



# INNOVATION UPDATE

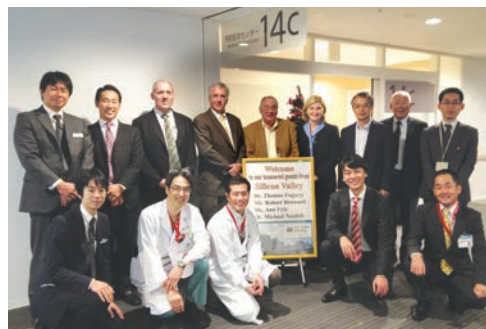


Thomas Fogarty, MD  
with Ann Fyfe, CEO.

As we head into the end of 2013, we want to reflect on the amazing progress we have made this year. We have so much to be thankful for – in the growth we have enjoyed, and the support that has made it possible. We have seen significant expansion in every area at the Institute. We have just added two new Board members who are sharing their time and talents with our organization. Please join me in welcoming Dr. William R. Brody and J. Casey McGlynn to our fold. Meanwhile, things are humming at the Fog Shop, our additional workshop space in the old El Camino Hospital building. We are incredibly grateful for our partnership with the hospital and their support is invaluable to our efforts. We now have 12 companies working hard to hone their concepts. And we're excited about plans based on our recent trip to Japan to confer with innovators there. Thanks to your support, our vision for improving patient care is truly taking shape. We sincerely thank you for your contributions and know that together we CAN make a difference. Happy Holidays.

## Partners in Innovation – VISIT TO JAPAN FURTHERS INNOVATIVE SPIRIT IN BOTH CULTURES

For seven days in October, three executives from the Fogarty Institute for Innovation traded their Silicon Valley desks for offices and boardrooms more than 5,000 miles away in Japan to help further the innovative spirit in both cultures.



Aso Iizuka Hospital staff gave the group an especially warm welcome.

This was the second visit to Japan for Dr. Thomas Fogarty, Ann Fyfe, CEO and Mike Needels, COO to meet with government officials, hospital CEOs and executives from some of Japan's major corporations. The Japanese hosts and their American visitors not only exchanged ideas but also established working relationships and fruitful associations for the future.

"Japan has made it a priority to foster and grow innovation in both business and health care in their country," says Ann. "They have many ideas, and they want to know more about how to bring those ideas to market."

This is exactly what the Fogarty Institute and its "international ambassadors" are able to offer, she says. "Because of our familiarity with Silicon Valley and its culture,

we can help them understand how innovation can and does work under the right circumstances."

The group's previous visit in April 2012 resulted in representatives from Mitsubishi Corporation establishing a research base at the Fogarty Institute.

The group also paid a second visit to Aso Iizuka Hospital, a private hospital run by the Aso Corporation, considered one of the highest quality hospitals in Japan. The hospital's applications of TQM (Total Quality Management) and activities to promote medical safety have attracted national attention.

"This is an exciting reciprocal relationship," says Ann. "Just recently a group from El Camino Hospital visited Aso to learn from a first-hand view of its operations, and this past summer, Aso sent its first "Fellow" over to this country to spend three months with us at the Institute.

**"As we know, innovation is the key to the future, especially in medicine. We are so pleased to have this opportunity to work with Japanese companies as they focus on the advancement of entrepreneurship and innovation in their country."**

## Small device a big win for patients



*Dr. Fred St. Goar with the MitraClip.®*

### MITRACLIP® GETS FINAL FDA APPROVAL

Thanks to the innovative thinking of Fogarty Institute Board member, Dr. Fred St. Goar, (and initial support and guidance from Dr. Fogarty), the invention of the MitraClip® device began more than 14 years ago. We are thrilled to report that on October 25 the MitraClip®, owned by Abbott, received final FDA approval for U.S. clinical use. U.S. cardiologists have the go-ahead to use this breakthrough treatment as a minimally invasive alternative to mitral valve surgery, which is especially beneficial for

patients who are at prohibitive surgical risk for the traditional method of open heart surgery.

“We wanted a way to reduce the risk, trauma and cost of open heart surgery, and create a therapeutic option for a large population of patients for whom surgery is too risky. The procedure has been successfully performed in over 10,000 patients in more than 30 countries. We are pleased to be able to finally offer this therapy to deserving patients in this country,” says Dr. St. Goar.

The device, a tiny clip implanted percutaneously through a catheter introduced via the femoral vein, keeps the mitral valve closed when needed, preventing inappropriate backward flow of blood in the heart. Mitral regurgitation is a common problem, affecting more than 4 million Americans — nearly one in 10 people aged 75 and above.

During the U.S. clinical trial for MitraClip®, in coordination with Fogarty Clinical Research, Incorporated. (FCRI), El Camino Hospital’s premier structural and valvular heart program, based at the Norma Melchor Heart and Vascular Institute, was one of the few centers in the country to offer access to this innovative therapy.

The FDA-approved MitraClip®, invented by Dr. Fred St. Goar, is now available as a less risky option than surgery for treating mitral valve regurgitation.

## Stories of support

### Tradition Plus Opportunity

FOR THIS YOUNG INVESTOR,  
NEW WAY OF SUPPORT “EXCITING”



*By investing, Lane Melchor, grandson of the late Norma Melchor, is expanding his family's long time support of hospital and community.*

Lane Melchor, grandson of Jack and the late Norma Melchor, knows firsthand the power of philanthropy. For more than 50 years, the Melchor family has supported El Camino Hospital through multiple major gifts, including the recent donation to the Heart & Vascular Institute, which was renamed in his beloved grandmother's memory.

“I've always been impressed with El Camino Hospital's use of innovative technology and patient care,” he says. “With the Fogarty Institute, a creator of innovative ideas, the two organizations have the potential to be real game changers for better health care.”

Lane, says he wanted to get involved on the investment side of health care as well. At a recent visit to our Fog Shop, he heard presentations by four of the companies-in-residence at the Institute, hand-selected by Lane according to his interests and with advice from respected sources. In just 20 minutes, he had picked three companies to support.

“I was sold,” he said. “These are young, creative people, ready to make a real difference in health care. Their companies have been well screened by Dr. Fogarty and the physicians at the Institute, so I felt comfortable with the risk.

“Getting involved at this point in a company's history — the incubation period — is fun and exciting. I challenge anyone to visit the Fog Shop and come away without feeling the same way.”

### The Difference Must Be Real

MARKKULA'S WANT TO IMPACT  
NEW IDEA'S CHANCE OF SUCCESS



*Fogarty Institute offers donors a way to make a difference say Linda and Mike Markkula.*

According to Mike and Linda Markkula, the best part of philanthropy is the knowledge that your gift is making a difference.

With their gift to the Fogarty Institute for Innovation, the difference is clear, says Mike, one of Silicon Valley's pioneers and an entrepreneur himself. Markkula provided critical funding to Steve Jobs and Steve Wozniak when they were founding Apple Computer; he later became the company's second CEO,

“I know from experience how difficult it is to get new ideas into the marketplace,” he says. The Fogarty Institute is unique, however. Here funds can have a direct impact, helping to speed up the process and make it more efficient. Dollars given to the Institute are where the rubber meets the road.”

Markkula credits his wife Linda and daughter Kristi Bowers, director of the Markkula Foundation, with the work of distributing funds from the family foundation. To the Markkulas, major financial supporters of the Markkula Center for Applied Ethics at Santa Clara University, it was natural to support Dr. Tom Fogarty in his efforts to keep medical innovation alive.

“Dr. Fogarty embodies the entrepreneurial spirit of Silicon Valley,” says Mike. “He has a passion for invention, always thinking out of the box. He's right up there with that other Tom, you know, the one that invented the light bulb.”

## No Ordinary Internship



*From left: Teresa St. Goar, Sydnee Hyman (pink shirt), Cambia Green, Mark de-Bettencourt, Jon Thompson, MD, Taira Hovden, and Marlie Adamson find the internship program uplifting.*

“I think the Fogarty Institute is a really exciting place with so many passionate, intelligent people from such diverse backgrounds, and I feel really fortunate to have gotten to work here.”

— Sydnee Hyman

SYDNEE IS A JUNIOR  
AT PURDUE UNIVERSITY  
IN WEST LAFAYETTE, INDIANA.

## UNIQUE SUMMER PROGRAM INSPIRES STUDENTS TO INNOVATE

The coolest educational opportunities this summer were likely the ones offered by the Fogarty Institute to high school and college students wanting to enter the extraordinary world of medical innovation. We offer the program to those interested in becoming physicians, bio-engineers, clinical research professionals or medical innovators.

“We have noticed that there is a real lack of programs for students to get exposure to the vast areas of medicine,” says Debbie Gairaud, Director, Human Resources and Educational Services. “At the Fogarty Institute, we certainly have the type of environment that could offer students a one-of-a-kind opportunity and we wanted to expose students to the real wonders of medicine.”

Four high school students, two college students plus one physician Fellow, who wanted to know more about inno-

vation in Silicon Valley, participated in the summer program with an overall goal of getting real time, hands-on information and experience about becoming an inventor, researcher and/or physician and how the Silicon Valley eco-system helps propel success.

Debbie developed a customized program based on the educational desires of participants. “Not only did participants contribute on real time issues and projects, but we assigned each a mentor, set up fact-finding interviews, coordinated physician shadowing and arranged for one-on-one time with Dr. Fogarty and other preeminent Silicon Valley icons to discuss the various educational opportunities available in medicine. Our overall goal was to open up the blinds and shine a light into the vast diversity that medical careers encompass.”

At the end of the summer, families and friends were invited to a special event to witness firsthand what the interns had been working on.” The program was satisfying to all — I think not only the students, but staff and mentors gained great knowledge,” says Debbie

“We’re excited about opening up the application process and meeting a whole new group of enthusiastic students next year.”

## New Board Members

We are pleased to announce two new additions to our Board of Directors. They bring wonderful expertise and experience to their roles and provide valuable depth and breadth to our organization. They will work closely with our continuing Board members to guide our progress in the coming year (Fredrick St. Goar, MD, Thomas Fogarty, MD, John Goodrich, JD, and Lewis Wexler, MD).



### DR. WILLIAM R. BRODY

Dr. William Brody, former president of the Johns Hopkins University, currently serves as president of the Salk Institute for Biological Sciences in La Jolla, CA. An acclaimed physician-scientist entrepreneur and member of Stanford University Board of Directors, Dr. Brody is renowned for his achievements in biomedical engineering, with two U.S. patents in the field of medical imaging.

“Dr. Brody’s efforts to encourage innovation and strengthen the U.S. economy through investments in basic research and education make him a perfect fit for the Fogarty Institute board,” says Dr. Fogarty. “This will be the beginning of what we know will be a truly fruitful relationship.”



### J. CASEY MCGLYNN

J. Casey McGlynn is a partner at Wilson Sonsini Goodrich & Rosati, and a nationally recognized leader in the representation of start-up and growth technology companies. He has been working with life science companies for over 30 years, and has represented dozens of companies that have made successful initial public offerings and secondary offerings.

“We are very fortunate to have a person of Mr. McGlynn’s caliber join our board,” says Fred St. Goar, MD, board member. “He is a respected, visionary leader in the investment and legal community, and as a Fogarty Institute board member, will be invaluable as we guide companies to a successful future.”

# Ideas by the dozen!

## INNOVATION IS ALIVE AND WELL WITH OUR COMPANIES IN RESIDENCE.

We are thrilled to now have 12 companies in house, all working on exciting new ideas designed to improve patient care in their respective areas. Not only are they heeding the expert advice of our mentors, but they are enjoying the collaborative feedback that comes from the collective group. Read below to learn more about the companies, and see what they have to say about their experiences here.

**Clear Ear:** Delivering hearing innovations through the Total Ear Care (TEC) system, a cost effective set of instruments designed to provide safe and easy ear care for a range of outer-ear procedures. The product's first application addresses ear wax impaction, the number-one cause of hearing loss and hearing-aid failure worldwide.

“For Clear Ear, being at FII means having a partner who shares in our company’s vision and is committed to finding the right resources to get our start-up off the ground and take us one step closer to bringing our innovation to the hearing loss patients in need. One of the most invaluable resources at FII is the level of peer-to-peer learning that comes from being in the trenches with the other innovators-in-residence.”

**CyberHeart:** Has developed a system to allow cardiologists to non-invasively treat cardiac arrhythmias, such as atrial fibrillation, in an outpatient setting and without anesthesia.

“The array of resources and expertise immediately available to entrepreneurs and young companies cannot be matched anywhere in the country.”

**EchoPixel:** True 3D (t3D) is a medical visualization software solution that enables physicians to uniquely visualize and interact with image data depicting tissue and organs as if they were real physical objects.

“The Fogarty Institute has provided us the clinical insights and knowledge that have allowed us to close our first sale and establish the company on a path to growth.”

**First Pulse Medical:** Developing a novel technology platform to improve fetal monitoring during labor and delivery. The intrauterine technology utilizes a non-fetally invasive sensor to capture valuable fetal vital signs that will give obstetricians critical information related to fetal well-being.

“The FII has been instrumental to our company’s development given all the resources and guidance they provide. One of the more immeasurable benefits is the sense of ‘entrepreneurial comradely’ and peer-to-peer encouragement that flows from the educational forums, feedback conferences and shared work environment.”

**InPress Technologies:** Developing a single-use medical device to treat the number one cause of maternal death worldwide: postpartum hemorrhage. The InPress device is a simple and elegant treatment for uterine atony, working with the body’s natural healing mechanism while avoiding the use of pharmaceuticals and invasive surgery.

“The Fogarty Institute has helped us to accelerate our progress and minimize some of the inherent risks of a medical device start up. They’ve welcomed us into an amazing and invaluable community of peers and advisors. We are incredibly thankful for the opportunity to be part of such an impactful organization.”

**InterVene:** The ReLeaf Catheter System™ is the first ever percutaneous, venous valve creation platform that does not require a permanent implant. The system creates new valves out of a patient’s own vein wall, preventing blood from flowing backwards, and treating the underlying cause of chronic venous ulcers.

“Our company could not be more fortunate than to be at the Fogarty Institute for Innovation. The exposure and oversight of mentors who are pioneers and world renowned in the field of vascular medicine have been and will continue to be essential to our own success in this area.”

**manhole:** Developing a novel vascular implant for the treatment of Peripheral Arterial Disease that retains the advantages of the “kissing” stent technique, without compromising access options for future treatments.

“The Fogarty Institute to us means providing enabling resources. More specifically facilitating engaged interaction with physicians and industry experts, as well as providing access to technical resources all in a cost effective manner. Patients suffering from peripheral arterial disease will one day soon benefit from our innovative technology. Without the Fogarty Institute this would not be possible.”

**Materna Medical:** Working to reduce the incidence of childbirth-related injuries to women during vaginal delivery with a device designed to prevent tearing and pelvic floor damage during childbirth.

“To us, the Fogarty Institute is a home that offers us everything we need to maximize our chances of success.”

**Medical Cue:** The NeoCue System intends to solve a major need in newborn monitoring and resuscitation by automatically sensing key physiologic data and offering decision guidance through neonatal resuscitation and rapid venous access.

“We at Medical Cue are so appreciative of the Fogarty Institute’s expanded commitment to innovators and entrepreneurs who are working toward improving the health and safety of pregnant women and newborns. With the intellectual and physical resources available to us, we are getting closer to making these improvements in patient care a reality.”

**nVision:** Developing a device designed to significantly advance the diagnosis and treatment of female infertility caused by fallopian tube dysfunction.

“The Fogarty Institute’s Fog Shop is a unique environment, offering us not only the opportunity to develop our ideas and our products under world class mentorship, but also to benefit from the ideas of others working in our same area of focus.”

**Prescient Surgical:** Working to improve patient surgical outcomes and reduce medical costs by developing CleanCision,™ a platform technology developed to reduce the risk of surgical wound infections. The company’s first product targets a patient segment having the highest risk of infection: obese patients undergoing colorectal surgery.

“Being located at the Fogarty Institute has provided the Prescient team with very professional office and engineering lab facilities in a prime location in Silicon Valley. It also has provided access to experts in many fields related to medical device development and also to medical technology investors. Being associated with the Institute was very helpful to the company in raising our recently closed seed funding round.”

**Vida Systems:** Developing VidaBody, a 3D content teaching engine for anatomy and physiology. VidaBody makes learning easy by engaging students with interactive, rich content, interwoven game mechanics, and a social layer.

“The Fogarty Institute to us means tremendous support through the ups and downs inherent in entrepreneurship. The Institute has enabled our success through this support, as well as valuable advice and access to mentors, investors, and partners.”

## Open House for Fog Shop

More than 200 friends of the Fogarty Institute attended a festive wine and hors d'oeuvre reception on October 24, celebrating the opening of our new Innovation Center. Called the Fog Shop, which Dr. Fogarty says was the name of his first lab, the 14,000 square foot space, with room for both offices and labs, was formerly an unused area in the Old Main Hospital which El Camino Hospital made available to the Institute. Guests had a chance to wander through the Fog Shop, mingling with Dr. Fogarty and our companies-in-residence who were eager to demonstrate their ideas and projects.



*Guests exploring EchoPixel's True 3D;  
Dr. Fogarty with Michael and Melinda Hubbard.*

[Visit us on Facebook to see more photos from the Open House event.](#)



## Clinical trials at Taft Center expand into new areas of research

As we expand our horizons, so does Fogarty Clinical Research Incorporated (FCRI) at the Taft Center, a subsidiary we formed in 2011, thanks to a gift from Edward and Pamela Taft.

According to Betty deBettencourt, executive director, the Taft funds have established FCRI as a true clinical research center, offering the community access to a range of clinical trials that represent some of the most advanced treatment options available today.

FCRI's initial clinical trial offerings centered around cardiac procedures and devices, says Betty. "We are now able to offer trials sponsored by the biotech and pharmaceutical industry such as for oncology or diabetes."

Guiding the long-term success of FCRI and assuring its adherence to ethical and regulatory standards is FCRI's board of directors. Joining Lewis Wexler, MD, Thomas Fogarty, MD and John Goodrich, JD are the board's newest members Wes Alles, PhD and Charles Semba, MD.

### LEARN MORE.

If you'd like more information or would like a personal tour of the Institute and our new "Fog Shop," please contact Ann Fyfe at [ann.fyfe@fogartyinstitute.org](mailto:ann.fyfe@fogartyinstitute.org) or call 650-988-7590.



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