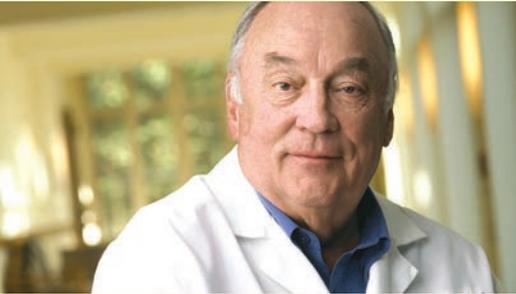




INNOVATION UPDATE



Thomas Fogarty, MD, Founder

I recently celebrated my 80th birthday, and many of you helped me do so at our gala fundraising event in February. Most who manage to reach this age would have long since retired. I haven't, because we still have important work to do. Work that can and will save lives. Work that we are asking YOU to support.

We founded the Institute, located on the El Camino Hospital campus, to pass on what we've learned about how to navigate the paths of medical innovation. We foster young innovators who have big ideas and small means. We bring in mentors to guide them in every facet of the process. We offer facilities to ease the process. And it's WORKING. As you read through these pages, you'll see for yourself. We hope you'll be moved to be part of the experience. The more we expand and support new ideas, the more support we need to do it well. Please consider helping us "find a better way" to spur innovation and improve patient care.

FII Alumni: Making Healthy Strides

"Success is measured in many ways, and we are pleased to see progress on all fronts."

— Thomas Fogarty, MD.

We have seen some very encouraging progress in the field of medical innovation in the last few years, both in the overall industry and from our own alumni. One of the first companies to graduate from the Institute was HeartFlow, co-founded by Charles A. Taylor, Ph.D. and Christopher K. Zarins, M.D. The colleagues spent years at Stanford University working on a non-invasive method of detecting cardiovascular stenosis, then came here to hone the idea. "The Fogarty Institute was very instrumental in the translation of our idea into patient care. They provided us with the space, mentorship, guidance and experience to help us understand how to create a business out of this exciting technology," said Taylor. Today, the innovative company provides physicians with a non-invasive test that provides functional and anatomic data to assist in the diagnosis of coronary artery disease. **HeartFlow has received CE mark in Europe and has a pending 510(k) application with the US Food and Drug Administration.**

Another successful alum is Niveus, maker of a device that provides electrical muscle stimulation for patients to prevent muscle deterioration during extended care. As one of the earliest innovators at the Institute, the Niveus team was in house before many of the current mentorship relationships were in place. The team benefitted from

the office and lab space provided, as well as convenient access to clinicians at El Camino Hospital for collaboration.

Brian Fahey, PhD, CEO, says "Having a relationship with the Institute, and by extension, the hospital gave us invaluable input in the early days that helped guide our plans." **Today, Niveus has an approved product in clinical use in hospitals and recently presented strong outcomes data at a conference for the American Thoracic Society.**

PQ Bypass, our most recent alum, has demonstrated impressive progress in developing a percutaneous approach to bypass the femoral artery with results that are comparable to traditional surgical bypass, but without the patient morbidity or hospital stay costs. The team spent two years at the Institute developing prototypes and collaborating with cardiovascular experts at every step of the process. Rich Lotti, CEO, credits the Institute with providing incredible resources that sped up the process. "Having cardiovascular specialists right across the hall who could provide feedback and input every week helped us move incredibly quickly. We went from concept to pre-clinical testing in just nine months."

PQ Bypass completed Series A financing of \$15 million in late 2012 and established operations in January 2013 in Sunnyvale, CA. The company is doing human clinical studies now in preparation for commercialization in Europe in 2015.

The Leteroff Fund

First awards given in honor of namesake, Tracy Leteroff.

“We are incredibly honored to have received the Leteroff grant. It is helping us reach our biggest milestone yet – clinical trials – we simply would not be at this point without the Institute’s overall support and this generous grant.” – Jessie Becker, CEO, InPress Technologies

The Leteroff Fund was established last fall to honor Tracy Leteroff, a remarkable leader in the life sciences industry and venture capital community who passed unexpectedly in June of 2013. The Leteroff Fund is a collaborative effort of California Healthcare Institute (CHI), the Fogarty Institute for Innovation (FII), and PricewaterhouseCoopers (PwC). Since the Fund’s inception, more than \$500,000 has been contributed to help further medical innovation in Tracy’s honor. We are pleased to announce the recipients of the first monetary awards, as selected by the advisory board. Awards totaling



2014 Summer Intern Program – Front row: Ann Fyfe, Sarah Long, Dr. Fogarty, Debbie Gairaud, Haley Reicher; Back row: Daniel Adler, Katherine Hobbs, Jamie Corley, Matthew Ingraham, Bret Pinsker, Fred St. Goar, MD.

roughly one fifth of the monies collected to date were awarded this month to support promising young people and innovative ideas that will create the next generation of new therapies and medical technologies. Awards were divided relatively equally in two areas, with half going to support education and half to support innovation. Recipients on the educational side include the blossoming internship and fellowship programs at FII, and the prestigious Innovator’s Workbench through Stanford’s Biodesign program. On the innovation side, funds were awarded to InPress Technologies, a young company that Tracy helped select for inclusion in the Institute’s mentorship program.



LETEROFF FUND ADVISORY BOARD

The Advisory Board provides oversight to the direction of the Fund and reviews recipient performance.

Allan Wil

Founder, The Foundry

Ann Fyfe

Fogarty Institute for Innovation

Casey McGlynn

Wilson Sonsini Goodrich & Rosati, PC

Dana Mead

Kleiner Perkins Caufield & Byers

Debbie Gairaud

Fogarty Institute for Innovation

Fred St. Goar, MD

Fogarty Institute for Innovation

Paul Yock, MD

Stanford Biodesign

Gordon Saul

Stanford Biodesign

Hank Plain

Lightstone Ventures

Jim Joye, DO

Fogarty Institute for Innovation

Mike Mussallem

Edwards Lifesciences

Molly Ingraham

California Healthcare Institute

Peter Claude

PricewaterhouseCoopers

Thomas Fogarty, MD

Fogarty Institute for Innovation

For more information or to make a donation, contact Ann Fyfe, President and CEO of the Fogarty Institute for Innovation. Call (650) 988-7590 or email ann_fyfe@fogartyinstitute.org

Stories of Support

STAR PLAYER IN THE INDUSTRY BACKS FOGARTY TEAM



Andrew Cleeland, President and CEO of Twelve, Inc., successful entrepreneur and business leader in medical innovation with Fred St. Goar, MD, interventional cardiologist and FII Board Member.

Andrew Cleeland has enjoyed considerable success as a medical innovator, and he knows what it takes to achieve it — a passionate team and experienced mentors. That’s why he’s been a generous donor to the Fogarty Institute for Innovation. “I know good ideas come to fruition only with the sustained effort of a committed team. Teamwork is the key to streamlined success, and that’s really the heart of the Institute.” Cleeland has known and worked with Tom Fogarty for years and ascribes to Tom’s philosophy that if you focus on truly fixing a problem for the patient, everything else will come. For those involved with the Institute, everything is coming through the comprehensive set of services provided by the Fogarty Institute. Cleeland is delighted to support this unique environment. “Capital is critically important for entrepreneurs, of course, but it’s only one aspect of development. The support provided for every facet of device inception through to commercialization at the Institute is unmatched anywhere.” While his current company is developing a percutaneous mitral valve replacement system, Cleeland actively supports other innovations with proceeds from his previous endeavors. “I have been fortunate to have had some degree of success in this field, solely due to the mentorship and collaboration I enjoyed. I can’t think of a better way to give back than to help nurture others as they explore their ideas.”

INDUSTRY LEADER HONORS LEFTEROFF’S LEGACY

Peter Milner, MD is an established triple threat in the field of medical innovation, so it’s an honor that he chose to make a substantial donation to the Lefteroff Fund. Milner’s CV includes a long list of accomplishments in each area of his career — board-certified cardiologist, university professor, and business leader. His skills in science, medicine and business intersect beautifully, and that was recognized by both Tracy Lefteroff and Tom Fogarty. Both men were supportive and influential in Milner’s successful efforts to bring products to market. “I worked with Tracy and Tom in various roles in the past — both made amazing contributions to medicine, the life sciences, and to me personally.”

With more than 50 patents to his credit and having been instrumental in invention and development of 3 marketed drugs, Milner has dedicated his life to developing safer, better therapies for patients. Tracy shared this passion, and the Fogarty Institute is founded on this mission. “Giving to the Lefteroff Fund is a perfect way for me to honor Tracy’s legacy by helping others follow in his footsteps with the help of the Fogarty Institute. I do it in his memory and in honor of his wife and boys.”



Peter Milner, MD, FACC; CEO Heart Metabolics and Co-Founder Optivia Biotechnology, CV Therapeutics, and ARYx Therapeutics; Chairman at Armethon; Member, Board of Directors at SinuSys Corp.

Celebration of Innovation | FEBRUARY 27, 2014

DR. FOGARTY'S BIRTHDAY CELEBRATION RESULTED IN FOND ADMIRATIONS AND HEALTHY CONTRIBUTIONS.



Ann Fyfe, CEO with Thomas Fogarty, MD, founder of Fogarty Institute for Innovation.

Our Celebration of Innovation held February 27th at the Tech Museum in San Jose was a success by any measure. Just under 400 people attended — a lively mix of entrepreneurs, physicians, innovators, dignitaries, friends, family and admirers who all turned out to wish Dr. Fogarty well and honor his life and legacy as a medical innovator. Attendees celebrated inventions past and present, toasted work in progress, and raised more than \$400,000 to fund the Fogarty Institute's efforts to foster medical advances to improve patient care.

“The overwhelming support for Tom and the Fogarty Institute was gratifying to see. It was clear that attendees were inspired by the progress made at the Institute.”

— Allan Will, Founder, The Foundry

The Tech Museum was transformed to showcase Dr. Fogarty's past and present projects, from his early inventions and his world-changing balloon catheter to his current focus on mentoring new innovators at the Fogarty Institute for Innovation. **After a cocktail reception featuring Fogarty wine, guests were ushered in to New Venture Hall for a surprise presentation in talk show format featuring important figures throughout Dr. Fogarty's career.** Allan Will (Founder of The Foundry) performed host duties, opening the program with memories of his first impressions and collaborations with Dr. Fogarty. Will then interviewed additional guests who regaled the audience with highlights and hijinks from Dr. Fogarty's illustrious career. Attendees heard stories and tributes from Vincent Gaudiani, MD; Mike Mussallem, Chairman and CEO of Edwards Lifesciences; Angela Macfarlane, President & CEO, ForSight Labs; David Douglass, General Partner, Delphi Ventures; and Ferolyn Powell, Director at Twelve and Chairperson of Prescient Surgical.

Dr. Fogarty took it all in stride, and in true form, got in some of the evening's best one liners. After the show, everyone convened downstairs to continue the celebration, visit with the companies in residence, and learn about FII's educational programs.



“The event brought together so many people who share a passion for improving patient care. It was a triumph to see how far we’ve come, and exciting to think about the future.”

— Liz McDermott,
Division Vice President, Abbott Vascular

“It was a celebration of milestones and memories, with 50 years for the Fogarty Catheter and 80 years for the man of the hour.”

— Mike Mussallem,
Chairman and CEO, Edwards Lifesciences



Pictured above, from left: Dr. Dennis McShane; Assemblymember Rich Gordon, Tomi Ryba, El Camino Hospital President/CEO; and Senator Jerry Hill.

Several distinguished speakers were on hand to bestow honors, including the Honorable Jerry Hill, California State Senate and Honorable Richard Gordon, California State Assembly, who presented Dr. Fogarty with a Resolution from the state legislature. Congresswoman Anna Eshoo had arranged for a flag to be flown over the capital in Dr. Fogarty’s name, and Senator Jerry Hill presented the honorary pennant. El Camino Hospital CEO, Tomi Ryba, spoke glowingly about Dr. Fogarty’s contributions and the collaboration between the two organizations, and Dr. Fogarty’s 14-year old granddaughter Anna closed out the evening with a heartfelt rendition of happy birthday.

“The celebration for innovation was a fantastic success and very much appreciated!”

— Dr. Fogarty



YOU CAN HELP US MAKE A DIFFERENCE.

Truly every dollar makes a difference. Please consider supporting our efforts to improve patient care. Call Ann Fyfe at 650-988-7590.

Collaboration Innovation

ALL IN A DAY'S WORK AT THE FOG SHOP

UPDATE: COMPANIES IN RESIDENCE Our company roster is evolving, as successful graduates move on and new entrepreneurs move in. Read on for news about our newest participants, along with updates on progress for all of our companies 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.

CyberHeart is now in clinical trials for cardiovascular indications and is currently seeking Series B equity funding.

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.

With the collaboration of FII and El Camino Hospital clinicians, EchoPixel successfully completed the 510(k) FDA submission of its first product – t3D Viewer.

G-Tech Medical: Developing a wireless, wearable patch (an “EKG for the gut”) designed to help doctors diagnose the underlying cause of functional gastrointestinal disorders, enabling more targeted therapies.

The concept has been proven in a 3-hour duration clinical trial that uses standard EKG equipment. A prototype wireless patch is now in the design phase for use in a clinical trial setting lasting 24 hours.

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.

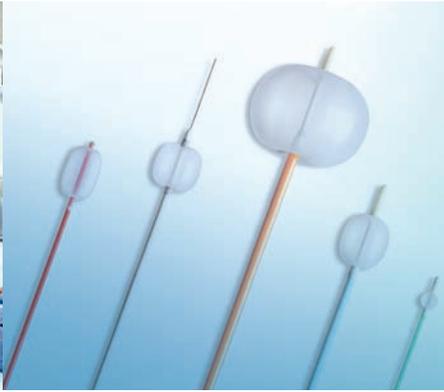
InPress has begun their First-in-Women clinical trial to show safety and proof of concept.

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.

InterVene closed a Note Financing round of \$2.1M in April of 2014, and is currently working toward clinical trials.

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.

Materna has received IRB approval to start clinical studies at Baylor College of Medicine in Houston, TX and is currently preparing devices for the study. Materna is also in the process of obtaining IRB approval at El Camino Hospital in Mountain View.



Medical Cue: The NeoCue system intends to solve a major need in newborn resuscitation by providing integrated decision guidance in neonatal resuscitation.

The company is actively team building, meeting with potential customers, and working on Series A fundraising.

nVision: Dedicated to advances in women's health, nVision is developing two new devices. One is intended to significantly advance the diagnosis and treatment of female infertility caused by fallopian tube dysfunction. Another device is designed for early detection of ovarian cancer.

In May 2014, nVision conducted a successful First-in-Women study.

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 site infections. The first application targets the highest infection rate in the most vulnerable patient segment — patients undergoing high-risk open abdominal surgeries such as colorectal surgery.

Prescient Surgical was awarded a NSF SBIR grant in early 2014 to fund initial clinical trials that returned compelling proof-of-concept results. The team is working diligently to expand the product line and generate further clinical evidence, actively raising Series A funding to fuel these efforts.

Stenomics: Developing a software system to optimize the deployment of prosthetic heart valves.

Initial feasibility studies are underway.

Vida Systems: Developing VidaBody, an online science teaching engine. The first application is in Anatomy and Physiology, like Google Earth for the human body. VidaBody makes learning easy by engaging learners with interactive, rich content, interwoven game mechanics, and a social layer.

Vida plans to release the private beta version of VidaBody in August. The company is actively recruiting customers and partners.

Zebra Medical: Developing the first micro-endoscopic system that enables in vivo visualization of cellular structure and dynamic processes in muscle and connective tissues. This technology has broad applications ranging from noninvasive imaging of the skin to improving the treatment of amyotrophic lateral sclerosis (ALS).

Proof-of-concept data has been collected through tests with healthy humans, and units are in production for sale to clients conducting scientific research. The company is also preparing for the next phase of human testing for ALS applications.



nVision Entrepreneur Honored by *Forbes*

SURBHI SARNA
MAKES PRESTIGIOUS
“30 UNDER 30” LIST



If ever there were proof that necessity is the mother of invention, it's Surbhi Sarna's story. Her personal experience with painful ovarian cysts inspired her to dedicate her venture-backed medical device company to fostering innovation in women's healthcare. Under the umbrella of the Fogarty Institute for Innovation, nVision is developing two catheter-based diagnostic tools whose potential led *Forbes* magazine to honor Ms. Sarna as one of 30 young entrepreneurs under 30. Both devices are currently in the R&D stage. One is intended for much-needed early detection of ovarian cancer, which is known as a “silent killer” because 70% of patients are not diagnosed until stages III or IV, gravely impacting 5-year survival rates. nVision's other device in development is a micro-endoscope gynecologists can use to detect blocked fallopian tubes in the examining room rather than sending the patient out for X-rays. Surbhi Sarna epitomizes the vision and drive that is the lifeblood of medical advancement, and we congratulate her on being named to this prestigious list.



Welcome to our Newest Board Member

THOMAS M. KRUMMEL, MD

Dr. Thomas M. Krummel has been an innovator since his surgical resident days, when he formed what was then the world's second ECMO team (Extracorporeal Membrane Oxygenation is a procedure that uses a machine to take over the work of the lungs and sometimes the heart). Dr. Krummel is the Emile Holman Professor and Chair, Department of Surgery at Stanford University and the Susan B. Ford Surgeon-in-Chief at Lucile Packard Children's Hospital. He also serves as co-director of Stanford's Biodesign Innovation Program. Over the course of his career, Dr. Krummel has received more than \$3M in research funding for pioneering work ranging from the study of scarless repair in the fetus to the use of information technology for surgical training and robotics. He is now immediate past president American Pediatric Surgical Association, President of the American Pediatric Surgical Association, and is one of the few surgeons ever elected to the American Institute for Medical and Biological Engineering. In addition to serving on the FII board, Dr. Krummel is Consultant to Morgridge Institute (Board membership in process til 2015) and serves as President of the International Scientific Committee at IRCAD in Strasbourg France.

“I'm thrilled to be able to put my background and experience to work in this way, helping to guide the Institute and young innovators.” — Thomas M. Krummel, 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 or call 650-988-7590.