A quarterly newsletter published by the
Alumni Network of Eli Lilly and Company

AlumniNews

Fall 2010 Issue XV

Dear Lilly Alum,

In our complicated world, establishing priorities can be a tricky business. To cut through the clutter, I've always found it useful to rely on a straightforward approach: decide on the few things that really matter, and do them really well.

Innovation Mandate

From a corporate perspective, innovation is at the top of our list—with the goal of providing new, better treatments to help patients fight diseases like cancer, diabetes, and Alzheimer's. To win that battle, we will continue to focus squarely on our high-quality pipeline, integrating efficient, cost-effective R&D capacity and adding molecules, funding, and expertise from partners around the world.

First Things First

Exciting collaborations are also in the works among Lilly alumni, as our colleagues translate their own priorities into action. This newsletter covers two impressive undertakings: the establishment of Indiana's first independent review board and the creation of a globally distributed drug discovery initiative to address neglected diseases.

Stories like this illustrate the progress that's possible when talented, intelligent people set high goals and go to work. I'm confident that with full knowledge of the good we can accomplish—and with an unrelenting passion to achieve it—we will find a way to deliver the breakthrough innovations that are so important to us all.

John C. Lechleiter, Ph.D.
Chairman, President, and Chief Executive Officer
Eli Lilly and Company

ALUMNI NETWORK SUMMARY

Registered Members:
1,089

18 UPCOMING EVENTS

San Francisco Breakfast at JP Morgan Conference, 2011
January 11, 2011

New Lilly Alumni site up and running!
Don't miss the chance to make new connections on LillyAlumni.com. Update your profile, join a group, start a discussion, or sign up for an event. Ideas for alumni stories and events are always welcome! Post them on LillyAlumni.com, email alumni_admin@lilly.com, or call 1-888-LLY-ALUM.

Lilly
Answers That Matter.

Bill Scott

Bill Scott's Global Road to Discovery

After 27 years at Lilly, chemist Bill Scott decided to apply his passion for drug discovery research in a setting outside the corporate environment—namely Indiana University-Purdue University Indianapolis, which has been a solid base for work that has taken him to Russia, Poland, Spain, and most recently Kenya. Bill took time to talk about the importance of addressing neglected diseases, bringing practical scientific experience to students, and continuing to implement new, economical ways to build on collective knowledge and apply it to the benefit of others.

Q: *What prompted your move from Lilly to IUPUI?*

A: I've always loved to teach, and I had the chance to take early retirement from Lilly and join IUPUI in 2002. The transition was easy. While at Lilly I taught part time at IUPUI and Butler University, and I had lots of contacts in the wider academic community. I also felt—and still strongly feel—that we must find innovative ways to tackle neglected diseases like malaria, tuberculosis, and leishmaniasis, and that universities currently offer an ideal environment to achieve that goal.

Q: *Have you made any progress to date?*

A: Right now my colleague Marty O'Donnell and I are in the process of rolling out a program we call Distributed Drug Discovery, or D3. We think D3 has a lot of promise. Simply put, we've created a strategy that enables students around the world to identify and synthesize large numbers of molecules that have the potential to be drug leads for neglected diseases.

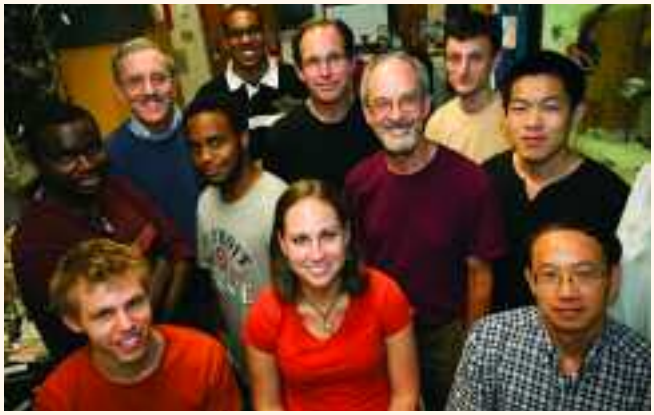
Q: *How does D3 work?*

A: As we looked for ways to further both discovery and learning with fairly limited resources, we realized that our typical methods of teaching chemistry synthesis could be better leveraged and more productive. It's relatively common, for example, for undergrad and even graduate students to assemble molecules that have been made before and then toss them out. With D3, we've put together a set of powerful synthetic procedures that can be performed by any chemist using relatively simple and inexpensive equipment. After synthesizing a control molecule, the students get creative and make new, unique molecules. They increase their understanding of chemistry while at the same time making molecules that can be screened and used to generate leads down the road.

Q: *Why the trips to Russia, Poland, Spain, and Kenya?*

A: In addition to our goal of involving students directly in research, a driving force and, I believe, a benefit of our model is the idea that the ability of students to engage in the disciplines of drug discovery should be universal and reproducible. With D3, a chemist in Moscow makes a new molecule using the same basic recipe and ingredients as a student in Indianapolis. If they can replicate each other's work, it can be repeated and scaled up with confidence.

The scope and potential for exploration and synthesis is much greater with distributed discovery around the world. I go out to universities to explain our program and engage them. My trip



to Nairobi, Kenya, in October was to see how our D3 project can help ANDI, the African Network for Drugs and Diagnostics Innovation. ANDI is working to help African nations establish sustainable R&D capabilities directed toward diseases that have a disproportionate effect on people in that region of the world.

Q: *What part, if any, do for-profit pharma companies play in your efforts?*

A: I would not have the depth of expertise in drug discovery if it hadn't been for the resources, both human and material, that are available in the for-profit pharmaceutical industry and at Lilly in particular. Even now, Lilly assists our efforts by providing the necessary analytical capacity to characterize the many new molecules our students make. If Lilly makes screens for neglected disease targets available through their PD^2 program, D3 will submit new molecules to that initiative too.

I'm hopeful that through testing our D3 compounds, companies like Lilly will find molecules that can be used to fight diseases for underserved populations. As D3's scope becomes more widespread, pharma could supply the managerial and technical expertise to coordinate this growing effort. We would welcome any Lilly alumni who see in D3 an opportunity to give back from their wealth of experience and talent and assist us in this effort. It's early days, but collaboration between public and for-profit institutions will be key as we search for cures.

Q: *Are you teaching at IUPUI as well?*

A: I teach two graduate-level classes there. One is on solid-phase combinatorial chemistry and the other is on drug discovery and action.

Q: *Any other projects in the works?*

A: I helped establish a community garden at an Indianapolis church, and I'm a huge proponent of public transportation. The last time I filled my gas tank was in March. I'm incurably drawn to projects and processes that involve frugality and cycles that renew themselves.

Biography

Now a research professor of organic and medicinal chemistry at Indiana University-Purdue University Indianapolis, Bill worked at Lilly from 1974-2001 in multiple therapeutic areas of drug discovery research. He earned his Ph.D. at the University of California, Los Angeles, and his B.A. at Williams College. Bill also served as an NIH postdoctoral fellow at Rockefeller University and California Institute of Technology.

Pearl IRB Founders Dedicated to High-Quality Service, Output

Diana Caldwell

Gretchen Bowker

As the gatekeepers of all clinical trials in the United States, institutional review boards (IRBs) make critical decisions that affect hundreds of potential medicines every year. IRBs traditionally have been the purview of hospitals and universities, where boards are staffed by volunteers who meet monthly to review submitted protocols. But as backlogs build, and as sponsor firms and the contract research organizations who serve them are looking for ways to minimize delays, commercial IRBs are receiving increased attention as an option for clinical protocol review.

Momentum Building for New Model

With that growing demand—and a host of other strategic goals—in mind, Lilly alumni Diana Caldwell and Gretchen Bowker founded Indiana's first commercial institutional review board, Pearl IRB, in 2010. Not affiliated with a particular university or hospital, and also known as a central or independent IRB, Pearl is based at the Indiana University Emerging Technologies Center near downtown Indianapolis. Pearl joins an estimated 20 to 30 other commercial IRBs nationwide.

"While we'd been planning for more than a year, we officially formed the company in February, trained staff in March and April, registered with the Office for Human Research Protections and the FDA in May, and got our first client in June," says Bowker, now chief operating officer. "We already have prospective clients calling from coast to coast, and they like the fact that we're centrally located. Things are moving along really well."

Caldwell, who serves as president, notes that for a similar price, Pearl offers several potential advantages over traditional IRBs. "Our company exists to provide ethical, high-value service to our clients, and we are very focused on efficiency, communication, and transparency," she says. "Since Gretchen and I have spent many years on both the service provider and sponsor sides, we know how important those qualities are when it comes to choosing—and now running—a high-quality IRB."

A key component of Pearl's strategy is to provide clients with a reliable timetable for reviews. The board meets every Thursday and issues a decision the week after the protocol is submitted. "And if we don't approve an application, we make sure our clients know the reasons, so they can address the issues. Good communication and transparency are critical," Bowker says, "because our ultimate goal is to help companies make progress for the benefit of patients."

Another advantage Caldwell sees to an independent IRB is the ability to centralize protocol review. "You may have 400 sites in and outside the U.S., which can be a nightmare to manage," Caldwell says. "With us, you can get it all done at one time, and if anything needs to be changed, it's easier to fix it from one central location."

Bowker adds that this view recently received support from Dr. Jerry Menikoff, director of OHRP, in the October 21, 2010 issue of the *New England Journal of Medicine*. In his article, "The Paradoxical Problem with Multiple-IRB Review," Menikoff says, "In terms of protocol review, the current system whereby multiple IRBs review a multi-site study leads to a diffusion of responsibility and reduces the likelihood that appropriate changes will be made to protocols."

To accomplish its mission, Pearl maintains a seven-member core board, which is supplemented with a panel of advisors when necessary. Bowker says that she has been amazed at the local talent pool from which she can draw reviewers and advisors. "I always have awesome resumes coming my way," she says, "and that means our clients get the benefit of very experienced, diverse reviewers who really understand the role and impact of an IRB's decisions." Caldwell and Bowker both hope that retaining such highly trained medical and scientific professionals will benefit the State of Indiana—in the form of greater employment opportunities as well as more significant clinical trial activity.

Caldwell's goals over the next few years include expanding services into Canada and earning AAHRPP (Association for the Accreditation of Human Research Protection Programs) accreditation. She says that based on client requests, Pearl already has begun offering services such as site monitoring, site rescue, protocol strategies and writing, IRB member training, and staff augmentation services in administration and operational support. "And if demand continues to grow," she adds, "we eventually will be able to run a board every day."

Prepared to Lead

Caldwell sees her 15 years with Lilly as instrumental in building the skill set required to start and run a business. Her experience began with a 1990 summer internship with the devices and diagnostics division at Hybritech in San Diego, after which she joined the core pharmaceutical business as a sales representative. Caldwell considers the 18 months she spent in the field as a Prozac rep as foundational for her career, with one interaction standing out in particular. "I was coming out of a pharmacy when an older gentleman approached me and asked if I worked for Lilly," she remembers. "When I said yes, he thanked me sincerely for 'giving him his wife back.' You don't get that kind of feedback in every industry, and in that moment I knew a life sciences career was what I wanted."

Caldwell later took on a range of roles in sales management and marketing, which included launching Evista in Latin America and building interactive e-marketing capabilities. After leaving Lilly, she spent three years with a local regulatory and compliance consulting company, where Gretchen Bowker also worked.

"We didn't meet until after we left Lilly, although our time overlapped and we knew many of the same people," says Bowker. A protein chemist by training, she spent 2 years in a medical school lab, 8 years at Boehringer Mannheim/Roche, and 10 years at Lilly. "I got a good grounding in basic research, diagnostics and devices, and then large molecule development and regulatory work," Bowker says. Since then, she's been applying her skills to helping start-ups make their way over myriad commercial and regulatory hurdles.

Reflecting on the activity and accomplishments of the past 18 months, Caldwell says, "Running a company is difficult but extremely rewarding. And I think often about how much the mentors, the training, and the experiences I had at Lilly contributed to my ability and desire to start this company with Gretchen."

Bowker agrees that being an entrepreneur is demanding. "It's been a lot more work than I envisioned, but it's nice to control your own vision and where you're going. I have really been impressed with the support we've received in establishing Pearl IRB—and a lot of that support has come from other Lilly alumni."

Lilly to Add Mirror Funds to Speed Innovation

Lilly has designed and is planning to invest in three venture capital funds to supplement the company's pipeline and expand access to innovation. The Mirror Funds will license drug candidates from Lilly and other companies and pay for clinical development and testing to take the compounds through clinical proof of concept.

Lilly is retaining rights to buy back all Lilly molecules licensed by the funds as well as to evaluate and acquire a limited number of external compounds. Within five to seven years, the funds are designed to pay for the development of a pipeline of compounds that mirrors Lilly's own pipeline.

Additional highlights include:

- Three experienced venture capital fund managers are raising money for the funds from investors such as insurance companies, pension plans, and endowments. Lilly has committed to invest about 20 percent in each fund.
- Each fund raises up to $250 million and invests in taking 15 to 20 molecules from Phase I through (in most cases) Phase IIa clinical development, which provides a data package including safety and early efficacy information.
- Over a period of five to seven years, the three funds will enable the early clinical development of up to 60 molecules, from Lilly and outside companies.

Jan Lundberg, Ph.D., executive vice president of science and technology and LRL president, says, "We believe that developing and participating in these funds gives us a more robust and reliable source of external innovation, while at the same time reducing our risk on some of our investments on novel, yet high-risk, internal molecules." This new approach complements LRL's existing partnering and acquisition strategy for new technologies and molecules.

For drug development work, fund managers have the option of using Chorus, a group of Lilly scientists that manages a portion of the company's molecule programs using outside scientists to do most clinical development work. Using Chorus can help generate high-quality data quickly, in the interest of determining whether compounds merit further development as potential therapies.

Connections (continued)

Jacques Tapiero, senior vice president and president of emerging markets, also attended the event. "It was great to see many old friends," he said. "Given their unique backgrounds with Lilly, they also could offer interesting perspectives on where we are going and opportunities that may help us get there. I am excited to hear more from them at the next opportunity."

In Los Angeles

On September 20, John Lechleiter hosted an event for area alumni in Los Angeles. "It was a real pleasure for the California group to meet John and actively talk in a small group setting," said Jim Stevenson of Santa Barbara.

"We had a wonderful dinner together," Lechleiter reflected, "and I took the opportunity to provide an update on what's going on within the company, and I took away with me some good advice, too!"

To read more or to provide a comment about either event, visit LillyAlumni.com.

Alumni Make L.A., Indy Connections

Email and online sites offer efficient means to communicate, but there's nothing like getting together in person! That's just what many Lilly alumni did at two recent Network events—one held at Lilly Corporate Center in Indianapolis and the other at the Intercontinental in Los Angeles.

In Indy

On August 10 in Indianapolis, alumni met with top Lilly leadership and enjoyed food and conversation on the newly redesigned board level. Bart Peterson, former two-term mayor of Indianapolis now serving as the company's senior vice president for corporate affairs and communications, offered an update on Lilly's activities to increase innovation, control costs, and speed development.

"It was inspiring to be in the presence of many of the people who helped bring life-changing medicines to people and who helped make Lilly the extraordinary company it is today," said Peterson.

(continued – see "Connections")

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