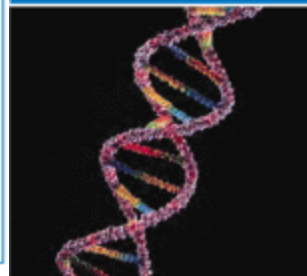




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## Boston Area Chapter

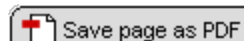
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## NEWSLETTER

November 2011, Volume XXI, No. 6

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### **President's Message: Another Award Winning Year for the Boston Area Chapter**



Dear ISPE Boston Area Chapter Members

Wow, it's only November and we've already had three major program events: the September Risk Management Educational Program, our world famous Product Show and the ISPE Annual Meeting in Dallas, where I was proud to be part of a Boston Area Chapter contingent of over 50 professionals who applauded the Chapter's three major awards (more about that later). I'm pretty sure we had the largest representation of any Chapter at Annual Meeting - GO BOSTON!!

Our first program of 2011-12 was held in September and featured two excellent presenters who shared their expertise on "Use of Risk Management in CAPA Root Cause Analysis" and "Mitigating Pharma Equipment Risk Through Human Factors." Our two presenters, Susan Reilly and Christina Mendat, gave us a lot of information plus some food for thought, and attendees came away with a new perspective on Risk Management (see related article).

The Boston Area Chapter proudly held its 20<sup>th</sup> Annual Product Show, where about 2,000 industry professionals gathered for this one day "can't miss" extravaganza. This year, Jonathan Kraft, President of the New England Patriots, joined the festivities as our keynote speaker. He regaled us with personal insights and stories on a wide variety of topics ranging from the true genius of Bill Belichick to his father's critically important contributions to the recently negotiated Collective Bargaining Agreement between owners and players. He even spoke of the possibility of a life sciences park near Gillette Stadium in the future. I hope you had the chance to hear Jonathan Kraft's message - if you didn't, you really missed something special.

The Product Show once again reset the standard for excellence in local trade shows. We had a lot of firsts this year (see related articles) and the Boston Area Product Show continues to be the envy of others. Andre

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Walker, CPIP, (2010-11 Chairman of the ISPE International Board of Directors) was presented with the Hank Moes Lifetime Achievement Award for his contributions to ISPE.

This year, we leveraged the popularity of the Product Show to create special incentives for our annual membership drive, available to new members who joined ISPE during the month of October. Until you travel to another area of the country, you won't know how lucky we are in Boston to have such a first rate event literally at our fingertips each and every year.

Annual Meeting was recently held in Dallas and was another award-filled gathering for the Boston Area Chapter. For the third consecutive year, our Chapter received the Platinum Grand Award for Excellence (formerly called the "Chapter of the Year" award). We were commended for our innovative education programs as well as our brand new scholarship program, and took home the Grand Award in Programs and Events for January's "dual-track" Automation Program. In the theme of being in "cowboy country," the Boston Area Chapter received extra recognition by winning the "Young Professional Roundup of 2011" for signing up the most Young Professional Members in the past six months. Our YPs won \$250 plus five free CPIP credential applications to reward them for this accomplishment.

Congratulations go out to all who helped with these efforts! Our own Andre Walker, outgoing chairman of the ISPE International Board of Directors gave a great farewell speech as he stepped down from his position. Andre joins a distinguished group of Boston Area Chapter Past Presidents who have gone on to serve on the International Board of Directors. We are honored to have Andre working locally with the Boston Area Chapter once again.

We are also pleased to announce a new reward for ISPE members who encourage their friends and colleagues to join ISPE. If a new member joins and indicates that you referred them to ISPE, you will receive a free month of membership toward next year's ISPE member dues. It's another way to encourage Members to spread the word and reward them for doing so.

Please consider volunteering for one of ISPE's committees. It's a great way to meet industry peers, network, and do something that will be a great service to others. Even if you can only spare an hour a year, give us a try; we'd really enjoy having you become a part of this great group of professionals. Check out our website, <http://www.ispeboston.org/> and click on committees to learn more.

- Product Show Committee
- Educational Program Committee
- Membership Services Committee
- Social Committee
- Communications Committee
- Young Professionals Committee

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A photograph of industrial water filtration equipment, showing large cylindrical tanks and complex piping systems.

- Student Chapter Committee

Keep your eye on our website and your emails, as we will soon be unveiling plans for the Boston Area Chapter's 20<sup>th</sup> Anniversary celebration in February. Yes, that's right, the Boston Area Chapter turns 20 this year. And we're going to celebrate in style!

And just one more thing. If ISPE emails are not reaching you, it probably means that you've told ISPE you don't want to receive email. Unfortunately, this may include email from both ISPE International and the Boston Area Chapter. You can fix this by changing your member profile to receive emails about all the exciting things the Boston Area Chapter is planning for the upcoming year. [Follow this link](#). Click on the "Login" icon (upper right), then enter your user ID (ie. member number) and password. In the next screen, select "Update Email Preferences," and check "My local ISPE Affiliate or Chapter." It's that simple!

Thank you,

Brian Hagopian  
President, ISPE Boston Area Chapter

### **ISPE Membership Dues Reduced for Young Professionals**

Are you a young professional? If so, all the benefits you love about your ISPE Membership are now more affordable than ever - you can enjoy a savings of more than 60 percent a year for the first four years you're out of school. Visit <http://www.ispe.org/young-professionals-new-to-industry> to see if you qualify for the new ISPE Young Professionals Membership, or contact the Chapter office at [office@ispeboston.org](mailto:office@ispeboston.org).

### **Chapter Scholarship Fund Applications Due November 15th**

The Boston Area Chapter Joel Goldenberg Memorial Scholarship Fund provides financial support to Chapter members who are continuing their formal education in the life sciences at an accredited college or university. Children of members entering their freshman year of college who plan to major in a life sciences field are also eligible to apply. Recipients receive up to \$2,000 or an amount equal to the cost of a specific course (including course-related fees and supplies) minus employer tuition reimbursement, whichever is less.

The application process has been designed for simplicity, with two due dates during the calendar year, November 15th for spring courses and June 15th for fall courses. Applicants are asked to describe their future goals and how the scholarship would help them meet those goals; their volunteer activities, prior academic or other significant achievements, and their need for financial assistance. They are also asked to provide basic information regarding the course to be covered by the scholarship and the names of three references. Decisions regarding scholarship awards are made by a committee consisting of the Chapter Officers and Immediate Past President. Please visit the Chapter website at <http://www.ispeboston.org/scholarship.html> for detailed information and an application.





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The Product Show provided the perfect opportunity for Chapter President Brian Hagopian to present scholarship awards totaling \$4000 to UNH sophomore Rebecca Cole and part-time BU student Mark Jodoin.

### Upcoming Chapter Events - Mark Your Calendar

Tuesday, November 15, 2011

"Pharmacogenomics: What the Future Holds for Us All"

Genzyme Science Center, Framingham, MA

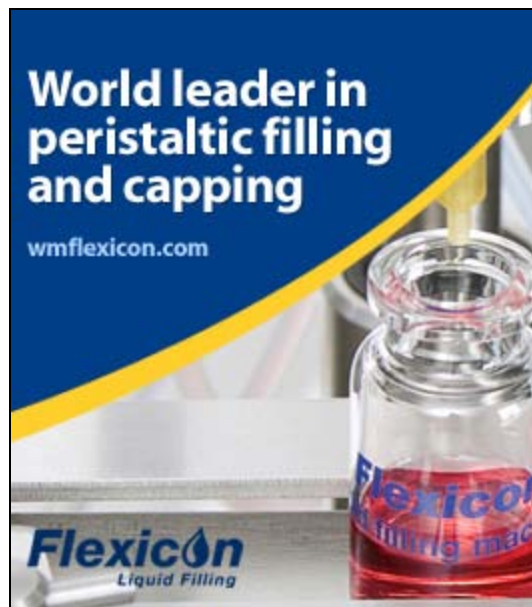
Pharmacogenomics, also known as personalized medicine, has received increased attention in recent years. But what is pharmacogenomics and it really a new idea? This presentation will focus on:

- What is pharmacogenomics? Is it really a new idea?
- How will pharmacogenomics impact the way we do clinical trials?
- How will pharmacogenomics affect new product development?
- How will pharmacogenomics change the way we practice medicine?
- Other interesting issues to ponder (time permitting)

During this interactive workshop, participants will be exposed to multiple examples of pharmacogenomics applications currently on the market, under development and on the drawing board.

Who Should Attend: Pharmaceutical Company to Doctor to Patient or anyone in between.

Pharmacogenomics is the study of how an individual's genetic inheritance affects the body's response



to drugs. Hear how the future may hold the promise that drugs might one day be tailor-made for individuals and adapted to each person's own genetic makeup. In this interactive workshop, Michael Drues will present where we are today and what people are already thinking about.

Register Today: [http://www.ispeboston.org/eventcal/calendar.html?action=display\\_event&oid=160](http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=160)

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Thursday, December 15, 2011

"Integrated Commissioning and Qualifications: Saving Time and Money Without Compromising Quality"

Genzyme Center, 500 Kendall Street, Cambridge, MA 02142

Use of Integrated Commissioning and Qualification models based on ASTM E2500 offers a rare opportunity - a chance to deliver projects that meet user and product needs, with the full documentation package required by regulatory authorities, and do it on time and within budget. However, having your cake and eating it too requires a departure from the traditional approach. This evening's program will lay out a series of C&Q models, explain how they work (or do not work) and use first hand case studies to highlight the benefits and risks of each. This workshop will be presented in two parts, the first will be a presentation of various models and chronicle their history and the second will address how to set up integrated C&Q programs. Bring your questions and do not hesitate to interrupt in this interactive workshop!

Register Today: [http://www.ispeboston.org/eventcal/calendar.html?action=display\\_event&oid=161](http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=161)

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Sneak Preview of Upcoming Events

Thursday, January 19, 2012

Educational Program focusing on Automation

Thursday, February 16, 2012

Educational Program focusing on Project Management

Thursday, March 15, 2012

Educational Program focusing on Water and Steam

Thursday, April 19, 2012

Educational Program focusing on Engineering Documentation

Thursday, May 10, 2012

Educational Program focusing on Process Design Principles

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## **New Features Make Product Show XX a Resounding Success**

*by Laurie Masiello, Masy Systems, with photos by Alastair Battson Photography*

The 20<sup>th</sup> Annual ISPE Boston Area Chapter Product Show this year realized record attendance and many new features and enhancements. Almost 2000 attendees were welcomed at over three hundred vendor booths. Vendors hailed from thirty-one states and Canada, and presented opportunities to see their latest products and services.



Gorgeous weather and an unbeatable view of Gillette greeted Product Show attendees on October 5th.

Sunday. What a treat for two lucky winners and their guests!

This year there was a larger show floor and a new layout, with the keynote address located on the other side of the stadium. What didn't change was the free food - the carving stations, varied and never-ending appetizers, cookies and desserts - and of course, the jumbo shrimp cocktail, our trademark!

Over 250 members participated in nine morning educational seminars and over 350 enjoyed insights and conversation with our keynote speaker, Jonathan Kraft, President of the Kraft Group and the New England Patriots. As a surprise, Mr. Kraft raffled off four tickets for premium seats on the 50-yard line to see the New England Patriots battle the New York Jets the following



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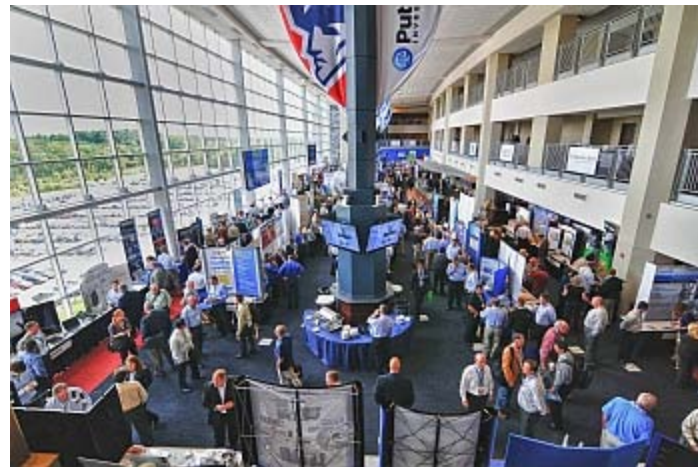
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This year the expanded exhibit area made room for over 300 vendor booths and 2000 visitors.

Eight companies with job openings participated in the Career Fair, doing their part to reduce unemployment in Massachusetts, at least in the biopharmaceutical field! Representatives from Abbott Bioresearch, Biogen Idec, Bristol-Myers Squibb, Genzyme, HireMinds, New England Controls, OPK Biotech and Vertex Pharmaceuticals posted their open positions, collected resumes and interviewed candidates.



As always, networking played an important role for visitors to the Product Show.

The day wrapped up with an exciting "after party" at nearby CBS Scene, where Patriots tight end Rob Gronkowski (graciously replacing the injured Jerod Mayo) mingled with guests and signed autographs. In addition, partygoers ate, drank, rested their tired feet after a long day and participated in late night raffles. Proceeds from the autograph-signing and raffles benefited the local nonprofit, Helping Our Troops, raising almost \$1500 for this worthy cause.

Immediately following this hallmark event, surveys were sent to Product Show attendees and vendor participants. Feedback will help the Product Show Committee improve next year's experience. If you would like to participate on the Committee, please contact co-chairs Mark Sitcoske ([mark.sitcoske@hp-ne.com](mailto:mark.sitcoske@hp-ne.com)) or Laurie Masiello ([lmasiello@masy.com](mailto:lmasiello@masy.com)). The committee meets monthly to plan all facets of the Gillette event - it's not too early to get involved. Product Show XXI is less than a year away!

### **Keynote Speaker Jonathan Kraft Shares Insights on Bill Belichick, Tom Brady & Life Sciences, Too**

by Janet Tice, GMP Piping, with photos by Alastair Battson Photography

What does an owner of the New England



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[October 2007, Volume... \(10\)](#)

Patriots have in common with Product Show attendees, other than Gillette? Over 350 made the trek to the opposite side of the stadium to find out (many pausing on the elevated walkway for a privileged peek at the Patriots on the practice field). And they weren't disappointed!

Jonathan Kraft, president and chief operating officer of The Kraft Group and president of the New England Patriots, opened his remarks by expressing his gratitude to the life sciences professionals whose efforts have brought health benefits to the lives of so many while at the same time creating a powerful engine of economic growth in Massachusetts. He also alluded to a life sciences "cluster" as one possible use for the "shovel ready" development site owned by the Krafts across Route 1 from Gillette.



A crowd of over 350 listened intently as Kraft delivered his remarks on life sciences, the Massachusetts economy and the New England Patriots.



Jonathan Kraft chats with Product Show Committee Chair Mark Sitcoske prior to the keynote address.

But Kraft had more to offer the audience than his respect for the life sciences, as he segued into a freewheeling discussion of the ins and outs of professional football. Topics included the Krafts' first meeting with management after purchasing the Patriots in 1994, the effects of the NFL salary cap, the management style of Parcells vs Belichick, what the team looks for in players, the recent NFL labor dispute and much, much more - all peppered with personal stories and anecdotes using wry humor that kept the audience smiling.

Even better, Kraft delivered his remarks with a degree of candor that made the audience feel like "insiders" - as if he had taken them into his confidence and were sharing opinions and insights not available to the general public - and he implored his listeners more than once to keep his remarks "confidential" and "off

the record." All in all, he delivered a thoroughly entertaining and, at the same time, erudite potpourri of opinion, analysis and personal experience that kept the audience fully engaged and wishing for more.

He concluded with a surprise, generously raffling off two pairs of tickets for premium seats at the Patriots game (vs. the New York Jets) the following Sunday. What a treat for two lucky winners and their guests! And a great way to wrap up an exciting keynote

## Product Show Educational Seminars Attract Record Turnout



## **Newsletter Archive**

*by John Sheridan, PMA Consultants, and Jack Campion, Genzyme, with photo by Alastair Battson Photography*

It is hard to "compete" with all the attractions of the annual Product Show that engage attendees from noon until late in the late evening: state-of-the-art products, networking, Jonathan Kraft, terrific food and drink and more. So this year the educational seminars were moved to the morning enabling a larger number of attendees to benefit without impacting their time on the show floor. Nine sessions - one long and eight short presentations - were held in the Gillette Clubhouse lounges and suites. Those who took advantage of these educational sessions were riveted on the presenters, respected subject matter experts with a wealth of knowledge and experience in their chosen fields.



Morning educational seminars featured respected subject matter experts with a wealth of knowledge and experience.

The long "feature" program was the ELSIE Symposium held from 9:00am to 12noon in the West Clubhouse, Main Club Level. The speakers were Douglas Ball (Pfizer), Lewis Kinter (AstraZeneca Pharmaceuticals) and Daniel Norwood (Boehringer Ingelheim Pharmaceuticals). They covered practical solutions to address safety and quality concerns from extractable and leachable (E&L) compounds that can enter the product during the manufacturing process. The audience was treated to an extended period of knowledge transfer unavailable elsewhere.

Also at 9:00am on the Red Level, "Biotech 101: Trends in Facility Design" with Marc Pelletier of CRB and "Risk Management: Next Steps" with Emma Ramnarine of Roche were offered. "Biotech 101" is a perennial favorite at the Product Show and attracted 62 attendees this year. Then "Cold Chain Distribution" with Anthony Rizzo of Cold Chain Technologies was offered in parallel with the panel discussion, "Every Gold Medal Winner has a Coach and Mentors." Dan Gee moderated a terrific panel, which included Dan Button and Kathy Freitas of Draeger Medical, Armando Llorente of HRe-sources LLC, Kerry Harrison of MIT Lincoln Laboratory, Tawnya Johnson of the Boston Red Sox and Joseph Maressa, Fitzgerald, Stevens & Ford/OI Partners.

For the next pair of sessions, Jack Campion of Genzyme Corporation presented "Introduction to Validation" to a crowd of over 45 professionals while down the hall Michael Druess of Vascular Sciences engaged his audience with an interactive presentation on "Future Manufacturing & Packaging Challenges" (You can also catch Michael at the upcoming educational program on November 15th at the Genzyme Science Center in Framingham where he will present "Pharmacogenomics - What the Future Holds for Us!"). The last two sessions included Daryl Roll of Astro Pak Corporation on "Rouge: Monitoring, Measuring and Remediating in Water and Steam Systems" and Gwen Acton of Vivo Group on "Thriving at the Intersection of Science and Business."

Discussions with the speakers continued long after the presentations were over, always a good sign that the topics covered were timely and thought-provoking. The morning of Educational Programs presented a wealth

of industry and professional knowledge in an incredible forum for a price that couldn't be beat!

## **André Walker Receives Hank Moes Lifetime Achievement Award at Product Show**

*by Janet Tice, GMP Piping, with photo by Alastair Battson Photography*

How appropriate for the Hank Moes Lifetime Achievement Award to be presented at the 20th Annual Boston Area Chapter Product Show. The award is named for Hank Moes, the Chapter's first president, and this year honors André Walker, CPIP, 2010-11 Chairman of the ISPE International Board of Directors and longtime member and enthusiastic supporter of the Boston Area Chapter.



Lifetime Achievement Award winner André Walker, CPIP (r) receives congratulations from Chapter President Brian Hagopian.

André has recently returned to the Boston area after a two-year tenure as Director of Manufacturing Engineering and Facilities for Biogen Idec's Large Scale Commercial Manufacturing Operation in Hillerød, Denmark. He became a member of the ISPE International Board of Directors in 2003 and served as Vice Chair prior to assuming the Chairmanship in 2010. His many contributions to the Society include four years on the North American Affiliate Council, two of which he served as chair, and several years on the Boston Area Chapter Board, including terms as vice president, program chair, and president. He also holds the CPIP credential.

Upon accepting the award from Chapter President Brian Hagopian, André expressed his thanks to the Chapter and applauded its continued growth and success from humble beginnings two decades ago. His concluding message to the audience? He described the many hours he spent contributing to the Chapter and to the International Society as both personally and professionally fulfilling and urged members to get involved by volunteering to help plan and implement the Chapter's many activities. "You won't regret it!" he promised.

Congratulations to André and our heartfelt thanks for his many years worth of contributions to the Boston Area Chapter and the International Society!

## **Overflow Crowd Mobs Product Show After Party at CBS Scene**

*by Christopher Opolski, Alexion Pharmaceuticals, with photos by Alastair Battson Photography*

After a whole day standing on your feet meeting people at the Product Show, what better way to relax than to enjoy the evening with friends and colleagues at the After Party Celebration at CBS Scene. Over 400 people attended this year's gathering, filling up three floors of the restaurant to overflowing.



Product Show exhibitors and attendees celebrate at CBS Scene following the event.

A special attraction at this year's event was second-year Patriot's tight end, Rob Gronkowski. For two hours, attendees were able to have pictures taken with him and get his autograph. And, as if that weren't enough, the event raised \$1400 in raffle donations for Helping Our Troops, a local nonprofit providing care packages to Massachusetts military personnel serving in Afghanistan and Iraq. The Chapter was able to donate \$2000 to the organization, and two lucky individuals won signed Patriots memorabilia for donating to the charity.

In fact, After Party attendance surpassed even our best-case estimates and nearly overwhelmed CBS Scene and its staff. Luckily, everyone was in a mellow mood after a long day of Product Show duty and more than content to roll with the punches. We're already looking for a local venue able to accommodate record crowds for next year's After Party and have our sights set on Toby Keith's I Love This Bar & Grill with its 85-foot long, guitar-shaped bar and Bullet the Mechanical Bull. Bull riding, anyone?

### **Vendor Training Camp Attendees Get a Patriot's Surprise!**

*by Laurie Masiello, Masy Systems, with photo by Mark Sitcoske*

Vendors planning to exhibit at the 20<sup>th</sup> Annual Boston Area Chapter Product Show got a special treat this year. Not only were they invited to a Vendor Training Camp on September 8th where they received a tour of Gillette Stadium and heard presentations designed to improve their Gillette experience, they had a private luxury box



viewing of the New England Patriots practice!



Vendor Training Camp attendees enjoy a free ride in the service elevator at Gillette.

The idea to create a Vendor Training Camp came from feedback from last year's attendees that noted vendors found it difficult to navigate around the stadium. The Product Show committee responded by providing a tour of the stadium and planned presentations by Gillette personnel and SER Expo Services, the company who provides exhibitor support on show day. A presentation on show etiquette and best practices was also developed as a refresher for exhibitors.

Participants ranged from first-time exhibitors to veterans of the Product Show from the early days at the Marriott in Newton and Howard Johnson's in Cambridge. Needless to say, all were thrilled at the opportunity to watch the pre-season NE Patriots practice! Questions were welcome throughout and ran the gamut from "Where's the loading dock?" to questions about the new after-party at CBS Scene. Vendors were able to see where their booth would be located and what companies would be located nearby.

Through their questions and comments, those who attended provided valuable insight on how to enhance next year's Gillette experience. Unfortunately, there is no guarantee that the 2012 Training Camp will include the private Patriot's practice. And that was an experience that will certainly be difficult to top!

### **Risk Management Principles & Practices: An Evening on the Charles**

*by Sean Brown, Barry-Wehmiller Design Group, and Mike Long, ConcordiaValSource, with photo by Joyce Chiu, Honeywell Safety Products*

The ISPE Boston Area Chapter held its first educational program of 2011-12 on Wednesday, September 14th with risk management as the evening's focus. The program took place at the picturesque Royal Sonesta overlooking the Charles River and was hosted by Educational Program Committee (EPC) Members Sean Brown and Mike Long.

The program attracted a large turnout for two reasons: risk management is at the forefront of our industry and the event provided a rare opportunity to hear from two leading experts on the subject.



Speakers Christina Mendat (l) and Susan Reilly (r) discuss risk management challenges during the Q&A session.

Risk management is more than performing a one-time risk assessment. Instead, it is about embedding it within the product and process lifecycle. The program focused on the application of risk management principles at two different points along the life cycle - in equipment design and in manufacturing - with the presenters describing how to better use risk management in the exciting field of "human factors" and the importance of the "root cause analysis" process. The EPC, under the able direction of Committee Chair Jack Campion, wanted to make certain that the program provided practical applications utilizing risk management principles and the event did not disappoint. Attendees queried the speakers well into the evening with challenging issues

they had encountered in both R&D and operations.

The evening began with registration in the second floor foyer with a gorgeous backdrop provided by the setting sun, the Boston skyline and the many boats docked along the Charles. Guests were welcomed by Amy Poole and Jamie Falzone from the Chapter office and enjoyed a networking cocktail reception with traditional New England fare prior to the presentations.

Chapter President Brian Hagopian opened the program by introducing several key areas the Chapter will be focusing on in the upcoming year: membership growth and retention, student chapters, educational curriculum expansion and increasing volunteer involvement across all committees. Brian went on to say, "the strength of the Boston Area Chapter is recognized at the national level of ISPE - as illustrated by our consecutive Chapter of the Year awards - and is due to our strong participation from volunteers." Brian urged the audience to contact members of the Chapter's various committees to seek opportunities to volunteer.

Following Brian's comments, Meeting Manager Sean Brown introduced the two guest speakers. The first was Susan Reilly, Principal, Reilly & Associates, with over 25 years of quality assurance, quality engineering, and regulatory compliance experience in the medical device field. Susan is an ASQ Certified Quality Engineer, Quality Auditor, and Quality Auditor-Biomedical and an RAB QMS Provisional Auditor and brings a wealth of industry experience with prior roles as Director, Quality Assurance and Compliance, at Medical Device Consultants and Manager, Quality Assurance at Deknatel Division, Pfizer Hospital Products Group.

The second speaker was Christina Mendat PhD, Director of Research and Human Factors at Radius Product Development where she provides technical oversight to the research and human factors teams and champions the integration of human factors in the product development process. Christina holds a doctorate in experimental psychology and ergonomics from North Carolina State University and is a member of the Human Factors and Ergonomics Society and the Association for the Advancement of Medical Instrumentation.

Susan's presentation, "Investigating the Problem: Use of Risk Management in CAPA Root Cause Analysis," was extremely interesting with many questions from the audience. Susan pointed out that the FDA's current enforcement activities make it very clear that a robust CAPA process is essential and provided tangible examples illustrating where her clients used it to align with the agency's expectations. The real world examples provided the audience with tools for ranking and prioritizing CAPAs utilizing risk management.

Christina's presentation, "Mitigating Pharma Equipment Risk Through Human Factors" was equally informative and entertaining, with the audience participating in several lively discussions surrounding the topic. Christina

described how companies go to great lengths to ensure that their products and equipment have met various standards, guidelines and technical feasibility - and that it leverages the appropriate technology - but that the same level of rigor, traceability and risk management is not applied to the human element of the product or equipment.

She continued by stressing that the integration of human factors and supporting research is a critical part of developing and maintaining the integrity of user requirements and mitigating any potential use-error risks. Her presentation included pharma case studies (e.g. bioreactor, filtration system) in which human factors integration resulted in equipment design that not only met product requirements from a technical perspective but also supported user requirements in a manner that fostered product compliance while minimizing use-errors.

Mike Long concluded the meeting with a Q&A session which provided an opportunity for attendees to ask questions. This part of the evening did not disappoint as the speakers addressed a range of questions from FDA expectations for formal risk management procedures to examples of "world class" use of the tools. The speakers continued the discussion long after the formal part of the evening concluded, showing the level of interest from the audience for this important topic.

Please visit the Chapter website at [www.ispeboston.org](http://www.ispeboston.org) for copies of the presentations. Or contact a member of the Educational Program Committee if you would like more information about this topic, if you have a subject you would like the Chapter to consider for future programs or would like to volunteer to join the Committee.

### **The Sun Finally Shines on the Chapter's Annual Golf Outing**

*by Christopher Opolski, Alexion Pharmaceuticals with photos by Brian Hagopian, Clearwater Consulting, and Christopher Opolski*



On October 17th, after a two month delay due to Mother Nature, the Boston Area Chapter hosted our annual golf tournament at the Indian Pond Country Club in Kingston, MA. This year was the first time the Chapter hosted our golf tournament at Indian Pond and the club didn't disappoint. This 18-hole championship course, which opened in 2001, measures almost 6800 yards over 160 acres of meticulously manicured grounds.

The weather was the complete opposite from the originally scheduled August 15th. Instead of the pouring rain, heavy clouds and high temperatures, the Chapter enjoyed a partly sunny day, lots of wind, and seasonable temperatures for October. After a chilly

morning the temperature warmed enough to justify the choice of shorts. The weather gods predicted a few sprinkles in the morning but none were seen. As with all our golf tournaments, the event wasn't just about the golf! Some of the special "extras" this year included Smith Optics sunglasses, cigars from Gina's Cigar Girls, Harpoon Beer to help golfers on the hole-in-one contest hole and tastings from Firefly Sweet Tea Vodka.

At the end of play, everyone enjoyed a cocktail reception in the club house. During the reception, fourteen contestants who previously sunk a 10-foot putt during play had a chance to win \$10K if they first sunk a 30-foot putt and then a final 50-footer. Unfortunately, not one golfer even made the 30-footer so there was no chance



at winning the \$10K. On the fifth, where a hole-in-one would pocket a golfer \$10K, no one made it but of each foursome, the golfer with the closest shot on the green won a 6-pack of Harpoon beer. After the relaxing cocktail reception, a spectacular buffet dinner was served followed by the presentation of awards and raffle prizes. Congratulations to all of the day's winners!

#### The Winning Teams

<u>First Place (61)</u>	<u>Second Place (62)</u>	<u>Third Place (63)</u>
The Wilkinson Companies	Middlesex Gases & Technologies	Robert W. Sullivan Engineering
Dan Paquette	Guy Sylvester	Paul Sullivan
Herb Aikens	Ron Perry	Tony Preteroti
Geoff Wilkinson Jr.	Ed Pendleton	Kevin Daly
Jeff Henderson	John Iannucci	Gary Doak

#### The Individual Winners

	<u>Men</u>	<u>Women</u>
Longest Drive	Herb Aikens	Ann Coffon
Closest to Pin	Jay Zaino (5' 11")	Pat Nugent (23' 3")
Straightest Drive	Gene Dennen	Ann Coffon

Finally, proceeds from the raffle ticket sales benefited the Chapter's Joel Goldenberg Memorial Scholarship Fund.

Many, many thanks to our Golf Outing corporate sponsors: Superior Controls, Decco, GxP Automation, Arion Water, Aztec Technologies, RoviSys, Sentrol, Structure Tone, Aztec Technologies, Suffolk Construction's Red & Blue Foundation, Emerson Process Management, Middlesex Gases + Technologies, The Richmond Group, R. W Sullivan Engineering, The Wilkinson Companies, RFWalsh Collaborative Partners, TRG Builders, SciTech Builders, ValSource & ConcordiaValSource and HDR - all of whom helped to make this event another big success for the Chapter.

A special thanks to the tournament committee and volunteers during the event: Gene Dennen, Jim Grunwald, Michelle Greaney, Jennifer Grimley, Fasha Onorato, Mike Severino, and Brian Hagopian whose support helped make this event a huge success.



For more pictures from this event go to the ISPE Boston Area Chapter Photo Gallery on our website.

### **Industry News in Brief**

*by Patti Charek, Boston Area Chapter Past President*

#### **Massachusetts Biopharma Growth and Investment Outpaces Others**

Massachusetts continues to outpace other states and countries for biotech industry growth and investment, according to an annual industry report, the 2011 MassBio Biotechnology Industry Snapshot. Biopharma industry employment topped 48,000 in 2010, and Massachusetts biotech companies received an all-time high share of venture capital investment last year, the report shows.

The latest data shows Massachusetts leads the nation in biotech research & development jobs, with over 26,000 positions in 2010. Massachusetts' pace of employment growth in research & development is second only to California. Overall, Massachusetts maintained its position as the leader in R&D within the physical sciences, as defined by industry concentration.

"Massachusetts is seen as a leader in biotechnology and life sciences and this report solidifies our reputation as a gateway for cutting-edge technology and investment," said Senator Karen Spilka, Senate chair of the Joint Committee on Economic Development and Emerging Technologies and co-chair of the Jobs Creation Commission. "Continued investment in these high-tech fields will not only present an opportunity for tremendous economic growth and job creation, it will also show our commitment to expanding health care options and our dedication to improving the overall quality of life of residents across the Commonwealth."

Venture capital figures have varied-with Massachusetts-based companies seeing the lowest quarter of biotech investment since 2004 in Q1 2011, but reaching an all-time quarterly high in Q2 2011. The percentage of start-up and seed stage investment was higher in 2010 than in 2006 or 2002, the other years for which that data was

available.

This year for the first time, MassBio released a look at the drugs in development from Massachusetts-based companies. Massachusetts-headquartered drug development companies have close to 900 investigational drug products in development, of which over 40 percent are focused on cancer. Between May 2010 and April 2011, 217 candidate drugs advanced in the development pipeline, a sign of strength for the future.

These statistics are compiled annually by MassBio from sources including the U.S. Bureau of Labor Statistics, the Quarterly Census of Employment & Wages and others. Additional highlights include:

- Massachusetts biopharma industry employment reached an all-time high in 2010, continuing the industry's seven year pattern of growth, and now accounts for \$4.6 billion in payroll.
- The industry rebounded from just 1 percent employment growth in 2009 to 3.9 percent growth in 2010.
- Massachusetts companies received 23.1 percent of all U.S. venture capital in 2010, an all-time high share.

### **Caliper Life Sciences to be Purchased by PerkinElmer**

Hopkinton-based Caliper has agreed to be sold to Waltham-based PerkinElmer in a deal that could be worth up to \$600 million. Analysts who track Caliper say the deal could allow the company to expand its sales reach globally, given new financial and infrastructure support from the much larger PerkinElmer. For PerkinElmer it represents an opportunity to acquire a company that analysts seem to agree has strong growth and profitability potential. Either way, analysts also suggested that the move will not likely mean cutbacks for Caliper's more than 200 local employees in the MetroWest region, as PerkinElmer is investing in the company to help it grow and increase revenues.

Analysts said Caliper fits in nicely with PerkinElmer. The two companies are similar in their core functions, but PerkinElmer is much larger, with 6,200 employees and operations in 150 countries. It recorded \$1.7 billion in revenues last year and has 2,900 patents. Caliper Life Sciences, on the other hand, has struggled to be profitable in recent quarters, but has posted steady revenue increases. The company finished 2010 with a \$4.3-million profit on \$123 million in revenues. It has about 200 employees in MetroWest. Kevin Hrusovsky, Caliper president and CEO, plans to remain with the company if the PerkinElmer deal is completed. (Source: Brandon Butler, MetroWest495 Biz, 15 September 2011)

### **RXi Pharmaceuticals to Separate into Two Publicly Traded Companies**

RXi Pharmaceuticals, a biotechnology company focused on discovering, developing and commercializing innovative therapies addressing major unmet medical needs using targeted biotherapeutics, reported that it will separate its programs into two publicly traded companies. Galena Biopharma will focus on the development of targeted cancer therapies; and RXi Pharmaceuticals will focus on the development of RNAi-based therapeutics. The RNAi programs have been contributed to the new RXi, which is expected to be spun off later this year. In connection with these transactions, the Company has changed its name to Galena Biopharma, but will continue to trade under the ticker symbol "RXII" until the completion of the spin-off.

Mark Ahn, Ph.D., the President and CEO of Galena Biopharma, will serve on the board of RXi. Anastasia Khvorova, Ph.D., will serve as RXi's Senior Vice President and Chief Scientific Officer, and Pamela Pavco, Ph.D., will serve as RXi's Senior Vice President of Pharmaceutical Development. A search for RXi's CEO is underway.

"We believe that the spin-off transaction will enhance shareholder value by providing a sharper strategic focus



for both of the Company's key programs," commented Dr. Ahn. "Galena will focus its resources on its lead product, NeuVax, a cancer immunotherapy that is expected to initiate its Phase 3 study in the first half of 2012. Galena also recently acquired Folate Binding Protein-E39 (FBP), a targeted vaccine scheduled to commence Phase 1/2 trials by year-end 2011."

Dr. Ahn also stated, "RXi will focus on advancing its lead anti-scarring and anti-fibrosis product, RXI-109, into the clinic in 2012, as well as unlocking the therapeutic potential of gene silencing more broadly through its proprietary, next generation RNAi platform with several ongoing and future partners." (Source: Globe Newswire, 26 September 2011)

## **Massachusetts Biopharma Industry Continues to Grow**

Massachusetts continues to outpace other states and countries for biotechnology industry growth and investment, according to an annual industry report produced by MassBio. Biopharma industry employment topped 48,000 in 2010, and Massachusetts biotech companies received an all-time high share of venture capital investment last year, the report shows. The report, the "2011 MassBio Biotechnology Industry Snapshot," was presented at a meeting of the Jobs Creation Commission.

"As the biotech industry matures and companies explore new business models and partnerships, Massachusetts continues to be the hub of innovation, research & investment," said Robert K. Coughlin, President & CEO of MassBio. "We must retain our commitment to this industry as it grows, adds jobs and finds new treatments & cures for patients around the world."

The latest data shows Massachusetts leads the nation in biotechnology research & development jobs, with over 26,000 positions in 2010. Massachusetts' pace of employment growth in research & development is second only to California. Overall, Massachusetts maintained its position as the leader in R&D within the physical sciences, as defined by industry concentration.

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"The continued growth we are seeing in the biopharma sectors speaks to our state's global leadership in the life sciences, and to the successful strategy that Governor Patrick, Lieutenant Governor Murray and our legislative leadership are pursuing to build on these strengths. This new data indicates that jobs are being created, investment dollars are flowing, and our pipeline of innovation remains strong, all good signs for the future of the life sciences in Massachusetts," said Dr. Susan Windham-Bannister, President & CEO of the Massachusetts Life Sciences Center.

These statistics are compiled annually by MassBio from sources including the U.S. Bureau of Labor Statistics, the Quarterly Census of Employment & Wages and others.

Additional highlights include:

Massachusetts biopharma industry employment reached an all-time high in 2010, continuing the industry's seven year pattern of growth, and now accounts for \$4.6 billion in payroll.

- The industry rebounded from just 1 percent employment growth in 2009 to 3.9 percent growth in 2010.
- Massachusetts companies received 23.1 percent of all US venture capital in 2010, an all-time high share.
- Massachusetts-headquartered companies account for about 10 percent of the US drug development pipeline and 5 percent of the global pipeline.
- While Massachusetts has outperformed most other states in biopharma manufacturing growth since 2006, this sub-sector contracted in Massachusetts in 2010.
- Among US counties, Middlesex County has the greatest number of biotechnology researchers in the US; Suffolk, Essex and Worcester counties also rank among the highest in the country.

The goal of the Jobs Creation Commission is bring together leaders in all types of industries as well as state officials, and interested members of the public to address and better understand the long-term implications of the changing nature of the Massachusetts economy, as well as the tools that will be needed to ensure job growth well into the future. (Source: Massachusetts Biotechnology Council Website, 27 September 2011)

## **In Study, Pfizer's Arthritis Pill Rivals Shots**

Pfizer's experimental pill for rheumatoid arthritis was as effective as Humira from Abbott Laboratories and showed no new side effects in study results the company plans to submit for US approval this year. Nine study summaries were released and will be presented at the American College of Rheumatology conference in Chicago in November. In one trial, both doses of Pfizer's drug, called tofacitinib, were slightly more effective than Humira across six categories of improvement in symptoms and patient mobility, though the study wasn't big enough to establish the pill's superiority.

Pfizer, the world's biggest drug maker, designed tofacitinib to compete with injectable drugs that dominate the market, led by Humira from Abbott, Johnson & Johnson's Remicade, and Amgen's Enbrel, which Pfizer shares. The new drug may bring in \$1.3 billion in 2015, according to analysts surveyed by Bloomberg.

Tofacitinib is the most-advanced pill in a family of experimental drugs to target a protein, called JAK, which leads to joint destruction in 1.3 million Americans with rheumatoid arthritis. Three biotech companies are trying to catch up to Pfizer with similar treatments: Rigel Pharmaceuticals, Incyte and Vertex Pharmaceuticals. Pfizer's pill is the only one to complete the third and final stage of tests generally needed for FDA approval.

The safety of tofacitinib was similar to what was seen in previous studies, and deaths and side effects were toward the lower end of a range of results from similar drugs, the company reported. Twelve deaths were reported among 3,030 patients who took the drug, compared with one death among 681 taking a placebo and one death among 204 patients on Humira across the Phase 3 studies completed by Pfizer. Rheumatoid arthritis is a chronic disease in which the immune system mistakenly attacks healthy tissue, causing inflammation in and around joints. (Source: Tom Randall, Bloomberg News, 9 September, 2011)

## **Alkermes May Seek Marketing Partner for ALKS 37**

Alkermes, whose shareholders recently approved its merger with Ireland's Elan Drug Technologies, may seek a partner to help sell its drug for opioid-induced constipation, chief executive Richard Pops said. "That's a drug that probably would require a large sales force because you want to call on a lot of GPs who are dispensing pain medications," Pops said. "You might have a partner that's going after the more garden-variety doctor's

office," while Alkermes may target specialty practitioners, he said.

The medicine, ALKS 37, is in the second of three phases of clinical trials generally required by US regulators for approval. Alkermes is just starting to look for a partner, Pops said. The company plans to begin a late-stage trial of the medicine next year, and "along the way we'll be talking to pharma," he said.

The company, based in Waltham, will move its headquarters to Ireland after closing its acquisition of Elan's drug technology unit. Alkermes, which agreed in May to buy the unit in a deal valued at \$960 million, said that 99.9 percent of shareholder votes were in favor of the merger. The deal combines two businesses that aim to improve the way medicines are delivered, and will allow Alkermes to focus on finding drugs on its own, Pops said. The company traditionally had worked on existing products with partners such as Johnson & Johnson, the world's second-largest health care company after Pfizer. Those collaborations yielded less revenue for Alkermes than would partnerships on drugs the company develops itself, Pops said. (Source: Meg Tirrell, Bloomberg News, 9 September, 2011)

## **Cancer Drug Trial Result a Surprise for Syndax**

Two months after reporting positive data from a clinical trial of its lead drug candidate for lung cancer treatment, Waltham-based Syndax Pharmaceuticals said that the same drug performed well in a Phase 2 breast cancer trial. The drug, entinostat, was tested in 130 postmenopausal women with a type of the disease known as estrogen receptor-positive breast cancer.

The women received either entinostat plus exemestane (Aromasin, made by Pfizer) or exemestane plus placebo. The combination containing Syndax's drug nearly doubled the amount of time women survived without their disease progressing, from 2.3 months to 4.3 months. Although such "progression-free survival" was the primary goal, the study also found overall survival increased by nearly seven months, to 26.9 months.

Syndax is pursuing drugs designed around epigenetics - the molecular changes in cells that can activate or deactivate genes without affecting the underlying DNA. Entinostat inhibits certain enzymes that influence specific epigenetic alterations. Those epigenetic alterations are believed to drive cancer growth and drug tolerance, so blocking them should enhance cancer treatment, Syndax's researchers believe.

The results were a pleasant surprise for Syndax's chief executive, Joanna Horobin, who was trained as a physician before joining the drug industry 25 years ago. "The study was not powered around overall survival, but it is still significant to see a seven-month benefit there," she said. Based on the positive results from the trial, Syndax plans to start a pivotal Phase 3 trial in early 2012.

Syndax also identified a biomarker that seems to indicate whether patients with breast cancer are responding to entinostat. The trial demonstrated that median progression-free survival rates in women with that biomarker increased to over six months. "Rather than waiting eight weeks to take a scan to see if it's working, we can take a blood sample before the treatment, then at day one, day eight, and day 15," Horobin said. "Then we can see if the drug is impacting the target."

Syndax will incorporate biomarker testing into the Phase 3 trials. If all goes well with the Phase 3 program, Horobin said, entinostat could become the first epigenetic therapy approved for patients with solid tumors. "There hasn't been much to improve the therapies available to breast cancer patients," Horobin said. (Source: Arlene Weintraub, Boston Globe, 12 September 2011)

## **Ex-Genzyme Chief Termeer Gives \$10m for MGH Cancer Unit**



Retired biotech exec Henri Termeer, who built Genzyme into the largest US company specializing in drugs to treat rare genetic disorders, is donating \$10 million to Massachusetts General Hospital to establish it as a world leader in personalized medicine.

The new Henri and Belinda Termeer Center for Targeted Therapies will be aimed at bringing the emerging field into the forefront of treatment and research. Its initial focus will be on drugs tailored to the genetic makeup of tumors, especially breast cancers, lung cancers, and leukemias. Currently, there are few effective treatments for patients with less common types of the diseases. Targeted therapies attack points of vulnerability in a tumor's genetic makeup, disabling pathways that enable the cancer to survive and grow.

"I hope this will help Massachusetts be recognized globally as the knowledge center in targeted medicines," said Termeer who stepped down as chief executive of Cambridge-based Genzyme last spring. "This is a global effort, but Massachusetts has the responsibility to lead, to use the talents and capabilities it has built over many years."

The center will be run by Dr. Jose Baselga, one of the world's leading cancer specialists, who was recruited from Vall d'Hebron Institute of Oncology in Barcelona last year to be chief of hematology-oncology at Mass General. It will be part of the 25-year-old Massachusetts General Hospital Cancer Center, led by Dr. Daniel A. Haber.

Termeer's gift is one of the largest earmarked for fighting cancer in the hospital's history, but the hospital will be soliciting additional money from Boston area philanthropists. Hospital officials hope to raise another \$10 million over the next two years to expand the center's work.

Mass General, the largest hospital in New England and the nation's largest research hospital, will use the Termeer donation to renovate space on the seventh floor of its Yawkey Center for Outpatient Care, where the Termeer Center will be located. The money will also be used to buy medical equipment, recruit new employees, and offset the cost of clinical trials it will host. Initially, the center will have about 25 staff members, including new hires and current hospital employees who will be redeployed.

Doctors and scientists working in the Termeer Center hope to test a new generation of molecular-based targeted drugs that could transform cancer care. "In the future, we're going to see cancers defined not only by their site of origin but by the molecular alternations that are the drivers of particular cancers," Baselga said.

Personalized medicine programs are underway in other area research labs, including at the Dana-Farber Cancer Institute in Boston, which like Mass General is a Harvard University teaching hospital, and the Broad Institute of MIT and Harvard in Cambridge. Mass General plans to work with both, along with other hospitals and universities in the US and abroad. It also will collaborate with drug makers such as Novartis AG and Sanofi SA, the French company that bought Genzyme for \$20.1 billion in April. (Source: Robert Weisman, Boston Globe, 13 September 2011)

## **Vertex Submits Application to FDA for First Drug to Target Underlying Cause of Cystic Fibrosis**

Vertex Pharmaceuticals has announced the submission of a New Drug Application to the FDA for Kalydeco (VX-770, ivacaftor), a medicine in development that targets the defective protein that causes cystic fibrosis (CF). Kalydeco was studied among people with CF ages 6 and older who have at least one copy of the G551D mutation in the cystic fibrosis transmembrane conductance regulator (CTFR) gene. In the US, approximately 4 percent of people with CF are estimated to have at least one copy of the G551D mutation in the CTFR gene. If

approved, Kalydeco will be the first treatment to target the underlying cause of CF.

The submission includes a request for Priority Review, which, if granted, would shorten the FDA's anticipated review time from 10 to six months. The FDA grants Priority Review status for several reasons, including if the medicine is considered a major advance in treatment. Vertex also plans to submit a marketing authorization application for Kalydeco with the European Medicines Agency (EMA) by the end of October 2011. The EMA has accepted Vertex's request for accelerated assessment, which is granted to new medicines of major public health interest and shortens the review time from 210 days to 150 days following the start of the review.

"Kalydeco represents a completely new approach to the treatment of CF by targeting the underlying cause of the disease," said Matthew Emmens, Chairman, President and CEO of Vertex. "This is our second new drug application in less than a year, which is a significant achievement and underscores our commitment to developing new medicines for people with serious diseases."

CF is a life-threatening genetic disease that is caused by mutations in the CFTR gene that result in defective or missing CFTR proteins. The absence of functional CFTR proteins results in poor flow of salt and water across cell membranes in a number of organs, including the lungs. This leads to the buildup of abnormally thick, sticky mucus that can cause chronic lung infections and progressive lung damage. Currently available medicines have helped improve treatment and care for people living with CF by treating the symptoms and some of the complications of the disease.

Various mutations in the CFTR gene lead to CF. In some people, CFTR proteins are present at the cell surface but do not function properly. This dysfunction is known as a gating defect, the most common of which is the G551D mutation. Approximately 4 percent of those with CF, or about 1,200 people in the United States, are believed to have the G551D mutation. Kalydeco is designed to keep the CFTR channels at the cell surface open longer to improve the transport of chloride ions across the cell membrane in people who have gating mutations.

Vertex initiated its CF research program in 1998 as part of a collaboration with CFFT, the nonprofit drug discovery and development affiliate of the Cystic Fibrosis Foundation. From 2000 through 2006, Vertex and CFFT amended and expanded the collaboration four times to support the accelerated discovery and development of Kalydeco and VX-809. VX-809, known as a CFTR corrector, is designed to help the protein reach the cell surface, while Kalydeco, known as a CFTR potentiator, aims to help the protein function more normally once it reaches the cell surface. In April 2011, Vertex and CFFT further expanded the collaboration to support development activities for VX-661, Vertex's second corrector to enter clinical development, and the discovery and development of next-generation correctors.

Vertex is working on new medicines to cure or significantly advance the treatment of hepatitis C, cystic fibrosis, rheumatoid arthritis, epilepsy and other life-threatening diseases. Founded more than 20 years ago in Cambridge, MA, Vertex now has ongoing worldwide research programs and sites in the US, UK and Canada, employing more than 1,900 employees around the world. (Source: Vertex Website, 19 October, 2011)

## **Abbott to Separate into Two Companies: Diversified Medical Products and Research-Based Pharmaceuticals**

Abbott Laboratories has announced that it plans to separate into two publicly-traded companies, one in diversified medical products and the other in research-based pharmaceuticals. The diversified medical products company will consist of Abbott's existing diversified medical products portfolio, including its branded generic pharmaceutical, devices, diagnostic and nutritional businesses, and will retain the Abbott name. The research-

based pharmaceutical company will include Abbott's current portfolio of proprietary pharmaceuticals and biologics and will be named later.

The research-based pharmaceutical company has nearly \$18 billion in annual revenue today and will have a sustainable portfolio of market-leading brands, including Humira, Lupron, Synagis, Kaletra, Creon and Synthroid. An attractive pipeline of innovative R&D assets - in important specialty therapeutic areas such as Hepatitis C, immunology, chronic kidney disease, women's health, oncology and neuroscience - will help drive future growth.

The diversified medical products company has approximately \$22 billion in annual revenue today and a durable mix of products balanced across four major businesses. It will continue to target double-digit ongoing earnings-per-share growth, with opportunities for geographic expansion, particularly in high-growth emerging markets. The company will have an extensive, broad-based pipeline of new products and technologies as well as opportunities for significant margin expansion.

The research-based pharmaceutical company will focus on select specialty products with breakthrough innovation that serve patient needs in some of the most critical medical areas, such as immunology, Multiple Sclerosis, chronic kidney disease, Hepatitis C, women's health and oncology. This company will continue to generate the majority of its revenue from developed markets. The company's sustainable portfolio and advancing pipeline, including established biologics expertise, have the potential to deliver accelerating revenue growth in the coming years.

The diversified medical products company will be one of the largest and fastest growing investment opportunities in medical products with strong sales and ongoing earnings-per-share growth and a large, broad mix of products addressing many essential areas of health care. It will generate nearly 40 percent of its sales in high-growth emerging markets, with further expansion expected in the coming years. (Source: Abbott Laboratories Website, 19 October, 2011)

## **Sanofi Appoints David Meeker Chief Executive Officer of Genzyme**

Sanofi has announced the appointment of David Meeker as Chief Executive Officer of Genzyme, a Sanofi company, effective November 1, 2011. He will report to Christopher A. Viehbacher, Chief Executive Officer of Sanofi, and will join the Group Management Committee. Christopher A. Viehbacher will retain the position of Chairman, Genzyme.

"After working closely with David over the past six months, I am confident that he is the best person to lead Genzyme," said Viehbacher, Chief Executive Officer of Sanofi. "David's commitment to employees, physicians and patients has been a key success factor in the successful integration of Genzyme as part of the Sanofi Group. His combination of medical and business experience will be essential to move Genzyme's broad portfolio of products forward and deliver much-needed therapies to patients."

Under David Meeker's leadership, Genzyme will incorporate the Rare Disease business and the Multiple Sclerosis franchise. Previous Genzyme divisions - Renal, Biosurgery and Oncology - have been integrated within the existing Sanofi portfolio giving them greater global scale and capabilities.

Meeker joined Genzyme in 1994 as Medical Director to work on the Cystic Fibrosis Gene Therapy program. Over the years he has held key positions of increasing responsibility as he led the development of treatments in the current rare disease portfolio. As President of the Global Rare Disease Business, he oversaw the global launches of Aldurazyme, Fabrazyme and Myozyme. In 2009, he was promoted to Chief Operating Officer of Genzyme and has played an important role in the Sanofi integration since April of this year. David received his



M.D. from the University of Vermont Medical School, and completed the Advanced Management Program at Harvard Business School in 2000. (Source: Genzyme Website, 24 October, 2011)

## **Cubist Pharmaceuticals to Acquire Adolor**

Cubist Pharmaceuticals and Adolor Corporation have announced that they have signed a definitive agreement under which Cubist will acquire all of the outstanding shares of Adolor for \$4.25 per share in cash, or approximately \$190 million on a fully-diluted basis, net of Adolor's third quarter 2011 cash balance. In addition to the upfront cash payment, each Adolor stockholder will receive one Contingent Payment Right (CPR), entitling the holder to receive additional cash payments of up to \$4.50 for each share they own if certain regulatory approvals and/or commercialization milestones for ADL5945 are achieved. The total transaction is valued at up to \$415 million, net of Adolor's third quarter 2011 cash balance, and is expected to be accretive in 2012.

Under the agreement, Cubist will commence a tender offer to purchase all of the outstanding shares of Adolor for the upfront cash payment and a CPR. The transaction, which has been unanimously approved by the Boards of Directors of both companies, is expected to close in the fourth quarter of 2011.

Adolor markets Entereg (alvimopan), the first and only FDA-approved therapy to accelerate the time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis. Entereg is an oral, peripherally-acting mu opioid receptor antagonist. Cubist, with its focus on addressing acute care and hospital needs, will leverage its existing commercial operations to promote Entereg. Launched in 2008, Entereg generated more than \$25 million in US sales in 2010 and \$15.7 million through June 30, 2011. Cubist anticipates peak Entereg sales of over \$100 million annually.

Adolor's lead development program is ADL5945, an oral, peripherally-restricted mu opioid receptor antagonist. It is currently in development for the treatment of chronic opioid induced constipation (OIC), a growing, multi-billion dollar, currently underserved market. Adolor announced positive Phase 2 data for ADL5945 in August 2011 and Phase 3 trials are expected to be initiated in 2012. Cubist plans to retain certain US and specialty rights while seeking a partner to assist with ex-US and primary care commercialization.

"This transaction is an excellent strategic fit for Cubist and the latest milestone in what has been a transformational year for the company," said Cubist President and Chief Executive Officer Michael Bonney. "Entereg is a first-in-class therapy with strong growth potential, and we believe our experienced sales force and strong commercial platform will realize the potential of this important hospital product. With the addition of ADL5945, Cubist will have a truly outstanding late-stage pipeline with three strong candidates addressing significant markets. We are excited about the acquisition of Adolor and believe it will deliver significant value to our shareholders, hospital customers, and patients." (Source: Cubist Website, 24 October, 2011)

## **Regulatory & Legislative Highlights**

*By Deepen Joshi, Sunovion Pharmaceuticals*

## **J&J Drug Receives EMA Approval for Metastatic Prostate Cancer**

The European Medicines Agency (EMA) has approved J&J's Zytiga (abiraterone acetate), a novel, once-daily, oral, androgen biosynthesis inhibitor. Abiraterone acetate is approved, in combination with prednisone or

prednisolone, for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. Metastatic castration-resistant prostate cancer, or mCRPC, occurs when cancer has metastasized (spread) beyond the prostate and disease progresses despite serum testosterone below castrate levels. In 2008, an estimated 370,000 new cases of prostate cancer were diagnosed in Europe, and nearly 90,000 men died from the disease.

"The European Commission approval of abiraterone acetate gives new hope to men who are suffering from this late stage of prostate cancer with very few treatment options left," said Professor Karim Fizazi, Department of Cancer Medicine, Institut Gustave Roussy, France, who was an investigator in the abiraterone acetate pivotal Phase 3 study. "The efficacy, safety and ease of use of abiraterone acetate, a medicine that can be taken at home, will address an important unmet medical need for many patients, helping them to live longer with a better quality of life and less pain."

Abiraterone acetate is an androgen biosynthesis inhibitor that inhibits the CYP17 enzyme complex which is required for the production of androgens. Androgens (e.g. testosterone) are hormones that promote the development and maintenance of male sex characteristics. However, in prostate cancer, androgens can fuel the tumor's growth. Androgen production primarily occurs in the testes and adrenal glands but, in men with prostate cancer, the tumor tissue is an additional source of androgens. Abiraterone acetate is the first oral treatment for metastatic castration-resistant prostate cancer that inhibits androgen production at all three sources.

"In patients who have exhausted standard treatment options, including chemotherapy, abiraterone acetate offers a novel, well tolerated option for treating this devastating disease," explained Professor Johann S. de Bono, MD, FRCP, MSc, PhD, The Institute of Cancer Research, The Royal Marsden NHS Foundation Trust, and one of the co-lead investigators for the Phase 3 clinical study. "In Europe, prostate cancer is the third most common cause of cancer deaths so it is essential that new treatments options like abiraterone acetate are developed." (Source: J&J Website, 7 September, 2011)

## **New Generic Lovenox Receives FDA Approval**

California biotech Amphastar Pharmaceuticals won FDA permission to sell a generic version of the blockbuster drug Lovenox, following a years-long battle that was unusually bitter even for the high-stakes world of drug approvals. Lovenox, known generically as enoxaparin, is a rapid-acting version of heparin, the widely used blood thinner critical to millions of heart patients.

The approval could shake up the multibillion-dollar-a-year market for a drug widely used in heart patients, hurting Lovenox maker Sanofi SA and Momenta Pharmaceuticals, a company that started selling a generic version of Lovenox last year in partnership with Sandoz, a unit of Novartis AG.

Branded Lovenox's global revenue was \$4.28 billion in 2010, but it fell to \$1.5 billion in the first half of this year, according to Sanofi. Momenta said in an earnings call in August that generic Lovenox had generated over \$1 billion since its launch in the fall of 2010.

Amphastar has agreed with leading generics maker Watson Pharmaceuticals to co-market generic Lovenox in the US. Amphastar was the first company to apply to make enoxaparin, filing for approval at the FDA in 2003. Momenta/Sandoz followed two years later.

As the FDA's consideration of both companies' applications dragged on for years, Amphastar complained that the FDA was biased toward Momenta. It cited the FDA's unexpected decision in November 2007 to add a specialized safety-testing requirement for all applicants seeking to sell generic Lovenox. That requirement put

Amphastar back at the same starting point as Momenta and came after Momenta's founder, a MIT scientist, lobbied the head of the FDA's drug division for tougher approval standards for drugs like generic Lovenox. The FDA has repeatedly denied any favoritism and Momenta has said it was also delayed by the new testing requirement.

In 2008, the Momenta founder was given a leading role by FDA officials in a high-profile agency task force investigating the source of heparin contamination from China linked to 81 deaths in the US. When the task force said it identified the contaminant in the Chinese supplies, Momenta's stock price rose. Meanwhile, Amphastar's application was on hold, because one of its Chinese suppliers was linked to a contaminated heparin batch, leading to numerous FDA inspections of Amphastar facilities, according to the company.

In the fall of 2010, a report by the Government Accountability Office, Congress's watchdog agency, said FDA actions involving heparin-related issues had contributed to a public perception of bias toward Momenta and risked the agency's integrity. The FDA said it should have been more careful about the appearance of conflict of interest.

Amphastar sued the FDA after the agency approved Momenta's application in July 2010, saying the FDA illegally quarantined Chinese heparin needed for its drug development. The agency said it acted appropriately; the suit is pending.

A third company seeking to sell generic Lovenox, Teva Pharmaceutical Industries, the world's top-selling maker of generic drugs, hasn't received its approval from the FDA yet, a company spokeswoman said. (Source: Alicia Mundy, Wall Street Journal, 20 September 2011)

## **FDA Reorganizes Area Responsible for Review of Drugs for Cancer Therapy**

The FDA has announced organizational changes within the office responsible for reviewing all drug and biologic applications for cancer therapies. The Center for Drug Evaluation and Research's (CDER) Office of Oncology Drug Products has been reorganized and renamed the Office of Hematology and Oncology Products (OHOP).

The previous structure contained three divisions: Division of Hematology Products (DHP), Division of Drug Oncology Products (DDOP), and Division of Biologic Oncology Products (DBOP). The new structure contains four divisions: Division of Hematology Products (DHP), Division of Oncology Products 1 (DOP1), Division of Oncology Products 2 (DOP2), and Division of Hematology Oncology Toxicology (DHOT).

Unique features of the reorganization include the creation of DOP1 and DOP2, the agency's primary review divisions for cancer solid tumor therapies, and the creation of DHOT, which will review nonclinical information. (Source: FDA Website, 12 September, 2011)

## **FDA approves Alexion's Soliris for Rare Pediatric Blood Disorder**

The FDA has approved Soliris (eculizumab) to treat patients with atypical Hemolytic Uremic Syndrome (aHUS), a rare and chronic blood disease that can lead to kidney (renal) failure and is also associated with increased risk of death and stroke. Atypical HUS accounts for 5 to 10 percent of all cases of hemolytic uremic syndrome. The disease disproportionately affects children.

This new indication for Soliris is being approved with an extension of the existing Risk Evaluation and Mitigation Strategy (REMS), to inform health care professionals and patients about the known risk of life-threatening meningococcal infections.

Soliris will continue to be available only through a restricted program, and prescribers must enroll in a registration program and provide a medication guide to patients who receive the drug.

Soliris was reviewed under the FDA's priority review program, which provides for an expedited six-month review of drugs that may offer major advances in treatment or that provide a treatment when no adequate therapy exists. (Source: FDA Website, 23 September, 2011)

### **FDA Approves Remicade for Ulcerative Colitis in Children 6 Years and Older**

The FDA has approved Remicade (infliximab) to treat moderately to severely active ulcerative colitis (UC) in children 6 years and older who have had inadequate response to conventional therapy. Remicade reduces signs and symptoms of UC and induces and maintains clinical remission in these patients. Remicade is manufactured by Janssen Biotech Inc. in Malvern, PA.

UC is a type of inflammatory bowel disease (IBD) that affects the lining of the large intestine (colon) and rectum. Symptoms of UC include abdominal pain, diarrhea, rectal bleeding, weight loss and fever. Between 50,000 and 100,000 children in the United States have IBD; of these, 40 percent have UC.

Remicade carries a Boxed Warning for risk of serious infections and cancer. Increased risks of infections include tuberculosis and infections caused by viruses, fungi or bacteria. There have been cases of unusual cancers reported in adolescent and young adult patients using TNF-blocking agents, including a rare and fatal type of cancer called Hepatosplenic T-cell Lymphoma.

Children should have all of their vaccines brought up to date before starting treatment with Remicade and should not receive live vaccines while taking Remicade. The most common side effects of Remicade are worsening of UC, upper respiratory infections, infusion-related reactions, and headache. (Source: FDA Website, 23 September, 2011)

### **FDA Seeks Comment on Streamlined Review of Lower Risk, New Technology, Devices**

The FDA has issued draft guidance for manufacturers that updates and streamlines the de novo review process used for certain innovative, low to moderate-risk medical devices that do not meet the requirements for clearance under the better-known 510(k) review process.

Before manufacturers may market most low to moderate-risk medical devices, such as certain catheters or diagnostic imaging devices, they must obtain FDA "clearance" of a premarket notification or 510(k), named after the section of federal law that describes this notification requirement. Generally, 510(k) submissions must demonstrate that the new device is substantially equivalent to another, legally marketed medical device that is also low to moderate-risk. However, some low to moderate-risk medical devices are novel and not comparable to an already legally marketed device. Legislation passed by Congress in 1997 created the de novo process for these types of devices.

The draft guidance outlines a pathway for a concurrent 510(k) and de novo petition without duplicative data requirements, trimming up to 90 days from the process and fostering more efficient, early interaction between manufacturers and the FDA. It also provides clarity for manufacturers on the suitability of a device for the de novo process.



This draft guidance is one of 25 action items listed in the FDA's Plan of Action for Implementation of 510(k) and Science Recommendations launched earlier this year to improve the predictability, consistency and transparency of the agency's pre-market review programs. (Source: FDA Website, 30 September, 2011)

## **New FDA Transparency Report Outlines Proposals for Enforcement Data, For Public Comment**

The FDA has released eight new draft proposals in a report titled "Food and Drug Administration Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency by Promoting Greater Access to the Agency's Compliance and Enforcement Data." These draft proposals are focused on making FDA's compliance and enforcement data more accessible and user-friendly, and they are part of FDA's ongoing efforts to increase the transparency of FDA's operations and decision-making.

In developing these draft proposals, FDA met with the Environmental Protection Agency (EPA) and the Department of Labor (DOL), both of which have well-developed and well-regarded enforcement data. At these meetings, EPA and DOL shared their insights to help FDA learn from, and build upon, their experiences. Like FDA, EPA and DOL recognize that transparency can drive good behavior and promote regulatory compliance.

FDA Commissioner Dr. Margaret Hamburg launched FDA's Transparency Initiative in June 2009. The initiative is overseen by a Task Force that includes key leaders of FDA. The report issued today advances that initiative and is part of FDA's response to President Obama's Presidential Memorandum on Regulatory Compliance, which directed federal agencies to make compliance information more publicly available, easily accessible, downloadable and searchable online. (Source: FDA Website, 03 October, 2011)

## **FDA Works to Improve Science Used to Approve Medical Devices**

The FDA's Center for Devices and Radiological Health (CDRH) has released a report highlighting scientific activities that support the medical device industry and product development, while maintaining the safety and effectiveness of the products. The report, "Regulatory Science in FDA's Center for Devices and Radiological Health: A Vital Framework for Protecting and Promoting Public Health," offers a look at the work FDA engages in every day to help foster science that enables and supports innovation and sound medical product development.

Regulatory science efforts cited in the report range from providing device designers with computer modeling of cardiovascular devices to developing standard tests for the durability and performance of spinal disc implants. The document is intended to give clinicians, researchers, patient groups and the medical device industry an idea of the scope of the scientific activities at CDRH and how they support device innovation and protect public health.

Investments in regulatory science help to maintain a robust medical device industry by reducing the time and resources needed to develop, assess and test new products. This can lead to quicker, more efficient device approvals, potentially decrease the size and duration of premarket clinical trials, and speed the rate at which breakthrough technologies reach the market. In August, the FDA released its "Strategic Plan for Regulatory Science." That plan touches on several priority areas identified in greater detail in CDRH's regulatory science report. (Source: FDA Website, 03 October, 2011)

## **FDA Awards Three Grants to Stimulate Development of Pediatric Medical**

## **Devices**

The FDA has announced the awards of three grants to boost the development and availability of medical devices for children. A panel of five experts with experience in medicine, business, and device development reviewed 10 applications for the grants, which will be administered by the FDA's Office of Orphan Products Development.

Children differ in terms of size, growth, and body chemistry and present unique challenges to device designers. In addition, the activity level and ability to manage some implantable or long-term devices may vary greatly among children. While this program is administered by the Office of Orphan Products Development, it is intended to encompass devices used in all pediatric diseases, not just rare diseases.

Legislation passed by Congress in 2007 established funding for grants to nonprofit groups to help stimulate projects to promote the development and availability of pediatric medical devices. These grants are meant to encourage the development of multiple pediatric device projects. While a small portion of the grants fund specific projects, the real spirit of this grant program is to provide information clearinghouses to promote multiple projects.

As part of the legislation, each of the grant recipients will coordinate among the FDA, device companies, and the National Institutes of Health's Eunice Kennedy Shriver National Institute of Child Health and Human Development to facilitate research and any necessary applications for device approval or clearance. (Source: FDA Website, 03 October, 2011)

### **FDA Outlines Plans for an Outside Network of Scientific Experts**

FDA's Center for Devices and Radiological Health (CDRH) is soliciting comment on a plan to create a network of outside scientific experts who would provide staff with rapid access to specific specialized knowledge about emerging technology, as well as other topics. To further enrich this comment period, CDRH will also conduct a 12-week pilot of the network through December 30, 2011.

CDRH has a world-class scientific staff that includes scientists, engineers, and clinicians. Nevertheless, there are times when staff must turn to external sources to further enhance their scientific understanding, given the rapid advancements in certain scientific fields, the development of pioneering technologies and increasingly complex medical devices.

The CDRH Network of Experts would allow CDRH staff to tap into a vetted network of scientists and engineers for detailed scientific information on topics related to medical devices.

CDRH will build the Network in partnership with leading scientific, academic and clinical organizations. The center will enter into agreements with these organizations and then call upon their membership for needed expertise. This will permit a fast and efficient exchange of knowledge with scientific leaders on an as-needed basis. (Source: FDA Website, 04 October, 2011)

### **FDA Approves Gel to Stop Blood Flow during Blood Vessel Surgery**

The FDA has approved LeGoo, a gel that allows surgeons to temporarily stop blood flow during surgery so that they can join blood vessels without clamps or elastic loops. LeGoo is manufactured by PluroMed Inc. of Woburn, MA.

To join blood vessels during surgery, it is necessary to temporarily stop blood flow to the area where a new vessel is being attached. Stopping blood flow prevents flooding the surgical area with blood, which makes it difficult for the surgeon to clearly see where to place sutures to connect the two vessels.

LeGoo is a temperature sensitive gel that is liquid at room temperature and solid at higher temperatures. When injected into a blood vessel, LeGoo forms a gel plug that molds to the shape of the blood vessel and stops blood flow for up to 15 minutes. After the blood vessels are joined, the plug is expected to dissolve on its own in 15 minutes. In the event the plug needs to dissolve sooner, the surgeon can dissolve the gel plug by applying a cold pack or cold saline to the blood vessel.

LeGoo is approved for temporarily stopping blood flow in blood vessels below the neck that are 4 millimeters or less in diameter. It is contraindicated for use on vessels supplying blood to the brain. (Source: FDA Website, 04 October, 2011)

## **FDA Commissioner Outlines Steps to Spur Biomedical Innovation, Improve Health**

FDA Commissioner Margaret A. Hamburg, M.D. has released a blueprint containing immediate steps that can be taken to drive biomedical innovation, while improving the health of Americans. Titled "Driving Biomedical Innovation: Initiatives for Improving Products for Patients," the blueprint addresses concerns about the sustainability of the medical product development pipeline, which is slowing down despite record investments in research and development.

While FDA has long been committed to promoting innovation with a number of efforts underway already this year, Dr. Hamburg recognized the need to create an FDA-wide framework to address the changing scientific landscape. This blueprint launches the Innovation Initiative, identifying additional steps the agency can take immediately to address the most pressing concerns facing patients and industry.

The report's proposals stem from a review of FDA's current policies and practices, as well as months of meetings with major stakeholders nationwide, including key industry leaders, small biotech, pharmaceutical and medical device company owners, members of the academic community and patient groups. (Source: FDA Website, 05 October, 2011)

## **FDA Approves Cialis to Treat Benign Prostatic Hyperplasia**

The FDA has approved Cialis (tadalafil) to treat the signs and symptoms of benign prostatic hyperplasia (BPH), a condition in which the prostate gland becomes enlarged, and for the treatment of BPH and erectile dysfunction (ED), when the conditions occur simultaneously. Cialis was approved in 2003 for the treatment of ED and is manufactured by Indianapolis-based Eli Lilly and Co.

Common symptoms of BPH include difficulty in starting urination and a weak urine stream; a sudden urge to urinate; and more frequent urination including at night. The FDA has approved eight other drugs to treat symptoms of BPH: Proscar, (finasteride), Avodart (dutasteride), Jalyn (dutasteride plus tamsulosin), and the alpha blockers: Hytrin (terazosin), Cardura (doxazosin), Flomax (tamsulosin), Uroxatral (alfuzosin) and Rapaflo (silodosin). (Source: FDA Website, 06 October, 2011)

## **FDA Approves Juvisync, First Combination Drug to Treat Type 2 Diabetes and High Cholesterol in One Tablet**

The FDA has approved Juvisync (sitagliptin and simvastatin), a fixed-dose combination (FDC) prescription medication that contains two previously approved medicines in one tablet for use in adults who need both sitagliptin and simvastatin.

About 20 million people in the United States have type 2 diabetes, and they often have high cholesterol levels as well. These conditions can lead to increased risk of heart disease, stroke, kidney disease and blindness, among other chronic conditions, particularly if left untreated or poorly treated.

Juvisync is approved with a Medication Guide that provides important information to patients. The most common side effects of Juvisync include upper respiratory infection; stuffy or runny nose and sore throat; headache; muscle and stomach pain; constipation; and nausea. (Source: FDA Website, 07 October, 2011)

## **FDA Approves Ferriprox to Treat Patients with Excess Iron**

The FDA has approved Ferriprox (deferiprone) to treat patients with iron overload due to blood transfusions in patients with thalassemia, a genetic blood disorder that causes anemia. Patients with thalassemia have excess iron in the body from frequent blood transfusions, a condition that is serious and can be fatal. These patients also have a risk of developing liver disease, diabetes, arthritis, heart failure or an abnormal heart rhythm. Ferriprox is marketed by ApoPharma of Toronto, Canada.

The standard of care to treat transfusional iron overload is chelation therapy - chemical agents that are used to remove heavy metals from the body. Ferriprox is intended for use when chelation therapy is inadequate.

The therapy is being approved under the FDA's accelerated approval program, designed to provide patients with earlier access to promising new drugs followed by further studies to confirm the drug's clinical benefit. ApoPharma has agreed to several post-marketing requirement and commitments. One commitment includes further study of the use of Ferriprox in patients with sickle cell disease who have transfusional iron overload. (Source: FDA Website, 14 October, 2011)

Unique features of the reorganization include the creation of DOP1 and DOP2, the agency's primary review divisions for cancer solid tumor therapies, and the creation of DHOT, which will review nonclinical information. (Source: FDA Website, 12 September, 2011)

## **FDA Outlines Plans for an Outside Network of Scientific Experts for CDRH**

FDA's Center for Devices and Radiological Health (CDRH) is soliciting comment on a plan to create a network of outside scientific experts who would provide staff with rapid access to specific specialized knowledge about emerging technology, as well as other topics. To further enrich this comment period, CDRH will also conduct a 12-week pilot of the network through December 30, 2011.

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for detailed scientific information on topics related to medical devices.

CDRH will build the Network in partnership with leading scientific, academic and clinical organizations. The center will enter into agreements with these organizations and then call upon their membership for needed expertise. This will permit a fast and efficient exchange of knowledge with scientific leaders on an as-needed basis. (Source: FDA Website, 04 October, 2011)

### **New Members**

Tolulope Ademoye, *Student*, University of Rhode Island

Mr. Theodore J. Aronis, *Validation Technician*, Lyophilization Services of New England

Mrs. Shannon Asselin, *Senior Engineer*, Superior Controls, Inc.

Mr. Paul M. Belliveau, *Manufacturing Supervisor*, Lantheus Medical Imaging

Mr. Francis W. Berthiaume, *Facilities Supervisor*, Genzyme

Mr. Paul M. Camara, Jr., *Vice President*, Atlantic Contracting & Specialties

Mr. James B. Cannon, *Head of OEM and Markets*, Mettler-Toledo Thornton

Mr. Maurizio V. Cattaneo, *Consultant*, Boston University

Daman Chadha, *Student*, IE Business School, Madrid

Mr. Mark W. Clark, CPMM, *Co-Founder*, BioPharma Management Systems

Mr. Peter Coe, *Supervisor Site Service*, Lantheus Medical Imaging

Mrs. Jean S. Cookinham, *Sr Project Manager*, Teva Pharmaceuticals

Mr. Thomas J. Corbett, *Sr. Scientist / Engineer*, P&G

Mr. John R. DeWaal, *President*, Coast Automation, Inc.

Mrs. Leslie L. Doyle, *Senior Validation Engineer*, ImmunoGen Inc

Mr. Mark D. Fazio, *Project Manager*, Genzyme

Lauren Feroli, *Process Engineer III*, Genzyme

Terrence Flanagan, *Manufacturing Supervisor*, Shire HGT

Mr. Shaun B. Francis, *Sr Manufacturing Technician*, Genzyme Corporation

Mr. John Giantsidis, *Director, Quality Systems Compliance*, Fresenius Medical North America

Mr. Kristian Hedstrom, PhD, *Postdoctoral Fellow*, Children's Hospital Boston

Mrs. Sabine A. Knedlik, *Reliability Engineer*,

Michael Lashua, *Site Superintendant*, Decco Inc

Mr. Alexander D. Lee, *Student*, University of Massachusetts Amherst  
Chris Lugbauer, *Director of Northeast Operations*, Global Automation Partners  
Ifte Mahmud, *Director*, Sanofi  
Mrs. Lisa A. Martins, *Facility Engineer*, Alexion Pharmaceuticals, Inc.  
Elizabeth Messana, *Graduate Student*, Regis College  
Ms. Irene Nkenggor-Acha, *Student*, University of Massachusetts-Lowell  
Mr. Pietro Paci, *President*, JPE SERVICES INC.  
Mrs. Swati J. Patel, *Sr. Systems Analyst*, Vertex Pharmaceuticals  
Mr. Joe Pillsbury, Pond Technical Sales Inc  
Mr. Glen Potvin, Splash Consulting  
William Powers, *Sr. Manager, Facilities & Logistics*, Alnylam Pharmaceuticals Inc.  
Mr. Scott W. Pray, *President*, D.F. Pray General Contractors  
Jean Quong, Genzyme Corp  
Mr. Mariusz Rdultowski, Jr., *Student*, University of Massachusetts Amherst  
Mr. Douglas B. Reddington, *Chief Estimator*, M+W Group  
Mr. Mike Ruhle, *Account Director*, New England Controls Inc  
Mr. Bryan Rydingsward, *HVAC Engineer*, BR+A  
Mr. Christopher B. Sears, *Associate Director of Manufacturing*, Acusphere, Inc.  
Mr. Michael G. Sears, *Sr. Marketing Director*, RDK Engineers  
Mr. Andrew J. Sides, *Responsible Systems Engineer*, Genzyme  
Ms. Kimberly J. Sousa, *Director Marketing & Development*, RDK Engineers  
Jaimes T. Spring, *Student*, Worcester Polytechnic Institute  
Ryan Stephansky, *Student*, Bridgewater State University  
Mr. Christopher J. Taylor, *Principal Validation Engineer*, Shire HGT  
Mr. Robert J.A. Wilson AIA, *Architect*, M+W Group

### **Member Anniversaries**

#### **20+ Years of Membership**

Mrs. Janice T. Abel, ARC Advisory Group

Dr. Debra A. Barngrover  
Mr. Randolph A. Cotter, Sr., Cotter Brothers Corporation  
Mr. Cesar B. Daou, PE, Daou Engineers Inc  
Ms. Greta W. Davis, Lantheus Medical Imaging  
Mr. John H. Evers, Lantheus Medical Imaging  
Mr. Donald M. Haiges, PE, WSP-Flack+Kurtz  
Mr. David C. Hardy  
Mr. Edwin L. Harmon, III, Genzyme Corp  
Mr. Stephen R. Higham, PE, Genzyme Corp  
Mr. David L. Hyde, Lantheus Medical Imaging, Inc.  
Mr. Thomas R. Jerome  
Mr. Robert W. Juffras, MS, Stryker Biotech  
Mr. Jerome E. Justin, Shire HGT  
Dr. Richard V. Levy, PDA  
Mr. Frank J. Manning, VNE Corp  
Mr. Hank Moes  
Mr. Thomas W. Moss, Applied Process Solutions, Inc  
Mr. Armen J. Nahabedian, Pfizer  
Mr. Richard D. Priestester, Strategic Facility Planning LLC  
Mr. Thomas A. Ramundo, New England Controls Inc  
Mr. Thomas C. Ransohoff, BioProcess Technical Consultants Inc  
Mr. Pasquale M. Sacco, Shire HGT  
Mr. Alexander E. Smith, Jr., M+W U.S., Inc.  
Mr. Jonathan F. Stenbuck, Stenbuck Enterprises

### **15 Year Anniversary**

Mr. David M. Schlesinger, MannKind Corporation  
Mr. Robert M. Stern, Genzyme Corporation  
Mr. Daniel Wang, PhD, Massachusetts Institute of Technology

## 10 Year Anniversary

Mr. Michael R. Allard, NewAge Industries/AdvantaPure

Mr. Michael J. Carr, Abington Group, Inc.

Mr. Edward A. Nahabedian, Pfizer

Mr. Don N. Reitano, CFM, Alkermes Inc

## 5 Year Anniversary

Mr. James E. Taylor, SLC Consulting LLC

Mr. Stephen E. O'Brien, Pfizer

Mr. Mark Goodsell, Genzyme Drug Discovery & Development

Mr. Kevin Schaffer, Etex Corporation

Mr. David G. Monson, Infinite Potential

Mr. Zachary Gendron, Sanofi Pasteur

Mr. Robert Lewis, Erland Construction Inc

Ms. Gael L. DeAmicis

Ms. Katherine M. Wallace, AstraZeneca

Mr. Jonathan D. Davis, Associates of Cape Cod, Inc

Mr. Jared B. Marshall, Genzyme Corp