Boston Area Chapter would like to thank Dr. Gregoire, the expert panel, and Shire HGT for their participation at the 2010 Product Show.

GAMP Forum Provides a Stimulating Intro to the Annual Product Show

by Deepen Joshi, Sunovion Pharmaceuticals

For the third year in a row, the Product Show was preceded by a half-day GAMP Forum, also held at Gillette. The ISPE Good Automated Manufacturing Practice (GAMP) Community of Practice (COP) sponsors these forums regionally around the world to present current hot topics and facilitate question and answer sessions. They are designed for biopharm professionals from a variety of disciplines who must work together to achieve reliable operation of critical computer systems while meeting regulatory requirements.

Early arrivals got comfortable over coffee and chatted with their peers while waiting for the first session to begin. Since one of the aims is to facilitate networking among peers, the forum was already well on its way toward meeting its goals! The first hour featured Stephen Reich and Kristin Murray, both from Pfizer, who presented "Quality Risk Management (QRM) Tool Selection: Getting to Right First Time." Theresa McCarthy, past chair, American Society of Quality Boston Section, followed with a presentation entitled "ISO 9001:2008 and 21 CFR 210, 211: Working Together for Quality." This topic included something for everyone, as she explained the similarities and differences between ISO and 210/211. She also touched on the legal implications of complying with these requirements.



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Newsletter Archive

During the lunch break, topics of conversation included the afternoon Product Show and the upcoming stadium tours, as well the information covered during the morning's presentations. A comment from one of the younger attendees provided a great endorsement for the value of the sessions: "It was a refreshing change to hear two different topics that covered the industry from multiple angles in less than two hours. I can't wait to hear the presentation on FDA's Part 11 initiatives. This is definitely better than a routine day and well worth the price." You can't get a more positive message than that!

Following lunch, Randy Perez of Novartis presented the "The FDA Part 11 Inspection Initiative" as a wrap-up topic. He gave examples of companies that were penalized for not complying with Part 11 requirements. He shed some light on FDA's plan for performing Part 11 inspections and suggested that there might be "some delay" in implementation. He also provided valuable tips on ways to prepare for an FDA Part 11 inspection.

Several of the attendees lingered after the Forum to spend time chatting and exchanging notes with their peers, while others headed to the Product Show. In general, attendees found the information presented both timely and useful. And the combination of the GAMP Forum and Product Show, both held together at the same time and place, provided a double benefit.

Young Professionals Overcome the "Fear Factor" at Product Show

by Jillian Willard, Genzyme Corporation with photos by Kent Van Vliet Photography



Young professionals gather with Dr Sylvie Gregoire following the keynote address

Professionals Committee has made an effort to have more of a visible presence at the Show. We have helped put on educational seminars the past two years and this year were able to include young professionals in what was, in the past, an evening reception for student members.

And hopefully, all of the young professional attendees from this year will be able to come to the Show next year ready to re-connect with other young professionals they have met through our events, both at the Show and at the other social and educational events the Young Professionals Committee has sponsored throughout the year.

Four years ago, I attended my first ISPE Boston Area Chapter Product Show. I had been in the industry for just over two years and, I have to admit, the show was pretty intimidating. Of the more than 1000 people in attendance, I probably knew about ten of them. And it seemed like everyone else somehow knew each other. All of the vendors, activity and people were pretty overwhelming. Four years, one job change, a couple of Chapter ski trips and a year of being on the Young Professionals Committee later - and the sheer size of the product show still amazes me. Now, though, I'm more concerned with finding the elusive platter of cocktail shrimp than someone I know to talk to!

The Product Show has grown by leaps and bounds since I first attended. If my first Show was intimidating, I can only imagine how first-timers feel now. This is why the Young



For the first time this year, young professionals joined student members at an evening reception

Oktoberfest - A New Tradition is Born!

by Janet Tice, GMP Piping, with photos by Chris Opolski, Alexion



The Chapter packed Tommy Doyle's for our first-ever Oktoberfest celebration

In what is sure to become a new tradition, over 125 Members and guests turned out for the Boston Area Chapter's first-ever Oktoberfest celebration on October 27th at Tommy Doyle's in Kendall Square. Was it the opportunity to network with Members that drew the record crowd? Was it the "best costume" contest? Or the chance to enjoy the Schwarze Schafe Oompah Band, choose from the variety of beers on tap and fill up on delicious munchies (all while wearing bright green Tyrolean hats)? Whatever the attraction, Project Place was the winner, with over \$1600 raised for this worthy non-profit offering hope and opportunity to homeless individuals in our local communities.

Many thanks to all those who helped make this event a

huge success:

- Ultrafiltronics, Alfieri Proctor Associates, Wise Construction, GxP Automation, RW Sullivan Engineering, Triumvirate Environmental and The Boston Bruins Foundation - who generously donated raffle items;
- Signer Harris Architects, P&IDC Construction

Professionals, RW Sullivan Engineering, Team SullyMac, Fort Point Project Management and Commissioning Agents - who sponsored the oompah band;

- all who dressed up to vie for the "best costume" award donated by Superior Controls (and congrats to winner...drum roll, please...Joyce Chiu);
- the many Members and guests whose generosity helped us to exceed our fund-raising goal by leaps and bounds;
- and the Social Committee whose energetic and enthusiastic volunteers have created yet another Chapter tradition!



Chapter President Jim Grunwald (l) greeted Members & guests (l to r) Sherwood Butler, Kim Young & Scott Davis

See you next year!



A new Chapter tradition is born, thanks to Oktoberfest committee members (l to r) Carly Starr, Chris Opolski, Michelle Greaney & Paul Sullivan

### **Young Professionals Combine Fun, Networking and Education**

*by Jillian Willard, Genzyme, with contributions by Jordan Croteau, Integrated Process Technologies and Josh Strauss, Commissioning Agents, and photos by Aarash Navabi, Genzyme*

The Young Professionals had a busy September and October. Not only did the YP Committee begin meeting again to discuss the upcoming year, but we sponsored our first two events of the season. First, we tested our sea legs with a voyage on the Boston Belle around Boston Harbor. Major topics of discussion were our hope for the Patriots after a disappointing baseball season and, of course, networking with the other young professionals lucky enough to catch the boat, all of whom were happy to share their experiences. Since the attendees represented a wide variety of fields and were at different stages in their careers, this proved especially interesting. Everyone had a great time with plentiful food and drink as Captain Mike of the Boston Belle entertained the crowd with seaman's stories.



Young professionals tested their sea legs in September with a voyage around Boston Harbor.

A week later, the Chapter's Young Professionals and Seasoned Veterans met on the beautiful Ebersol fields along the bank of the Charles River in an epic softball showdown. The game began with a live performance of the national anthem by Kim Young of P&IDC. Although the Seasoned Veterans took an early lead, the youthful energy and endurance of the Young Professionals led them to final victory. Afterward, the two teams took a short walk down the street to make peace over food and drink.



Young Professionals and Seasoned Veterans prove they're still friends following an epic softball showdown on the beautiful Ebersol Fields in Boston

The Committee has also been working on a couple of other upcoming events. The first YP educational event will be held on November 17th at Genzyme Center in Kendall Square. Topics covered will be Protein Purification using Chromatography and Project Management. In addition, the YP's will hold their first social event on dry land on December 7th at Flat Top Johnny's, also in Kendall Square. The event will include free pool and appetizers provided by the YP Committee. If you would like to come network with other young professionals or can't wait to hear more of Captain Mike's tales, watch for announcements of upcoming events (including next year's boat cruise and softball games) from the Boston Area Young Professionals.

### **Industry News In Brief**

*by Patti Charek, RF Walsh Collaborative Partners*

#### **Novartis to Add 300 New Jobs, Invest \$600M to Expand in Cambridge**

Novartis announced today that it will add 300 new jobs and invest \$600 million over the next five years to expand its global Research headquarters campus on Massachusetts Avenue in Cambridge. "Novartis was the first global pharmaceutical company to move its Research headquarters to Massachusetts just a few years ago. It has achieved prominence and, we believe, helped to amplify Cambridge's magnetism for others in the biomedical field to follow," said Mark Fishman, President of the Novartis Institutes for BioMedical Research. "Our scientists and physicians here already have discovered a host of new medicines, and established fruitful collaborations with academic, clinical, and biotech institutions. The constellation of talent and environment are unmatched. We look forward to the next wave of new medicines coming from this center."

The company plans to expand its current Massachusetts Avenue campus, adjacent to MIT, by more than 400,000 square feet, including laboratory, office and retail space. Construction is expected to begin in 2011. The new campus will be built on a four-acre parcel that Novartis is leasing from MIT under an expanded agreement originally signed in 2009. "Novartis' commitment to expand and create more jobs in Massachusetts is an affirmation of the Commonwealth's international leadership and investments in the life sciences," said Governor Deval Patrick. "Novartis is a life sciences leader and exemplary corporate citizen in Cambridge," said Cambridge Mayor David Maher. "This is a global company that acts locally through a wide variety of programs in our community. Their decision to grow here is great news for Cambridge and a testament to the dynamic life sciences climate here."

Since 2002 Novartis has steadily grown its operations in Cambridge. Today the company employs more than 2,000 associates and occupies more than 1 million square feet of laboratory and office space -- making it the city's largest corporate employer. The company's operations in Cambridge include the global headquarters for the Novartis Institutes for BioMedical Research; Novartis Molecular Diagnostics, a dedicated business unit focused on developing tests to advance patient tailored treatment; Novartis Vaccines and Diagnostics, a division focused on providing vaccines and diagnostic tools to prevent diseases and protect societies worldwide, and the US office of the Novartis Venture Funds. (Source: Novartis Institutes for Biomedical Research Website, 27 October, 2010)

#### **FDA Approves Alkermes' Vivitrol to Treat Opioid-Dependent Patients**

The FDA has approved Alkermes' Vivitrol to treat and prevent relapse after patients with opioid dependence have undergone detoxification treatment. Vivitrol is an extended-release formulation of naltrexone administered by intramuscular injection once a month. Naltrexone works to block opioid receptors in the brain. It blocks the effects of drugs like morphine, heroin, and other opioids. It was approved to treat alcohol dependence in 2006.

"Addiction is a serious problem in this country, and can have devastating effects on individuals who are drug-dependent, and on their family members and society," said Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research. "This drug approval represents a significant advancement in addiction treatment."

The safety and efficacy of Vivitrol were studied for six months, comparing Vivitrol treatment to placebo treatment in patients who had completed detoxification and who were no longer physically dependent on opioids. Patients treated with Vivitrol were more likely to stay in treatment and to refrain from using illicit drugs. Thirty-six percent of the Vivitrol-treated patients were able to stay in treatment for the full six months without using drugs, compared with 23 percent in the placebo group.

Patients must not have any opioids in their system when they start taking Vivitrol; otherwise, they may experience withdrawal symptoms from the opioids. Also, patients may be more sensitive to opioids while taking Vivitrol at the time their next scheduled dose is due. If they miss a dose or after treatment with Vivitrol has ended, patients can accidentally overdose if they restart opioid use.



Side effects experienced by those using Vivitrol included nausea, tiredness, headache, dizziness, vomiting, decreased appetite, painful joints, and muscle cramps. Other serious side effects included reactions at the site of the injection, which can be severe and may require surgical intervention, liver damage, allergic reactions such as hives, rashes, swelling of the face, pneumonia, depressed mood, suicide, suicidal thoughts, and suicidal behavior.

Vivitrol should be administered only by a physician as an intramuscular injection, using special administration needles that are provided with the product. Vivitrol should not be injected using any other needle. The recommended dosing regimen is once a month. (Source: FDA Website, 12 October, 2010)

LabCorp to Purchase Genzyme Genetics for \$925 million

Genzyme Corporation recently announced that Laboratory Corporation of America Holdings (LabCorp) will acquire Genzyme Genetics for \$925 million in cash. Under the terms of the agreement, LabCorp will purchase the business in its entirety, including all testing services, technology, intellectual property rights, and its nine testing laboratories. LabCorp is committed to offer employment to the unit's approximately 1900 employees upon closing, including senior management. The agreement is subject to customary closing conditions, including the Hart-Scott-Rodino Antitrust Improvements Act of 1976, with the goal of closing before the end of the year.

"This transaction demonstrates the strategic value of Genzyme Genetics and the strong franchise we've built over a twenty year period," said Henri A. Termeer, chairman and chief executive officer of Genzyme Corporation. "It also shows how our management team is uniquely positioned to unlock the underappreciated value of Genzyme's diverse businesses for shareholders. The completion of this sale allows us to focus our resources on core growth areas and create stronger returns on invested capital."

Genzyme announced in May that it would seek strategic alternatives for three units as part of a five-part plan to increase shareholder value. The plan builds on the robust set of operational, organizational and board changes made over the past year to strengthen the company. Plans to divest the two other Genzyme business units, Diagnostic Products and Pharmaceutical intermediates, remain on track. Proceeds from these transactions may be used to finance the second half of the company's \$2 billion stock buyback to be completed by May 2011.

Genzyme Genetics is an industry leading provider of reproductive and oncology testing in the United States, specializing in esoteric testing, with nine laboratories performing more than a million tests a year. The business, which also has the largest nationwide network of board-certified genetic counselors, had revenue of \$371 million in 2009. LabCorp is one of the nation's largest laboratory testing companies specializing in routine testing, with 38 primary testing locations and more than 1,500 patient service centers.

The terms achieved with LabCorp meet the three foundational requirements Genzyme established for divestitures: (1) to recognize the value of employees with appropriate treatment as part of the transaction, (2) to create a future for Genzyme Genetics in which customers continue to be served well, and (3) to create value for Genzyme shareholders.

Mr. Termeer continued, "LabCorp is the right strategic partner for Genzyme Genetics. LabCorp intends to invest in growing its operations. The business will have the opportunity to continue to grow, serve its customers and fulfill its potential to bring continued innovation to important areas of the diagnostics field." (Source: Genzyme Website, 13 September 2010)

Cubist Expansion Work Gets Underway

Cubist Pharmaceuticals, a Lexington biotech developing antibiotics to treat infections and viruses, has begun building 104,000 square feet of laboratory and administrative space. The project, which is scheduled to be completed in early 2012, will take advantage of a \$1.7 million state tax incentive. As part of its incentive agreement with the Massachusetts Life Sciences Center, which is administering the state's 10-year, \$1 billion life sciences initiative, Cubist has committed to adding 58 jobs this year. Governor Deval Patrick and Susan Windham-Bannister, president of the life sciences center, attended a ceremony at Cubist in Lexington on September 8, 2010 marking the start of the expansion project. (Source: Robert Weisman, Boston Globe, 9 September 2010)

Biogen Idec to Rearrange Drug Lineup

According to the Boston Globe, by the end of the year, George A. Scangos, who arrived at Weston-based Biogen Idec in July, will unveil an operating blueprint calling for intensifying the focus on some drug programs while deemphasizing - or even selling off - others and accelerating the pursuit of drug development partnerships with other companies.

Biogen Idec's portfolio and pipeline of drugs are concentrated in neurology, immunology, oncology, hematology, and generic medicines. Scangos said it is too soon to specify which could be spun off, though he suggested the company might expand work in neurology, where it is a leader in multiple sclerosis therapies. As the MS field becomes more competitive - Swiss drug maker Novartis won US approval in September for the first oral treatment (see Regulatory Highlights for details) - Scangos said Biogen Idec, which is in late-stage development with its own MS pill, also could target other neurological disorders, such as Parkinson's or Lou Gehrig's diseases.

Biogen Idec has three blockbuster drugs (ie. those generating at least \$1 billion a year in sales): Avonex and Tysabri for MS, and Rituxan for non-Hodgkin lymphoma. Scangos, however, said he would like to introduce a "more focused mentality" at the company, pressing forward into personalized medicine, where drugs can be designed for population subsets.

By developing more tests to identify which patients benefit from a drug and which are vulnerable to safety issues, Biogen Idec might be able to reduce costs and speed up the time it takes to get a new drug on the market, by sponsoring smaller and more narrow clinical trials, Scangos said. He said Biogen Idec is making progress in developing a test to screen for the brain infection known as PML, or progressive multifocal leukoencephalopathy, which affects about one of 1,000 Tysabri patients.

Scangos said he also would like to see Biogen Idec become the "partner of choice" for small biotechnology companies while also expanding collaborations with academic research labs and large pharma companies in the region. (Source: Robert Weisman, Boston Globe, 6 October 2010)

Sepracor is Now Sunovion

Sepracor, the Marlborough drug company with a new owner, has officially changed its name to Sunovion Pharmaceuticals Inc. Last year, Dainippon Sumitomo Pharma Co., a Japanese drug maker, disclosed plans to buy Sepracor for \$2.6 billion. Sepracor is perhaps best known for its sleep aid Lunesta. In July, Dainippon Sumitomo said it would change Sepracor's name

to Sunovion on roughly the first anniversary of the sale. A statement from Sunovion president Mark Iwicky said, "The meaning of Sunovion combines the strength of the sun with innovation." "Sunovion integrates under one brand the distinct competencies of Sepracor and the former Dainippon Sumitomo Pharma America Inc.," a news release stated. (Source: Boston Globe, 13 October 2010)

Pfizer to Buy King Pharmaceuticals for \$3.6 Billion

Pfizer will buy a company specializing in pain drugs in a \$3.6 billion deal meant to shore up the portfolio of the world's largest drug company. The deal to buy King Pharmaceuticals is Pfizer's largest since it bought Wyeth for \$68 billion in 2009. Pfizer already has a large stake in the pain drug market with its drugs Lyrica and Celebrex, which combined had more than \$5 billion in sales in 2009.

The company is betting King's work on "abuse-resistant" pain drugs will pay off and help make up for the revenue it will lose when top sellers such as the cholesterol drug Lipitor lose patent protection in a few years. King markets one such drug, Embeda, and is seeking approval for two others, Remoxy and Acurox. Remoxy is similar to Purdue Pharma LP's OxyContin, the top-selling painkiller in the US. Both are designed to treat pain by slowly releasing the narcotic oxycodone. But the time-release mechanism on OxyContin can be defeated if the drug is crushed or dissolved, allowing users to get a high similar to heroin's. Embeda is also designed to resist abuse, but it contains morphine.

The FDA has held up approval of Remoxy and Acurox, partly because it wants more proof they will cut down on abuse. King plans to file a new application for Remoxy in the fourth quarter of 2010 and one for Acurox in the first quarter of 2011. The deal also gives Pfizer products like EpiPen, a pre-filled injection designed to quickly treat serious allergic reactions. (Source: Associated Press, 13 October 2010)

Pfizer to Acquire 40 Percent Stake in Brazilian Generics Manufacturer

Close on the heels of its \$3.6 billion acquisition of King Pharmaceuticals, Pfizer has announced that it is entering into a partnership with Laboratório Teuto Brasileiro S.A., a leading company in the Brazilian generics industry, to develop and commercialize generic medicines. Pfizer will acquire a 40 percent stake in Teuto and the companies will also enter into a series of commercial agreements. The partnership will enhance Pfizer's position in Brazil, a key emerging market, by providing access to Teuto's broad portfolio of approximately 250 products in more than 400 presentations. Through this partnership, Pfizer will have access to significant distribution networks in rural and suburban areas in Brazil and the opportunity to register and commercialize Teuto's products in various markets outside Brazil. In addition, Pfizer will have two representatives on Teuto's board of directors. (Source: Pfizer Website, 20 October 2010)

Pfizer Ends Celldex Vaccine Pact

Pfizer is pulling out of an agreement with Celldex Therapeutics to fund the development of an experimental brain tumor vaccine. The vaccine, called rindopepimut or CDX-110, is "no longer a strategic priority of Pfizer," which will return the rights to the therapy to Celldex on November 1st, Needham-based Celldex said. The treatment is in the second of three stages of testing generally required to win US regulatory approval.

New York-based Pfizer, the world's biggest drug maker, licensed rights to the product in 2008 from Celldex for as much as \$440 million, plus royalties. If approved, the brain cancer vaccine could have \$450 million in peak annual sales and come on the market in 2013, Joseph Pantginis, an analyst at Roth Capital, said in May.

"We see this as a tremendous opportunity for Celldex, our shareholders, and patients," Celldex chief executive Anthony Marucci said on a call with investors. "We believe rindopepimut is very well-positioned to advance into pivotal clinical studies." (Source: Bloomberg News, 4 September 2010)

Bristol-Myers to Cut Work Force by Three Percent

Drug maker Bristol-Myers Squibb has said it plans to reduce its work force by about 3 percent in the next six months to cut costs and create a "more agile" organization. The company announced the planned job cuts as part of a "streamlining initiative" in an internal communication to employees, said spokeswoman Sonia Choi. "We're reviewing the organization across the board," Ms. Choi said. "There's no specific area we're targeting."

Ms. Choi declined to say exactly how many jobs were being eliminated. BMS had about 28,000 employees world-wide as of December 31, the most recent head count the company has provided. A 3 percent reduction would translate into about 840 lost jobs.

The layoff announcement comes just two days after drug and medical-products maker Abbott Laboratories announced it would lay off about 3,000 workers, or 3 percent of its work force. The pharmaceutical industry has shed thousands of jobs in recent years as it grapples with patent expirations for top-selling drugs and difficulties bringing new products to market.

New York-based BMS has contracted in recent years through a combination of layoffs and divestitures of nonpharmaceutical businesses. The company employed more than 40,000 workers as recently as late 2007. (Source: Peter Loftus, Wall Street Journal, 24 September 2010)

Abbott to Pay for Kidney Drug Rights

Abbott Laboratories and Reata Pharmaceuticals today announced that they have entered into a collaboration agreement to develop and commercialize bardoxolone methyl (bardoxolone), which is currently in late Phase 2 trials for the treatment of chronic kidney disease (CKD). Bardoxolone is an oral, first-in-class antioxidant inflammation modulator that works by increasing the estimated glomerular filtration rate (eGFR) of the kidneys. In two Phase 2 clinical trials, bardoxolone significantly improved kidney function in patients with advanced CKD and Type 2 diabetes. CKD currently affects more than 50 million adults worldwide, and the number of patients is rapidly increasing throughout the world.

Under terms of the agreement, Reata will grant to Abbott exclusive rights to develop and commercialize bardoxolone outside the US, excluding certain Asian markets. Reata will receive upfront and near-term cash payments of \$450 million for the licensing rights to bardoxolone and a minority equity investment in the company. Upon completion of certain development and approval objectives for bardoxolone and other molecules in the licensed territories, Reata will receive additional milestone payments. Reata also will receive royalties on any future product sales in the Abbott territories. Additionally, Abbott obtains rights to develop and commercialize certain other Reata compounds for chronic kidney disease, and for cardiovascular and metabolic indications, in these territories.



"Early clinical studies suggest that bardoxolone could be a significant improvement to the current standard of care for CKD and possibly prevent patients from progressing to the later stages of the disease and dialysis," said John Leonard, M.D., senior vice president, pharmaceuticals, research and development, Abbott. "This agreement builds on Abbott's existing experience in renal care, while adding a promising compound to our later-stage pipeline." (Source: Abbott Laboratories Website, 23 September 2010)

Bristol-Myers Squibb to Acquire Biotech Company ZymoGenetics

Bristol-Myers Squibb and ZymoGenetics announced in September that the companies have signed a definitive agreement providing for the acquisition of ZymoGenetics by Bristol-Myers Squibb. The transaction, with an aggregate purchase price of approximately \$885 million, or approximately \$735 million net of cash acquired.

"The acquisition of ZymoGenetics brings us full ownership of a promising investigational biologic that strengthens our very diversified Hepatitis C portfolio. Building on our leadership in virology, we are developing a strong portfolio to help patients with Hepatitis C," said Lamberto Andreotti, chief executive officer, Bristol-Myers Squibb. "In addition, ZymoGenetics brings proven capabilities with therapeutic proteins and revenue from a marketed specialty surgical biologic. This acquisition is another example of our strategic, targeted approach to business development."

"By joining forces with Bristol-Myers Squibb, we believe we will enhance the long-term potential of ZymoGenetics' portfolio of assets, while providing a compelling valuation for our shareholders," said Douglas E. Williams, Ph.D., chief executive officer of ZymoGenetics. "Our collaboration with Bristol-Myers Squibb in the development of PEG-Interferon lambda has been extremely positive and it has given us an opportunity to fully appreciate their capabilities. We believe that this transaction will maximize the potential for our products and product candidates to make a meaningful difference for patients in need."

Bristol-Myers Squibb gains the following as a result of the acquisition:

- Full ownership of pegylated-interferon lambda, a novel interferon in Phase IIb development for the treatment of Hepatitis C infection, which, if approved, could be an important contributor to Bristol-Myers Squibb's future growth. The companies have collaborated on the development of pegylated-interferon lambda since January 2009.
- RECOTHROM<sup>®</sup>, a recombinant thrombin approved by the FDA for use as a topical hemostat to control non-arterial bleeding during surgical procedures.
- IL-21 protein, a cytokine currently being tested in an open-label, Phase II clinical study as a potential immunotherapy treatment for metastatic melanoma.
- An earlier-stage pipeline of six biologic drug candidates, including an anti-IL-31 antibody, currently in pre-clinical development for atopic dermatitis.
- Potential milestone and royalty payments from six partnered programs in various stages of clinical development by EMD Serono, an affiliate of Merck KGaA, and Novo Nordisk.

"ZymoGenetics is a leader in advancing novel biologics, particularly genomics-based therapies," said Elliott Sigal, M.D., Ph.D., executive vice president and chief scientific officer, Bristol-Myers Squibb. "We expect ZymoGenetics' pipeline and biologics capabilities to complement and enhance our existing efforts in Hepatitis C, oncology and immunoscience." (Source: Bristol-Myers Squibb Website, 7 September, 2010)

Novartis to End Two Drug Programs

Novartis AG said it would take a third-quarter charge of \$590 million as it discontinued development of a potential hepatitis C drug and an antifungal product. The Swiss company and its partner Human Genome Sciences Inc. had expressed concerns earlier in the year that the potential hepatitis C treatment Joulferon, known as Zalbin in the US, would not pass regulatory reviews. Novartis also said it is ending development of the antifungal agent Mycograb, which was aimed at treating a common yeast infection.

Analysts have estimated the total market for hepatitis C drugs at \$9 billion, and several companies are working on new treatments. Merck & Co. is developing boceprevir, which it acquired through its merger with Schering-Plough. Vertex Pharmaceuticals and partner Tibotec are developing telaprevir, which also has produced positive results. Vertex plans to seek approval by the end of the year. Bristol-Myers Squibb and Zymogenetics also are developing a drug candidate.

Novartis has said it was further streamlining its business in anticipation of expected product approvals and new specialty medicines. The move included creating three specialty businesses, focused on multiple sclerosis, respiratory disease, and neuroscience. The company has an existing oncology business. (Source: Associated Press, 6 October 2010)

Novartis and Immunogen to Work Together on Cancer Drugs

Novartis and Immunogen have signed a collaboration deal to develop novel cancer treatments based on Immunogen's technology. As part of the collaboration, Immunogen will receive an upfront fee of \$45 million. Milestone payments are also possible and could reach around \$200 million per research target, the number of which hasn't been disclosed, Immunogen said.

Under the arrangement, Novartis and Immunogen will work together to develop so-called antibody drug conjugates to treat cancer, a novel technology that is considered to be more effective than traditional chemotherapy. Unlike in chemotherapy, where cancerous and healthy cells are destroyed during treatment, Immunogen's technology includes cancer-killing agents that are attached to an antibody that can be directly transported to affected cells. This targeted therapy helps to reduce side-effects that are common in chemotherapy.

Immunogen already has partnerships with Swiss drug maker Roche and Sanofi-Aventis. The collaboration with Roche includes experimental breast cancer drug T-DM1 that, if approved, could turn into a potential blockbuster with more than \$1 billion in sales. Although the medicine recently failed to win priority review from US regulators, recent data suggests the medicine could become an effective treatment in breast cancer. Other experimental drugs include SAR3419, which is currently tested in non-Hodgkin's lymphoma and is licensed to Sanofi-Aventis. (Source: Goran Mijuk, Wall Street Journal, 12 October 2010)

Synthetic Genomics and J. Craig Venter Institute Form New Company, Announce Collaboration with Novartis

The company Synthetic Genomics Inc. (SGI) and the not-for-profit research organization, the J. Craig Venter Institute (JCVI) have announced the formation of a new company, Synthetic Genomics Vaccines Inc. (SGVI). The privately held company will

focus on developing next generation vaccines using JCVI's genomic sequencing and synthetic genomic research expertise, coupled with the intellectual property and business acumen of SGI, to significantly advance and enhance vaccine development.

SGVI also announced a three-year collaboration agreement with Novartis to apply synthetic genomics tools and technologies to accelerate the production of the influenza seed strains required for vaccine manufacturing. The seed strain is the starter culture of a virus, and is the base from which larger quantities of the vaccine virus can be grown. The agreement could ultimately lead to a more effective response to seasonal and pandemic flu outbreaks.

Currently Novartis and other vaccines companies rely on the WHO to identify and distribute live reference viruses to create seasonal or pandemic vaccines. Under this collaboration, Novartis and SGVI will work to develop a "bank" of synthetically constructed seed viruses ready to go into production as soon as WHO identifies the flu strains. The technology could reduce the vaccine production time by up to two months, which is particularly critical in the event of a pandemic.

JCVI is currently working to sequence genes representing the diversity of several viruses including influenza virus. Novartis has been working with JCVI for more than a decade to apply their findings in the genomics field to develop novel vaccines that prevent disease. The last collaboration introduced the use of genomics in vaccines research, a technology today known as "reverse vaccinology."

In May 2010 researchers at JCVI published results in the journal Science describing the construction of the first self-replicating, synthetic bacterial cell. The team synthesized the 1.08 million base pair chromosome of a modified Mycoplasma mycoides genome. The synthetic cell is called Mycoplasma mycoides JCVI-syn1.0 and is the proof of principle that genomes can be designed in the computer, chemically made in the laboratory and transplanted into a recipient cell to produce a new self-replicating cell controlled only by the synthetic genome.

Using these same synthetic genomics advances it is conceivable that more universal vaccines could be developed to target a wide range of infectious disease agents in addition to new influenza vaccines. "We are excited to apply our advanced synthetic genomics technologies to revolutionize vaccine production. We look forward to working with Novartis, a world leader in vaccine development and production, on our first application area in influenza," said Fernanda Gandara, President, SGVI. (Source: Synthetic Genomic Vaccines Website, 7 October 2010)

#### Genzyme to Slash 1,000 Positions Worldwide

Genzyme recently said it will eliminate 1,000 jobs, about 10 percent of the workforce, over the next 15 months to save money. In a memo to employees, Henri A. Termeer, Genzyme's chief executive, said the cuts are needed to achieve "substantial annual target savings" by 2012. He did not say how many of the company's 4,500 jobs in Massachusetts will be lost. "For the first time in our company's history, we are faced with the need to make these painful decisions," Termeer said in the memo, which was obtained by the Globe.

Genzyme is the state's largest biotechnology firm, with a stock market value of more than \$18 billion. It has carved out a lucrative niche in the drug industry by selling expensive treatments for rare genetic disorders. Last year, the company earned \$422.3 million on sales of \$4.5 billion even as it struggled with production problems and supply shortages stemming from a virus at its Allston Landing plant that forced the rationing of doses for two key drugs.

Genzyme has about 12,800 workers globally, but plans to sell three divisions it does not consider essential. The 10 percent reduction figure does not include employees in those divisions. The looming loss of jobs is a blow to the Patrick administration, which championed a \$1 billion initiative to boost the state's life sciences sector. "We will continue to monitor the situation for any potential impact on Massachusetts employees," said Susan Windham-Bannister, president of the Massachusetts Life Sciences Center, a state agency set up to implement the 10-year initiative.

Termeer's memo came less than two weeks after Genzyme's board rejected an \$18.5 billion takeover offer from Sanofi, or \$69 a share. "The recent takeover proposal reinforces how important it is to take control and maximize the value we bring to patients and shareholders," he wrote. (Source: Robert Weisman and Steven Syre, Boston Globe, 11 September 2010)

#### Synta Stock Surges on Drug-Test News

Shares of Lexington-based Synta Pharmaceuticals surged more than 17 percent after the company said it is expanding a clinical trial of a lung cancer drug after an initial stage of testing produced encouraging results. Synta said it will broaden its phase-two clinical trial of STA-9090 to 146 patients, from 69. The participants are in certain stages of non-small-cell lung cancer. STA-9090 is a potent, second-generation, small-molecule Hsp90 inhibitor, the company said. The company aims to identify cancer types that will be especially responsive to treatment with STA-9090.

In the first phase of clinical trials, more than 70 percent of patients showed "a high disease-control rate," said Vojo Vukovic, Synta's chief medical officer. "This early signal, combined with the objective responses seen following treatment with STA-9090, is very encouraging, particularly as the patients have been heavily pretreated and are refractory to many standard-of-care drugs," he added. (Source: Associated Press, 14 September 2010)

#### Amylin, Lilly and Alkermes Announce Receipt of Complete Response Letter from FDA for Type 2 Diabetes Drug Bydureon

Amylin Pharmaceuticals, Eli Lilly and Alkermes have announced that the FDA has issued a complete response letter regarding the New Drug Application (NDA) for Bydureon (exenatide extended-release for injectable suspension). The companies' goal is to submit their reply to the complete response letter by the end of 2011, pending discussions with the FDA. Based on the requirements for additional data, this will likely be considered a Class 2 resubmission requiring a six-month review.

"We are committed to working closely with the FDA to resolve the issues raised in the complete response letter so that Bydureon can be approved, and we can make this important treatment available to patients with type 2 diabetes as quickly as possible," said Orville G. Kolterman, M.D., senior vice president, chief medical officer, Amylin Pharmaceuticals. "We remain confident in Bydureon based on the extensive exenatide database, including more than seven years of clinical experience with Byetta, the twice-daily form of exenatide that is available in more than 60 countries worldwide."

Bydureon is a once-weekly formulation of exenatide, the active ingredient in Byetta (exenatide) injection. Byetta has been available in the US since June 2005 and is used in more than 60 countries worldwide to improve glycemic control in adults with type 2 diabetes. Bydureon and Byetta belong to the glucagon-like peptide-1 (GLP-1) receptor agonist class of medications. (Source: Alkermes Website, 19 October, 2010)



## Regulatory & Legislative Highlights

*by Janet Tice, GMP Piping, Inc.*

### FDA Approves New Drug for Gout

The FDA has approved Krystexxa (pegloticase), manufactured by Savient Pharmaceuticals of East Brunswick, NJ, for treatment of gout in adults who do not respond to or who cannot tolerate conventional therapy. Gout occurs due to an excess of the bodily waste uric acid, which is eventually deposited as needle-like crystals in the joints or in soft tissue. These crystals can cause intermittent swelling, redness, heat, pain and stiffness in the joints. Gout is strongly associated with obesity, high blood pressure, high cholesterol and diabetes, and occurs more often in men, in women after menopause, and in people with kidney disease.

"About 3 percent of the three million adults who suffer from gout are not helped by conventional therapy. This new drug offers an important new option for them," said Badrul Chowdhury, M.D., director of the Division of Pulmonary, Allergy, and Rheumatology Products in the FDA's Center for Drug Evaluation and Research.

For patients with gout, the conventional therapy is to receive drugs that lower the amount of uric acid in the blood, as, for example, the xanthine oxidase inhibitors Zyloprim (allopurinol) and Uloric (febuxostat). Krystexxa is an enzyme that lowers uric acid levels by metabolizing it into a harmless chemical that is excreted in the urine. The drug is administered to patients every two weeks as an intravenous infusion.

Since one out of every four patients in the clinical trials experienced a severe allergic reaction when receiving an infusion of Krystexxa, health care providers should dispense a corticosteroid and an antihistamine to their patients beforehand to minimize the risk of such a reaction. Other reactions during the clinical trials included gout flare, nausea, injection site bruising, irritation of the nasal passages, constipation, chest pain and vomiting. Physicians are also being warned to be cautious about administering Krystexxa to patients with congestive heart failure because the drug was not studied in this patient population.

Krystexxa is being approved with a Risk Evaluation and Mitigation Strategy that includes a medication guide for patients and materials for healthcare providers to communicate the risk of severe infusion and allergic reactions. (Source: FDA Website, 14 September, 2010)

### Forest Pharmaceuticals Agrees to Guilty Plea for Violating FDA Laws

The FDA, working in close coordination with the US Department of Justice (USDOJ), has announced that Forest Pharmaceuticals entered into a plea agreement in which the company accepted responsibility for criminal actions including distribution of an unapproved new drug, distribution of a misbranded drug, and obstruction of an FDA inspection.

To resolve these charges and a related civil suit, the company has agreed to pay more than \$300 million, including \$164 million in criminal penalties. This plea agreement is the culmination of a multiyear investigation conducted by FDA's Office of Criminal Investigations in cooperation with its law enforcement partners and the US Attorney's Office for the District of Massachusetts.

Charges against Forest Pharmaceuticals are primarily for its marketing of Levothroid (levothyroxine sodium tablets, USP), an unapproved drug used for the treatment of hypothyroidism. A 1997 Federal Register notice announced that these products are considered "new drugs" within the meaning of the Federal Food Drug and Cosmetic Act (FDCA) and that manufacturers who wished to continue marketing these products must obtain approved applications from the FDA by August 2000. Because levothyroxine was considered a medically necessary product, the FDA permitted a gradual phase-out with all distribution of unapproved levothyroxine sodium drug products to cease no later than August 2003.

Forest Pharmaceuticals did not obtain drug approval, increased its distribution of Levothroid rather than scaling down, and ignored a subsequent Warning Letter to stop the manufacture and distribution of Levothroid. "These charges should serve as a warning to industry that the FDA takes seriously its role to protect the public from unapproved drugs," said Deborah M. Autor, director of the Office of Compliance in FDA's Center for Drug Evaluation and Research. "Any company that operates in violation of the FDCA and ignores FDA's warnings should be aware that a criminal action could follow."

Forest Pharmaceuticals, Inc. also is charged with distribution of a misbranded drug for its off-label promotion of Celexa for pediatric use when it was approved only for use in adults. Celexa is the brand name for the prescription drug citalopram, a selective serotonin reuptake inhibitor (SSRI) drug for the treatment of adult depression.

Consumers should be aware that the Levothroid product currently marketed by Forest Pharmaceuticals, Inc. is not the subject of today's actions. Forest Pharmaceutical's guilty plea and criminal penalties relate to the marketing of the previously unapproved Levothroid product. The current Levothroid product now has an approved New Drug Application and is compliant with FDA regulations. (Source: FDA Website, 15 September, 2010)

### FDA Approves Novartis Drug to Reduce MS Relapses

The FDA has approved Gilenya capsules (fingolimod) to reduce relapses and delay disability progression in patients with relapsing forms of multiple sclerosis (MS). Gilenya is made by Novartis, Basel, Switzerland.

"Gilenya is the first oral drug that can slow the progression of disability and reduce the frequency and severity of symptoms in MS, offering patients an alternative to currently available injectable therapies," said Russell Katz, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research. Gilenya is the first in a new class of drugs that block some blood cells in lymph nodes, reducing their migration to the brain and spinal cord, which may help with reducing the severity of MS.

MS is a chronic, often disabling, disease that affects the central nervous system - the brain, spinal cord, and optic nerves. According to the National Multiple Sclerosis Society, there are about 400,000 people in the United States and 2.1 million people worldwide with MS. The progress, severity, and specific symptoms of MS are unpredictable and vary from one person to another. Symptoms can be mild, such as numbness in the limbs, or severe, such as paralysis or loss of vision.

Patients using Gilenya should be monitored for a decrease in heart rate upon starting the drug. Gilenya may also increase the risk of infections. Cases of serious eye problems (macular edema) have occurred in patients taking the drug and an ophthalmologic evaluation is recommended. The most frequent adverse reactions reported by patients taking Gilenya in clinical trials include headache, influenza, diarrhea, back pain, elevation of certain liver enzymes and cough. (Source: FDA Website,

22 September, 2010)

#### FDA Restricts Use of GlaxoSmithKline Diabetes Drug Avandia

The FDA has announced that it will significantly restrict the use of the diabetes drug Avandia (rosiglitazone) to patients with Type 2 diabetes who cannot control their diabetes on other medications. These new restrictions are in response to data that suggest an elevated risk of cardiovascular events, such as heart attack and stroke, in patients treated with Avandia.

Avandia, manufactured by GlaxoSmithKline (GSK), is in a class of drugs known as thiazolidinediones, or TZDs. It is intended to be used in conjunction with diet and exercise to improve glucose (blood sugar) control in patients with Type 2 diabetes mellitus.

The FDA will require that GSK develop a restricted access program for Avandia under a risk evaluation and mitigation strategy, or REMS. Under the REMS, Avandia will be available to new patients only if they are unable to achieve glucose control on other medications and are unable to take Actos (pioglitazone), the only other drug in this class. Current users of Avandia who are benefiting from the drug will be able to continue using the medication if they choose to do so.

Doctors will have to attest to and document their patients' eligibility; patients will have to review statements describing the cardiovascular safety concerns associated with this drug and acknowledge they understand the risks. The agency anticipates that the REMS will limit use of Avandia significantly.

"Allowing Avandia to remain on the market, but under restrictions, is an appropriate response, given the significant safety concerns and the scientific uncertainty still remaining about this drug," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research.

Also today, the FDA ordered GSK to convene an independent group of scientists to review key aspects of the company's clinical trial known as RECORD, which studied the cardiovascular safety of Avandia compared to standard diabetes drugs. During the course of the FDA's review of the RECORD study, important questions arose about potential bias in the identification of cardiovascular events. The FDA is requiring this independent review to provide additional clarity about the findings.

In addition, the agency halted the GSK's clinical trial known as TIDE and rescinded all of the regulatory deadlines for completion of the trial. The TIDE trial compares Avandia to Actos and to standard diabetes drugs. The FDA may take additional actions after the independent re-analysis of RECORD is completed. (Source: FDA Website, 23 September, 2010)

#### FDA Issues Final Rule on Safety Information during Clinical Trials

The FDA today issued a final rule that clarifies what safety information must be reported during clinical trials of investigational drugs and biologics. According to Rachel Behrman, M.D., associate director for medical policy in the FDA's Center for Drug Evaluation and Research, this final rule will expedite FDA's review of critical safety information and help the agency monitor the safety of investigational drugs and biologics.

The new rule requires that certain safety information that previously had not been required to be reported to FDA be reported within 15 days of becoming aware of an occurrence. These reports include:

- findings from clinical or epidemiological studies that suggest a significant risk to study participants;
- serious suspected adverse reactions that occur at a rate higher than expected;
- serious adverse events from bioavailability studies which determine what percentage and at what rate drug is absorbed by the bloodstream and bioequivalence studies which determine whether a generic drug has the same bioavailability as the brand name drug.

The rule also provides examples of evidence that would suggest that an investigational product may be the cause of a safety problem. Under current regulations, drug sponsors often report all serious adverse events, even if there is little reason to believe the product caused the event. Such reporting complicates and delays the FDA's ability to detect a safety signal. The examples address when a single event should be reported or when there is need to wait for more than one occurrence.

In addition, the rule revises definitions and reporting standards so that they are more consistent with two international organizations, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and the World Health Organization's Council for International Organizations of Medical Sciences. The changes are designed to help ensure harmonized reporting of globally conducted clinical trials.

Along with this final rule, the FDA also issued a draft guidance for industry and investigators that provides information and advice about the new requirements and other information. (Source: FDA Website, 28 September, 2010)

#### NIH and FDA Announce Awards to Advance Regulatory Science

The National Institutes of Health will award \$9.4M over three years to support four research projects in regulatory science. This research is conducted in partnership with the FDA, which will contribute approximately \$950K. These projects will better inform scientists and regulatory reviewers alike about medical product safety, and improve the evaluation and availability of new medical products to the community. The projects include research on nanoparticles and their characterization, a heart-lung model to test the safety and efficacy of drugs, innovative clinical trial design, and a novel strategy to predict eye irritation.

The awards follow a February 2010 announcement by the NIH and the FDA to work together in an unprecedented manner on important public health issues. As part of that effort, the agencies established an NIH-FDA Joint Leadership Council to spearhead collaborative activities. In addition, the NIH and the FDA issued a request for applications to stimulate a new research initiative in a priority area, Advancing Regulatory Science through Novel Research and Science-Based Technologies.

Regulatory science involves the development and use of the scientific knowledge, tools, standards, and approaches necessary for the assessment of medical product safety, efficacy, quality, potency, and performance. For more information on the Regulatory Science Program <http://commonfund.nih.gov/regulatoryscience/>

"These projects show the potential breadth of opportunity that comes from advancing regulatory science. The results are likely to have broad application to researchers across scientific disciplines and will result in better-informed regulatory decision-making and faster drug development and approval processes," said Commissioner of Food and Drugs Margaret A. Hamburg, M.D. (Source: FDA Website, 27 September, 2010)

#### FDA Orders Halt to Sales of Unapproved Oral Colchicine



The FDA has taken action against companies that manufacture, distribute, and/or market unapproved single-ingredient oral colchicine, a medication commonly used for the daily prevention of gout, to treat acute gout flare-ups, and for the treatment of Familial Mediterranean Fever (FMF). The companies are expected to stop manufacturing single-ingredient oral colchicine within 45 days and must stop shipping this unapproved product in interstate commerce within 90 days. A small amount of unapproved colchicine is expected to be available after these dates until supplies are exhausted.

Many single ingredient oral colchicine products have been used by the medical community for decades. These and a variety of other medications have not received the mandatory modern-day FDA-approval required of all prescription drugs.

Colcris is the only FDA-approved single-ingredient oral colchicine product available on the U.S. market. Approved by the FDA in 2009, Colcris' prescribing information contains important safety data and recommendations on drug interactions and dosing not available with unapproved products.

The manufacturer of Colcris, Mutual Pharmaceutical/URL Pharma, has established a Patient Assistance Program (PAP) and a Co-Pay Assistance Program (CAP) to ensure that all patients will be able to continue affordable access to colchicine. The company also has informed FDA that it will maintain the programs at a minimum until there is FDA-approved generic competition for Colcris.

Today's action is part of the FDA's broader initiative against marketed unapproved drugs, announced in a June 2006 Compliance Policy Guide describing the agency's risk-based enforcement approach for marketed unapproved drug products. "The need for drugs to go through the FDA approval process is clearly demonstrated by our review of oral colchicine tablets," said Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research (CDER). "Without our safety review and proper drug labeling, the old standard of care would likely have continued, to the detriment of patients."

Unapproved versions of colchicine are not generic drugs. Generic drugs are approved by the FDA to assure that the approved generic drug products meet the same standards as the innovator drug. All single-ingredient oral colchicine products, other than Colcris, that are currently being marketed are unapproved drugs and have never been evaluated by the agency.

"It is a priority for the FDA to get unapproved medications, such as older versions of single ingredient oral colchicine, either updated to conform to FDA's current approval standards or off the market," said Deborah M. Autor, director of CDER's Office of Compliance. "The FDA remains committed to ensuring that prescription drugs have the necessary FDA approval. We encourage companies to actively pursue approval or face the type of action announced today."

The FDA previously took action against unapproved colchicine for injection products on Feb. 6, 2008. This ongoing initiative is designed to bring all unapproved medications, including single-ingredient oral colchicine, up to modern-day safety, efficacy, labeling, and quality standards by ensuring that they comply with FDA approval requirements. The FDA is committed to working with companies to ensure that marketed drugs are safe and effective, and meet appropriate standards for manufacturing and labeling. (Source: FDA Website, 30 September, 2010)

#### Public Hearing Held on Biologics Price Competition and Innovation Act

The FDA held a two-day public hearing on Nov. 2-3, 2010, on the implementation of the Biologics Price Competition and Innovation (BPCI) Act of 2009. The BPCI Act establishes an abbreviated approval pathway for biological products that are demonstrated to be highly similar (biosimilar) to, or interchangeable with, an FDA-licensed biological product.

The purpose of the hearing was to receive input on the act's implementation from the public, health care professionals, health care institutions, manufacturers of biomedical products, industry and professional associations, patients and patient associations, third party payers, and current and prospective biological license application and new drug application holders.

The BPCI Act is consistent with the FDA's policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing. However, the implementation of an abbreviated approval pathway for biological products can pose scientific and technical challenges associated with the larger molecular structure and manufacturing of biological products. Most are produced in a living system such as a microorganism, plant, or animal cells, while small molecule drugs typically are manufactured through chemical synthesis. (Source: FDA Website, 4 October, 2010)

#### FDA Awards \$2.9 Million for Tuberculosis Research

The FDA has announced the award of \$2.9 million to support six research projects that will help with the diagnosis, treatment, and prevention of tuberculosis (TB). TB remains a major public health challenge with an increasing prevalence worldwide.

Two recent articles published by FDA's Office of Critical Path Programs note that advances are urgently needed in TB drug development to shorten therapy and to treat drug-resistant disease. "FDA recognized an urgent need for the engagement and leadership of public health institutions to promote this critical, but neglected, area of medical therapeutics," said FDA Commissioner Margaret A. Hamburg, M.D.

Launched in 2004, the Critical Path Initiative is the FDA's strategy for driving innovation in the way medical products are developed, evaluated, and manufactured. (Source: FDA Website, 4 October, 2010)

#### FDA Awards \$904K to Pan American Health Organization for Information Hub

The FDA has announced the award of a \$904K cooperative agreement to the Pan American Health Organization (PAHO) to research and develop an information hub for medical products and related regulatory processes and systems in the Americas Region.

The award will help FDA, and all PAHO member states, to better understand other countries' regulatory systems, support capacity to use harmonized standards and guidelines across countries, and prevent, and if necessary respond more quickly to, problems in the medical product supply chain. The "hub" will collect and produce data and map structures and processes in the areas of medical products, including drugs, biologics, vaccines, medical devices and other medical products, and related regulatory processes and systems.

"National regulatory agencies play a critical role in ensuring access to safe, effective, quality medical products for patients and consumers," said FDA Commissioner Margaret A. Hamburg, M.D. "Improved data access and transfer will help the monitoring of medical products, ingredients, and components throughout the supply chain and help reduce the risk of importing unsafe products and/or their ingredients into the marketplace."

Established in 1902, PAHO works to improve the health and the quality of life of people of the Americas and serves as the Regional Office for the Americas of the World Health Organization. PAHO member states today include 38 countries in North, Central and South America, and the Caribbean.

Regulatory agencies in the Americas Region have different legal and regulatory frameworks, different institutional and administrative structures, different standards and guidelines, and different ways of collecting and analyzing information. Better collaboration among these agencies will build confidence and knowledge among the participants, stakeholders, and ultimately benefit patients and consumers throughout the region, according to Hamburg. (Source: FDA Website, 6 October, 2010)

Abbott Laboratories Agrees to Withdraw Obesity Drug Meridia

The FDA recently announced that Abbott Laboratories has agreed to voluntarily withdraw its obesity drug Meridia (sibutramine) from the US market because of clinical trial data indicating an increased risk of heart attack and stroke.

"Meridia's continued availability is not justified when you compare the very modest weight loss that people achieve on this drug to their risk of heart attack or stroke," said John Jenkins, M.D., director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research (CDER). "Physicians are advised to stop prescribing Meridia to their patients and patients should stop taking this medication. Patients should talk to their health care provider about alternative weight loss and weight loss maintenance programs."

Meridia was approved by the FDA in November 1997 for weight loss and maintenance of weight loss in obese people, as well as in certain overweight people with other risks for heart disease. The approval was based on clinical data showing that more people receiving sibutramine lost at least 5 percent of their body weight than people on placebo who relied on diet and exercise alone.

The FDA requested the market withdrawal after reviewing data from the Sibutramine Cardiovascular Outcomes Trial (SCOUT). SCOUT was initiated as part of a postmarket requirement to look at cardiovascular safety of sibutramine after the European approval of this drug. The trial demonstrated a 16 percent increase in the risk of serious heart events in a group of patients given sibutramine compared to another given placebo. There was a small difference in weight loss between the placebo group and the group that received sibutramine. (Source: FDA Website, 8 October, 2010)

FDA Warns of Possible Increased Risk of Thigh Bone Fracture with Bisphosphonates

The FDA has issued a warning about the possible risk of atypical thigh bone (femoral) fracture in patients who take bisphosphonates, a class of drugs used to prevent and treat osteoporosis. A labeling change and Medication Guide will reflect this risk.

Bisphosphonates inhibit the loss of bone mass in people with osteoporosis; they have been shown to reduce the rate of osteoporotic fractures in people with osteoporosis. While it is not clear whether bisphosphonates are the cause, atypical femur fractures, a rare but serious type of thigh bone fracture, have been predominantly reported in patients taking bisphosphonates. The optimal duration of bisphosphonate use for osteoporosis is unknown, and the FDA is highlighting this uncertainty because these fractures may be related to use of bisphosphonates for longer than five years.

The labeling changes and Medication Guide will affect only those bisphosphonates approved for osteoporosis, including oral bisphosphonates such as Fosamax, Fosamax Plus D, Actonel, Actonel with Calcium, Boniva, Atelvia, and their generic products, as well as injectable bisphosphonates such as Reclast and Boniva. Labeling changes and the Medication Guide will not apply to bisphosphonates used for Paget's disease or cancer/hypercalcemia such as Didronel, Zometa, Skelid, and their generic products.

"The FDA is continuing to evaluate data about the safety and effectiveness of bisphosphonates when used long-term for osteoporosis treatment," said RADM Sandra Kweder, M.D., deputy director, Office of New Drugs in the FDA's Center for Drug Evaluation and Research. "In the interim, it's important for patients and health care professionals to have all the safety information available when determining the best course of treatment for osteoporosis."

The warning follows a March 10, 2010, Drug Safety Communication announcing the FDA's ongoing safety review of bisphosphonate use and the occurrence of atypical femur fractures. The FDA has since reviewed all available data on bisphosphonate use, including data summarized in the American Society for Bone Mineral Research Task Force report. The report recommended additional product labeling, better identification and tracking of patients experiencing these breaks, and more research to determine whether and how these drugs cause the serious but uncommon fractures. (Source: FDA Website, 13 October, 2010)

Botox Approved for Treatment of Chronic Migraine

The FDA has approved Botox injection (onabotulinumtoxinA) to prevent headaches in adult patients with chronic migraine. Botox is manufactured by Allergan of Irvine, CA.

Chronic migraine is defined as having a history of migraine and experiencing a headache on most days of the month. "Chronic migraine is one of the most disabling forms of headache," said Russell Katz, M.D., director of the Division of Neurology Products in the FDA's Center for Drug Evaluation and Research. "Patients with chronic migraine experience a headache more than 14 days of the month. This condition can greatly affect family, work, and social life, so it is important to have a variety of effective treatment options available."

Migraine headaches are described as an intense pulsing or throbbing pain in one area of the head. The headaches are often accompanied by nausea, vomiting, and sensitivity to light and sound. Migraine is three times more common in women than in men. Migraine usually begins with intermittent headache attacks 14 days or fewer each month (episodic migraine), but some patients go on to develop the more disabling chronic migraine.

To treat chronic migraines, Botox is given approximately every 12 weeks as multiple injections around the head and neck to try to dull future headache symptoms.

OnabotulinumtoxinA, marketed as Botox and Botox Cosmetic, has a boxed warning that says the effects of the botulinum toxin may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism. Those symptoms include swallowing and breathing difficulties that can be life-threatening. (Source: FDA Website, 15 October, 2010)

Boehringer Ingelheim Drug Pradaxa Approved for Prevention of Stroke

The FDA has approved Pradaxa capsules (dabigatran etexilate) for the prevention of stroke and blood clots in patients with abnormal heart rhythm (atrial fibrillation). Atrial fibrillation, which affects more than 2 million Americans, involves very fast and uncoordinated contractions of the heart's two upper heart chambers (atria) and is one of the most common types of abnormal heart rhythm.

"People with atrial fibrillation are at a higher risk of developing blood clots, which can cause a disabling stroke if the clots travel to the brain," said Norman Stockbridge, M.D., Ph.D., director of the Division of Cardiovascular and Renal Products in the FDA's Center for Drug Evaluation and Research.

Pradaxa, manufactured by Boehringer Ingelheim Pharmaceuticals of Ridgefield, CT, is an anticoagulant that acts by inhibiting thrombin, an enzyme in the blood that is involved in blood clotting. The safety and efficacy of Pradaxa were studied in a clinical trial comparing Pradaxa with the anticoagulant warfarin. In the trial, patients taking Pradaxa had fewer strokes than those who took warfarin. "Unlike warfarin, which requires patients to undergo periodic monitoring with blood tests, such monitoring is not necessary for Pradaxa," Stockbridge says.

As with other approved anti-clotting drugs, bleeding, including life-threatening and fatal bleeding, was among the most common adverse reactions reported by patients treated with Pradaxa. Pradaxa was approved with a Medication Guide that informs patients of the risk of serious bleeding. The guide will be distributed each time a patient fills a prescription for the medication. (Source: FDA Website, 19 October, 2010)

FDA: Include Warnings on Risk for Class of Prostate Cancer Drugs

The FDA has asked manufacturers to add new warnings to labeling of gonadotropin-releasing hormone (GnRH) agonists, a class of drugs primarily used to treat men with prostate cancer. The warnings would alert patients and their health care professionals to the potential risk of heart disease and diabetes in men treated with these medications.

Prostate cancer is the second most common type of cancer among men in the United States, behind skin cancer, and usually occurs in older men. This year an estimated 217,730 new cases of prostate cancer will be diagnosed and about 32,050 men will die from the disease, according to the Centers for Disease Control National Center for Health Statistics and the National Cancer Institute.

GnRH agonists are drugs that suppress the production of testosterone, a hormone involved in the growth of prostate cancer. This type of treatment is called androgen deprivation therapy, or ADT. Suppressing testosterone has been shown to shrink or slow the growth of prostate cancer. GnRH agonists are marketed under the brand names: Eligard, Lupron, Synarel, Trelstar, Vantas, Viadur, and Zoladex. Several generic products are available. (Source: FDA Website, 20 October, 2010)

New Label Changes for Genentech's HIV Drug Invirase

The FDA has announced that new safety information has been added to the label for the HIV antiviral drug Invirase (saquinavir), describing potentially life-threatening side effects on the heart when used with Norvir (ritonavir), another HIV antiviral medication. Invirase is marketed by Genentech; Norvir is marketed by Abbott Laboratories.

In February 2010, the agency warned patients and health care professionals that when used together, the two drugs could cause prolongation of the QT and PR intervals, indicators of heart rhythm activity seen on an electrocardiogram. Prolongation of the QT or PR intervals may lead to abnormal heart rhythms known as torsades de pointes or heart block, respectively, in which patients may experience lightheadedness, fainting or abnormal heart beats. In some cases, torsades de pointes may progress to a life-threatening irregular heart beat known as ventricular fibrillation.

The FDA is also requiring a medication guide for patients using Invirase that will describe these potential risks. Patients at greater risk of developing one of the serious heart events described above include those with underlying heart conditions or those that have existing heart rate or rhythm problems. (Source: FDA Website, 21 October, 2010)

New Members

- Nadia Adam, *Professor*, University of Wyoming
- Mrs. Kristen DL Aldweib, *QA Supervisor*, Shire HGT
- Mr. David R. Bartorelli, *Operations Design Specialist*, Organogenesis Inc.
- Mr. John E. Bigelow, *Umass Amherst*
- Christopher Bitzas
- Mr. Timothy J. Blaser, *VP Operations*, Advanced MicroSensors
- Mrs. Virginia H. Cater, *Quality Assurance Engineer*, New England Controls, Inc.
- Jingwen Chai, *Student*, University of New Hampshire
- Mr. Varun Chalupadi, *Student*, University of Massachusetts Amherst
- Rebecca E. Cole, *Student*, University of New Hampshire
- Mr. Jordan R. Croteau, *Automation Engineer*, Integrated Process Technologies
- Dr. Steven C. Davy, *Senior Process Engineer*, NNE Pharmaplan
- Amanda N. Devine, *Student*, University of New Hampshire
- Michael A. DeVita, Jr., *Sr Account Executive*, Surveillance Specialties
- Kim R. Doherty, *Engineering PPE*, Genzyme Corp
- Mr. Anthony L. Dragich, *Student*, University of Rhode Island



Jeannette M. Gerry, *Student*, Worcester Polytechnic Institute  
Katherine K. Hird, *Student*, University of New Hampshire  
Christopher E. Jenkins, *Project Manager*, Siena Construction Inc  
Mr. Mark J. Jodoin, *Business Development Manager*, University of Phoenix  
Mr. Benjamin R. Klouda, *Student*, University of Massachusetts Lowell  
Mr. Anthony LaViola, *Student*, University of Massachusetts Amherst  
Mr. Christopher Lowe, *Student*, University of Massachusetts Amherst  
Mr. Joseph S. Macek, *Project Manager*, Gxp Automation  
Mr. Francis M. Maheno, *Account Manager*, Webb Bio-Pharm  
Ms. Elizabeth A. Masen, *Process Engineer*, Abbott Bioresearch Center  
Chris McLaughlin, *Systems Engineer*, New England Controls  
Mr. Alexander J. Misch, Worcester Polytechnic Institute  
Paula Phenix, Millipore Inc  
Mrs. Cindy Philbrick, Worcester Polytechnic Institute  
Ms. Carole A. Piscitelli, *Project Coordinator*, CRB Consulting Engineers  
Mr. Daniel Post, *Sr. Project Manager*, Structure Tone Inc.  
Jake Pritchard, *Senior Controls Engineer*, Pfizer  
Mr. Johnson R. Quartey, *Student*, Mount Wachusett Community College  
Ms. Marianne R. Reilly, *Validation Specialist*, Pfizer  
Mr. William Riordan, *Sr. Project Manager*, Shire HGT  
Jeannine M. Ripley, *Manager, Talent Acquisition*, Bristol-myers Squibb  
Martin W. Rochford, *Validation Specialist*, Commissioning Agents Inc  
Mr. Eric L. Russo, *Student*, University of New Hampshire  
Swetha Sampathgiri, BiogenIdc  
Mr. Mark Schores, *Account Executive*,  
Ms. Caroline Silliman, MA, *Manager Sales & Business Dev*, Lonza  
Dakota R. Smith, *Student*, University of New Hampshire  
Emily A. Smith, *Student*, University of New Hampshire  
Mr. Kranthi Tata, *Product General Manager*, GE Measurement and Control Solutions (Kaye)  
Mr. Jason Theberge, *Sr. Project Manager*, Shire  
Mr. Geoffrey C. Wilkinson, Jr., *VP of Operations*, The Wilkinson Companies  
Xiyang Zhang, *Student*, Worcester Polytechnic Institute

**Member Anniversaries**

**20+ Years of Membership**

Mr. David C. Hardy  
Mr. Thomas W. Moss, Applied Process Solutions, Inc  
Mr. Hank Moes  
Mr. Stephen R. Higham, PE, Genzyme Corp  
Ms. Sandra Illich, Pfizer  
Mr. Armen J. Nahabedian, Pfizer  
Mr. Jonathan F. Stenbuck, Stenbuck Enterprises  
Mr. Michael A. Boenitz, DUSA Pharmaceuticals Inc  
Dr. Richard V. Levy, PDA  
Mr. Donald M. Haiges, PE, WSP-Flack+Kurtz  
Mr. Randolph A. Cotter, Sr., Cotter Brothers Corporation  
Mr. Cesar B. Daou, PE, Daou Engineers Inc  
Mr. Thomas R. Jerome

Mr. Robert W. Juffras, MS, Stryker Biotech  
Mr. Frank J. Manning, VNE Corp  
Mr. Alexander E. Smith, Jr., Parsons  
Ms. Greta W. Davis, Lantheus Medical Imaging  
Mr. John H. Evers, Lantheus Medical Imaging  
Mr. David L. Hyde, Independent Contractor  
Mr. George C. Enos, Hart Design Group  
Mr. Pasquale M. Sacco, Shire HGT

**15 Year Anniversary**

Mr. James P. McLaughlin, Neurotech, USA

**10 Year Anniversary**

Mr. William C. Dawes, Jr., Lantheus Medical Imaging  
Ms. Paige E. Kane, Pfizer Pharmaceuticals  
Mr. Kosal Keo, Genzyme Co  
Mr. Leighton S. Terwilliger, Integra Companies Inc

**5 Year Anniversary**

Mr. Paul S. Tierney, Jr., Northeast Engineering, Inc.  
Mr. James Curry, OpStat Group Inc.  
Mr. David A. Campanella, SAIC  
Mr. Michael F. Garvey, ImmunoGen, Inc.  
Ms. Laura L. Ward, ImmunoGen, Inc.  
Mr. Andrew Timofeev, Shire HGT

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