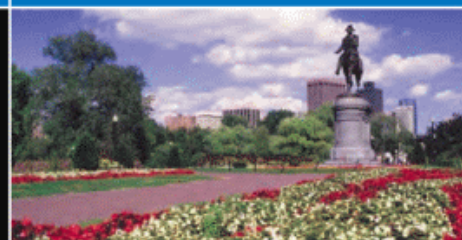
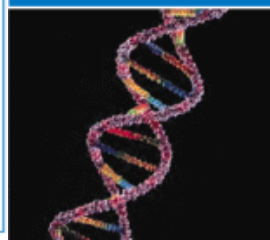




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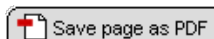


NEWSLETTER

February 2009, Volume XIX, No. 1

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President's Message:

What is the Boston Area Chapter doing to Help Members Survive the Down Economy?

Dear ISPE Boston Area Chapter Members,

The Boston Area Chapter hasn't figured out how to get the banks to lend money again, but we're working on other ways to help our members get through this economic storm.

Networking is an important part of the Chapter's mission and even more important in a down economy with an uncertain job outlook. As an example of the Chapter's commitment, I've just come back from our Annual Holiday Party, held at Flat Top Johnny's in Cambridge, where over a hundred attendees gathered to socialize and share information with their peers in the industry. This event also served as a benefit for the Marine Parents Care Package Project, with attendees donating items that will be sent to a facility in Missouri for shipment to Marines in Iraq and Afghanistan. Since my son David is now a Marine (serving at the moment in North Carolina, for which his parents are very thankful) this Care Package Project has special significance for me. Thanks to Sylvia Beaulieu for thinking of it and to all of you for donating so many useful items.



There was recent news from Pfizer of the layoff of as many as 800 researchers, 5-8 percent of its 10,000 research employees. Instead of creating new drug products in house, Pfizer will now have to acquire more new products by purchasing IP or entire small companies such as those flourishing here in the Boston area. Many of the major pharmaceutical companies are facing the same problem, with their older products (that generated so much cash) coming off patent and little in the pipeline to replace them. Take a look at "Top Six Layoffs of 2008" at <http://www.fiercepharma.com/special-reports/top-5-layoffs-2008> - locally important companies such as Wyeth, AstraZeneca, and Abbott all figure in this list. In a way, this trend could bode well for some of our members in the Boston area since many of the small, innovative companies and products that Big Pharma wants to buy are here. Furthermore, Big Pharma has the cash in hand so their acquisitions of smaller firms can proceed in spite of the lousy credit markets.

In addition to sponsoring networking events, what else is ISPE doing to respond to these conditions? For one, if you do become unemployed ISPE waives your membership fee until you find employment, provided you have been a member for at least five consecutive years. Many of our local members come from Big Pharma companies and we have seen a number of them become unemployed recently. And even more people have some concern about the stability of their company or the security of their job. For those who are unemployed - or simply keeping an eye out for new opportunities - ISPE is offering a new "Career Exchange" page on the Chapter's website. Visit http://www.ispe.org/cs/boston_area_chapter_section/boston_area_chapter_career_exchange to post your resume or learn about job openings in the local area and beyond. And speaking of those resumes, our Membership Services Committee sees a need for a "Let's Help You Spruce Up Your Resume, Sharpen Your Interview Skills and Help You Get A New Job" networking party/event (we are still working on the title). We hope to gather a mix of professionals in the recruiter/HR field and experienced fellow ISPE members to help make this a very useful and fun evening. Look for it on the Events Calendar soon.

With many companies cutting back on travel expenses, ours is one of the first Chapters to pilot a new initiative whereby we rent educational programs from the International Society and use their materials and speakers to offer those programs locally, either for one company or for the general population. Our first session of this type was "Biotechnology 101" taught by Jeff Odum at Shire and it was very well received. Mike Denault is organizing this effort and we plan to have a similar course open to the public in the spring.

We held an excellent seminar entitled "Keeping It Clean - Sanitary Pumps" out in Devens on November 18th (see the article in this issue). The high attendance makes me think we're on to something by trying to hold more Chapter events outside Route 128 and keeping meeting fees lower. More of our members now work outside the 128 belt and we want to make it convenient for you to network and learn, without worrying about traffic or parking. In addition, we have recently reduced our registration fees, charging \$20-25 instead of \$50 or more to attend these sessions. This lower price does not cover the cost of the room and food but we want more of our members to be able to attend, even if their companies have decided not to reimburse them. Check the Chapter's Web page or the "Mark Your Calendar" section of this newsletter for upcoming events.



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Finally, we have begun an initiative to encourage younger professionals to participate more actively in ISPE and we are calling this the Young Professionals Initiative (YPI). This group, still in its formative stages, is already busy planning events to appeal to the 25-35 year old professional in terms of content and ambiance. And it's still looking for members. Read the article in this issue of the newsletter and watch for more to come on our Web page.

As always, we are looking for people who would like to volunteer their services - contact the office at ISPE@camhq.com if you're interested in helping. You're also welcome to drop me a line and let me know what you think. My personal email address is below.

Sincerely,

Doyle Johnson

President, ISPE Boston Area Chapter
bioengr@mac.com

Upcoming Events - Mark Your Calendar!

Thursday, February 5, 2009

Young Professionals Meeting

6:00 pm to 9:00 pm

Flat Top Johnny's Billiards

Kendall Square, Cambridge, Massachusetts

Tuesday, February 17, 2009

ASTM E2500 Standard and Its Use in the Real World

Biogen Idec, Cambridge, Massachusetts

Speakers:

Robert Chew, Commissioning Agents, Inc.

Robert Smith, Parsons Corporation

Click here for full information and to download a registration form -

http://www.ispe.org/galleries/boston-files/Feb17_09_ProgramFlyer.pdf

March 2 - 5, 2009

ISPE Tampa Conference

Grand Hyatt, Tampa Bay, Florida

Click here for full information and to register -

http://www.ispe.org/cs/2009_ispe_tampa_conference/2009_ispe_tampa_conference

Friday, March 6, 2009

Annual Ski Trip

Loon Mountain, New Hampshire

Wednesday, March 11, 2009

Magnetic Nanoparticles in Bioprocessing

Joint Meeting with Massachusetts Institute of Technology, Professional Institute

Location to be determined

Tuesday, April 21, 2009

Business Partnering and Contract Manufacturing

Royal Sonesta, Cambridge, Massachusetts

Thursday, June 18 - Friday, June 19, 2009

Spring Training

Radisson Hotel, Boston, Massachusetts



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Monday, August 17, 2009
7th Annual Golf Tournament
Ferencroft Country Club, Middleton, Massachusetts

Wednesday, October 7, 2009
Annual Product Show
Gillette Stadium Clubhouse, Foxborough, Massachusetts

Members Visit Devens for “Keeping It Clean – Sanitary Pumps 101”

by Jim Verhulst

On November 18, 2008, members of the Boston Area Chapter traveled west to Devens, MA to attend an educational seminar presented at the pleasant and spacious conference center of the Springhill Suites Hotel. This time the subject was sanitary pumps, with the program developed especially for engineers, validation, and quality personnel who have recently entered the biopharmaceutical workplace and who wanted to learn the basics of sanitary pump design and operation. Perhaps because of its location, or perhaps because of its topic, a somewhat different cross section of members was present than at similar seminars held in Cambridge.

The speakers for the evening were two veterans of the pump and mechanical seal business, Allen LeBoeuf, Product Manager for Oliver M. Dean and Mark Atkinson, District Sales Manager for Watson-Marlow Bredel Pumps. Allen began by walking the group through the basic steps of choosing either a centrifugal or a positive displacement rotary lobe pump for a hygienic pumping application. The discussion centered around how each pump design works and which technology to use for a specific fluid. It also covered the operation and control considerations, critical piping design issues, pump efficiency, pump metallurgy considerations, and how to evaluate pump designs that require optimum clean-ability, drain-ability and CIP-ability. Numerous photographs and cut away diagrams of the pump internals helped to illustrate how design affects function and usability.

These two types of pumps work well in very different situations and understanding where to apply which type is important. For example, centrifugal pumps work best for low viscosity fluids. The reverse is true for rotary lobe pumps; they work best when the fluid viscosity is above 500 Cps. Centrifugal pumps are best suited for medium to high flows at moderate pressures. Rotary lobe pumps are better suited for low to medium flows at medium to high pressures. Rotary lobe pumps can also deliver very precise flow rates under the right conditions.

Material of construction is an important issue for sanitary pumps. Biotech applications generally favor type 316L stainless steel with polished or electropolished finishes. Elastomers in the pumps are usually the same as the rest of the piping system. Well-designed sanitary pumps can meet 3A, BPE, and other industry standards. Specifying the correct pump seal is also a critical issue. Most sanitary pump seals are of a hydraulically balanced design. This enables the seal to handle pressure spikes, and reversal of flow without contamination problems.

One huge area for potential operational problems is piping design. Suction conditions at the pump must be well understood. Allen stated that a good rule of thumb is to remember that the fluid needs to be able to get to the pump suction, under sufficient pressure (no vaporization), as fast as the pump wants to take it. If flow is restricted, the pump will cavitate, a condition in which the fluid first forms bubbles which then collapse near the impeller causing destructive mechanical abrasion. Allen presented photographs that showed how cavitation can quickly ruin a pump.

Rotary lobe and centrifugal pumps vary greatly in power consumption and efficiency. Positive displacement pumps are generally highly efficient, typically in the 90 to 99 percent range. Centrifugal pumps are much simpler in design, but their efficiencies seldom exceed 70 percent. In some instances, efficiencies as low as 10 percent have been observed.

There are also big differences in cleanability, drainability, and CIP-ability. Centrifugals should be checked for 3A or similar certification, internal finish, low point drains, and the way gaskets and O-rings are used. Positive displacement pumps should include vertical porting, drainable cusps, and a smooth, flat, flush rotor case. Engineers specifying either type of pumps should examine the mechanical seal position to be sure it is cleanable.

Our second presenter for the evening, Mark Atkinson, is an expert on peristaltic pumps. His presentation covered the basic application and installation information required to successfully specify a peristaltic pump. After explaining how a peristaltic pump works, Mark got into the features of this type of pump and what to specify. Peristaltic pumps have a wide performance range. They are, however, best suited for low to medium flows at low to moderate pressures. They are low shear so that they do not damage the fluid being pumped, and they can be used for fluid metering applications. These types of pumps are also self-priming, can handle mixed-phase flow, and can be run in reverse if required. They have no mechanical seals and can be completely sanitary, even sterile, because there is no contact between the pump and the product - only the tubing is wetted.

In specifying a peristaltic pump, one needs to determine the required flow rate, the pressure at both suction and discharge, the fluid being pumped, and the duty cycle. Peristaltic pumps are manufactured in many different sizes with different types of controls. Many are used in the lab where only manual adjustment of the pump speed is needed, but they can also be supplied with sophisticated computer control interfaces for manufacturing floor applications.



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The flexible tubing used in a peristaltic pump is a disposable element and in many ways determines what a pump can do. Tubing selection should be based on the pressures and flow rates required, the fluid being pumped, whether autoclaving is required, and the required duration of use.

Both presentations were very well received by the audience, who used the Q&A sessions to further clarify a few points. All in all, the evening was good chance to learn some pump basics while meeting old friends and making new acquaintances during the networking reception.

Another Memorable New Year's Party at Flat Top Johnny's

by Christopher Ciampa with photos by Doyle Johnson and the author

Once again erasing any doubt that the ISPE Boston Area Chapter isn't solely focused on professional/educational events, the annual Holiday Social was held at Flat Top Johnny's Billiards in Kendall Square on January 15th, 2009. This date has become a tradition (the Holiday Social used to be held in December but that changed thanks in part to the ill-timed blizzard of 2007) and, thankfully, the weather did cooperate! This annual gathering of the brightest minds in the life sciences again drew over a hundred guests from a cross-section of the Chapter's membership, with operating companies, academic and research institutions, vendors and contractors all well represented.



Flat Top Johnny's provides a comfortable backdrop for January's Holiday Party.

Guests were treated to an array of hearty hors d'oeuvres: finger sandwiches, beef teriyaki, egg rolls, meatballs, potato skins and buffalo tenders. Not to mention warm chocolate chip cookies for dessert. The food was plentiful and enough to satisfy both your typical process engineer and water analysis consultant. Even better than the food was the constant buzz of conversation regarding the latest what's what and who's who in the industry. And some folks even shared ideas for other types of Chapter social events, including a bowling night and a fishing trip. One thing is certain: members of the Boston Area Chapter don't lack for ideas when it comes to future social events!

In addition to food, drink and conversation, there were raffles and prize giveaways throughout the evening sponsored by A/Z Corp, Columbia Construction, CRB Consulting Engineers, F.W. Webb, GxP Automation, RDK Engineers, Sentrol and Spectra Automation. Prizes included gift cards to Capital Grille and Legal Sea Foods, and Bruins or Celtics tickets! Not only did the Chapter reward its valued members, it also used the Social as a benefit for the Care Package Project sponsored by Marineparents.com, an organization devoted to supporting marines overseas. Attendees donated requested items such as single-use cameras, toiletries, batteries and food items for shipment to marines in Iraq and Afghanistan.

Along with the raffles and prizes, attendees were treated to a speech by Chapter President Doyle Johnson, who daringly "took the stage" (and set a new Chapter precedent) by standing on a high chair, hoping not to fall off! A great speech - Doyle thanked people for attending and being a part of the Boston Area Chapter. Following Doyle, Dan Ramsey introduced the Young Professionals Initiative (YPI), a venture that is being

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Brian Hagopian of MARCOR, Dan Rufo of MassBioLogics and Sharon Jozkos of Berry Construction (left to right) compare notes on a joint project.

piloted by the Boston Area Chapter.

Dan explained that the initiative is just getting underway and is looking to expand its membership. Its goals are to provide younger Chapter members a chance to network with one another and to develop programs geared towards people who are fresh in their

careers. It may even go as far as to reach out to the ISPE Student Chapters whose members may end up joining ISPE upon graduation and will look for new ways to "bridge the gap" between students and young professionals and the Chapter's seasoned members. (Currently, the majority of ISPE programs are geared towards seasoned professionals already well-established in their careers.)

Who says scientists, engineers and validation specialists don't know how to party? Once again, the Chapter proved that its hard-working members are interested in having fun, not to mention networking with their peers in the industry. Networking is even more important in these difficult times, with the economy weak and the job outlook uncertain, and the Chapter does a wonderful job of getting everyone together to share information with contacts both old and new.



Steve Kennedy of Parsons, Larry Weiner of Biogen and George Price of Shire HGT (left to right) share industry news.

Many thanks to the sponsors of this event and to the many hard-working Chapter volunteers who made this tremendous night possible. Kudos to you! We're already looking forward to next year!

LEED – The Path to Environmental Enlightenment

by Lee J. Ward with photos by Doyle Johnson

January 20th saw the ISPE Boston Area Chapter host a program designed to whet your appetite. The often discussed but not widely understood subject of LEED was tackled from two different perspectives and delivered to a mixed audience of facility owners, supporters and generally interested attendees.

Realizing the Value of LEED

The first presenter of the evening, Mr. Fred Doherty, LEED AP and Certified Energy Manager, approached the subject based on the definition of LEED and what is generally understood by this far reaching concept. He then went on to describe what LEED will *not* do for a facility. "It's all about the need to attain a desired level and the process you take to get there," explained Doherty, as it became clear that there are implications and hidden secrets to LEED than are not apparent at first.

Fred proceeded to educate the audience on the areas of interest LEED initiatives can delve into, then quickly turned to the subject of cost as attendees asked questions regarding the perceived "On Cost" of pursuing a LEED project. This prompted Fred to adopt a more light-hearted tone and neatly segue onto the subject of energy and how we all curse the energy companies for their high prices and equally high profits, likening them to being the "devil." Fred was then swift to point out that these companies themselves are targeted to reduce their output.

The presentation then took a turn in a related direction: how the energy companies actively compensate end users for employing energy efficient systems in their facilities. Fred explained that this gives energy companies a direct impact on the cost of implementing LEED design in a new or existing

structure. He then quickly disavowed his original disparaging comment and proclaimed, "In fact, energy companies are *not* the devil. They can help fund these initiatives, leading to long term cost reduction and sustainability."

Next, Fred focused on a subject with a serious impact on all of us, the subject of "carbon footprint" and how each and every consumer will begin to feel the effect of its reach in all that we buy or use. He went on to explain how this concept will begin to creep into legislation, as it has done in other major economies throughout the world, and the financial impact this will have. This, in turn, bought us cleanly back to the subject matter we began with and the simple message that could help us all. Namely, that what we do now by employing green initiatives will help defer the impact of carbon taxation in the future.

This ended the first presentation and opened up the room to questions, all of which were met with the enthusiasm I have come to admire in Fred. He tackled each question head on and offered to discuss various specifics directly with individuals at the end of the night.

LEED Certification Overview

The second presenter of the evening, Ms. Susan Dieker, an MBA and LEED Accredited Professional focused on Commercial Interiors, approached the subject from an entirely different perspective. Susan focused her presentation on the process involved in gaining accreditation and the associated requirements and pitfalls. In complete contrast to the first presentation, Susan added her own brand of entertainment to the proceedings. In an Educational Program Committee first, she introduced an interactive element that tested the ability of the attendees to absorb the information presented and measured their answers to specific questions.



Presenter Susan Dieker and audience member Arturo Blanquera.



Attendees included Shannah Schodle and Gordon Leichter from the Delaware Valley and New Jersey Chapters, respectively.

At one point, Susan asked the audience a multiple choice question regarding the program. Amazingly only 5 percent indicated that they were attending for the "social" aspects of the event, a great endorsement for the choice of subject matter. Statistics are not my thing, let me tell you, however it is interesting to note how my concentration and interest level increased when I knew I would be faced with a question requiring a "public" answer. This concept certainly added another dimension to the program, an idea we would certainly like to explore in a future program.

Susan proceeded to enlighten us all by providing detailed insight into the differing requirements and who or what resource to engage when faced with the daunting prospect of attaining LEED certification. Useful Web sites and online templates, as well as some of the associated costs, were all made clear to the audience.

In summary, a lot of valuable information was delivered over the course of the evening to a very discerning audience. Excellent as the presentations were, they only just "broke the ice" with respect to this new and exciting topic. The Educational Program Committee plans to further explore the practical aspects of LEED with two other events to be scheduled over the course of 2009. Be sure to look for them as the year progresses.

YPI to Grow the Presence of Young Professionals within ISPE

by Jim Grunwald with photo by Doyle Johnson

Since the last issue of our Newsletter, the Young Professionals Initiative (YPI) has met a number of times to set a course for the year. The YPI Charter includes creating a forum for young professionals (post-graduate to 35) to expand their knowledge and network within our industry.



YPI Member Dan Ramsey enjoys a word with former Chapter President Dave Novak of AMEC.

To date the planning meetings that have been held have been used to generate interest in forming a core group that is now beginning to plan this year's programs and establish the goals and roadmap needed to grow the presence of young professionals within ISPE locally and nationally. Of special note was the assistance that the core YPI group provided with the planning and execution of the very successful Holiday Social at Flat Top Johnny's on January 15th.

If you are interested in learning more about this initiative or have young professionals within your organization who would like to gain more insight into the opportunities that abound within ISPE and our industry, please contact me at jgrunwald@a-zcorp.com for more information.

Tech Talk:
Improve Your Plant's Efficiency and Reduce Cost with Variable Speed Drives

by Andre L. Narbonne

Equipment driven by electric motors often operates at less than full capacity. The motor may turn on and off or there may be a clutch mechanism to disengage the motor to match the equipment's power requirements. Either design wastes energy compared to a variable speed drive (VSD), which changes the frequency and voltage of the electric power that drives the motor so that the output of the motor matches the capacity requirement. This study shows the benefits of using a VSD oil-free air compressor compared to a standard oil-free air compressor and provides lessons that can be applied elsewhere in a production facility. For example, VSDs are seeing more application in centrifugal chillers (as opposed to inlet vane control), cooling towers (for fan speed control based on temperature), circulating pumps, and HVAC fans.

In this case study, clean air is produced by two oil-free rotary screw air compressors. One serves as the primary while the other is the backup. These roles are automatically switched weekly to balance the wear on the two machines and to ensure the backup is always operational.

In March, 2008 one of the oil-free screw-type air compressors experienced a problem. One of the air ends had seal leakage that required a major repair. Although the repair would be covered under warranty, we conducted a study to quantify the benefits of an oil-free VSD compressor. Compressed air is known to consume 15 percent of the average manufacturing plant's electricity. This, and the recent increases in energy costs, suggested there could be a significant opportunity for savings.

An important consideration is the cost of electricity to power the 50 hp motor of the air compressor. At \$0.13 per kWh electricity cost:

Electricity cost (\$/yr)

$$= \text{Motor Size (hp)} \cdot 1/\text{Power Factor or Efficiency} \cdot \text{Conversions (hr/yr) (kW/hp)} \cdot \text{Elec Cost (\$/kW-hr)}$$
$$= 50 \text{ hp} \cdot 1/0.95 \cdot 8760 \text{ (hr/yr)} \cdot 0.746 \text{ (kW/hp)} \cdot \$0.13 \text{ (\$/kW-hr)}$$
$$= \$44,713 \text{ per year}$$

The units in this example do not have Variable Speed Drives (VSD), but rather cycle between loaded and unloaded state, running at a constant speed. For example, the motor runs at full load 37 percent of the time, running unloaded the rest of the time. While the above calculation does (incorrectly) assume that the motor is run at full load all the time, the electricity cost is still substantial, since the motor still consumes 20 percent of the maximum electric power when unloaded.

VSD technology in air compressors can achieve cost savings in two ways:

- Load Matching - Instead of cycling between a loaded and unloaded state, the machine varies its speed to the required load. When the motor is running unloaded it is consuming electricity but performing no useful work. The greater the time the motor load is below peak capacity, the greater the savings (see Fig. 1).
- Instead of running in a wide pressure band (typically 10-20 psi) the VSD can maintain a steady output pressure. This reduces generation cost due to the greater energy required to generate air pressure above the set point and reduces parasitic losses due to greater leakage at higher pressures. A 10 psi reduction in output pressure reduces generation costs by about 5 percent.

The study was set to determine if buying a new VSD air compressor would be more cost effective than repairing the existing unit. The study involved using a clamp-on current meter and system pressure recorder to record load data on the system over one week. This data was then graphed and it was clear that the use pattern was, in fact, conducive to a VSD-type of unit (see Fig. 2).

Because a VSD machine can run at less than full capacity, it is able to turn down to deliver just the quantity of compressed air actually required without going through load and unload cycles. It is this cycling that causes energy waste. We used the collected data and AIRMaster+ software (the Department of Energy-approved calculation tool) to quantify the expected savings shown in Table 1.

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WINTER OFF-PEAK AVG. HOURLY	6.4	2,533	16,314
SUMMER PEAK AVG. HOURLY	5.8	1,112	6,501
SUMMER OFF-PEAK AVG. HOURLY	6.4	1,086	6,992
SUMMER KW REDUCTION	6.1		
WINTER KW REDUCTION	6.1		

AVG HOURLY KW SAVING	HRS	KWH/YR	\$/KWH	TOTAL SAVINGS
6.1	8,760	53,436	\$0.13	\$6,947

Table 1. Expected Savings

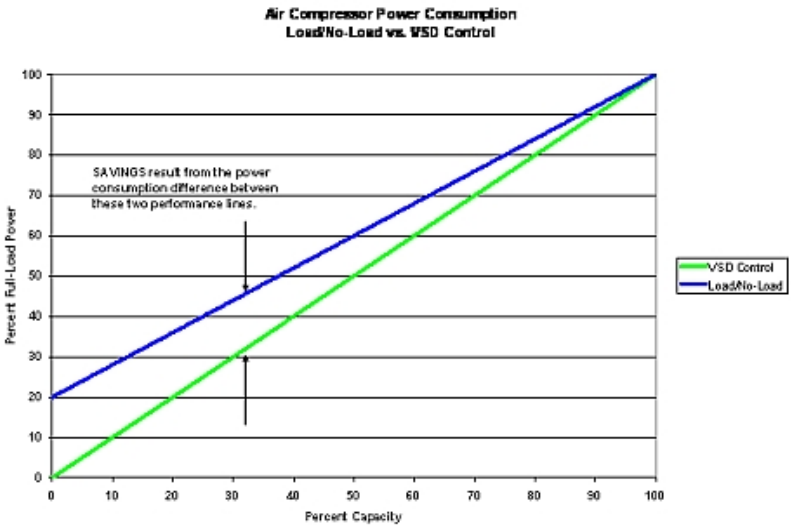
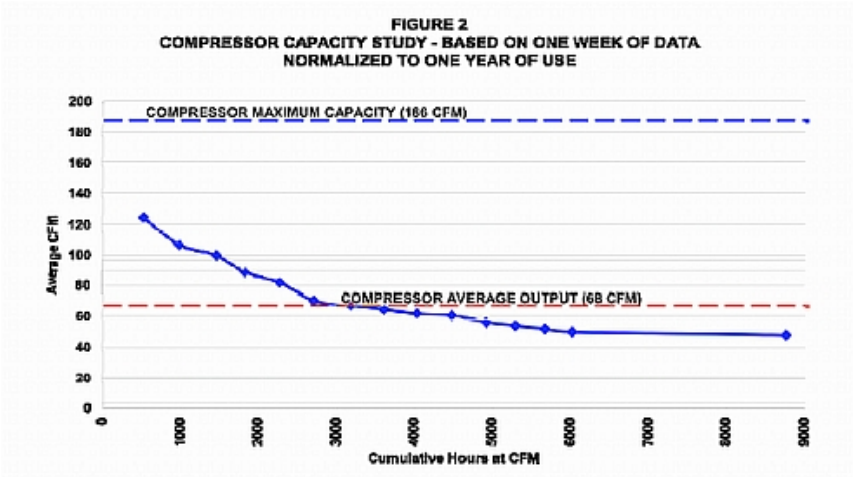


Figure 1. Power consumption of a VSD unit versus that of a Load/No-Load unit.



We examined the cost savings from the decreased electricity usage of a VSD unit but this alone did not justify the expense of the new machine. Since electric utilities encourage the use of energy efficient equipment by offering incentives, we captured this benefit into our analysis. In addition we worked with the equipment supplier to "buy back" the existing (three-year old) machine for \$10,000. We applied a Net Present Value (NPV) analysis to compare the value of buying a new VSD machine versus having the old machine fixed.

The results showed a return so favorable that even if the old machine had not broken we would still have been better off replacing it with a new machine.

<u>NPV analysis for compressor repair or purchase new</u>				
Basis of analysis:	Cost of Capital:	5%	List Price New Compressor	\$54,182
	Life of Equipment (years):	10	Salvage Credit for existing compressor	-\$10,000
			Installation Cost (approx)	\$3,000
			Utility Company Rebate	-\$10,758
			Net Cost New Compressor	\$36,424
Case 1 - Buy New Machine				
	Expenditure			
	-\$36,424	1-Apr-08	Net Cost of New, Installed Compressor	
	\$6,947	1-Apr-09	Electricity Savings Each Year at 53,436 kw @ \$0.13/kwh	
	\$6,947	1-Apr-10		
	\$6,947	1-Apr-11		
	\$6,947	1-Apr-12		
	\$6,947	1-Apr-13		
	\$6,947	1-Apr-14		
	\$6,947	1-Apr-15		
	\$6,947	1-Apr-16		
	\$6,947	1-Apr-17		
	\$6,947	1-Apr-18		
	\$2,000	1-Apr-18	Salvage Value of 10 year old air compressor	
NPV	\$18,440		A positive result means this is a good investment	
Case 2 - Repair Existing Machine				
	\$0	1-Apr-08	Repair cost covered under warranty	
	\$2,000	1-Apr-18	Salvage value	
NPV	\$1,227		A smaller positive result means this is not as good an investment	

Table 2. Net Present Value Analysis of repair or purchase new options.

The NPV analysis in Table 2 shows the advantage of buying the new machine versus repairing the old one. You may want to look for VSD applications in your own plant if you want to save money on ever-increasing electric costs.

Andre L. Narbonne, PE , Qualified AIRMaster+ Specialist, is a Sales Engineer with Ingersoll-Rand Industrial Technologies, Air Solutions Division. He has 10 years experience in compressed air systems providing a wide range of equipment and service solutions to help improve productivity, reliability and efficiency.

Industry News In Brief

by Patti Charek

Pfizer to Acquire Wyeth in \$68 Billion Deal

Pfizer, the world's biggest drug maker, has announced that it is buying Wyeth in a \$68 billion deal that will quickly boost Pfizer's revenue and profit and transform it into a more diversified company, a one-stop shop for vaccines, biotech drugs, traditional pills, and nonprescription products for both people and animals. The cash-and-stock deal, one of the biggest in the history of the drug industry, is expected to close late in the third quarter or in the fourth quarter.

The acquisition will also significantly expand Pfizer's presence in the Boston area. The company, whose roster is topped by the best-selling cholesterol treatment Lipitor, has about 400 employees in Massachusetts, including 140 who work at the Pfizer Research Technology Center and Regenerative Medicine unit in Cambridge, said company spokesman Jack Cox. "One of Pfizer's strategic priorities is to become a top-tier player in biotherapeutics and vaccines. The work we are doing in Cambridge and the acquisition of Wyeth accelerates our ability to pursue these goals," Cox said.

Wyeth is already one of the state's top biotechnology employers, with 2,400 workers, including about 700 at its oncology research center in Cambridge and 1,700 employees at its manufacturing plant in Andover. The company had pledged to add 100 positions in exchange for recent highway improvements near the Andover manufacturing facility, which makes bone morphogenic protein (BMP), the hemophilia treatment BeneFIX, and Herceptin for Genentech. Wyeth also plans to make the pneumonia vaccine Prevnar 13 in Andover once it wins approval from the FDA, said Wyeth spokesman Doug Petkus.

Officials at both companies said no decisions have been made regarding job cuts or additions at their Massachusetts facilities. (Source: Jenn Abelson, The Boston Globe, 27 January, 2009)

Biogen Idec to Move its Main Offices to Weston

Biogen Idec will move its headquarters from Cambridge to an office building being built in Weston adjacent to Rtes 20 and 128. The 350,000-square-foot building, which the company plans to move into in 2010, marks the largest lease deal in Boston's suburbs this year. Biogen Idec said it will save money by moving management and administrative functions to the suburbs. The company is likely to pay an annual lease rate of close to \$45 a square foot, while space in Cambridge can cost more than \$60 a square foot.

Between 400 and 600 employees will move to the new building in Weston. Biogen Idec has 1,800 employees in Massachusetts and 4,500 worldwide. The company now occupies about 960,000 square feet in Cambridge, including space for offices, manufacturing and research. After the Weston move, the Cambridge headquarters on Main Street near Kendall Square will initially remain vacant. Over time, however, the company will convert about 375,000 square

feet of office space into laboratory facilities, expanding Biogen Idec's R&D presence in the heart of the state's biotech cluster. (Source: Jeffrey Krasner, The Boston Globe, 3 December, 2008)

FDA Approves EPIX Imaging Agent to Enhance Scans of Blood Flow

The FDA has approved Vasovist Injection (gadofosveset trisodium), the first contrast imaging agent for use in patients undergoing magnetic resonance angiography, or MRA, a minimally invasive test for examining blood vessels. Vasovist Injection is manufactured by EPIX Pharmaceuticals of Lexington, Massachusetts.

Although MRA can be performed without the use of a contrast imaging agent, Vasovist administration provides a clearer image in patients who are suspected of having blockages or other problems with the blood vessels in their abdomen or limbs. The MRA is performed using magnetic resonance imaging (MRI), which relies on magnetic fields to create highly detailed images of the inside the body. The active substance in Vasovist is gadolinium, a rare earth metal element that is detected by MRI scanners. When injected, gadolinium interacts with water molecules in the body, giving a stronger signal and, in turn, a better picture.

When blood vessels are scanned using MRA without any contrast, radiologists are unable to interpret the images about 10 to 30 percent of the time. As a result, radiologists have typically used X-rays to detect blood vessel abnormalities. But this is a lengthy procedure and requires sticking a needle into an artery to inject the X-ray dye, a procedure with potential risk for the patient. (Source: FDA Web Site, 24 December, 2008)

Merck Plans Generic Biologic Drug Unit

Merck will start a new unit to copy biotech medicines, becoming the first big US maker of conventional drugs to leap into the \$94 billion market for treatments based on living cells. Merck will invest \$1.5 billion in its new BioVentures division by 2015 and a "substantial amount" after that as it begins selling at least six new biologic generic medicines by 2017, said Merck's president of research, Peter Kim, at a meeting with analysts.

No other US-based maker of brand-name medicines has jumped into generic biologics, a business not yet possible under US law. President Barack Obama supports making copies of biologic medicines available, and Congress is expected to debate next year how to establish a regulatory pathway to get such products on the market.

Generic drug makers can copy traditional, chemical-based medicines after patents expire, usually without extensive human testing. The FDA likely will require more testing for biologic copies. Merck needs new products as it braces to lose patent protection on \$8 billion worth of medicines through 2012. (Source: Bloomberg News, The Boston Globe, 10 December, 2008)

Pfizer Will Sell Off Fledgling Drugs

Pfizer wants to sell to other drug makers 100 experimental medicines for conditions ranging from obesity to high cholesterol. The world's biggest drug maker is cleaning out its chemical compound closet and cutting 800 researchers, or 8 percent of its science staff, as it focuses on developing medicines to treat cancer, brain disorders, and pain, said Martin MacKay, the company's research chief. Some compounds Pfizer wants to sell have been tested on humans.

Pfizer is halting early-stage development of medicines for heart failure, high cholesterol, and obesity to focus on more profitable diseases. The research cuts add to the elimination of 1,200 scientists last year with the closing of Pfizer's Ann Arbor, Michigan laboratory. (Source: Bloomberg News, 14 January 2009)

Endo to Buy Indevus Pharmaceuticals

Endo Pharmaceutical Holdings said that it will buy Lexington, Massachusetts-based Indevus Pharmaceuticals for \$370 million upfront, or \$4.50 per share, acquiring Indevus's urology and hormone drug candidates in the process. The upfront price represents a premium of 45.2 percent to Indevus's closing price of \$3.08. The boards of both companies approved the deal, and Endo's tender offer for Indevus shares will remain open for 45 days. Endo could pay an additional \$267 million, or \$3 per share, if Indevus's long-acting testosterone drug candidate, Nebido, and its acromegaly treatment candidate, ocreotide, reach development and sales milestones. Chadds Ford, Pennsylvania-based Endo said the deal will decrease its profit in 2009 and add to its profit in 2010, although it did not detail the effects.

Indevus is developing Nebido to treat hypogonadism, a hormonal condition that interferes with the functioning of the testes. The ocreotide implant is designed to treat acromegaly, a hormone disorder that can make the feet, hands, nose, and mouth grow to unusually large sizes. The company plans to send the FDA new data on Nebido in the first half of 2009, as it seeks approval to market the drug in the United States. Endo will pay up to \$2 per share, depending on Nebido's regulatory approval and sales results. It will pay up to \$1 per share if the FDA approves the ocreotide implant for sale.

Indevus is also hoping to relaunch its bladder-cancer drug, Valstar, in 2009. It was withdrawn from the market in 2002 after one of its inactive ingredients was determined to be unstable. The company is waiting for inspections of the third-party manufacturer of the drug to be completed.

Endo sells pain drugs including the Lidoderm patch, Opana, and Opana extended-release.

The company reported \$913.2 million in revenue through the first three quarters of 2008, while Indevus posted \$77.8 million in the fiscal year ended September 30th. (Source: Associated Press, 6 January 2009)

Synta Gets \$15M from Glaxo on Cancer Drug

Synta Pharmaceuticals said it received \$15 million from British drug maker GlaxoSmithKline PLC under a development agreement for the potential cancer treatment elesclomol. The Lexington biopharmaceutical company said it is eligible for a total of \$585 million in milestone payments from Glaxo for making progress in the clinic or with regulatory filings. Elesclomol, which has not been approved in any market, is being studied as a treatment that triggers cancer cell death. (Source: The Boston Globe, 13 December 2008)

Targanta Therapeutics Fetches \$42M in Sale to NJ Pharma

Cambridge biotech Targanta Therapeutics is being bought for about \$42 million by Medicines Co., a New Jersey drug company. The sale comes after Targanta's lead drug candidate failed to win recommendation from a federal advisory panel in November and the stock price plunged. The drug, oritavancin, is an antibiotic intended to treat complex skin infections, but panelists said it has not yet been proven safe and effective. In December, the company said it was laying off 86 employees, about 75 percent of its workforce. Still, Medicines Co. is optimistic oritavancin will eventually win FDA approval. Medicines Co. also said Targanta shareholders may be entitled to receive additional cash payments if certain milestones for oritavancin are met. (Source: Chris Reidy, The Boston Globe, 14 January 2009)

Advanced Cell Technology and Korean Biotech Form New Stem Cell Joint Venture

Worcester biotech Advanced Cell Technology (ACT) and Korean biotech CHA Biotech Co. Ltd. have formed a new stem cell technology development company called Allied Cell Technology, to be based in Worcester. The international joint venture will use ACT's hemangioblast cell technology to develop human blood cells. The developments may be used to address the human blood shortage, particularly in military situations.

Allied Cell Technology will be majority owned by CHA, with ACT licensing its technology for a \$500K license fee from CHA, the companies reported. ACT will also work to pull in funding grants for the new joint venture. Leading the new company will be Young Chung, as well as Shi-Jiang Lu and the ACT hemangioblast team. Robert Lanza of ACT will serve as the chief scientific advisor of Allied Cell Technology.

ACT is operating on a limited budget, but has reduced its debt from \$49 million to \$13 million in the last three years, according to CEO William M. Caldwell IV. To cut operating expenses, the company announced its plans to close a Charlestown research facility and Alameda, California headquarters; the plan relocates the ACT headquarters to its founding city of Worcester. (Source: Mass High Tech, 5-11 December, 2008)

Merrimack Pharmaceuticals and BIND Biosciences Expanding in Cambridge

Merrimack Pharmaceuticals has expanded by 18,748 square feet of additional laboratory and office space in Building 600/700 at One Kendall Square in Cambridge. The company will now occupy 50,495 total square feet in the complex, where Merrimack will renovate former Genzyme lab space on the fourth floor, and is expected to move in April 2009. Merrimack Pharmaceuticals is a biotechnology company focused on the discovery and development of novel treatments for autoimmune disease and cancer. Built in 1916, Building 600/700 is a 234,631-square-foot, five-story, Class A research facility that houses both lab space and office space.

BIND Biosciences has subleased 26,148 square feet of lab and office space from Alkermes at the University Park at MIT, located at 64 Sidney Street in Cambridge. BIND Biosciences is a privately held biopharmaceutical company that is developing a new class of targeted therapeutics based on multifunctional nanoparticles. (Source: Mass High Tech, 2-8 January, 2009)

Vertex Pharmaceuticals Chooses Cambridge Over South Boston

Vertex Pharmaceuticals, a Cambridge biotech that once was looking to relocate to the South Boston waterfront, has instead extended the leases for its headquarters for five years. The company - which is developing a drug to treat hepatitis C and HIV infections - had been considering moving into a proposed office building at Fan Pier. That deal stalled late last year as the developer struggled to obtain financing for the project as a result of the credit crisis and slowing economy. The renewed leases, which will run through 2015, cover approximately 292,000 square feet of space at 130 Waverly Street and 200 Sidney Street. Spokesman Zachry Barber said the lease extensions still give the company the opportunity to reach its goal of consolidating from nine buildings in Cambridge into one campus. (Source: Erin Ailworth, The Boston Globe, 16 January, 2009)

New Biotech Group Forms Locally

New England biotech executives and experts know there is strength in numbers so they created a new regional organization called the New England Biotech Association, according to its first chair person Paula Newton, who is also president of the New Hampshire Bio/Medical Council.

The new group is made up of biotechnology associations from each New England state, the national Biotechnology Industry Organization, biotechnology companies, universities and other groups that support the biotechnology industry. "We'll be a larger force to be reckoned with," Newton said.

"When we know there are matters before the US House or Senate, we can go as a group and speak on the issues, which will mean much more than going as individuals," she said.

The group's bylaws call for an elected 20-member board of directors, with 16 of those seats now full. The vice chair is Paul Pescatello of Connecticut United for Research Excellence and the treasurer is Kathie Shields of the Rhode Island BioGroup. Also on the board are Maria Cahill, of Abbott Laboratories in Worcester, Robert Coughlin of the Massachusetts Biotech Council and Christopher Anderson of the Mass High Tech Council. (Source: Eileen Kennedy, Worcester Business Journal, 24 November 2008)

Forma Therapeutics Bucks Trend, Raises \$25m from Investors

Forma Therapeutics, a stealth biotech start-up trying to develop cancer drugs, is lifting its corporate veil. The one-year-old Cambridge company, which has previously been secretive about its mission and finances, plans to disclose it has raised \$25 million in venture capital, grants, loans, and other funding over the past year - a feat that has become increasingly rare as the economy slid into recession, the stock market plunged, and the market for initial public offerings disintegrated. The economic turmoil has forced many venture capital firms to divert money from promising start-ups to later-stage companies frozen out of the public markets. "It's been a very challenging economic environment to do fund-raising," said Steven Tregay, Forma's chief executive.

Tregay formerly worked as managing director at the Novartis Option Fund - one of the venture funds run by Swiss drug maker Novartis AG - and persuaded the fund to become one of Forma's initial key investors. The other major investor is BioOne Capital, a venture fund backed by the government of Singapore, where Forma has facilities.

Forma hopes to develop cancer-fighting drugs by using data from the Cancer Genome Atlas project, a collaboration

of the National Cancer Institute and the National Human Genome Research Institute. As the project identifies new genes linked to cancer, Forma intends to use high-powered screening to find out whether any known compounds appear to be effective in controlling those genes.

Forma has about 42 employees, nearly half of whom work in Cambridge, with plans to grow to 55 to 60 by year-end. Three cofounders - Stuart Schreiber, Todd Golub, and Michael Foley - are connected to the Broad Institute in Cambridge, a research organization affiliated with MIT and Harvard. (Source: Todd Wallack, The Boston Globe, 6 January 2009)

Genzyme Elects \$1.38B Stem Cell Deal with Osiris

Making its own Election Day news, Genzyme has struck a deal with Osiris Therapeutics of Columbia, Maryland to commercialize and develop two adult stem cell treatments in a variety of diseases. If all goes as planned, one of the two, called Prochymal, could become the first stem-cell therapy to be approved by the FDA. The treatment is in late-stage clinical trials for graft-versus-host-disease, a complication of bone marrow and cord blood transplants, and for the bowel disorder Crohn's disease. The results of those studies are expected in 2009. The other stem-cell treatment, Chondrogen, is in mid- to late-stage development for osteoarthritis of the knee. Both treatments are intended to control inflammation, regenerate damaged tissues, and to stymie scar formation, according to the companies.

Genzyme has agreed to pay Osiris \$130 million (\$75 million initially and \$55 million in July 2009) in upfront fees and up to \$1.25 billion in potential milestone payments to commercialize Prochymal and Chondrogen in markets outside the US and Canada. Osiris retains rights to market the treatments in U.S. and Canada.

This isn't Genzyme's first deal with Osiris. Last year the two firms agreed to partner on the development of Prochymal to treat radiation sickness, and in January 2008 the Department of Defense awarded the two firms a \$224.7 million contract to develop the treatment for this purpose, the companies said. (Source: Ryan McBride, Xconomy, 4 November 2008)

FDA Approves Genzyme Drug to Boost Stem Cell Yield for Bone Marrow Transplants

The FDA has approved Mozobil (plerixafor), a drug that helps increase the number of blood stem cells for bone marrow transplantation in patients with certain forms of blood cancer. Mozobil is intended to be used in combination with the growth factor granulocyte-colony stimulating factor (G-CSF) for treatment of adults with multiple myeloma or non-Hodgkin's lymphomas.

Multiple myeloma is cancer of the plasma cell, a cell in the bone marrow that produces antibodies to help fight infection and disease. Non-Hodgkin's lymphomas are a diverse group of blood cell cancers derived from lymphocytes, a type of white blood cell. Prior to receiving high-dose chemotherapy or radiation therapy, patients with these forms of cancer sometimes undergo a procedure known as apheresis in which blood stem cells are collected and stored for reinfusion after therapy.

G-CSF is commonly administered to help release and collect stem cells from the bone marrow. Mozobil is an injectable drug that, when used in combination with G-CSF, boosts the number of stem cells released from the bone marrow into the blood stream. (Source: FDA Web Site, 18 December, 2008)

Genzyme Gets Extension from FDA for New Version of Drug

Genzyme said the FDA has extended until February 28 its deadline for reviewing Genzyme's application to market a new version of Myozyme, a drug for Pompe disease that's manufactured at the company's Boston plant. The biotech giant already has permission to market Myozyme made at its smaller plant in Framingham but it's seeking approval to market the version made at its larger facility in Allston. Pompe disease is a progressive, debilitating, and life-threatening inherited disorder affecting approximately 2,000 people in the US. (Source: Todd Wallack, The Boston Globe, 18 November 2008)

Regulatory & Legislative Highlights

By Deepen Joshi

FDA Approves Drug for Patients with Advanced Prostate Cancer

The FDA has approved the injectable drug degarelix, the first new drug in several years for prostate cancer. Degarelix, manufactured for Ferring Pharmaceuticals of Parsippany, NJ by Rentschler Biotechnologie GmbH of Laupheim, Germany, is intended to treat patients with advanced prostate cancer. It belongs to a class of agents called gonadotropin releasing hormone (GnRH) receptor inhibitors. These agents slow the growth and progression of prostate cancer by suppressing testosterone, which plays an important role in the continued growth of prostate cancer.

Other hormonal treatments for prostate cancer may cause an initial surge in testosterone production before lowering testosterone levels. This initial stimulation of the hormone receptors may temporarily prompt tumor growth rather than inhibiting it. Degarelix does not exhibit this effect. (Source: FDA Web Site, 29 December, 2008)

FDA Approves Novartis' Gleevec to Prevent Recurrence of Gastrointestinal Cancer

The FDA has approved Gleevec (imatinib mesylate) for a new indication: keeping cancer from growing in patients following surgical removal of a gastrointestinal stromal tumor or GIST, a fairly rare form of cancer that originates in cells found in the wall of the GI tract. These cells, known as interstitial cells of Cajal, are part of the autonomic nervous system, which helps to control the movement of food and liquid through the stomach and intestines.

Gleevec is manufactured by Novartis AG of Basel, Switzerland and was first approved by the FDA in 2001. It is one of the first drugs in a class of agents that block cellular communications that result in tumor growth. (Source: FDA Web Site, 19 December, 2008)

New FDA Recommendations on Cardiovascular Risk in Drugs for Type 2 Diabetes

The FDA has recommended that manufacturers developing new drugs and biologics for type 2 diabetes provide evidence that the therapy will not increase the risk of such cardiovascular events as a heart attack. The recommendation is part of a new guidance for industry that applies to all diabetes drugs currently under development.

The FDA also recommends that manufacturers have any cardiovascular events in their clinical trials analyzed by committees of outside cardiologists who are unaware of which patients received the tested products and which were on placebo.

More than 23 million people in the United States have been diagnosed with type 2 diabetes or diabetes mellitus, a chronic metabolic disorder characterized by abnormally high blood sugar levels known as hyperglycemia. Patients with diabetes have a two- to four-times greater risk of heart disease than their non-diabetic counterparts, and none of the currently approved antidiabetic therapies has been convincingly proven to reduce that risk. Because diabetes often requires life-long treatment, prescribers and patients need to know more about whether their antidiabetic therapies put patients at increased risk of heart attack.

The FDA remains confident that currently marketed antidiabetic therapies are safe and effective when used according to approved labeling and advises patients to work with their healthcare professionals to select the most appropriate therapy to achieve adequate blood glucose control. (Source: FDA Web Site, 17 December, 2008)

FDA Teams with WebMD for New Online Health Information

The FDA and WebMD today announced a collaboration that expands consumers' access to the agency's health information. According to the FDA, this joint effort reflects the agency's emphasis on using innovative, technology-based strategies to carry out its foremost mission, which is to promote and to protect the public health. The partnership includes:

- **A new online consumer health information resource on WebMD.com** (www.webmd.com/fda): Consumers can access information on the safety of FDA-regulated products, including food, medicine and cosmetics, as well as learn how to report problems involving the safety of these products directly to the FDA. In addition, WebMD will bring the FDA public health alerts to all WebMD registered users and site visitors that request them. The cross-linked joint resource will also feature FDA's Consumer Updates, timely and easy-to-read articles that are also posted on the FDA's main consumer Web page (www.fda.gov/consumer).
- **The FDA contributions to WebMD The Magazine:** FDA Consumer Updates will also be featured at least three times a year in WebMD's bimonthly magazine, which reaches nearly nine million consumers. The magazine is distributed to physician office waiting rooms across the country. (Source: FDA Web Site, 3 December, 2008)

FDA Approves New Drug from Eisai to Treat Severe Form of Epilepsy

The FDA has approved a new drug, Banzel (rufinamide), manufactured by Eisai Medical Research Inc. of Woodcliff Lake, NJ, for use as an add-on treatment for seizures associated with Lennox-Gastaut syndrome. Banzel was granted orphan drug designation by the FDA.

Lennox-Gastaut syndrome is a severe form of epilepsy that usually begins before 4 years of age and can be caused by brain malformations, severe head injury, central nervous system infection and inherited degenerative or metabolic conditions. Most children with Lennox-Gastaut syndrome experience some degree of impaired intellectual functioning or information processing, along with developmental delays and behavioral disturbances. (Source: FDA Web Site, 20 November, 2008).

FDA OKs Describing Off-Label Drug Uses

FDA officials have finalized guidelines that make it easier for pharmaceutical companies to use medical journal articles to promote drugs for unapproved uses. The final guidelines, which have been criticized by some lawmakers as too lenient, allow companies to distribute articles about their products to doctors - even when they involve uses that have not been federally approved.

For their part, companies like Pfizer and Eli Lilly said the guidelines merely reauthorize a longstanding policy that benefits doctors and patients. Companies are not allowed to advertise products for "off-label" uses, or those that have not been cleared by the FDA as safe and effective. However, FDA has allowed company salespeople to distribute articles about such uses if they are published in a peer-reviewed medical journal. The law permitting that practice expired in 2006, and drug makers have been lobbying the agency to renew it ever since.

The reliability of medical journal articles came into question last year when Merck was accused of ghostwriting articles about its painkiller Vioxx, which was withdrawn from the market in 2004 for safety reasons. The FDA said the new guidelines are designed to discourage ghostwriting and recommend companies disclose financial relationships with article authors. (Source: Associated Press, 13 January, 2009)

FDA's First Foreign Branch Opened in Beijing

The US has opened a branch of the FDA in the Chinese capital, the first of several overseas offices that will seek to regulate the safety of food and medicine bound for American supermarkets and pharmacies. The opening follows a string of scandals involving contaminated Chinese-made products, including toys, toothpaste, pet food, cough syrup, and milk. Later this week, the agency will open inspection stations in Shanghai and Guangzhou; in the coming months, it plans to establish offices in India, Latin America, and Europe.

Secretary of Health and Human Services Michael Leavitt, who traveled to China to preside over the ribbon cuttings, said the overseas offices would ensure the safety and quality of goods that make up 15 percent of the food Americans consume. All three outlets will work with Chinese counterpart agencies to inspect products bound for the US. They will also certify third-party inspectors who can approve the quality of exports. (Source: The International Herald Tribune, 20 November 2008)

New Members

Ms. Julie Bagley, Amerifit, Inc.
Mr. Scott M. Piegza, Vanderweil P&IDC LLC
Mr. Jeffrey D. Salocks, Payette Associates Inc
Mrs. Lourdes M. Santamarina, Bristol-Myers Squibb
Mr. Gerard Mansfield, Parsons
Ms. Linda E. Rich, Abbott Bioresearch Center
Dr. Peter Skorpil, NeoMed Management
Mr. Christopher A. Walton, Capaccio Environmental Eng Inc.
David G. Fontaine, Parsons Corporation
Mr. John D. Kaye, Parsons
Mr. Stephen J. Lynch, Parsons
Kevin J. Porter, Genzyme Corporation
Daniel Noberini, Bristol-Myers Squibb
Mr. Peter Damiano, AstraZeneca, LP
Mr. Kristopher D. Cui, Superior Controls Inc
Mr. Abebe Negash, Decco Process Solutions
Mr. Simon Ng, Parsons
Eileen Garry, Advanced Instruments Inc
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