Boston Area Chapter
ENGINEERING PHARMACEUTICAL INNOVATION

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NEWSLETTER
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## IN THIS ISSUE



# ISPE Students Attend Washington Conference

*by Rick Pierro*

*From left to right: Laurene Dykiel, Dawn Eriksen, Cy Chan, Rick Pierro, Prerana Katti, Jeremy Saurer, and Mike Denault.*

It started off as a challenge. As Chairman of the Student Affairs Committee, I said, "If you students can find a way to reach the ISPE Student Leadership Conference in Washington, DC this May, I'll take you all out for dinner and we'll tour the Washington monuments."

Five courageous students from the UMass-Amherst ISPE Student Chapter took up the challenge. Prerana Katti, Cy Chan, Jeremy Sawyer, Dawn Eriksen, and Laurene Dykiel drove 450 miles to attend the two-day Student Leadership Workshop for ISPE students. They also toured the vendor show, listened to fascinating talks about recent developments in the biotech industry, met other ISPE students from all over the country, and learned about real-life strategies to start their careers after college.

*Concludes on page 3.*

## 2006 Calendar of Events

**ISPE Boston Area Chapter Annual Golf Tournament**
17 August, Granite Links Golf Club, Quincy, MA

**2006 ISPE Boston Classroom Training and GAMP Americas Forum**
11 - 15 September, Hyatt Regency Cambridge, Cambridge, MA

**ISPE Boston Area Chapter Program:**
**CIP, COP, SIP, and Cleaning Chemicals for Pharmaceutical and Biotech**
26 September, Royal Sonesta Cambridge, Cambridge, MA

**ISPE Boston Area Chapter Product Show**
18 October, Gillette Stadium Clubhouse, Foxboro, MA

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# President's Message

Dear ISPE Boston Area Chapter Members,

With the gorgeous (and sticky) days of summer upon us, it's hard to be thinking ahead to fall and winter, but that's what the ISPE Boston Area Chapter Committees are focusing on. We tend to take the summer off from hosting educational programs, but make up for it in the darker months of the year.

This year we'll kick off the season with a educational program on Clean in Place (CIP) systems on Tuesday, 26 September. Please come join us; CIP systems always bring about lively discussion and interesting cases of 'lessons learned.'

The big news is that our Annual Product Show is moving from the Newton Marriott, as we had outgrown the venue. The motto of this year's product show is "thinking big," and to that end we'll be attracting 250 vendors and nearly 2000 attendees to the Gillette Stadium Clubhouse. As requested, we're attracting more process development vendors to the product show who cater to the in-between segment of our business. We'll also be adding many more supply chain and manufacturing vendors. This will be an historic event for the Boston Area Chapter, so block out the afternoon of 18 October now. And if you are lucky, you may come away with a special raffle prize…

Also on the horizon for this fall is the ISPE Annual Meeting, held this year at Disney World. With a theme of "A New World of Innovation," the meeting's focus will be on "imagineering" and problem-solving in life science. The meeting will provide over 30 educational seminars, highlight 250 vendors, facilitate international networking, and, of course, give you an opportunity to experience the magic of The Magic Kingdom.

This fall will be a great season for the ISPE Boston Area Chapter, but we can't do our job well without your feedback and support. Have an idea to improve on educational content? Shoot us an e-mail and let us know. Offer a unique product or service? Attend our Annual Product Show and display your wares. Feel like getting to know some of your professional peers in a casual and fun environment? Join one of our Chapter Committees — the Communications and Student Relations Committees are actively seeking new members to help plan and execute goals for 2007.

Enjoy the last few weeks of summer, but keep your options open for Chapter fun in the months ahead. You'll be glad you did.

**Niall Johnson**
President, ISPE Boston Area Chapter

Mark Your Calendar!

## 2006 ISPE Annual Meeting

***"A New World of Innovation"***

**5 - 8 November**
**Walt Disney World Dolphin Resort**
**Orlando, Florida**

**For details, visit www.ispe.org.**

**Register on-line or call ISPE at +1-813-960-2105 to reserve your spot at the Annual Meeting.**

## ISPE Students...

*Continued from page 1.*

Specifically, they were challenged to develop their networking skills (the student gathering the most business cards – Dawn Eriksen – won the prize), learned resume writing and interviewing tips (be concise), and were taught proper dining etiquette (start with the outside fork). By the time it was over, all five students claimed that the ISPE Leadership Conference was well worth their journey and the most informative and beneficial conference they'd ever attended.


*From left to right: Jeremy Saurer, Cy Chan, Dawn Eriksen, Rick Pierro, and Laurene Dykiel.*

And then on Sunday night, we all celebrated and went out for dinner: five inquisitive and excited students along with Dave Novak, past Boston Area Chapter President, Mike Denault, current Vice President, and me. Several hours flew by as we shared stories about our careers and exciting innovations upcoming in the biotech industry. We gave advice about getting first jobs and listened to the everyday challenges the students face at school. Later we all strolled past the Lincoln Memorial, down to the Washington Monument, and ended with a rest at the World War II Memorial.

After many thanks (including a "certificate of appreciation" for their host – see photo above) and praise for an excellent and informative meeting, the students climbed back into their car for the long ride home. I reflected that times like these make me proud to be an ISPE volunteer. Rick Pierro can be reached at rpierro@superiorcontrols.com and is looking for volunteer speakers for this fall's Student ISPE meetings.

# Nanomaterials for Drug Delivery: Potential Benefits and Risks

*by Brenda E. Barry and Jo Anne Shatkin, The Cadmus Group, Inc., Watertown, MA*

Nanotechnology is providing exciting new tools and materials to the pharmaceutical industry that have the potential to dramatically improve drug delivery methods. Improving drug delivery is critically important because more than 100,000 deaths per year occur in even those people who take drugs properly (Langer 2006). Nanomaterials (NM) include an array of engineered materials that, by definition, are designed and produced to have at least one dimension that is 100 nanometers (nm) or less (1,000 times smaller than the width of a human hair). Although researchers are currently designing and testing a variety of NM such as carbon nanotubes (CNT), fullerenes, and quantum dots for use as drug delivery devices, their potential toxicity is not currently well understood. This raises an important health question: Can the potential benefits of NM as drug delivery devices be achieved while minimizing the possible risks for patients?

The application of nanotechnology to the life sciences has been termed nanobiotechnology (Mazzola 2005). The very small size and high surface-to-volume ratio of several types of NM makes them ideal candidates for drug delivery (Bianco et al. 2005; Colvin 2003; Hardman 2006; LaVan et al. 2003). Carbon nanotubes (CNT) are simply single sheets of carbon atoms rolled into tubes less than 5nm in diameter. Fullerenes, also called Buckminster fullerenes or buckyballs, are spherical configurations of 60 carbon atoms that resemble a soccer ball (1-2 nm). Quantum dots (QDs) are semiconductor nanocrystals (2-100nm); bioconjugated QDs are being evaluated as tools for site-specific gene and drug delivery. Some newly generated NM, such as CNT and fullerenes, are completely insoluble in all solvents. However, they can be modified and made more soluble, and potentially less toxic and less immunogenic, by a process called functionalization. Functionalization adds chemical components, such as hydroxyl groups, peptides, or proteins, to NM surfaces.

One or more therapeutic drugs can be attached to or placed inside these NM vehicles. The NM/drug combinations can also be designed to attach to specific target cells and organs by decorating the NM surface with selected binding agents. This target-specific approach can avoid many of the systemic side effects often caused by drug treatments, such as those from potent chemotherapeutic agents. In addition, the small size of NM/drug combinations can enable them to pass across the selectively impervious blood-brain barrier for treatment of difficult, and often fatal, brain cancers. Another potential benefit of NM/drug combinations is sustained dosage delivery using time-release drug preparations. In contrast to traditional drug delivery methods, such as injections or pills, sustained dosage delivery can avoid the fluctuations of drug concentrations in the system that may produce adverse reactions and even deaths in patients.

An important question that emerges from the potential use of NM for drug delivery is whether they present new and unanticipated risks for patient health and safety. The same characteristics that provide NM unique advantages also raise concerns about their potential toxicity because common elements like carbon behave differently at the nanoscale level. That is, the properties of graphite do not predict the properties of CNT or fullerenes. One unique property of NM that may contribute to their toxicity is their enhanced reactivity due to the large surface area relative to size. It is also possible that NM will move within the body. Recent research suggests that NM can migrate from one part of the body to another. For example, inhaled NM can pass from the lungs to the blood and on to other organs; and inhaled nanoparticles may reach the brain through the olfactory nerve (Oberdorster 2004). There is also the potential for NM to bioaccumulate, that is, build up in the body. Whether NM can be broken down in the body and eliminated is not known.

The Food and Drug Administration (FDA) is the federal regulatory agency responsible for evaluating the potential health risks of NM/drug combinations. Nanotechnology has been included under FDA's Critical Path Initiative that is designed to facilitate review of innovative science and technologies (Sadrieh 2006). The FDA has previously reviewed products containing nanoscale materials, such as sunscreens and cosmetics. Whether a new NM submission is categorized as a drug-device, drug biologic or device-biologic product will determine which FDA Center will have jurisdiction regarding regulation. General considerations for NM product approval include characterization, safety issues related to specific delivery route (inhalation, dermal, ingestion, injection), and environmental impact. The FDA recommends monitoring the Federal Register and the FDA Web site for updates on regulatory requirements for NM. The FDA will also hold a nanotechnology public meeting this fall (see related article on page 6).

In conclusion, the potential for nanobiotechnology and innovative NM/drug combinations as medical treatments presents exciting opportunities. Those who work in this emerging field should have up-to-date information about NM toxicology, potential health and safety risks, and the regulatory environment that will impact its transfer to patient use. Understanding both the benefits and the risks of these new NM drug applications can inform good decision-making for drug developers, regulators, and ultimately the consumers and patients who will use this new drug delivery technology.

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### About the Authors

**Brenda E. Barry, PhD** is Senior Toxicologist at the Cadmus Group, in Watertown, Massachusetts (www.cadmusgroup.com) with expertise in nanotoxicology, occupational health, and biosafety. **Jo Anne Shatkin, PhD** is a Principal at Cadmus and risk assessment expert. They will present a half-day seminar, "Nanotechnology: Managing Health and Environmental Risks" on 12 September 2006. For more information, e-mail nanotech@cadmusgroup.com.

### ISPE Boston Area Chapter Presents:

## CIP, COP, SIP, and Cleaning Chemicals for Pharmaceutical and Biotech

**5:30 pm, Tuesday, 26 September 2006**
**Royal Sonesta Cambridge, Cambridge, MA**

#### CIP System Design
- Once through vs. recirculated
- Fixed place vs. portable
- When to use 1,2, or 3 tank designs

#### COP System Design
- Side Jet
- End Jets
- Applications

#### Spray Device Selection
- Static vs. dynamic
- Placement in tank

#### Cleaning Chemical Selection
- Selection criteria & coupon testing
- Built detergents vs. commodity chemicals
- Testing for residuals

#### SIP of the Process
- Principles
- Temp. mapping

***Please join us!***
**Check out our Web site at www.ispe.org/boston for more details.**

# Industry News in Brief

***by Patti Charek***

***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.*

## Bristol-Myers Squibb to Build $660M Drug Plant, Create 550 Massachusetts Jobs

Global drug maker Bristol-Myers Squibb has announced it will build a $660 million manufacturing plant on the former Fort Devens U.S. Army base, bringing as many as 550 jobs to Massachusetts and marking a milestone in the state's efforts to attract new business. The decision marked the culmination of an eight-month competition between Massachusetts, Rhode Island, New York and North Carolina, all of which were on the drug giant's short list of sites for the new plant, scheduled to open in 2009. The plant is expected to produce a newly-approved drug for rheumatoid arthritis with possible future expansion into other products. It is the biggest private investment by far at the decommissioned army base, which is already home to about 80 companies.

Although the Massachusetts drug industry is chiefly known for its small, research-oriented biotech companies, Bristol-Myers Squibb joins several large pharmaceutical firms in planting its flag in the state. Novartis AG and Merck & Co. have both opened significant research facilities in the past few years, and two other global drug makers – Wyeth and Abbott Laboratories – already manufacture biotechnology drugs in Massachusetts.

*(Source: Stephen Heuser, The Boston Globe, 2 June 2006).*

## Vertex Forges $545 Million Deal with J&J

Cambridge-based Vertex Pharmaceuticals notched a major endorsement for its experimental hepatitis C drug recently when global drug giant Johnson & Johnson said it would pay up to $545 million for rights to sell the treatment in Europe and other overseas markets. The deal will pay Vertex $165 million immediately, plus as much as $380 million in further payments if the drug is successfully approved and launched. It would also pay Vertex a royalty of 20 percent on sales of the drug and reimburse much of the development costs.

Though so far tested in only 60 people, the drug has drawn attention for its ability to rapidly reduce blood level of hepatitis C, a virus that can lurk in the body undetected for years before erupting and destroying the patient's liver. The drug is currently entering its second phase of human tests, in about 1000 patients, with the first results expected later this year. If results confirm the earlier suggestions of effectiveness, Vertex would file for US approval as early as 2008.

The drug has galvanized Wall Street analysts for its potential to change the treatment of a disease with more than 8 million patients in the US and Europe alone. The only treatment currently available is a 12-month series of injections with heavy side effects that works only half the time. Success could vault Vertex from a money-losing firm known primarily for its research expertise, into one of the region's largest drug makers.

*(Source: Stephen Heuser, The Boston Globe, 1 July 2006).*

## Millipore to Acquire Serologics Corp.

Millipore Corp., a Billerica company that makes sophisticated filters and other tools used by biotechnology companies and research labs, said it will buy Serologicals Corp. of Georgia for $1.4 billion. Through this purchase, Millipore will acquire a broad line of antibodies, stem cells, and other research supplies, as well as the nutrients needed to help cell cultures grow in biotech facilities. The deal marks an ambitious expansion for the 52-year-old company that has transformed itself from an industrial water-filtration firm into a leading supplier to the biopharm industry. Millipore has 4,800 employees worldwide, including about 1,150 in Massachusetts.

"Tool" companies such as Millipore have been quiet beneficiaries of the life-sciences boom, with many seeing steady growth and profits by selling products and services to their neighbors in the riskier drug development business. "The parallel people often use is the California gold rush," said Charles Wagner, Millipore's vice president of strategy and corporate development. "People got rich selling picks and shovels."

Serologicals, founded in 1971, spent three decades collecting and selling human plasma, then transformed itself into a company that sold specialized proteins to lab scientists and biotech companies. Under the name Celliance, it sells cell nutrients and other products. Under the name Chemloon International, it sells antibodies, stem cells and other tools needed by research labs. Serologicals has 1,000 employees and is based in Norcross, Georgia.

*(Source: Stephen Heuser, The Boston Globe, 26 April 2006).*

## Therion to Close After Drug Trial Fails

Therion Biologics, a 15-year-old Cambridge company widely considered a leader in the field of therapeutic vaccines, will be shuttered and sold after its most-promising drug candidate failed a pivotal human test. Half of the company's 100-person staff will be laid off as the company prepares itself for sale. Therion was founded in 1991 to develop vaccines against AIDS and began to target cancer in the late 1990s.

The company had hoped its vaccine Panvac, designed to treat pancreatic cancer, would extend patients' average life expectancy from three to five months. The failure of the trial marks another high-profile setback for the concept of cancer vaccines, highly specialized treatments that doctors hope can train the patient's immune system to hunt down and kill cancer cells. Unlike a typical shot to prevent measles or flu, so-called "therapeutic vaccines" are designed not to prevent cancer but rather to teach the immune system to recognize cancer cells and attack them before they can spread. Therapeutic vaccines are unrelated to Gardisil, the recently approved vaccine that prevents a virus that can trigger cervical cancer (see related article on page 15).

*(Source: Stephen Heuser, The Boston Globe, 29 June 2006).*

## Industry News in Brief

*Continued.*

### Study Says Number of Drugs Entering Testing Up 52 Percent

The number of drugs that entered clinical testing surged 52 percent in the three years ending in 2005, signaling the pharmaceutical industry may be emerging from its "research and development drought," according to the results of a study recently released by the Tufts Center for the Study of Drug Development. The increase represents a turnaround from the 21 percent decline in medicines entering testing seen when the five-year period ending in 2002 as compared with the previous five-year period.

The pharmaceutical industry has been experiencing a new product drought for years and that has prompted companies to be more aggressive in their efforts to find promising drug candidates, according to Kenneth Kaitlin, director of the Center. Last year the FDA approved 20 new drugs, down from 36 in 2004. But in 1996, the industry introduced 53 new drugs and debuted 30 or more in each of the following three years.

Kaitlin said the improvement seen in the recent study is a result of new technologies that enable scientists to better judge a drug candidate's likelihood of success and an increase in products licensed from other companies. However, it will take several years to determine if these new drug candidates will turn into viable products; it takes an average of seven years to complete clinical trials and receive market approval.

The study was done by examining commercial databases on ten companies with the highest pharmaceutical sales in 2004.
*(Source: Theresa Agovino, The Associated Press, 8 May 2006).*

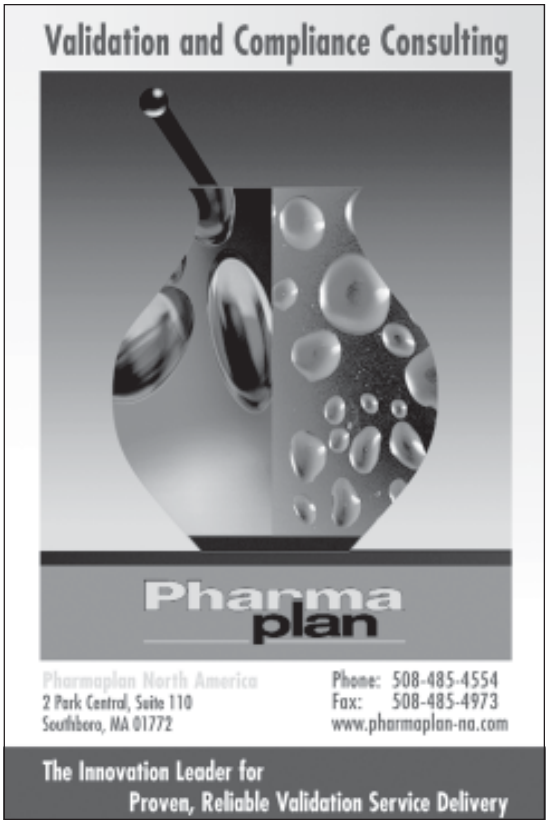
### Biogen Idec, Seeking Clout in Cancer Drugs, To Buy Conforma

Moving to fill its pipeline of drugs in development and to bolster its position as a provider of cancer treatments, Biogen Idec said it would buy Conforma Therapeutics Corp. of San Diego. Biogen Idec, one of the country's largest biotech companies, will pay $150 million plus as much as $100 million if Conforma's early-stage cancer-fighting technology advances toward commercialization. "This is the first major deal we've done since the downsizing in September, and it's a clear signal that we are in the process of adding to our pipeline," said Dr. Burt Adelman, executive vice president of development for Biogen Idec. "We're going to be doing more of these deals, and we're also targeting deals involving late-stage products."

Conforma's experimental cancer drugs are only in the first stage of human testing which means it would probably be 5 to 10 years before they could be sold. Conforma's technology works to inhibit "heat-shock protein 90," which helps cancers and tumors grow. The field, while young, is already hotly contested. Last year Cambridge-based Infinity Pharmaceuticals started human tests of a heat-shock inhibitor that

*Continued on page 10.*





# "Water... Water Everywhere, but Nary a Drop to Drink"

***by Tony Urciuoli***

As its title suggests, this year's water program presented by the Boston Area Chapter's Educational Program Committee addressed more broadly focused aspects of what is, arguably, our industry's most important resource. The structure of the program was somewhat of an "upside down" pyramid, beginning with a global perspective on water resources, proceeding to the practical aspects of Massachusetts' drinking water delivery and treatment system, and "bringing the topic home" with a discussion on validating WFI systems.

Ted Lawson of GE Water & Process Technologies initiated the program with a compelling view of our "global water challenge." Water scarcity and purity issues around the globe ultimately affect each of us in our respective industries and homes. Would it surprise you to know that, according to the World Health Organization (WHO), over 8,000 people die each day worldwide due to water-related purity and scarcity issues? Ted provided WHO data indicating water-related deaths are inversely proportional to investment in infrastructure. As you might expect, the African continent is in most dire need for this investment, while Europe - surprisingly not the Americas - maintains the lowest per capita water-related death rate. Ted's presentation made the point keenly clear: solving water scarcity and purity issues universally needs to become a priority to ensure prosperity in health and wealth as the "global economy" continues to expand. For additional information, contact edward.lawson @ge.com.

Stephen Estes-Smargiassi is Director of Planning at the MWRA and brought the water discussion closer to our everyday lives by providing "question inspiring" insight into the complex system which collects, purifies and distributes our drinking water each day. The Quabbin Reservoir in central Massachusetts is Boston's primary water source. According to Stephen, Boston is very fortunate to have four-years worth of water inventory even without a single additional day of precipitation! An inherent benefit to the large inventory is the water's long residence time before distribution, which serves as a natural filter for suspended material.

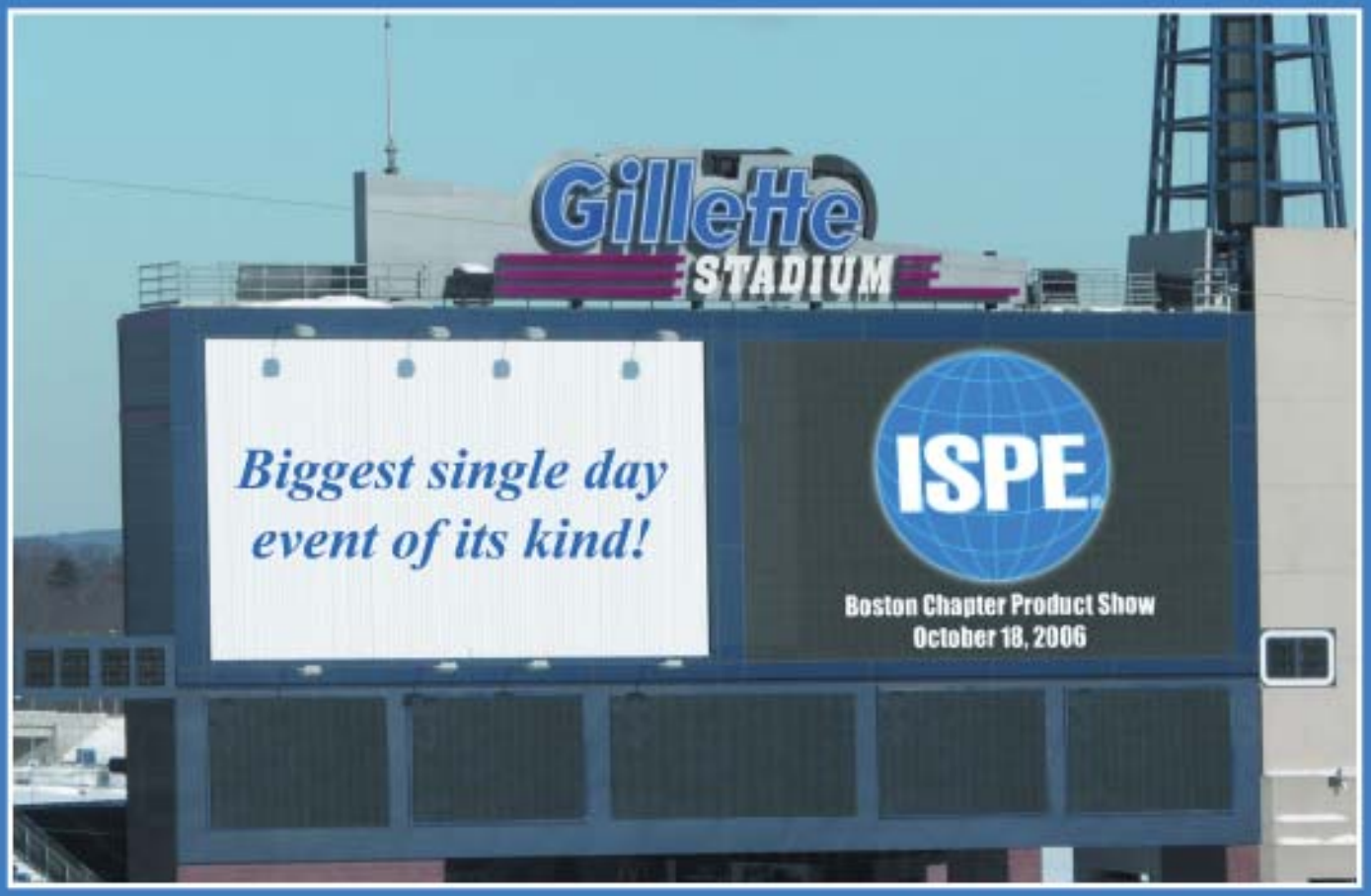
Seminar attendees learned about new and upgraded treatment systems recently implemented in Massachusetts, utilizing ozone as a primary disinfection method in place of the traditional chlorine-based products. The transition in disinfectant technology has been ongoing for several years in direct response to the EPA's more stringent limits on trihalomethanes (THMs). THMs are by-products of the reaction between chlorinated compounds and organic matter in water and are considered harmful to human health. For additional information, contact stephen.estes-smargiassi@mwra.state.ma.us.

Mike Harrison of Acambis closed the program by bringing the discussion "home" to our Chapter's operating companies. Mike's presentation demonstrated his practical validation experience by providing "do's and don'ts" for validating WFI systems. His "do's" included development of specifications in partnership with the end user. This helps to avoid misunderstandings and potential rework. His cost-saving "don'ts" included FATs for stills, based on the fact that this process is redundant with SAT. He also recommended system revalidation be done *only* as a result of major changes to the generation, storage and/or distribution of the WFI. In addition, annual revalidation should be unnecessary, according to Mike, as long as a company's EM program is in place and robust. He recommended frequent review of EM data by management to verify that the system remains in control.

In addition, Mike's presentation reiterated the importance of developing good specification documents (URS, FRS and DS) in planning for capacity and use. Many audience members nodded in agreement when Mike pointed out the necessity of having final and *perfect* drawings throughout the IQ effort, as well as the need for GAMP-compliant controls qualification. He recommended doing a dry run for all novel OQ testing, and a Maximum Drop Use Test to determine whether the system will achieve air aspiration or a condition of zero flow.

Mike advised that investigations into each Alert/Action limit excursion (including speciation of all organisms) yielded a dual benefit: understanding a WFI system at its baseline, and providing the information needed to make intelligent corrective actions where necessary. For additional information, please contact mike.harrison@acambis.com.

# We Scaled It Up!




## Boston Chapter Product Show XV

## October 18, 2006 1 - 8 PM

*Be a part of the largest gathering of biotechnology professionals in Metro Boston!*

Educational programs from industry leaders
Over 1,700 attendees expected
Huge influx of new exhibitors
Stadium tours
Free Parking

*Check out our website at: www.ispeboston.org Questions? Email ISPE@camihq.com or call 781.647.4773*

## Industry News in Brief

*Continued from page 7.*

works against blood cancer and stomach tumors. Novartis AG signed a research deal on heat-shock proteins with a British company and expects to begin human testing later this year. So far, none of these potential drugs has emerged from human testing.
*(Source: Jeffrey Krasner, The Boston Globe, 4 May 2006).*

### High-Priced Genzyme Drug is OK'd

Genzyme Corp. won federal approval for the first drug to treat a rare genetic disorder called Pompe disease, an incurable condition that causes muscle wasting in adults and fatal heart and lung failure in infants and is currently known to affect only about 1,000 people. The drug, Myozyme, is an intravenous treatment that will be one of the most expensive in the world at more than $200,000 per patient annually. The development of Myozyme, which has cost Genzyme an estimated $500 million since 1998, illustrates the technical and medical challenges that have made biopharmaceuticals one of the most cash-intensive industries in the country. It is also an extreme case study of the economics of the modern drug industry, which is shifting toward medicines designed to treat narrower segments of the patient population.

By developing life-saving treatments for extremely rare illnesses, Genzyme has become the largest drug company in Massachusetts and one of the biggest biotechnology companies in the world. It has also emerged as a target for critics who say the healthcare system can't afford a growing stream of high-priced drugs like Myozyme, which could generate more than $100 million annually by 2010. Nearly 300 patients are already on the drug, most of them under programs that grant access to experimental drugs for humanitarian reasons. Genzyme expects to roll out the drug commercially and start sending bills to those patients for future treatment, shifting the focus from regulators to insurers. Along with the drug, Genzyme is releasing a genetic test that should help doctors diagnose more cases. Under the Orphan Drug Act, Genzyme is allowed to sell Myozyme in the U.S. without competition for seven years, virtually setting its own price.
*(Source: Stephen Heuser, The Boston Globe, 29 April 2006).*

### Portal to Link Research Projects to Investors

On May 1, the Massachusetts Technology Transfer Center (MTTC) and the Massachusetts Association of Technology Transfer Offices launched a web portal that catalogs ongoing research projects at the state's research institutions. MTTC Director Abigail Barrow said the information on the site provides an open-access list for universities, venture capitalists, scientists, government agencies and entrepreneurs. The primary goal of the portal is to illuminate statewide research to a local and international audience of investors. A secondary hope is that researchers will use the site to judge how competitive their research is compared with other scientists'.

Research projects are sorted into 30 categories including viruses, electrical engineering, and photonics. Each entry contains the name of the lead researcher and summary of the project. One thousand projects from eight institutions are already listed, with the goal to have 20 institutions listed over the summer. The portal is linked directly with each university's network. Every 24 hours an automated system crawls through each university's tech-transfer database to search for new listings.

Technology transfer experts agree the site helps highlight work at smaller research institutions in addition to the research giants MIT and Harvard. MTTC officials claim its version is the first to centralize listings across institutions. The portal is just one part of an effort to spur state economic development in the midst of Massachusetts' population losses and lagging job growth.
*(Source: Catherine Williams, Mass High Tech, 28 April – 4 May 2006).*

### Pharma Exports Soar in 2005 for Bay State Firms

International exports of pharmaceutical products from Massachusetts reached $2.8 billion in 2005, a 36 percent gain when compared with 2004, according to a study by the Massachusetts Alliance for International Business. The value of pharma exports from the state has doubled over the past two years, the study says. "The goal of developing a manufacturing base for biotech and pharma products discovered here is working," Said Brian Gilmore, vice president of the Associated Industries of Massachusetts, whose organization is affiliated with the alliance.

Overall, Massachusetts manufacturers set a new revenue record of $22 billion for exporting merchandise to international markets during 2005. Instrument exports took the top spot among export sectors with $4.7 billion, followed by electric machinery at $4.5 billion, then industrial machinery at $3.1 billion, and organic chemicals at $1.1 billion.

Though pharma showed a significant gain, Massachusetts exports as a whole grew by only 1 percent, while national exports expanded 10 times as fast.
*(Source: Dyke Hendrickson, Mass High Tech, 31 March – 6 April 2006).*

### Initial Report Clears Parexel

Investigators in Britain have ruled out contamination, overdose, and procedural problems in the case of an experimental biotechnology drug that sent six patients to the intensive care unit of a London hospital in March. The drug test, run by Waltham-based Parexel International Corp, is still under investigation, but an interim report suggested the problem is more likely to lie with the drug itself, which had never been tested in humans before. The drug, an antibody designed to fight leukemia, rheumatoid arthritis, and multiple sclerosis, was being tested in a London hospital when all six paid volunteers who received doses had dramatic inflammation reactions and were sent to intensive care. Two suffered life-threatening organ failure.

The trial has become widely watched as a case study on the risks and complexity of modern drug testing. The drug was developed by TeGenero AG, a small German biotech company, and manufactured for testing by German pharmaceutical giant Boehringer Ingelheim. The trial was run by Parexel, an international company that runs human drug tests on behalf of drug developers.
*(Source: Stephen Heuser, The Boston Globe, 6 April 2006).*

### Merck to Buy New Hampshire Biotech in Record Bid

A small New Hampshire firm with a new idea for making biotechnology

## Industry News in Brief

*Continued.*

drugs said it would be acquired by global pharmaceutical giant Merck & Co. for $400 million in cash, the largest such deal ever reported for a private biotechnology company. Six-year-old GlycoFi Inc. of Lebanon, co-founded by Dartmouth engineering professors, has only 55 employees and specializes in genetically altering yeast cells so they can produce useful human proteins. The deal will give Merck "enormous capabilities" to expand its presence in biotech drugs, said a Merck executive.

As injectable proteins become a larger and more profitable part of the US pharmaceutical industry, major drug makers like Merck have been racing to expand beyond traditional pills into the complex realms of biotechnology, which involve growing human proteins in large vats of living cells. The deal will result in a major payday for the New Hampshire firm's venture backers, including Polaris, which invested $10 million into GlycoFi and will cash out for more than $100 million when the deal goes through.

*(Source: Stephen Heuser, The Boston Globe, 10 May 2006).*

### Ariad Wins $65M in Patent Fight with Drug Giant Eli Lilly

A jury told drug giant Eli Lilly and Co. to pay $65 million to a small Cambridge biotech company, saying two of Lilly's top-selling drugs infringed on patents licensed by Ariad Pharmaceuticals Inc. The verdict marked an unexpected victory for Ariad, a drug-development company with 110 employees and no products on the market. It will share the money with co-plaintiffs Harvard University, the Massachusetts Institute of Technology, and the Whitehead Institute, whose scientists made the original discoveries described in the patent. Lilly said it would appeal the verdict.

Ariad's patent describes a specific process inside the body's cells to which the company had licensed the commercial rights. Jurors found that Lilly infringed on its patent because its drugs Evista and Xigris worked through the same cellular process. Evista is a pill to treat osteoporosis and Xigris is an intravenous drug for septic shock. Lilly has sold about $3 billion worth of the drugs since the suit was filed in 2002 and currently sells more than $750 million a year of the two combined in the U.S. The case offers a window into the cutting edge of intellectual property law, in which high-priced legal teams duel for years over whether a company has the right to patent certain kinds of ideas, and whether a competitor has violated those patents.

*(Source: Stephen Heuser, The Boston Globe, 5 May 2006).*

### Biovest Moves To Fast Track With Cancer Vaccine

Most companies find it difficult to win approval from the FDA for a single project, but Biovest International Inc. recently received positive news from the FDA on two: a proposed vaccine and a device to help develop new vaccines.

The Worcester company received Fast-Track status for a vaccine focused on follicular non-Hodgkin's lymphoma. Company officials say Biovest's Phase 2 trials showed that after a lengthy, closely-focused trial, 19 of 20 patients treated with BiovaxID remained in either complete or partial remission. Biovest is now enrolling for Phase 3 trials to be conducted in collaboration with the National Cancer Institute. Non-Hodgkin's lymphoma is found in approximately 65,000 new patients each year in the US. In a separate development, the company received FDA approval to market its AutovaxID device, an instrument designed to produce cells or cell-derived products for personalized medicine applications. Potential customers include academic laboratories and pharmaceutical research facilities.

Industry leaders in the region say Biovest is one of the few life-sciences companies in New England developing both devices and therapeutics. Biovest was founded in 1983 and has developed a business of selling biologic materials for research and clinical trials. They began developing vaccines in 1999.

*(Source: Dyke Hendrickson, Mass High Tech, 10-25 May 2006).*

### GTC Therapeutic's Atryn may become First Drug Made in a Genetically Altered Animal to Win Regulatory Approval

The tiny Massachusetts biotechnology company GTC Biotherapeutics won a surprise victory in its bid to develop the first-ever approved drug made in the body of a genetically-altered animal. The scientific committee of the European Medicines Agency recently reversed a February decision and said it would recommend approval of Atryn. Atryn is an anticlotting drug grown in the milk of goats. European regulators are expected to issue a final decision on the application by the end of September.

GTC keeps 1,400 goats on a farm in the town of Charlton, essentially using the herd as a living drug factory. It alters the goats' genes before they are born so they produce a human blood protein in their milk. The milk is then purified and the human protein extracted to make an injectible anticlotting drug for people with a hereditary lack of the protein.

Biotechnology companies see transgenic goats as a potentially inexpensive source of protein drugs that are currently too complex to make with traditional techniques. Another local company, Merrimack Pharmaceuticals, is producing its experimental biotechnology drug in goats that live on GTC's Charlton farm.

*(Source: Stephen Heuser, The Boston Globe, 3 June 2006).*

# Regulatory and Legislative Highlights

***by Janet Tice***

*__Regulatory and Legislative Highlights,__ a regular feature of the Boston Area Chapter Newsletter, 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.*

## Congress Pressures FDA to Unclog its Generics Pipeline

Alarmed by the upward spiral in healthcare costs, some members of Congress are pressuring the FDA to quicken its pace when it comes to approving generic drug applications. The agency currently has 800 such applications in its queue. The stats speak for themselves: generics accounted for 56 percent of prescriptions written last year in the US. According to the Generic Pharmaceutical Association, Americans spent $22.3 billion on generic drugs last year as compared with $229.5 billion for brand-name drugs.

In addition to speeding the approval process for generic copies of traditional drugs, the agency is also being called upon to develop a policy for approval of biogenerics (see related article below). During a recent Senate hearing, acting FDA commissioner Andrew von Eschenbach said the agency has improved the way it processes generic drug applications by prioritizing drug types with few generic competitors. According to a statement made by von Eschenbach last month, the FDA, on average, currently approves one new generic drug every day.

*(Source: CHI Pharma Week e-News and the Boston Globe, 30 April 2006).*

## FDA Clears Novartis' Generic Growth Hormone

In a breakthrough that allows the company to sell its first copy of a biotech product in the US, the FDA has approved Novartis' Omnitrope, a generic human growth hormone used to treat children and adults with growth disorders. The FDA determined that the generic is so similar to branded products already on the market, that the agency could use its extensive knowledge of those drugs to approve Omnitrope. However, the agency stopped short of resolving how it will approve more complex generic biotech products.

The multibillion dollar question remains: How long will it take the FDA to decide on an approval process for these products? As third-party payers and generic drug manufacturers are quick to point out, the absence of such guidelines is delaying generic competition that would reduce prices on biotech drugs for consumers and insurers. On the other side of the issue, the FDA faces pressure from pharma and biotech companies who argue the science used to create biological drugs is too complex for the FDA to use shortcuts in approving generic versions of their products. European drug regulators pre-empted the FDA by issuing their own guidelines for biogenerics and granting approval for Omnitrope in advance of the FDA's action.

*(Source: The Boston Globe, 1 June 2006).*

## Pfizer and Merck Protect Blockbusters from FDA Approved Generics

By 2011, 70 top-selling brand name drugs will lose their patent protection, cutting US prescription costs by an estimated $49 billion as consumers switch to generics. Recent actions by Pfizer (Zoloft) and Merck (Zocor) exemplify the tactics being adopted by leading pharmaceutical manufacturers whose blockbuster drugs are threatened by generics.

Close on the heels of FDA approval for a generic version of its blockbuster Zoloft (sertraline), Pfizer has confirmed that it is prepared to release its own generic version of the drug. This common practice – whereby branded-drug makers compete with generics by releasing their own generic versions of the branded drugs they control – is beginning to receive greater attention from Congress and the FDA as more blockbuster drugs lose patent protection. In 2005, Zoloft was the sixth highest-selling brand-name drug in the United States, with retail sales totaling over $2.5 billion.

In a related development, Merck will price its Zocor cholesterol pill below Teva Pharmaceuticals Industries' generic version, an unprecedented move designed to salvage sales of its best-selling product. Some insurers have declined Merck's discount offer in order to continue to promote use of generics by their members. Zocor had $4.4 billion in sales in 2005.

*(Source: The Boston Globe, 23, 24, and 30 June 2006).*

## FDA Grants Tentative Approval of Three-Component AIDS Drug

The FDA has issued the first tentative approval for a three-ingredient, fixed-dose tablet for use as a stand-alone antiretroviral treatment for HIV infection in adults. The product contains the active ingredients in the widely used antiretroviral drugs Epivir (lamivudine), Retrovir (zidovudine), and Viramune (nevirapine). FDA may grant tentative approval if it concludes that a drug product has met all of the required clinical safety and efficacy, and manufacturing quality standards for marketing in the US but cannot be granted full approval because of existing patents and/or exclusivity.

The fixed-dose combination tablet, manufactured by Aurobindo Pharma Ltd. in Hyderabad, India, will be available for purchase and distribution in 15 countries under the President's Emergency Plan for AIDS Relief (PEPFAR) designed to combat the AIDS epidemic in the worst affected countries. According to Michael Leavitt, Secretary of Health and Human Services, fixed-dose combination products are an important tool in the PEPFAR program since they simplify treatment for individuals who find it difficult to maintain a regimen requiring the use of several different drugs.

*(Source: FDA Web site, 30 June 2006).*

## FDA Approves Genentech Treatment for Age-Related Macular Degeneration

The FDA has approved Genentech's Lucentis for the treatment of pa-

## Regulatory and Legislative Highlights

*Continued.*

tients with neovascular or "wet" age-related macular degeneration (AMD). Lucentis, a biologic product administered by injection into the eye, is the first treatment that can maintain the vision of more than 90 percent of patients with wet AMD when dosed monthly. The drug was approved under the FDA's priority-review mechanism, which cuts about four months off the typical 10-month drug-review time and is usually reserved for drugs that the agency deems a "significant improvement" compared with existing treatments.

AMD is a retinal disease causing severe and irreversible vision loss; it is a major cause of blindness in individuals older than 55. The vision loss in wet AMD is caused by the growth of abnormal leaky blood vessels that eventually damage the area of the eye responsible for central vision. Lucentis is designed to block new blood vessel growth and leakiness, which ultimately lead to disease progression and vision loss. Untreated, the majority of eyes affected with wet AMD may become functionally impaired.

Lucentis is a new molecular entity (NME), meaning it contains an active substance that has never before been approved for marketing in any form in the US. In addition, Lucentis will be the first FDA-approved product to provide information in the new format mandated for prescription drug package inserts.

*(Source: FDA Web site, 30 June and The Wall Street Journal, 1 July 2006).*

### US Award Nearly $1 Billion Worth of Bird Flu Contracts

Several companies have received five-year contracts from the US Department of Health and Human Services (HHS) to develop cell culture-derived influenza vaccines. The awards are part of a larger HHS initiative to expand the US domestic influenza vaccine infrastructure. Cell culture-derived influenza vaccine production enables more flexible, faster start-up of vaccine manufacturing as compared with current chicken egg-derived vaccines. This is because egg-derived vaccine production requires a lead time of several months to order and receive eggs. With increasing demand for seasonal influenza vaccine and the threat of a pandemic, a system that allows surge capacity in an emergency is needed. Companies reporting HHS-awarded contracts include: Novartis Vaccines, up to $220 million; Medimmune, $170 million; Solvay Pharmaceuticals, $298 million; and DVC LLC, a Computer Sciences Corporation company, $242.5 million. DVC will lead a collaborative effort with Baxter Healthcare to develop the vaccines.

Novartis has been testing an influenza vaccine manufactured using cell lines that were originally derived from canine kidney cells in the 1960s. Such cell lines can be quickly produced and frozen for later use. Novartis has said it plans to apply for approval of a cell-based vaccine with European regulators by the end of the year.

*(Source: CHI Pharma Week e-News, 4 May 2006 and The Wall Street Journal, 5 May 2006).*

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## Regulatory and Legislative Highlights

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### FDA Gives Accelerated Approval for Bristol-Myers Squibb's Sprycel

The FDA has granted accelerated approval for Bristol-Myers Squibb's Sprycel (dasatinib), a new oral treatment for patients with chronic myeloid leukemia (CML). CML, affecting about 4,600 people annually in the US, is a rare cancer characterized by the uncontrolled growth of white blood cells. In addition to the accelerated approval for treatment of CML, the FDA gave regular approval to Sprycel for use in the treatment of adults who have Philadelphia chromosome-positive acute lymphoblastic leukemia, a more serious form of leukemia. Both approvals are for patients who have experienced resistance or intolerance to prior therapy.

Sprycel is considered an orphan drug for each of these indications. Under the Orphan Drug program, sponsors of medications intended for fewer than 200,000 patients in the United States can receive seven-year marketing exclusivity, tax credit for the product-associated clinical research, research design assistance by FDA and grants of up to $200,000 per year. Sprycel works by reducing the activity of one or more proteins responsible for the uncontrolled growth of the leukemia cells and has been shown to reduce, and in some cases eliminate, detectable leukemia cells in the blood and bone marrow of patients with CML. As provided for under FDA accelerated approval regulations, studies are underway to demonstrate that these improved white blood cell counts also result in clinical benefit such as improved survival or improvement in leukemia-related symptoms.
*(Source: FDA Web site, 29 June 2006).*

### FDA Licenses Merck Vaccine for Prevention of Cervical Cancer

The FDA has announced the approval of Merck's Gardasil, the first vaccine developed to prevent cervical cancer and certain other conditions caused by the human papillomavirus (HPV). The vaccine is approved for use in females 9-26 years of age. It was evaluated and approved in six months under FDA's priority review process designed for products with potential to provide significant health benefits.

HPV is the most common sexually-transmitted infection in the United States. The Centers for Disease Control and Prevention (CDC) estimates that about 6.2 million Americans become infected with genital HPV each year and that over half of all sexually active men and women become infected at some time in their lives. Worldwide, cervical cancer is the second most common cancer in women and is estimated to cause over 470,000 new cases and 233,000 deaths each year. The vaccine is effective against the HPV types that cause approximately 70 percent of cervical cancers and approximately 90 percent of genital warts.

Gardasil is a recombinant vaccine (contains no live virus) and is given as three injections over a six-month period. Immunization with Gardasil is expected to prevent most cases of cervical cancer due to the HPV types included in the vaccine. However, females are not protected if they have been infected with HPV prior to vaccination, indicating the importance of immunization before potential exposure to the virus. This has prompted the Advisory Committee on Immunization Practices, which advises the CDC, to recommend that the vaccine be added to the routine vaccination schedule for children and adolescents.
*(Source: FDA Web site, 8 June and The Wall Street Journal, 30 June 2006).*

### FDA Approves Two Drugs for Treatment of Parkinson's Disease

The FDA recently approved two drugs for the treatment of Parkinson's disease, Teva Pharmaceutical Industries' Azilect (rasagiline) and Novartis' Exelon (rivastigmine tartrate). Azilect, a new molecular entity, is a monoamine oxidase type-B (MAO-B) inhibitor that blocks the breakdown of dopamine, a chemical that sends information to the parts of the brain that control movement and coordination. Azilect was approved for use as an initial single drug therapy in early Parkinson's, and as an addition to levodopa, a standard treatment for the disease, in more advanced patients. Novartis' Exelon treats the mild to moderate dementia associated with Parkinson's and was previously approved for the treatment of Alzheimer's.

Parkinson's disease is a chronic, progressive neurodegenerative condition caused by the destruction of the brain cells that produce dopamine. As the level of this chemical declines, messages from the brain telling the body how and when to move are delivered more slowly, leaving a person incapable of initiating and controlling movements in a normal way. In addition to physical symptoms, about 0.2 to 0.5 percent of people over 65 years of age are affected by Parkinson's dementia and experience such symptoms as impairments in reasoning, memory and attention.
*(Source: FDA Web site, 17 May and 27 June 2006).*

### FDA Approves Pfizer's Chantix for Smoking Cessation

The FDA has announced the approval of Chantix tablets to help cigarette smokers stop smoking. The active ingredient in Chantix, varenicline tartrate, is a new molecular entity that received a priority FDA review because of its significant potential benefit to public health. Chantix acts at sites in the brain affected by nicotine and may help those who wish to give up smoking in two ways: by providing some nicotine effects to ease the withdrawal symptoms and by blocking the pleasurable effects of nicotine from cigarettes if they resume smoking.

According to the Centers for Disease Control and Prevention (CDC), an estimated 44.5 million adults in the United States smoke cigarettes and more than 8.6 million of them have at least one serious illness caused by smoking. Based on data from the American Cancer Society, tobacco use causes nearly one-third of US cancer deaths and, on average, smokers die 13 years earlier than nonsmokers.

The effectiveness of Chantix in smoking cessation was demonstrated in six clinical trials, which included a total of 3659 chronic smokers who were treated with varenicline. Five of the six studies were randomized, controlled clinical trials in which Chantix was shown to be superior to placebo in helping people quit smoking. The downside: a year after they stopped taking the drug, half of those who quit smoking had again taken up the habit.
*(Source: FDA Web site, 11 May and Diedtra Henderson, The Boston Globe, 12 May 2006).*

## Regulatory and Legislative Highlights

*Continued.*

### Biogen Idec's Tysabri Receives FDA and EU Approval for Return to Market

Biogen Idec and partner Elan Corp. won permission from the FDA to resume marketing Tysabri (natalizumab). Tysabri is a monoclonal antibody used to treat patients with relapsing forms of multiple sclerosis (MS). Elan Corp., the drug's distributor, plans to raise the price of the drug by as much as 21 percent when it reenters the market in July, from $23,500 to $28,400 a year per patient.

Tysabri was initially approved by the FDA in November 2004, but was withdrawn by Biogen Idec in February 2005, after three patients in the drug's clinical trials developed progressive multifocal leukoencephalopathy (PML), a serious and rare viral infection of the brain; two of the cases were fatal. Based on this information, FDA put clinical trials of the drug on hold in February 2005, allowing them to resume in February 2006, following confirmation that there were no additional cases of PML among patients who had participated in the previous trials.

FDA determined that Tysabri can return to market based on a thorough review of the risk management plan developed by Biogen-Idec and changes to its original marketing application. In a related development, the European Commission approved the drug for patients with the severest cases of MS and those who haven't been helped by older treatments. According to analysts, Tysabri is eventually expected to reach $2 billion in annual sales.

*(Source: FDA Web site, 5 June and The Boston Globe, 10 June and 30 June 2006).*

### FDA Announces Plans for Nanotechnology Public Meeting

The FDA will be holding a public meeting in the fall of 2006 designed to gather information about current developments in the use of nanotechnology materials in FDA regulated products. The agency is holding the meeting to further its understanding of developments in the field, specifically:

- new types of nanotechnology products under development in the areas of human and animal drugs and human biologics and medical devices as well as foods (including dietary supplements), food and color additives, animal feeds, and cosmetics;
- scientific issues relevant to the FDA's regulatory role that are related to the development of these products;
- any other issues concerning the use of nanotechnology in FDA-regulated products; and
- hurdles that may be inhibiting the use of nanotechnology in medical product development.

While the agency is not accepting registrations at this time, it would appreciate receiving expressions of interest from those planning to attend or present at the meeting. Information can be provided to Poppy Kendall at Poppy.Kendall@fda.hhs.gov or 301-827-3360. Details about the venue, specific date, time, and registration will be provided in a Federal Register notice closer to the meeting and via updates at www.fda.gov/nanotechnology.

*(Source: FDA Web site, 13 April 2006).*

## New Members

**Daniel M. Agustin,** Senior Engineer, Alkermes/Engineering
**Benny Ber,** QA Manager Comp. Systems, Inotek Pharmacuticals Corp
**Chris Blanchard,** Manager, Lonza Biologics
**Maurice R. Boiteau,** Regional Sales Manager, Pneumatic Scale Corp.
**Deborah Botham,** Manager of Marketing, DECCO Inc
**Christopher Brown,** Supervisor Facilities, Bristol-Myers Squibb
**Shawna Burke,** Innovative Process Solutions
**Geddie J. Busanovich,** Senior Project Manager, Wyeth Biotech
**Timothy P. Chicoine,** Account Manager, Chalmers & Kubeck North
**Bruce Davidson,** Sales Executive/Business Development Manager, Arbour Group LLC
**Joseph F. Devlin,** Director, Business Dev., Skanska USA Building Inc.
**Amy Foley,** Project Planner, The Richmond Group Inc.
**Ernest P. Gabriel,** Engineer, Wyeth/BIS
**Linda Gilbert,** Corp. Program Manager, Millipore Corp.
**David A. Harding,** Operations Manager, Tuchenhagen Flow Components LLC
**Brian M. Krikorian,** Process Engineer II, Genzyme Corp.
**Roxanne Lau,** Engineer, Epic Therapeutics Inc.
**April L. Mascia,** Assoc Manager, Clinical Trial Materials Mgmt., Sepracor Inc.
**John Mathew,** Senior Research Engineer, Cabot Corp.
**Charles E. Mirabal,** Validation, Biogen Idec
**Nikolai G. Mongroo,** Director of Manufacturing, Lonza Biologics
**Hillary Murphy,** Manager, Clinical Trial Materials Mgmt., Sepracor Inc.

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## New Members

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**Edward J. Nickerson,** Project Manager, GMP Piping Inc.
**Dina M. Petagna,** Engineering Document Supervisor, Wyeth BioTech
**Duncan Phillips,** Training Specialist, Millipore Corp.
**Jeffrey S. Rosen,** Senior Industrial Engineer, AstraZeneca
**Norma Santana,** Engineering Document Associate, Wyeth
**Seth T. Shapiro,** Senior CMC Regulatory Affairs, Ariad Pharmaceuticals Inc.
**John F. Shaw,** President, J.F. Shaw Co. Inc.
**William Small,** National Account Manager, Optimation Technology
**Rob Smith,** Regional Sales Manager, MasterControl Inc.
**Ian M. Striffler,** Validation Engineer, Abbott Bioresearch Center
**Michael Taylor**
**Daniel Trimberger,** Senior Manager, Momenta Pharmaceuticals
**Michael J. Wojcik,** Sales Engineer, Tenergy Christ Water LLC
**Timothy M. Zetts,** Regional Sales Manager, Topline Process Equipment Co.

## New Student and Faculty Members

**Mayank D. Bhavsar,** Doctoral Candidate, Northeastern University
**Tracy L. Blasingame,** Student, University of Rhode Island
**Dr. Edward G. Bozzi,** Professor, University of Rhode Island
**Cy M. Chan, Student,** University of Massachusetts Amherst
**Suman Dandamudi, PhD,** Student, Northeastern University
**Anthony C. Desmarais,** Student, University of Rhode Island
**John N. Halverson,** Student, Trinity College
**Abhishek G. Joshi,** Student, UMASS Lowell
**Ashish V. Kalra, Student,** Northeastern University
**Monalisa Murray,** URI
**Rishikesh M. Sawant,** Graduate Student, Northeastern University
**Lipa K. Shah,** Student, Northeastern University
**Aniket R. Songade,** Student, UMASS Lowell
**Gayathri R. Turaka,** Student, UMASS Lowell
**Lilian E. Van Vlerken,** Doctoral Student, Northeastern University
**Jia Yin,** Graduate Student, Northeastern University