Connecting a World of Pharmaceutical Knowledge

Boston Area Chapter

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NEWSLETTER

January 2013, Volume XXIII, No. 1

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President's Message: The Boston Area Chapter Again Wins Top Honors at ISPE Annual Meeting

Dear Fellow Boston Area Chapter Members,

As I write this message, it has only been a short three days since the horrific tragedy in Newtown, CT and as a father of three, I am sure I speak for all when I say our hearts and prayers go out to all those who have senselessly lost their lives and those who have lost loved ones and will live with the pain for a lifetime. As we have done in the past, we as a Chapter will be looking for ways we can help those in need during this very difficult time, so if anyone has suggestions, please let one of us know.

Moving on to Chapter business, I know this may start to sound like a broken record but for the fourth time in a row, we have more reasons to reiterate, "It has been another fantastic year for the ISPE Boston Area Chapter." Last month, ISPE held its Annual Meeting in beautiful San Francisco and many Chapter Members were there to witness history: the Boston Area Chapter took home many awards! We would like to thank our many volunteers for all their hard work - work that continues to earn the Boston Area Chapter recognition for almost everything we do and everything we have pioneered.

The details are in the Annual Meeting article in this newsletter so I won't go into all the awards we received but I would like to add a special thank you to all those involved with our outstanding Young Professionals group and our very well-recognized contribution to the worldwide CPIP™ program. Over half of the country's and over a third of the world's current CPIPs are a result of the efforts of individuals from the Boston Area Chapter. It seems like every other week we receive word of another Boston Area Chapter Member achieving CPIP certification! So if there are any of you out there who would like to join this elite group of pharmaceutical professionals, there is no better place to prepare yourself - just join one of the upcoming CPIP study groups.

Boston Area Officers and Board Members proudly display the Chapter's awards.

With all the encouraging news, we want to make sure to keep the momentum going so, as promised, here is a recap of our goals and results to date:

- Membership Growth

Our goal this year is to add 50 new regular Members and 15 Young Professional Members. Since August, we have added 11 regular Members and 8 Young Professional Members so we are well on our way to exceeding our goal.

An important factor in membership growth is Member retention - keeping our current Members renewing their membership year after year. Our goal is to raise our retention rate from 80 to 84 percent. We are currently at 81.28 percent which is one the highest retention rates in the world - way to go!

Retention rate is a measure of how well we are doing supporting and delivering value to our Members. Many thanks to all who completed the recent membership survey. On quick review, we know we are doing many things very well; plus we have received many excellent suggestions for continuous improvement. We are currently compiling the feedback received and will be putting plans in place to continue to meet all of your expectations.

- Student Chapter Growth and Development

Our goal for Student Chapters this year is 50 new Student Members. As stated in the last newsletter, we got off to a slow start but I am pleased to announce that since August we have added 7 additional Student Members! This is good progress and we expect the pace to pick up as the year progresses. In fact, we're looking forward to winning next year's award for innovation in Student Chapter Programs!

- Educational Program Excellence

We are continuing to deliver high quality educational programs to our membership with great success and look forward to a full calendar of upcoming events, including those created especially by and for our young professionals.

Together we can continue to make the ISPE Boston Area Chapter a great resource for all our Members. Again, I thank you for giving me the opportunity to help lead the way.

Sincerely,

Jay Zaino
President
ISPE Boston Area Chapter

Chapter Bulletin Board

Congratulations to Our Newest Certified Industry Professional™ (CPIP™)

The Chapter's CPIP Study Groups continue to add to the roster of Certified Pharmaceutical Industry Professionals™ (CPIPs). The latest additions are:

- Michael Beckwith, Commissioning Agents,
- Chad Michael, Commissioning Agents,
- James Carmichael, Alexion and
- Michael Harrison, Biotechnicians Network.

Congratulations to this illustrious group of Boston Area Chapter CPIPs!

The CPIP credential recognizes comprehensive industry knowledge. Candidates are assessed based on both education and experience, and must also pass an exam to be awarded the credential. The current CPIP Study Group began on September 18 at Biogen Idec in Cambridge. Future plans include a session combining participants from both the Boston Area and New England Chapters. Keep an eye on this space for more information.

Advertise on www.ISPEBoston.org

Did you know the Boston Area Chapter Website attracts over 8000 visits monthly from the region's life sciences professionals? Now you can reach the same audience by advertising on www.ispeboston.org. A limited number of advertising spots are now available - including some with animation - so don't delay. Ads are sold on a first-come, first-served basis. To learn more about this unique opportunity and reserve your space, contact Amy Poole, Chapter Manager, at 781-647-4773 or office@ispeboston.org.

Want to Become a Chapter Sponsor? It's Easy!

Ever wonder how to become the Sponsor of a Chapter educational program or social activity? Or how to land one of the coveted eNewsletter or website advertising spots? To answer these questions, the Chapter has created a new website resource at www.ispeboston.org/sponsorship containing all the information you need to know to become a Chapter Sponsor. So don't delay, visit our website and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members.

Upcoming Chapter Events - Mark Your Calendar

Thursday, January 10, 2013
Awards Celebration and New Year's Social

Ice Skating at 300 Athenaeum Street, Cambridge, MA 02142
Social at 650 East Kendall Street, Cambridge, MA 021425

In early November at the ISPE Annual Meeting in San Francisco, the Boston Area Chapter was awarded the top honor, the North American/South American Affiliate Council "Platinum Grand Award for Excellence and Innovation" for the fourth year in a row! Join your friends and colleagues for ice skating, live music, and celebrating at the Kendall Square Ice Skating Rink!

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=326

Thursday, January 17, 2013
Building Information Modeling (BIM): From Concepts to Substantial Completion (and Beyond)

UMass Medical School (UMMS), 55 North Lake Avenue, Worcester, MA 01655

There continues to be a great deal of conversation around the topic of building information modeling (BIM) in the design, construction, and facilities management worlds. For designers, BIM offers the opportunity to engage with users in real time to reflect design decisions of lab spaces. Modifying the model during the user meetings, designers and lab users get it right during the design process in lieu of understanding the concept at move-in. BIM also presents new opportunities for streamlining the facilities management process once construction is complete. Using the data in the model allows facilities managers the opportunity to better control space allocations and tracking, evaluate move management and control equipment management. This two-part presentation will use real-world case studies to help attendees understand the realized benefits of an effective BIM implementation, not just in concept but in time and money as well. Brian Sykes, AIA, of HDR Architectures will discuss a number of projects for which BIM was leveragesd. John Baker of UMass Medical School and Tom Watson of Suffolk Construction Company will present a current project, UMass Medical School's 500,000 square-foot Albert Sherman Center. Virtual models will be utilized and a tour of the facility will also be included in the evening's activities.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=291

Wednesday, January 23, 2013
Young Professionals Biotech Trivia Night

Tommy Doyles, 1 Kendall Square #100, Cambridge, MA 02139-1562

Come join the ISPE Boston Area Chapter Young Professionals for a night of trivia, appetizers, and socializing. Put your thinking caps on for a session of Geeks who Drink Trivia, and compete with your fellow pharmaceutical nerds for bragging rights, exciting prizes, and a raffle to benefit The Red Sox Foundation and Massachusetts General Hospital's Home Base Program. Proceeds of the event and the 50/50 raffle will be donated to the charity. Register early; there are a limited number of spots available. We'll set up the teams, so all you need to do is be ready to show off your trivia skills.

Register Today: http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=325

Sneak Preview of Upcoming Events

Thursday, February 7, 2013
ISPE Young Professionals Biotech 101 Educational Program

Thursday, February 21, 2013
Joint Educational Program with the ISPE New England Chapter

Thursday, March 15, 2012
Educational Program focusing on Commissioning and Qualification

Boston Area Chapter "Sweeps" at Annual Meeting

by Brian Hagopian, CPIP, Clear Water Consulting, Inc. with photos by Annual Meeting Staff Photographer

This year's ISPE Annual Meeting was held in San Francisco, a city with a vibe that makes many Bostonians feel right at home. From the ocean views to the great seafood, to the bustling but manageable downtown area, this was a great place to hold the Annual Meeting. And Boston brought one of the largest out-of-town contingents, with over 100 people flying in for the programs, events, meetings, and festivities.

Dan Ramsey (second from left), Chair of the ISPE Young Professionals Committee and Boston Area Chapter Vice President, happily accepts the Committee of the Year Award.

Our Chapter continued its tradition of "kicking off" Annual Meeting by hosting a social open to Chapter Members and invited guests. Attendees had a chance to catch up in a relaxed environment and the social really set the tone for the rest of the meeting.

Monday's Plenary session featured several speakers including ISPE President/CEO Nancy Berg, incoming ISPE Chair Charlotte Enghave Fruergaard, and an inspiring speech by the FDA's Deputy Commissioner for Medical Products and Tobacco, Dr. Stephen P. Spielberg (not to be confused with his Hollywood

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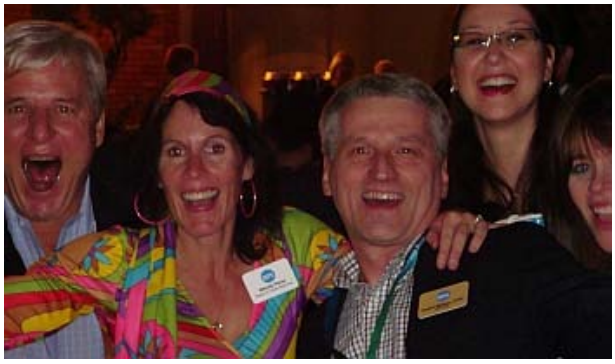
namesake). Dr. Spielberg presented the FDA's vision of forging stronger collaboration between FDA and professional societies such as ISPE, with ISPE's role being to help industry "get the science right." He cited three cases of new drugs that were approved at breakneck pace (3 months, as opposed to the normal 6-24 months) because the "science" was right.

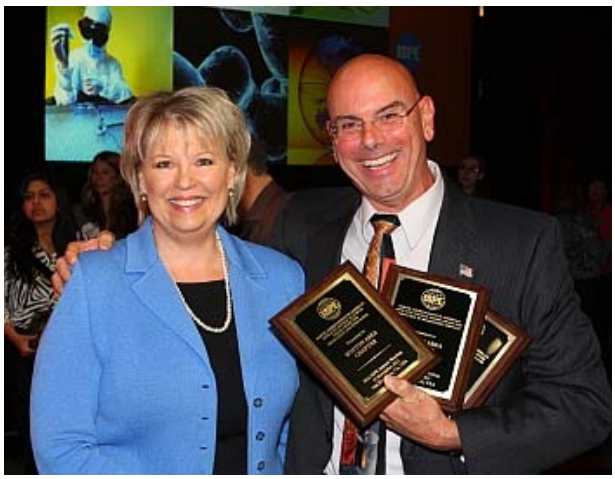


Chapter Past Presidents Dick Priester (left) and André Walker (second from right) join the celebration.

Everyone from Boston was particularly proud of the CPIP™ display area at Annual Meeting. A poster recognizing all the new CPIP certifications conferred in 2012 was dominated by Boston Area Chapter Members, with over 60 percent of the 2012 CPIPs having passed through a Boston Area Chapter Study Group. Way to go!

At the luncheon on Tuesday, members of the Boston Area Chapter were further reminded of all the great things the Chapter does on a regular basis during the awards ceremony. And the Chapter did something that's never been done before - we won excellence awards in every category that we entered. That's right, for the first time ever, Boston swept the awards, winning the Platinum Grand Award as Chapter of the Year (for the fourth consecutive year), the Innovation in Member Services Award for last year's successful membership drive and the Innovation in Programs and Events Award for our CPIP study group, world renowned Product Show and our collaborative program with ISPE International which helped launch ISPE's new Water and Steam System Baseline Guide. Oh, and if that's not enough, our own ISPE awarded its "Committee of the Year" Award to the Young Professionals Committee, chaired by Boston Area Chapter Vice President Dan Ramsey. Stay tuned for our upcoming winter social, where all the awards will be on display and we can celebrate locally together!

Toward the end of Annual Meeting, ISPE always holds an evening bash, and this year's event focused on the diversity of San Francisco, from Alcatraz to Chinatown to Fisherman's Wharf. At the end of the bash, the DJ played "Sweet Caroline" at our request and everyone from Boston was drawn to the stage for one of the greatest "sing alongs" we've ever experienced! We were all hoarse for days!



ISPE President and CEO Nancy S. Berg congratulates Immediate Past President Brian Hagopian on the Chapter's success.

Annual Meeting also had a lot of educational, business, communities of practice, and committee gatherings

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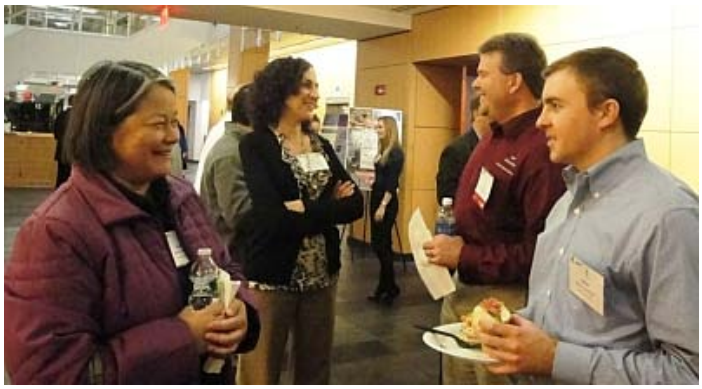
where members come together to share ideas and best practices with other Chapter officers from around the country. New ISPE publications are planned and the direction of the society is charted out for the future. Great things are happening both locally and internationally, so stay tuned!

Marketing Yourself: How to Increase Your Value in the Workplace

by Michael Levesque, Co-Chair, Boston Area Chapter Educational Programs Committee with photos by Jamie Falzone, ISPE Office

The November 15 educational program was held at the Genzyme facility in Framingham. The program served to provide a rare insight into the minds of hiring managers, recruiters and HR professionals as they seek to fill jobs and promote employees. This session was hosted by the Boston Area Chapter, and sponsored by Tufts University, Gordon Institute. The meeting was co-chaired by Andrea Massa of Burkert Contromatic Corporation and Michael Levesque. Andrea and Mike are members of the Boston Area Chapter and serve on the Chapter's Educational Programs Committee (EPC). Andrea is also a Young Professional, and Mike is EPC co-chair.

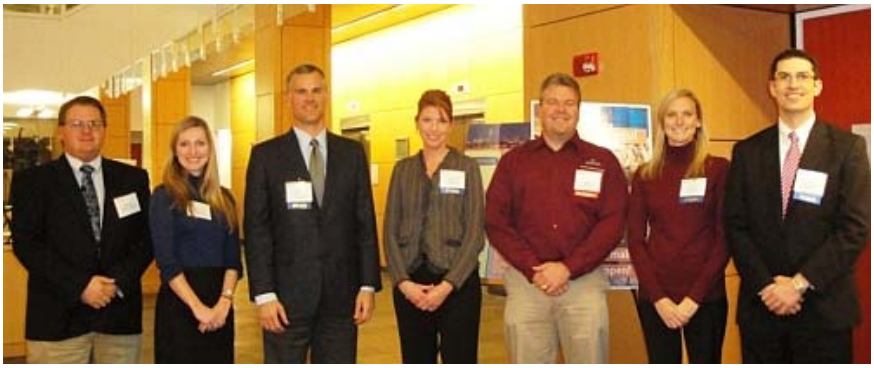


The networking reception provided time to relax with fellow attendees. Shown are Nancy Buczko, representing event sponsor Tufts Gordon Institute, and Chapter President Jay Zaino (back); and Jean Quong and Jared Marshall, both from Genzyme (front).

Approximately 40 attendees gathered for the event. This was a relatively rare soft-skills presentation, as many of our sessions naturally focus on the technical aspects of our jobs. For many, this was their first ISPE educational program. As with all of these events, the evening started with refreshments and an opportunity for networking.

The guest speakers were introduced by Andrea and included: Alison Neely, Recruiting Partner, Pharmaceutical Operations & Technology, Biogen Idec; Laura Poisson, Vice President, Clear Rock; Brian Jochim, Account Executive, Aerotek Scientific; and Michael Pelletier, Director, Engineering and Facilities, Lonza Biologics.

Alison Neely covered the challenging topic of interviewing core behaviors. She emphasized focusing on priorities, innovation and creativity. Collaboration/teamwork and people management were also noted as key elements, as well as mutual respect, trust, integrity and ethics. The main takeaway message was that preparation and follow-up are absolutely essential to success. You need to research the company, position and interviewers before stepping in the door. Alison noted that fortunately, this has never been easier, thanks to online tools such as LinkedIn.



The November program was a well-coordinated team effort combining the efforts of (l to r) Meeting Managers Mike Levesque and Andrea Massa,

speakers Michael Pelletier and Laura Poisson, Chapter President Jay Zaino and Speakers Alison Neely and Brian Jochim.

Laura Poisson specializes in leadership development and outplacement. Her topic was networking, which can be extremely challenging for the 25 to 49 percent of the population that identifies themselves as introverts. People are our greatest resource and you will inevitably need help from someone in order to reach your goals. Laura recommends viewing networking as farming (not hunting), focusing on a few key contacts, being memorable when meeting new people (practice your elevator pitch), knowing your desired outcome before the conversation begins, following through after the event (regularly stay in touch) and reaching out to help others.

Brian Jochim identified best practices for a job search. He recommends using network connections before recruiters, and using blind online applications only as a last resort to apply to companies where you have neither network nor recruiter connections. He also discussed social networking, emphasizing the importance of maintaining a professional online presence. He stressed the importance of maintaining control of where your resume is sent, and the use of cover letters. Companies are looking for good fit, teamwork and the potential to build long-term relationships with potential employees. Brian stressed researching press releases and websites, with the goal of understanding the company's values prior to an interview.

Michael Pelletier provided an employer's perspective on managing careers. He underscored the importance of networking and LinkedIn, as well as the unique internship opportunities available to set students apart from their peers upon entering the job market after graduation. He emphasized the criticality of punctuality, and a flawless resume and appearance for interviews, as these are your first impressions with a potential employer. He noted that these factors are equally critical for an employee interviewing for an internal job or promotion. Once you have been hired, you need to build relationships and find mentors who can help you progress in your career. To truly get ahead, one must be flexible, take risks, and show initiative, which may include changing departments and relocating to take advantage of opportunities to gain valuable experience in different parts of the business. Companies continuously evaluate succession plans, and refusing such opportunities is likely to severely limit upward mobility. Michael stressed that above all else, always do excellent work, keep your skillset fresh and be open to criticism.

Following each presentation, many excellent attendee questions were answered by the panelists. At the close of the evening, a longer Q&A session was held, followed by even more one-on-one questions. Each of the panelists was extremely generous and willing to help, and encouraged the audience to follow up after the session.

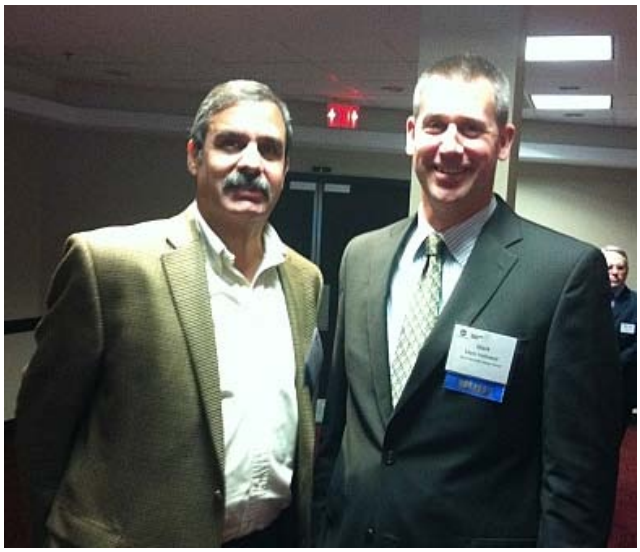
Many thanks to our distinguished panelists, to Genzyme for hosting the event and to our generous sponsor, Tufts University Gordon Institute.

December Program Sheds Light on Serialization Regulations & Technology

article and photo by Sean Brown, Barry-Wehmiller Design Group

On December 13, 2012 the Boston Area Chapter hosted an educational program with two distinguished speakers on the topic of “Serialization Regulations and Technology: Navigating the New Demands of the Distribution Chain.” The speakers were Mark Hallowell, a serialization expert from Barry-Wehmiller Design Group, and Mike Salinas, a regulatory expert from M+W.

The topic of serialization is currently in the forefront as the industry seeks to secure the supply chain and mitigate the risk of product diversion and counterfeiting. The program was very well attended, with a festive atmosphere as the holiday season was quickly approaching.



Presenters and subject matter experts (l to r)
Mike Salinas and Mark Hallowell.

The evening kicked off with Mike Salinas presenting the global counterfeiting drug problem with a focus on the potential market, and industry regulations. Mike outlined what it takes for cradle-to-grave e-pedigree implementation, discussed some of the associated challenges, and concluded with a reality check - a perspective of what was happening in this market space, and how more and more companies, both clients and vendors alike, were turning to the likes of global EPC firms to help them address implementation.

Mike explained that manufacturers (generic and brand) must conform to the California law; they must pedigree 50 percent of their products by 2015, the remaining 50 percent by 2016, and throughout the supply chain up to the pharmacy by 2017. Mike emphasized that coding, serialization and track and trace was not an “off the shelf” product. He stressed the importance of taking a holistic enterprise level approach with support from all levels of management (since there were Brand, Quality, and Regulatory implications, as well). Mike concluded by stating that protecting the public from counterfeit drugs was not hard to support. The problem is huge and affects patient safety. It’s the law, time is running out, and counterfeit drugs won’t go away by themselves. He cautioned, however, that the global infrastructure might not be in place to meet the deadlines. During the presentation a very interactive audience had many questions.

Mark Hallowell followed up with the “dos and don’ts” for implementing serialization solutions and provided practical examples obtained from numerous client projects. During his presentation, Mark introduced the term “track and trace” and explained the need for manufacturers to verify product integrity throughout the supply chain. He went on to illustrate the typical challenges manufacturers face as they upgrade existing equipment, build new packaging lines, integrate the data transfer throughout the supply chain and provide the reporting to verify compliance.

At the conclusion of the presentations the audience was eager to ask question while these two experts were in the room. Stephanie Smith of AstraZeneca inquired about the regulations and associated fines. Mike Salinas explained the manufacturer can be fined $5000 per unit for not implementing serialization and it applies to both the supplier and the distributor. Mark Hallowell was asked to comment on how prepared the industry is to comply with these regulations. Mark explained, “the current industry estimate is 20 percent of companies have implemented some form of serialization, while the other 80 percent have not started.” A quick poll of the companies participating in the meeting, showed similar levels of investment and the need to ramp up investment to insure compliance in the near future.

The program provided an excellent overview of the serialization topic and much food for thought. As the evening wrapped up, many of the attendees followed the speakers from the room to learn more about the topic and share a cold pint with the presenters.

Find the Cure for Cabin Fever with Upcoming YP Events

by Dave Gallagher, GxP Automation

Over the last few months, the Boston Area Chapter YP Committee has been planning what we expect to be a very successful year of educational and social events. Starting with our Biotech Trivia social event in January, YPs have managed to plan an event for every month this year!

On January 23 we will be hosting our BioTech Trivia event at Tommy Doyle's in Kendall Square. Come join us for a session of "Geeks Who Drink Trivia" and test your knowledge of the industry as well as network with fellow industry professionals. There will be appetizers on hand and a 50/50 raffle to benefit The Red

Sox Foundation and Mass General's Home Base Program. Teams will be made at random at the beginning of the event, so all you need to do is be ready to show off your trivia skills. The event is already open for registration on the Chapter website, so make sure to register ASAP as there are a limited number of spots available.

Our February event will be the BioTech 101 educational program to be held on the 7th at Biogen Idec. This topic is always a big hit with the Young Professional demographic. The details are still being worked out but the event will be geared toward a broad overview of what this ever-changing industry has to offer. Check the Chapter website in the upcoming weeks for more info about this popular crowd pleaser.

The YPs have also been exploring new means of communication to spread the word about our upcoming events. We'll be sending regular emails to let our current members know what's going on within the group and there is a new LinkedIn group for the Boston Area Chapter YPs, so make sure to join!
We hope to see you at the BioTech Trivia event on the January 23 - Happy Holidays!

Industry News in Brief

by Lauren Melton, Alnylam

Industry News In Brief, a regular feature of the Boston Area Chapter Newsletter, presents news items concerning companies in the pharma, biotech, medical device and related fields, with an emphasis on companies with a local presence and topics of special interest to our readers.

Ironwood to Expand in Cambridge

Ironwood Pharmaceuticals, which had considered building a new headquarters on the South Boston Waterfront, Route 128, or elsewhere in Cambridge, has instead signed a two-year extension on its lease and taken additional space at its 301 Binney Street site near Kendall Square in Cambridge.

The extended lease will allow Ironwood, which plans to launch its drug to treat irritable bowel syndrome with constipation in the United States this year, to add 93,000 square feet on the fourth floor of the Binney Street building. It currently uses the building's second and third floors. The expansion would give it about 300,000 square feet. Ironwood's lease was set to expire in 2016. (Source: www.BostonGlobe.com by Weisman 10 October, 2012)

AVEO to Cut 45 Jobs, 17 Percent of its Workforce

AVEO Oncology announced a strategic restructuring designed to optimize resources and reduce expenses to ensure AVEO is well positioned for a successful launch of tivtozanib in renal cell carcinoma (RCC) and continued development in other cancer types, while maintaining a focused research engine. In addition, AVEO reported consolidated financial results for the third quarter of 2012, updated its financial guidance and summarized recent developments. "AVEO's primary focus is on the approval and successful commercialization of tivozanib, which will drive the near term future of the company and will be our greatest opportunity for value creation," said Tuan Ha-Ngoc, president and chief executive officer of AVEO. "AVEO's drug discovery, translational research and Human Response Platform capabilities remain long-term core value drivers. We believe the cost savings resulting from the reduction in the scope of the R&D activities and associated resources outside of tivozanib position us well to successfully execute the planned launch of tivozanib, as well as make progress toward our goal of becoming a fully integrated oncology company."

The company plans to explore further development of ficlatuzumab and certain discovery assets through external collaborations, including with academic partnerships and cooperative groups. The company plans to focus its Human Response Platform™ and discovery capabilities on supporting the clinical development of tivozanib, advancing biomarker identification and development across AVEO's clinical stage programs, and developing novel, high potential programs.

AVEO's strategic restructuring and projected cost savings are being achieved through a combination of reduced spending on early stage research programs and a reduction in force of approximately 45 positions, or 17 percent of AVEO's workforce, as well as elimination of 30 open positions. This refocusing of resources and reduction of expenses is expected to provide AVEO approximately $100 million in cost savings over the next three years compared with prior projections, with approximately $37 million in 2013, and is expected to extend its cash runway through 2013. (Source: AVEO Oncology Website, 31 October, 2012)

FDA Accepts AVEO NDA for Drug to Treat Advanced Renal Cell Carcinoma

Cambridge-based AVEO Oncology and Astellas Pharma have announced that the FDA has accepted for filing the New Drug Application (NDA) for tivozanib with the proposed indication for the treatment of patients with advanced renal cell carcinoma (RCC). Tivozanib is an investigational medicine and is not currently approved in any country. Its safety and efficacy have not yet been fully established. The FDA's acceptance of the NDA triggers a $15 million milestone payment to AVEO under its development and

commercialization agreement with Astellas.

AVEO Oncology is a cancer therapeutics company committed to discovering, developing and commercializing targeted therapies to impact patients' lives. AVEO's proprietary Human Response Platform™ provides the company unique insights into cancer biology and is being leveraged in the discovery and clinical development of its cancer therapeutics.

Astellas Pharma, headquartered in Tokyo, is a pharmaceutical company with approximately 17,000 employees worldwide. It is committed to becoming a global category leader in Oncology, Urology, Immunology (including Transplantation) and Infectious Diseases, Neuroscience and DM Complications and Kidney Diseases. (Source: AVEO Oncology Website, 28 November, 2012)

ImmunoGen Announces FDA Priority Review Status for Breast Cancer Drug

ImmunoGen, a Waltham biopharmaceutical company that develops anticancer products using its Targeted Antibody Payload (TAP) technology and antibody expertise, today announced that Genentech, a member of the Roche Group, has disclosed that the FDA has officially accepted the Biologics License Application (BLA) for trastuzumab emtansine and granted it Priority Review. The proposed indication is for the treatment of people with HER2-positive, unresectable locally advanced or metastatic breast cancer who have received prior treatment with Genentech's Herceptin (trastuzumab) and a taxane chemotherapy. It also disclosed that Roche's Marketing Authorization Application for trastuzumab emtansine for people with HER2-positive metastatic breast cancer has been accepted for review by the European Medicines Agency.

The FDA grants Priority Review designation to drugs that may offer major advances in treatment or provide a treatment where no adequate therapy exists. For applications granted Priority Review, the FDA's goal is to complete the review and deliver a decision on marketing approval within six months. The FDA has assigned this BLA a Prescription Drug User Fee Act (PDUFA) goal date of February 26, 2013.

ImmunoGen develops targeted anticancer therapeutics using the company's expertise in tumor biology, monoclonal antibodies, potent cancer-cell killing agents and engineered linkers. The company's TAP technology uses monoclonal antibodies to deliver one of ImmunoGen's proprietary cancer-killing agents specifically to tumor cells. There are now ten TAP compounds in clinical development, of which three are wholly owned by the company. Roche is developing trastuzumab emtansine (T-DM1) globally under an agreement between ImmunoGen and Genentech, a member of the Roche Group. (Source: Immunogen Website, 06 November, 2012)

Boston Scientific Moving HQ To Marlborough, Acquires California Firm

Medical device maker Boston Scientific announced that it will be moving its world headquarters from Natick about 13 miles away to Marlborough. The move will be to a property with LEED-Certified buildings purchased in 2004. According to the company, the move will occur in phases, starting in the spring, and it expects employees to be out of the Natick facility by mid-summer 2014, when construction of a new Marlborough building is complete.

"A new global headquarters in Marlborough will more effectively support our long-term strategic plans," said Boston Scientific President and CEO Mike Mahoney. "Consolidating our Natick and Marlborough facilities is expected to foster greater collaboration and efficiency, benefiting our employees, our customers, and, ultimately, the patients they treat."

"The City of Marlborough is thrilled to be the new expanded home of Boston Scientific," said Marlborough Mayor Arthur Vigeant. "The company has already been an outstanding corporate citizen and we look forward to having Boston Scientific play an even larger role in our community."

The company also announced today that it's made its third acquisition in as many months. The firm said it has signed a definitive agreement to purchase Vessix Vascular of Laguna Hills, California in a deal expected to close this month. Vessix will be part of the Peripheral Interventions business at Boston Scientific, which includes products to treat vascular system blockages. Boston Scientific will pay $125 million initially, with up to $300 million more between 2013 and 2017, based on clinical and sales-based milestones, the company said.

The privately-held Vessix, founded in 2003, has developed a catheter-based renal denervation system for the treatment of uncontrolled hypertension, according to Boston Scientific. Mahoney said the new technology represents potential for a breakthrough therapy in treating the condition. "The acquisition of Vessix Vascular adds a second generation, highly differentiated technology to our hypertension strategy while accelerating our entry into what we expect to be a multi-billion dollar market by 2020," he added.

Boston Scientific said the therapy is important because hypertension is the leading cause of death worldwide, despite the availability of antihypertensive medications. Renal denervation is a catheter-based therapy for medication-resistant hypertension that uses radiofrequency energy to disrupt the renal sympathetic nerves whose hyperactivity leads to uncontrolled high blood pressure, Boston Scientific. The company expects hypertension therapies to be a key growth driver for it going forward.

The Vessix Vascular V2 Renal Denervation System has received CE Mark in Europe and TGA approval in Australia, which are manufacturing conformity requirements. Vessix expects to launch the treatment in CE Mark countries in 2013. (Source: Jacquelyn Gutc, WBJournal.com, 08 November, 2012)

Alnylam and Tekmira Restructure Relationship and Settle All Litigation

Alnylam Pharmaceuticals has announced that they and Tekmira Pharmaceuticals have restructured their relationship with a new licensing agreement and have resolved all litigation between the parties in a settlement agreement. The new license agreement consolidates and clarifies certain intellectual property (IP) elements related to lipid nanoparticle (LNP) technology for RNAi therapeutics.

Further, Alnylam has elected to independently manufacture its LNP-based RNAi therapeutic products and to buy-down certain future potential milestone payments and a significant portion of future potential royalties for its ALN-VSP, ALN-PCS, and ALN-TTR02 programs. The settlement of all ongoing litigation between the two companies allows Alnylam to continue to focus its efforts on advancing innovative medicines to patients.

"With this restructuring of our Tekmira relationship, we are gaining independence in our LNP manufacturing and decreasing the milestone and royalty burdens on several of our LNP-based products. Further, the companies have created clarity around the overall patent estate for LNP-based products, while ensuring Alnylam's full access to use this technology for our products in the future. Of course, we are also pleased to put this legal matter behind us and continue our focus on advancing RNAi therapeutics through clinical trials with the goal of bringing them to the market where we can make an impact in the lives of patients and their caregivers," said Barry Greene, President and Chief Operating Officer of Alnylam.

Under a new license agreement, Alnylam and Tekmira have agreed to consolidate certain IP elements related to LNP technology for the systemic delivery of RNAi therapeutic products. Specifically, certain patents and patent applications, including the MC3 lipid family, will be assigned by Alnylam to Tekmira. Alnylam retains full rights to use this IP for advancing RNAi therapeutic products to the market, including the rights to sublicense IP on a product-by-product basis. Alnylam has also agreed to grant five additional non-exclusive therapeutic licenses to Tekmira.

Finally, Alnylam and Tekmira have agreed to settle all ongoing litigation between the parties. The parties have also agreed to a resolution of the interference proceeding related to Alnylam-owned US Patent No. 7,718,629 directed to an siRNA component in ALN-VSP. In addition, Tekmira and AlCana Technologies, Inc. have agreed to drop their claims and counterclaims in both the Massachusetts and British Columbia lawsuits. Finally, the parties have agreed to a covenant not to sue on matters related to the current dispute in the future, which includes liquidated damages to be paid if the covenant is breached, and have also agreed to resolve any future disputes that might arise over the next three years with binding arbitration. (Source: Alnylam Website, 12 November, 2012)

RXi Sees Revenue Boost, Narrows Losses

RXi Pharmaceuticals of Westborough narrowed its losses in the third quarter and took in $57,000 in revenue as the company pushed ahead in the clinical-trial phase of a drug that reduces scarring in surgical and trauma patients. The young company did not take in revenue in the third quarter of 2011. Its net loss of $1.6 million was about 20 percent less than the $2 million in the same quarter last year. Meanwhile, the company improved its cash position from $503,000 to $6.3 million over the 12 months.

During the quarter, the company completed the dosing portion of its first Phase 1 study for RXi-109, its anti-scarring drug. RXi said there are no FDA-approved drugs on the market to reduce scarring, which would make its product "a great benefit" for trauma and surgical patients.

"We have continued to execute according to plan in the third quarter of 2012, with the final reports for our first Phase 1 study due in Q1 2013," said Dr. Geert Cauwenbergh, president and CEO of RXi. "As a new independent company, we are very pleased with our continued transition from a technology platform company into a company developing commercially viable assets."

Cauwenbergh said the next Phase 1 study, which will focus on multiple dosing in volunteers, should begin by the end of the year. "All this has been done with a cash burn completely in line with our projections and assets," he said. (Source: Rick Saia, WBJournal.com, 14 November, 2012)

Sanofi Appoints Dr. Gary J. Nabel as Chief Scientific Officer

Sanofi announced the appointment of Dr. Gary J. Nabel, M.D., Ph.D., Senior Vice President, Chief Scientific Officer and Deputy to the President for Global R&D, effective December 3, 2012. Dr. Nabel will report to Dr. Elias Zerhouni, President, Global R&D, and will join the group's Global Leadership Team. He will be based in Cambridge.

Dr. Nabel joins Sanofi from the National Institutes of Health, where he served as Director of the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases since 1999. During his tenure at the NIH, Dr. Nabel provided overall direction and scientific leadership of the basic, clinical, and translational research activities of the VRC and guides development of novel vaccine strategies against HIV and other emerging and re-emerging infectious diseases, including Ebola/Marburg hemorrhagic fevers, influenza, chikungunya and other viruses. (Source: Sanofi Website, 14 November, 2012)

Boston Scientific Reportedly Loses Bid for Gene Therapy Rights

A California company announced it has won patent rights to key methods for the application of cardiovascular gene therapy in Europe, which Natick-based Boston Scientific was also vying for. The decision was made by the European Patent Office, according to a statement by San Diego-based Cardium Therapeutics, the patent winner. Cardium is employing the methods in its Generx gene therapy to treat coronary heart disease, which is in late-stage trials in Europe, according to the company. Boston Scientific had applied for the same rights, according to Cardium, resulting in opposition proceedings in Europe and interference proceedings in the United States. (Source: Emily Micucci, WBJournal.com, 20 November, 2012)

Pfizer Venture Joins $33M Funding Round for Rhythm Pharmaceuticals

Rhythm, a Boston peptide therapeutics company focused on metabolic diseases, has secured an additional $8 million in financing to complete its $33 million Series B round. Joining existing investors MPM Capital, New Enterprise Associates, Third Rock Ventures, and Ipsen is Pfizer Venture Investments, the venture capital arm of Pfizer. Pfizer Venture is investing, independent of a partnership or program collaboration, Rhythm President and Co-founder Bart Henderson told Mass High Tech.

The biotech company will use the new funds, plus the $25 million it received in June, to push development of its small-peptide therapeutics for metabolic diseases, including RM-131, a ghrelin agonist currently in Phase 2 clinical trials for the treatment of diabetic gastroparesis, a condition which effects up to 30 percent of Type 1 and Type 2 diabetics, and GI functional disorders. The company recently received Fast Track review status by the FDA for RM-131.

The additional financing will also be used for RM-493, a melancortin 4 receptor that is in Phase 1 clinical trials for the treatment of obesity and diabetes.

In total, Rhythm has raised $73 million. "We are excited to have the support of Pfizer Ventures as we advance both metabolic programs through Phase 2 trials," Henderson said. "The Pfizer team has deep commercial and development experience that we intend to leverage as we expand the clinical trial program for these two important new therapeutics." (Source: Patricia Resende, Boston Business Journal, 27 November, 2012)

Broad Institute Partners With Roche to Repurpose Abandoned Drugs

Roche will make available to the Broad Institute a collection of 300 compounds with various indications in hopes of identifying alternative uses for the drugs using the research institute's screening technologies. The multi-year collaboration aims to help Roche generate value by reviving the prospects for success of compounds that failed to meet critical Phase II milestones or whose development was halted for strategic reasons.

Financial terms were not disclosed for the agreement, which will link the drug candidates comprising the Roche Repurposing Compound Collection (RRCC) to new patient populations through common biochemical pathways, with the goal of yielding new drug discovery targets.

"In the course of this project, we will be using multiple, novel methods developed at the Broad Institute to identify these new therapeutic indications. By partnering with Roche, we hope to bring the benefits of these discoveries to patients," Brian Hubbard, director of the Broad Institute's Therapeutics Discovery and Development Platform, said in a statement.

The agreement is the third announced between Broad and a major pharma company this year. In September, the institute agreed to carry out screening and hit-to-lead chemistry through its chemical biology platform to identify targets for new AstraZeneca drugs from Broad's 100,000-molecule library of Diversity-Oriented Synthesis (DOS) compounds, with AZ developing and commercializing potential compounds deemed high-quality leads.

In March, Broad Institute and Novartis made public results from the Cancer Cell Line Encyclopedia, a compilation of detailed cancer genome data and predictors of drug response authored by scientists at the Broad Institute, Dana-Farber Cancer Institute, the Genomics Institute of the Novartis Foundation, and the Novartis Institutes for Biomedical Research. In a paper published in Nature, researchers revealed three novel candidate biomarkers based on reported genomic predictors of drug sensitivity. (Source: Genetic Engineering & Biotechnology News, www.genengnews.com, 28 November, 2012)

ACT Makes Progress in Clinical Trials

Marlborough-based Advanced Cell Technology (ACT) has finished treating three more patients in its two U.S. clinical trials for embryonic stem cell therapy to reverse macular degeneration and dystrophy, the biotechnology company said. The second cohort of patient testing for both treatments is now complete, with the fifth and sixth patients participating in ACT's clinical trial for dry age-related macular degeneration - completing the second cohort of patients - and the sixth patient participating in the company's clinical trial for Stargardt's macular Dystrophy. All three patients are recovering, according to a statement by the company.

The company is now anticipating a third round of clinical trials for the treatments, according to Gary Rabin, chairman and CEO of ACT. A total of three rounds will be conducted in the U.S. and Europe, the company said. (Source: Emily Micucci, WBJournal.com, 28 November, 2012)

$2M Grant Launches Autism Personalized Medicine Effort

Autism Speaks today said it awarded a $2 million grant to its nonprofit venture philanthropy affiliate Delivering Scientific Innovation for Autism (DELSIA) to partner with Seaside Therapeutics in discovering biomarkers toward development of new personalized treatments of autism spectrum disorders (ASD).

The partnership aims to find genetic and protein biomarkers for use in identifying patients most likely to benefit from arbaclofen (STX209), the most advanced program in the autism clinical pipeline, with potential to deliver the first medical therapy for a core symptom of autism. "The broad heterogeneity of ASD suggests that optimal treatment will need to be personalized," Randy Carpenter, CEO of Seaside Therapeutics, said in a statement. Arbaclofen is an oral selective gamma-amino butyric acid type B (GABA-B) receptor agonist designed to improve social and communication functions in autism and Fragile X syndrome.

In June, Seaside entered into an alliance with Roche to expand its efforts at developing treatments for Fragile X syndrome and ASD. Seaside agreed to license exclusively to Roche patents covering the use of mGluR5 antagonists for neurodevelopmental disorders, in return for Roche leading development and commercialization of the compounds for the treatment of FXS and ASD. Seaside also agreed to continue clinical development of STX209, but allowed Roche to hold options to commercialize the drug candidate upon completion of undisclosed clinical development phases in FXS and ASD. (Source: Genetic Engineering & Biotechnology News, www.genengnews.com, 03 December, 2012)

Moderna Therapeutics Launches With $40M

Moderna Therapeutics has been launched with a $40 million round of financing led by Cambridge-based Flagship Ventures, after 18 months of being incubated at Flagship VentureLabs. The company has a novel technology platform based on technology licensed from Harvard University, that the company's CEO said will enable the discovery of hundreds of new treatments for previously incurable diseases.

The technology involves injecting patients with a chemically-altered form of messenger RNA, which takes messages from DNA to proteins. This altered messenger RNA would prompt the body to create therapeutic proteins. This has promise as a new type of protein replacement therapy for a large number of diseases, the company said.

Flagship Ventures Managing Partner Noubar Afeyan is co-founder and Chairman of Moderna. The company will be led by CEO Stephane Bancel, the former CEO of French diagnostics juggernaut bioMerieux. Bancel also held management positions at Eli Lilly. Bancel said the promise of the technology is what drew him to lead a tiny startup after helming a large global company.

"I thought, wow, if this is safe in man, we know it works," Bancel said. "This is an opportunity to maybe spend the next ten years of my life working towards new treatments for patients that could revolutionize the whole biotechnology industry."

Bancel said that while there are 22,000 proteins in the human body, available drugs on the market only address diseases related to about 100 of those proteins. He said he expects the technology to have a big impact in rare genetic diseases, but also in larger indications, such as cancer. He said that because the same mechanism could be used with hundreds of different proteins, the Moderna technology would help speed up drug development and lower the cost of getting new treatments to patients. He said this could result in lower drug prices, or increased willingness, on the part of drug companies, to go after diseases with very small patient populations. (Source: Julie Donnelly, Boston Business Journal, 05 December, 2012)

Baxter Buying Swedish Device Maker for $2.76B

Drug and medical device maker Baxter International plans to buy the privately held Swedish company Gambro AB for about $2.76 billion to broaden its dialysis product portfolio. Gambro makes dialysis products for patients with acute or chronic kidney disease, and Baxter said it had sales of about $1.6 billion last year.

Baxter International, based in Deerfield, Illinois, said dialysis treatment rates are rising by more than 5 percent annually, partly due to growing rates of diabetes and high blood pressure. More than 2 million people globally are on some form of dialysis.

Dialysis involves removing blood from a patient, running it through a machine that cleans out impurities and then returning it to the patient's body. Baxter's medical device division makes products for kidney dialysis and intravenous administration sets to deliver medicines and fluids to patients. Baxter also has a bioscience division that makes vaccines and high-tech treatments for hemophilia and other bleeding disorders, burns and shock, immune deficiencies, and other blood-related conditions.

Baxter will pay for the deal with a combination of debt and cash generated from overseas operations. It expects the acquisition to close in the first half of next year. The deal is worth about $4 billion, counting debt. (Source: Associated Press via Boston Globe, 05 December, 2012)

Ariad Announces Early FDA Approval of Iclusig for Patients with CML

Ariad Pharmaceuticals of Cambridge has announced that following a priority review, the FDA has granted accelerated approval of Iclusig (ponatinib) for the treatment of adult patients with chronic, accelerated or blast phase chronic myeloid leukemia (CML) that is resistant or intolerant to prior tyrosine kinase inhibitor (TKI) therapy or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) that is resistant or intolerant to prior TKI therapy. The FDA had not been expected to complete its review until late March 2013.

CML is characterized by an excessive and unregulated production of white blood cells by the bone marrow due to a genetic abnormality that produces the BCR-ABL protein. After a chronic phase of production of too many white blood cells, CML typically evolves to the more aggressive phases referred to as accelerated phase and blast crisis. Ph+ ALL is a subtype of acute lymphoblastic leukemia that carries the Ph+ chromosome that produces BCR-ABL. It has a more aggressive course than CML and is often treated with a combination of chemotherapy and tyrosine kinase inhibitors. The BCR-ABL protein is expressed in both of these diseases.

Iclusig is a kinase inhibitor. The primary target for Iclusig is BCR-ABL. Iclusig was designed using Ariad's computational and structure-based drug design platform specifically to inhibit the activity of BCR-ABL. Iclusig targets not only native BCR-ABL but also its isoforms that carry mutations that confer resistance to treatment, including the T315I mutation, which is the most common mutation among resistant patients. Iclusig is the only TKI that is effective in CML and Ph+ ALL patients with this mutation.

"Within less than five years, we were able to bring Iclusig from the start of clinical development to U.S. approval, achieving a major milestone in Ariad's history. We have now transformed Ariad into a commercial oncology company addressing major unmet medical needs for cancer patients," stated Harvey J. Berger, M.D., chairman and chief executive officer of Ariad.

Additional clinical trials of Iclusig in other cancers are ongoing. Ariad is also studying AP26113, another molecularly targeted medicine, in certain forms of lung cancer. (Source: Ariad Website, 14 December, 2012)

FDA Grants QIDP Designation to Two Cubist Phase 3 Antibiotic Candidates

Cubist Pharmaceuticals has announced that the FDA has designated two of the company's Phase 3 antibiotic candidates, CXA-201 (ceftolozane/tazobactam) and CB-315, as Qualified Infectious Disease Products (QIDP). The QIDP designations will enable Cubist to benefit from certain incentives for the development of new antibiotics, including priority review, eligibility for fast-track status, and if CXA-201 or CB-315 are ultimately approved by the FDA, a five year extension of Hatch-Waxman exclusivity. These incentives are provided under the Generating Antibiotic Incentives Now Act (GAIN Act), which received strong bipartisan support in Congress and was signed into law by President Obama in July 2012 as part of the FDA Safety and Innovation Act (FDASIA), the fifth authorization of the Prescription Drug User Fee Act.

CXA-201 is currently being studied in pivotal Phase 3 trials as a first-line intravenous therapy for the treatment of complicated intra-abdominal infections and complicated urinary tract infections caused by Gram-negative bacterial infections, including those caused by multi-drug resistant Pseudomonas aeruginosa. The FDA's QIDP designation applies to CXA-201's treatment of complicated intra-abdominal infections. CB-315 is currently being investigated in Phase 3 trials as an oral therapy for Clostridium difficile-associated diarrhea, or CDAD.

"We are delighted that both of our Phase 3 antibiotic candidates, ceftolozane/tazobactam and CB-315, have received QIDP designation under the GAIN Act," said Cubist's Chief Scientific Officer Steve Gilman. "With antibiotic resistance rates on the rise and many companies having already left antibiotic R&D altogether, we believe the provisions of the bipartisan GAIN Act are a critical first step in our country's efforts to spur meaningful investment into this space." (Source: Cubist Website, 06 December, 2012)

Biogen Idec and Isis Pharmaceuticals Begin New Collaboration for Antisense Drugs

Biogen Idec and Isis Pharmaceuticals have announced that they have entered into a global collaboration agreement under which the companies will discover and develop antisense drugs against three undisclosed targets to treat neurological or neuromuscular disorders. Biogen Idec and Isis are also developing antisense drugs to treat spinal muscular atrophy and myotonic dystrophy type 1 under previously established collaborations.

"Our latest collaboration with Isis to discover and develop novel targets for the treatment of neurological disorders is a perfect fit within our early-stage research strategy," said Richard Brudnick, vice president and co-head of business development at Biogen Idec. "This will be our third collaboration with Isis, which is reflective of our respect for them as a partner and as a leader in antisense technology. By combining Isis' knowledge with Biogen Idec's expertise as a leader in neurology, we believe this latest discovery collaboration holds great potential for finding novel approaches to treating neurologic diseases."

Under the terms of the agreement, Isis will receive an upfront payment of $30 million and is responsible for the discovery of a lead antisense drug for each of the three undisclosed targets. Isis is eligible to receive substantial development milestone payments to support research and development of each program prior to the exercise by Biogen Idec of its option to license each program.

Biogen Idec has the option to license a drug from each of the three programs through the completion of Phase 2 trials. Isis could receive up to another $200 million in a license fee and regulatory milestone payments per program. In addition, Isis will receive double-digit royalties on sales of drugs.

Isis will be responsible for development of the drugs through the completion of the initial Phase 2 clinical trial, with Biogen Idec providing advice and assistance on research and the clinical trial design and conduct and regulatory strategy for each program. If Biogen Idec exercises its option, it will assume global development, regulatory and commercialization responsibilities. (Source: Isis Website, 10 December, 2012)

Amgen to Acquire deCODE Genetics, a Global Leader in Human Genetics

Amgen and deCODE Genetics announced that the companies have entered into a definitive agreement under which Amgen will acquire deCODE Genetics, a global leader in human genetics, headquartered in Reykjavik, Iceland. The all-cash transaction values deCODE Genetics at $415 million, subject to customary closing adjustments, and was unanimously approved by the Amgen Board of Directors. This transaction does not require regulatory approval, and is expected to close before the end of 2012.

"deCODE Genetics has built a world-class capability in the study of the genetics of human disease," said Robert A. Bradway, president and CEO at Amgen. "This capability will enhance our efforts to identify and validate human disease targets. This fits perfectly with our objective to pursue rapid development of relevant molecules that reach the right disease targets while avoiding investments in programs based on less well-validated targets."

Founded in 1996, deCODE Genetics is a global leader in analyzing and understanding the link between the genome and disease susceptibility. Using its unique expertise and access to a well-defined population in Iceland, deCODE Genetics has discovered genetic risk factors for dozens of diseases ranging from cardiovascular disease to cancer.

"One of the ways to truly realize the full value of human genetics, is to make our research synergistic with drug development efforts where target discovery, validation and prioritization efforts can be accelerated," said Kari Stefansson, M.D., Dr. Med., founder and CEO at deCODE Genetics. "We believe Amgen's focus and ability to incorporate our genetic research into their research and development efforts will translate our discoveries into meaningful therapies for patients." (Source: Amgen Website, 10 December, 2012)

Genzyme and Isis Provide Update on EMA Action on Kynamro (mipomersen)

Genzyme, a Sanofi company, and Isis Pharmaceuticals have announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a negative opinion for its marketing authorization application (MAA) for Kynamro (mipomersen) for the treatment of patients with Homozygous Familial Hypercholesterolaemia (HoFH). Genzyme plans to request a re-examination of the CHMP Opinion.

"We are disappointed by the Committee's recommendation. Patients with HoFH carry extreme, ongoing cardiovascular risk with significantly elevated LDL-C levels despite use of currently available therapies," said David Meeker, President and CEO, Genzyme. "This is a rare disease patient population, with a life-threatening condition, in need of new therapies. We will work closely with the CHMP during the re-examination process to address the Committee's concerns, with the goal of making this important medication available to HoFH patients in Europe."

"We believe that we have generated significant evidence in support of Kynamro," said B. Lynne Parshall, Chief Operating Officer and CFO of Isis. "Patients are in need of new options and we will continue to work with our colleagues at Genzyme toward the marketing approval of Kynamro."

An application for Kynamro is currently under review by the FDA. In October 2012, Kynamro received a positive vote by an FDA advisory panel that Genzyme had provided sufficient efficacy and safety data to

support the marketing of Kynamro for the treatment of patients with Homozygous Familial Hypercholesterolaemia (HoFH). (Source: Genzyme Website, 14 December, 2012)

Regulatory & Legislative Highlights

By Deepen Joshi, Sunovion Pharmaceuticals

Regulatory & Legislative Highlights, a regular feature of the Boston Area Chapter Newsletter. It reviews recent actions by the FDA and other regulatory agencies and governmental bodies, both federal and regional, with the potential to impact the pharma, biotech and device industries, and related fields.

FDA Approves Jetrea for Eye Condition

The FDA has approved Jetrea (ocriplasmin), the first drug approved to treat an eye condition called symptomatic vitreomacular adhesion (VMA). VMA can contribute to eye problems if the vitreous (jelly in the center of the eye) starts to move away from the macula (a part of the retina responsible for reading vision). This movement can lead to damage of the macula due to pulling or tugging on the macula.

Jetrea is an enzyme that breaks down proteins in the eye responsible for VMA. The breakdown of these proteins allows a better separation between the vitreous and macula and can reduce the chances that tugging will occur. The alternative treatment for this condition is a surgical procedure called a vitrectomy. Jetrea is manufactured by ThromboGenics based in Iselin, New Jersey. (Source: FDA Website, 18 October, 2012)

FDA Approves Fycompa to Treat Seizures

The FDA has approved Fycompa (perampanel) tablets to treat partial onset seizures in patients with epilepsy ages 12 years and older. Partial seizures are the most common type of seizure seen in people with epilepsy. Epilepsy is a brain disorder in which there is abnormal or excessive activity of nerve cells in the brain. Partial seizures affect only a limited or localized area of the brain, but can spread to other parts of the brain. Seizures cause a wide range of symptoms, including repetitive limb movements (spasms), unusual behavior, and generalized convulsions with loss of consciousness.

Fycompa, manufactured by Eisai Inc. of Woodcliff Lake, New Jersey, will be dispensed with a patient Medication Guide that provides important instructions on its use and drug safety information. (Source: FDA Website, 22 October, 2012)

FDA Approves Synribo for Chronic Myelogenous Leukemia

The FDA has approved Synribo (omacetaxine mepesuccinate) to treat adults with chronic myelogenous leukemia (CML), a blood and bone marrow disease. Synribo is intended to be used in patients whose cancer progressed after treatment with at least two drugs from a class called tyrosine kinase inhibitors (TKIs), also used to treat CML.

Synribo blocks certain proteins that promote the development of cancerous cells. It is injected subcutaneously twice daily for 14 consecutive days over a 28-day cycle until white blood cell counts normalize (hematologic response). Synribo is then administered twice daily for seven consecutive days over a 28-day cycle as long as patients continue to clinically benefit from therapy.

Synribo was approved under the FDA's accelerated approval program, which allows the agency to approve a drug to treat a serious disease based on clinical data showing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit to patients. This program provides earlier patient access to promising new drugs while the company conducts additional clinical studies to confirm the drug's clinical benefit and safe use. Synribo also received orphan-product designation by the FDA because it is intended to treat a rare disease or condition. Synribo is marketed by Teva Pharmaceuticals, based in Frazer, Pennsylvania. (Source: FDA Website, 26 October, 2012)

FDA Issues 483 Following Inspection at Framingham Compounding Facility

The FDA released a copy of the FDA Form 483 issued to the New England Compounding Center (NECC). The FDA observed and has since confirmed contaminated products and listed a number of observations regarding conditions in the clean room at NECC's Framingham facility.

The investigators also observed problems with NECC's ability to maintain its clean room, which is the enclosed space that is designed and maintained to have a controlled environment with low levels of airborne particles and surface contamination. Production of sterile drug products in a properly functioning and maintained clean room reduces the risk of the introduction of microbial contamination into the drug during processing, including filling into its final container.

The FDA issues a 483 at the end of an inspection when the investigators believe that they observed conditions or practices that, in their judgment, may indicate violations of the Federal Food, Drug, and

Cosmetic Act, or related regulations.

The 483 does not constitute a final FDA determination that any observation listed on the 483 is a violation of the Federal Food, Drug, and Cosmetic Act or any related regulations.

The FDA considers the 483 along with an Establishment Inspection Report (EIR), prepared by FDA investigators, and any other relevant information, including any responses received by the company. The agency then considers whether further action, if any, is appropriate. The inspection report for NECC has not been completed and is not being shared at this time.

The FDA continues to work closely with the Centers for Disease Control and Prevention and state partners, including the Massachusetts Board of Registration in Pharmacy, to investigate the outbreak of fungal meningitis among patients who received NECC's compounded preservative-free methylprednisolone acetate (80mg/ml), an injectable steroid. (Source: FDA Website, 26 October, 2012)

FDA Reports Voluntary Recall of All Ameridose Drug Products

The FDA has announced that Ameridose, LLC, based in Westborough is voluntarily recalling all of its unexpired products in circulation. A complete list of all products subject to this recall can be accessed at www.ameridose.com.

The FDA is currently conducting an inspection of Ameridose's facility. Although this inspection is ongoing, the FDA's preliminary findings have raised concerns about a lack of sterility assurance for products produced at and distributed by this facility. Use of non-sterile injectable products can represent a serious hazard to health that could lead to life-threatening injuries. Most products produced at and distributed by this facility are represented by Ameridose to be sterile products. Ameridose entered into a voluntary agreement with the Massachusetts Board of Registration in Pharmacy to cease all pharmacy and manufacturing operations starting on October 10, 2012.

The FDA has identified some Ameridose products that currently appear on the critical shortage list. These products were in shortage before the Ameridose recall, but supplies may be further affected as a result of the Ameridose recall. The FDA is working with alternative manufacturers to maintain supplies of these life-saving drugs. (Source: FDA Website, 31 October, 2012)

FDA Expands Use of Xarelto to Treat, Reduce Recurrence of Blood Clots

The FDA has expanded the approved use of Xarelto (rivaroxaban) to include treating deep vein thrombosis (DVT) or pulmonary embolism (PE), and to reduce the risk of recurrent DVT and PE following initial treatment.

Blood clots occur when blood thickens and clumps together. DVT is a blood clot that forms in a vein deep in the body. Most deep vein blood clots occur in the lower leg or thigh. When a blood clot in a deep vein breaks off and travels to an artery in the lungs and blocks blood flow, it results in a potentially deadly condition called PE.

Xarelto is already FDA-approved to reduce the risk of DVTs and PEs from occurring after knee or hip replacement surgery (July 2011), and to reduce the risk of stroke in people who have a type of abnormal heart rhythm called non-valvular atrial fibrillation (November 2011). The FDA reviewed Xarelto's new indication under the agency's priority review program, which provides an expedited six-month review for drugs that offer major advances in treatment or that provide treatment when no adequate therapy exists.

Other drugs approved by FDA to treat or reduce the risk of blood clots include Lovenox (enoxaparin), generic versions of enoxaparin, Arixtra (fondaparinux), Fragmin (dalteparin), Coumadin (warfarin), and heparin.

Xarelto is marketed by Janssen Pharmaceuticals based in Raritan, New Jersey. (Source: FDA Website, 02 November, 2012)

FDA Approves Xeljanz for Rheumatoid Arthritis

The FDA has approved Xeljanz (tofacitinib) to treat adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to, or who are intolerant of, methotrexate. RA is an autoimmune disease, in which the body's immune system mistakenly attacks healthy tissue leading to inflammation of the joints and surrounding tissues.

According to the Centers for Disease Control and Prevention, RA affects an estimated 1.5 million Americans. Xeljanz, a pill taken twice daily, works by blocking molecules called "Janus kinases," which are important in the joint inflammation of RA.

The use of Xeljanz was associated with an increased risk of serious infections, including opportunistic infections (infections that occur primarily when the immune system is suppressed), tuberculosis, cancers and lymphoma. Xeljanz carries a Boxed Warning regarding these safety risks. Xeljanz treatment is also associated with increases in cholesterol and liver enzyme tests and decreases in blood counts.

The FDA approved Xeljanz with a Risk Evaluation and Mitigation Strategy (REMS), which consists of a Medication Guide advising patients about important safety information and a communication plan to inform health care providers about the serious risks associated with Xeljanz. Xeljanz is marketed by New York-based Pfizer Inc. (Source: FDA Website, 06 November, 2012)

FDA Approves Pump for Patients Awaiting Heart Transplant

The FDA has approved the HeartWare Ventricular Assist System, a left ventricular assist device (LVAD), to support heart function and blood flow in patients with end-stage heart failure who are awaiting a heart transplant. The HeartWare Ventricular Assist System is manufactured by Framingham-based HeartWare Inc.

An LVAD is a mechanical pump used to support heart function and blood flow in people who have weakened hearts. LVADs are the most common type of ventricular assist devices, and they help the heart's left ventricle pump oxygen-rich blood to the body. The HeartWare System includes an implantable pump with an external driver and power source and is designed for use inside or outside the hospital.

Heart failure occurs when the heart is unable to pump blood normally throughout the body. Factors that can lead to heart failure include high blood pressure, narrowing or blockages in the heart's blood vessels, and heart infections. Heart failure is considered end-stage when the underlying condition remains severe and no longer responds to medical therapy or other treatment options. Those with end-stage heart failure may need a heart transplant to survive. LVADs can be used as a "bridge" therapy for these patients until a suitable donor heart becomes available. (Source: FDA Website, 20 November, 2012)

FDA Approves First Flu Vaccine Manufactured Using Cell Culture Technology

The FDA has announced the approval of Flucelvax, the first seasonal influenza vaccine licensed in the United States produced using cultured animal cells, instead of fertilized chicken eggs. Flucelvax is approved to prevent seasonal influenza in people ages 18 years and older.

The manufacturing process for Flucelvax is similar to the egg-based production method, but a significant difference is that the virus strains included in the vaccine are grown in animal cells of mammalian origin instead of in eggs. Cell culture technology has already been in use for several decades to produce other U.S. licensed vaccines.

Cell culture technology is another manufacturing alternative to conventional egg-based influenza vaccine production. Advantages of cell culture technology include the ability to maintain an adequate supply of readily available, previously tested and characterized cells for use in vaccine production and the potential for a faster start-up of the vaccine manufacturing process in the event of a pandemic. Flucelvax is manufactured by Novartis Vaccines and Diagnostics GmbH of Marburg, Germany. (Source: FDA Website, 20 November, 2012)

FDA Approves Cometriq to Treat Rare Type of Thyroid Cancer

The FDA has approved Cometriq (cabozantinib) to treat medullary thyroid cancer that has spread to other parts of the body (metastasized). Medullary thyroid cancer develops in cells in the thyroid gland that make a hormone called calcitonin, which helps maintain a healthy level of calcium in the blood. This type of cancer may occur spontaneously or in families with certain genetic mutations that result in one or more cancers of the endocrine system, including the thyroid gland.

The FDA completed review of Cometriq's application in six months under the agency's priority review program. This program provides for an expedited six-month review for drugs that may offer major advances in treatment or that provide a treatment when no adequate therapy exists. Cometriq also received orphan-product designation by the FDA because it is intended to treat a rare disease or condition.

The prescribing information for Cometriq includes a Boxed Warning alerting patients and health care professionals that severe and fatal bleeding and holes (perforations and fistula) in the colon occurred in some patients. Cometriq is marketed by Exelixis, based in South San Francisco. (Source: FDA Website, 29 November, 2012)

FDA Announces Public-Private Partnership to Speed Access to New Medical Devices

The FDA has announced that it is part of the first public-private partnership to promote medical device regulatory science with a focus on speeding the development, assessment, and review of new medical devices.

The new Medical Device Innovation Consortium (MDIC) is an independent, nonprofit corporation, created by LifeScience Alley (LSA), a biomedical science trade association. The MDIC will receive input from industry, government, and other nonprofit organizations. MDIC will prioritize the regulatory science needs of the medical device community and fund projects to help simplify the process of medical device design and

pathway to market for these innovations.

The MDIC will bolster the country's investment in regulatory science research by pooling people, funding, resources, and ideas to develop new tools, models, and methods that may be utilized to better and more efficiently evaluate new devices. FDA staff may collaborate with the MDIC on MDIC-supported research and other projects. (Source: FDA Website, 03 December, 2012)

FDA Expands Zytiga's Use for Late-Stage Prostate Cancer

The FDA expanded the approved use of Zytiga (abiraterone acetate), a pill that decreases the production of the male sex hormone testosterone, to treat men with late-stage (metastatic) castration-resistant prostate cancer prior to receiving chemotherapy. The FDA initially approved Zytiga in April 2011 for use in patients whose prostate cancer progressed after treatment with docetaxel, a chemotherapy drug.

In prostate cancer, testosterone stimulates prostate tumors to grow. Drugs or surgery are used to reduce testosterone production or to block testosterone's effects. Some men have castration-resistant prostate cancer, meaning the prostate cancer cells continue to grow even with low levels of testosterone.

The FDA reviewed Zytiga's application for this new indication under the agency's priority review program. The program provides for an expedited six-month review for drugs that may offer major advances in treatment or provide a treatment when no adequate therapy exists. Zytiga is marketed by Janssen Biotech based in Horsham, Pennsylvania. (Source: FDA Website, 10 December, 2012)

Health Canada Approves Vertex Drug for Cystic Fibrosis

Vertex Pharmaceuticals has announced that Health Canada has approved Kalydeco (ivacaftor), the first medicine to treat the underlying cause of cystic fibrosis (CF), for people ages 6 and older who have at least one copy of the G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

Cystic fibrosis is a rare genetic disease for which there is no cure. It is caused by a defective or missing CFTR protein resulting from mutations in the CFTR gene. In people with the G551D mutation, Kalydeco helps the defective or missing CFTR protein to function more normally. Approximately 100 people in Canada with CF are believed to have this mutation.

The gene that causes CF was identified in 1989 as a result of collaborative research led by Lap-Chee Tsui, Ph.D., and Jack Riordan, Ph.D., at The Hospital for Sick Children in Toronto and Francis Collins, M.D., Ph.D., at the University of Michigan. Kalydeco was discovered as part of a collaboration with Cystic Fibrosis Foundation Therapeutics, the non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation.

In 2009, Vertex established a research and development site in Laval, Quebec through the acquisition of Virochem Pharma. Vertex employs approximately 50 researchers and support staff in Laval and has established Commercial and Medical teams in Canada, including an expansion to support the launch of Kalydeco. (Source: FDA Website, 03 December, 2012)

New Members

Jay Ankers, *Director of Technology,* M+W US Inc

Mr. Johnathan W. Antonizio, *Process Engineer II,* Shire

Mr. Kenneth Bernstein, Blind Biosciences

Mr. Richard Bixby, *Vice President,* Magna-Safe International Inc

Daniel Boyd, *Director, Capital Projects and Capital Management*

Mr. Ben P. Burds, *Estimator,* Schneider Electric

Mr. Joseph D'Alton, *President,* Surplus Solutions

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Dr. Abu Ferdous, *Sr. Scientist II,* Millennium Pharmaceuticals

Ms. Christina A. Herron, *Director of Business Developement,* AHP Architects

Mr. David E. Hohrath, *Manufacturing Engineer,* Life Technologies

Ms. Tiffany Hubanks, *Senior Business Development Manager,* Gilbane Building Company

Ms. Jane F. Kepros, *Lab Planner,* Perkins + Will

Mr. Mark Levanites, *NE Regional Manager,* Sequence Validation Inc.

KerriAnn MacNeill, *Engineer II, Plant,* Biogen Idec

Thomas Murphy, *Sales,* Lewa Inc.

Kristy Nevens, *Business Systems Analyst,* Genzyme

Mr. Christopher S. Peterman, *Process Engineer,* Lonza Biologics Inc

Ms. Juliana M. Rose, *Process Engineer,* DPS Biometics

Heather Schwalje, *Consultant,* Emerson Process Management

Aayush Seth, *Marketing Analyst,* Microfluidics Corporation

Mr. Jeffrey M. Simeone, *Senior Engineer,* Biogen Idec

Jean Skarbek, *Manager SWTQM,* PAREXL

Mr. Prisco Tammaro, *Mechanical Engineer,* CRB Engineering

Mr. Daniel Turcott, P.E., *Manager,* Design Group Facility Solutions

Issoufou Yacouba-Issa, Sr., Roxbury Community College

Member Anniversaries

Join us in celebrating the 5, 10, 15 and 20+ year anniversaries of Boston Area Chapter Members. Congratulations to all of our long term Chapter members - your loyalty helps make us successful, year after year!

20+ Years of Membership

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Mr. John P. Alleruzzo

Mr. Richard Caires, Jr., Shire Human Genetic Therapies

Mr. Richard P. Capobianco

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Mr. Michael S. Cheney, Biogen Idec

Ms. Denise R. Connelly, Genzyme Corp

Dr. Charles L. Cooney, Massachusetts Institute of Technology

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Mr. Daniel J. Dumont, Dynamic Systems Inc

Mr. George C. Enos, Aztec Technologies Inc

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Mr. David G. Harney, Microfluidics

Ms. Shelly Henderson, NNE Pharmaplan

Mr. Stephen R. Higham, PE, Genzyme Corp

Mr. David L. Hyde, Lantheus Medical Imaging, Inc.

Mr. Thomas R. Jerome

Mr. Robert W. Juffras, MS, Olympus Biotech

Mr. Jerome E. Justin, Shire HGT

Peter F. Levy, PL Consulting, LLC

Dr. Richard V. Levy, PDA

Mr. Dwight C. Long, Integra Companies Inc

Mr. Frank J. Manning, VNE Corp

Mr. Daniel J. Mariani, M+W Group

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Mr. Christopher R. Perley, Biotech Ops Consultants

Mr. Stephen R. Potter, Baxter

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Mr. Stanley E. Rotkiewicz, Jr., Genzyme Corporation

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Mr. Pasquale M. Sacco, Shire HGT

Mr. Hooman F. Sajedian, Pfizer Inc

Mr. Robert J. Sheehan

Mr. Alexander E. Smith, Jr., M+W U.S., Inc.

Mr. Jonathan F. Stenbuck, Stenbuck Enterprises

Mr. Robert P. Vecchione, Christ Aqua Pharma & Biotech NA

Mr. James D. Vogel, PE, The BioProcess Institute

Mr. Lawrence W. Weiner, Biogen Idec

Mr. Jack N. Wentz, Lantheus

Mr. David A. Wilson, Abbott Bioresearch Center

Mr. Gary V. Zoccolante, Siemens Water Technologies Corp

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Mr. Erik M. Caldwell, Northeast Water Svcs, Inc.

Mr. James J. Hanly, Thermax Inc

Mr. Jay A. LeClerc, MBraun Inc

Mr. Christopher R. Mansur, OPK Biotech

10 Year Anniversary

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Mr. Albert A. Marquez, Jr., Marquez Process Service, Inc.

Mr. Matthew Niloff, Xcellerex LLC

Mr. Mark P. Tarricone, Northeast Electrical Distributors

5 Year Anniversary

Monica J. Cahilly, Green Mountain Quality Assurance, LLC

Ms. Virginia Corbin, Waters Corporation

Mr. Nicholas A. Morin, Notch Mechanical Constructors

Mr. Kenneth R. White, Richard White Sons Inc

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