

LANKENAU INSTITUTE FOR MEDICAL RESEARCH

CATALYST

FALL 2024 / WINTER 2025

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Lankenau Institute for Medical Research (LIMR) is a nonprofit biomedical research institute located on the campus of Lankenau Medical Center and is part of Main Line Health. Founded in 1927, LIMR's mission is to improve human health and well-being. Using its ACAPRENEURIAL™ model that integrates academic and entrepreneurial approaches, faculty and staff are devoted to advancing innovative new strategies to address formidable medical challenges including cancer, cardiovascular disease, tissue regeneration, gastrointestinal disorders, and diabetes, arthritis and other autoimmune diseases. LIMR's principal investigators conduct basic, preclinical and clinical research, using their findings to explore ways to improve disease detection, diagnosis, treatment and prevention. They are committed to extending the boundaries of human health through technology transfer and training of the next generation of scientists and physicians.

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George C. Prendergast, PhD

*The Havens Chair for Biomedical Research
President and CEO
Lankenau Institute for Medical Research,
Main Line Health*

A research institute that is greater than the sum of its parts

This year marks my 20th in leading the Lankenau Institute for Medical Research, and as I reflect, I realize that a key part of our success is that no one works in a silo here. In our culture, researchers gather frequently to present their latest work and ideas to colleagues, not only through insightful questions and feedback but in discovering how one line of work connects to others.

That lesson underpins our cover story on the research of Maggie Wallon, PhD, which introduces her development of a blood test that can predict the occurrence of chemotherapy-induced delayed nausea before a patient receives treatment. The test was built on laboratory research into molecular stress that different cells experience when exposed to chemotherapy — glutathione recycling efficiency — which varies among people. This research arose from conversations with colleagues at Lankenau Medical Center about delayed nausea. Identifying patients' susceptibility to the problem before it strikes allows for special treatments to mitigate it.

In developing her test, Dr. Wallon surmised that it might be applied to also identify cancer patients who are prone to chemotherapy-induced peripheral neuropathy. The condition is characterized by burning, tingling, numbness or pain in the hands and feet. In the most severe cases, it may never go away, damaging a cancer survivor's ability to have a normal sense of touch in their hands and feet (leading to a permanent need for help in dressing, for example.) Now, oncologists can identify these individuals before a treatment regimen is completed, signaling that an alternate approach is needed to avoid or minimize the condition.

Dr. Wallon is now collaborating with a team of cardiac surgeons to explore yet another use for her test: predicting postoperative atrial fibrillation (AFib) in patients scheduled for cardiac or other thoracic surgery. Those with AFib are five times more likely to have a stroke, meaning that

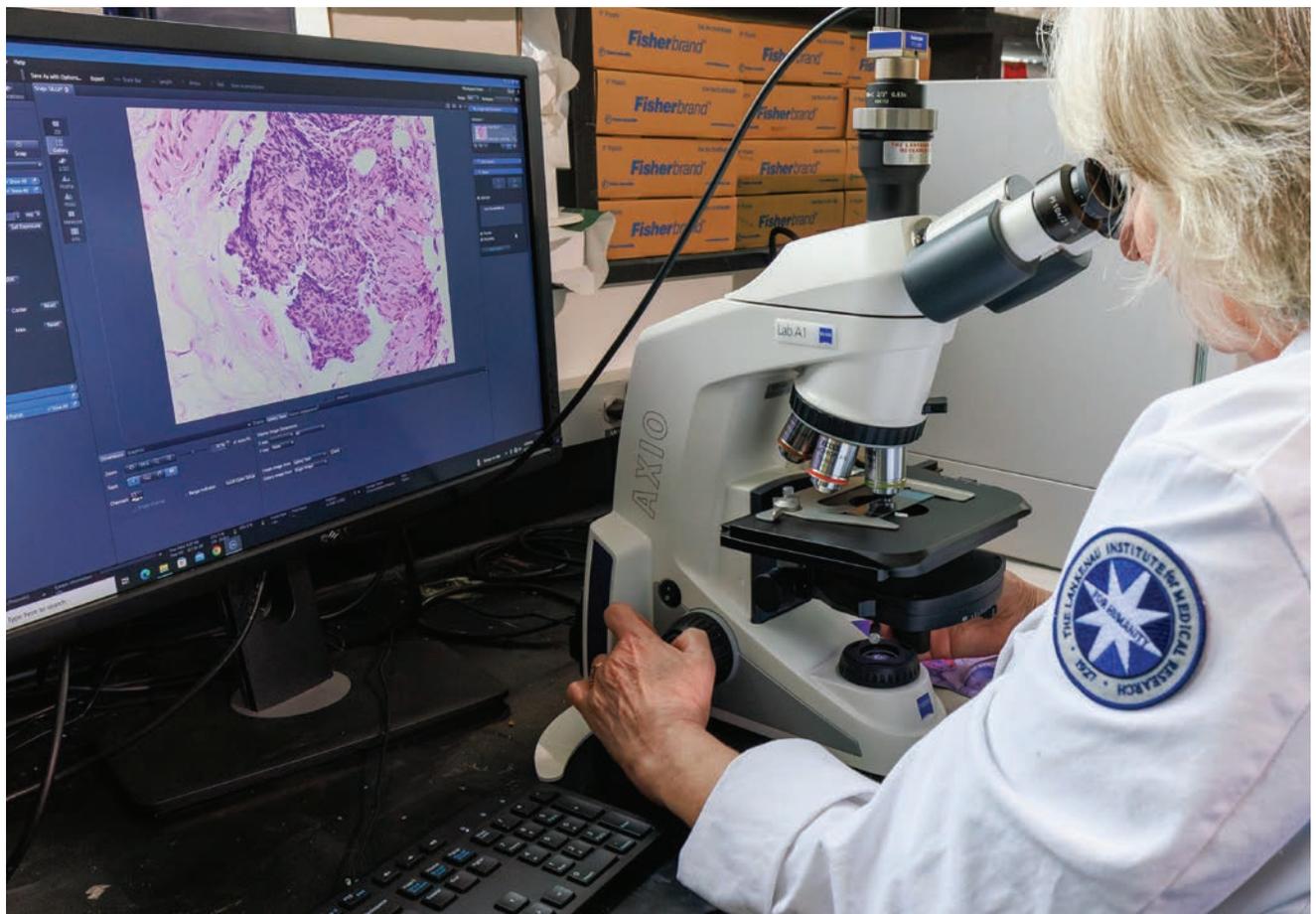
identifying patients who need special attention to prevent this condition can save lives.

Another story in this issue covers the work of Scott Dessain, MD, PhD, with spirulina, a superfood consumed by NASA astronauts. Dr. Dessain has learned how to genetically modify this blue-green algae to synthesize and deliver antibodies and other biologics with therapeutic uses. His success heralds the development of spirulina strains that can orally administer antibodies and other healthful biologics to the body safely and inexpensively like other probiotics. Initial proof-of-concept focuses on Dr. Dessain's polio antibodies aimed at clearing vaccine-resistant polio outbreaks worldwide. LIMR also offers an array of other possibilities to pursue: anti-Bin1 antibody, to treat inflammatory bowel disease and perhaps Alzheimer's disease (Sunil Thomas, PhD, and me) anti-RhoB, to treat autoimmune disease (Lisa Laury-Kleintop, PhD); and anti-IDO2, to treat rheumatoid arthritis (Dr. Laury-Kleintop and Laura Mandik-Nayak, PhD).

Another story covers our researchers' capabilities in advanced imaging, a vital component of our ability to offer trials of novel clinical devices and procedures for cardiac patients. Advanced types of echocardiography as well as cardiac MRI and CT scans set us apart from many institutions, allowing Main Line Health to offer trials to treat diseases of the tricuspid and mitral valves, as well as other trials aimed at preventing strokes associated with AFib.

Lastly, I would be remiss if I did not urge you to read about the promotion of Matt Finley, PhD, our new Vice President. Dr. Finley has demonstrated outstanding leadership capabilities over the last four years, giving me the confidence to turn over day-to-day operations at LIMR and focus on improving the Institute's regional presence, fundraising and ACAPRENEURIAL™ activities.

I hope you enjoy this edition. ✨



Dr. Maggie Wallon, who developed the MyNauseaRisk blood test, examines a breast cancer specimen.

Easing patients' battle with chemotherapy side effects

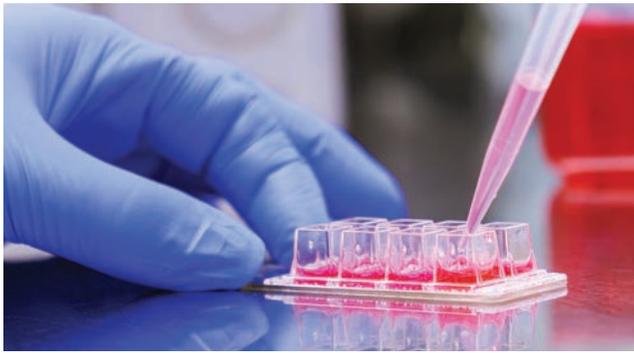
BLOOD TEST MAKES IT POSSIBLE TO IDENTIFY THOSE WHO WILL DEVELOP NAUSEA AND PREVENT IT FROM GETTING OUT OF CONTROL

Bridget Dougherty, a 41-year-old from Delaware County, couldn't understand it. Her neighbor was diagnosed on the same day with the same type of breast cancer, had the same oncologist and same surgeon, and was undergoing a similar chemotherapy regimen. "She hardly missed work and was able to take her kids to baseball practice, yet I couldn't get myself out of bed some days," Dougherty says. "The nausea was so bad I had to go to the emergency room. I thought I was a crazy person."

Due to Dougherty's participation in a clinical trial of a blood test designed to address that very problem, however, researchers had an explanation for her severe symptoms. Although patients generally aren't told their trial results, principal investigator Maggie Wallon, PhD, Assistant

Professor at Lankenau Institute for Medical Research (LIMR), and Dougherty's oncologist, Zonera Ali, MD, felt an exception was crucial because their patient direly needed some peace of mind to help weather the remaining infusions.

The blood test, called MyNauseaRisk™, is designed to predict who will suffer from chemotherapy-induced delayed nausea and vomiting, which starts in patients between days two to five after treatment. Results on more than 250 patients have shown with 80% accuracy that platinum-based chemotherapy will cause those who fail to generate enough of an antioxidant called glutathione to develop the condition. "Bridget had the lowest levels we ever saw," Dr. Wallon says. "We ran the test twice because we thought maybe it was wrong."



While the information provided welcome reassurance for Dougherty, the goal is to get the diagnostic tool out into the medical mainstream so doctors know which patients will be affected before nausea strikes. Once delayed nausea kicks in, it is often too late to control it, but if patients get the right medication beforehand, it can be manageable.

No extra blood draws are required to undergo the MyNauseaRisk test. It can be run using the same samples collected when a patient undergoes testing to be cleared to start chemotherapy. Results take only two hours.

LIMR has a licensing agreement with MYNARI Biomedical, a biotech startup working to secure Food and Drug Administration approval and commercialize the product. Currently, this experimental test is available only to customers who can afford the cost, which is not yet covered by insurance. If MYNARI gets regulatory approval, insurance reimbursement would likely follow.

Critically, Dr. Wallon says, she hopes insurance companies will agree to cover the most potent — and also the most expensive — anti-nausea drugs, rlapitant and granisetron (given as a patch), for those flagged by the test. Usually, patients must have unsuccessfully tried other less powerful anti-nausea drugs before insurance approves rlapitant or granisetron.

Such preventive treatment might keep patients like Dougherty out of the emergency room. Starting in February 2022, she underwent an 18-week cycle of chemotherapy (six cycles of an infusion every three weeks). Her nausea struck with very little delay.

“It seemed to start right away, and it powered through the whole way,” she says. “People would drop off many things for me to try in addition to standard-of-care prescriptions. Ginger is supposed to be soothing, so they gave me ginger candies and ginger mints.”

The condition left Dougherty so dehydrated she had to go to the emergency room. A home care nurse was sent to teach her to give herself IV fluids at home, and that kept her out of

the hospital for the rest of her regimen. In June 2022, she finished her chemotherapy and rang the bell to celebrate.

“It was a real scene,” she says. “I rang it real loud so everyone in the office heard.” A month later, she underwent a double mastectomy and reconstruction. She recovered well, is back to work and feels great.

It appears Dr. Wallon’s test can predict more than one condition. She has evidence that the same biomarker can predict which patients are likely to develop chemotherapy-induced peripheral neuropathy. The culprit is the same — oxidative stress, which is caused by chemotherapy agents killing off normal cells. Oxidative stress is an imbalance where the body has too many molecules called free radicals and not enough antioxidants. Excess free radicals cause harm to the body’s cells and tissues.

“The onset of peripheral neuropathy is a slower process than chemotherapy-induced nausea, but it can be more severe and even irreversible,” says George Prendergast, PhD, President and CEO of LIMR. “The goal is to identify neuropathy early on so we can adjust the patient’s care,



Biomedical research assistant Katie Fleck works with an assay set-up of patient samples to determine risk of chemotherapy-induced nausea and vomiting.

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From left: Dr. Zonera Ali, Dr. Maggie Wallon and patient Bridget Dougherty.

which, even if it doesn't eliminate the condition, might reduce the severity of the symptoms. Dr. Wallon's test is one of the most exciting developments at LIMR because we believe it will illuminate other disorders caused by oxidative stress that can be accurately predicted and responded to before the patient is affected. For that reason, we are keenly focused on getting the test into doctors' hands."

Peripheral neuropathy usually affects the legs, feet, arms and hands. When nerves are damaged, symptoms can include burning, tingling, numbness or pain. It can also affect a patient's ability to feel pain.

"A normal nerve is protected so the signal can go from your fingertip to your brain, saying, 'Your finger is on a hot plate, move your hand,'" Dr. Wallon says. "But if you have neuropathy, the signal can leak out in different spots so you don't feel it at all, or it is delayed. You think you're touching something, but you don't know what it is. That can be quite dangerous. At a minimum, since many people use keyboards these days, it can significantly impact your ability to work." ✨



Bridget Dougherty's survivor bracelet shows the date of her diagnosis: January 21, 2022.



Dr. Scott Dessain working to turn superfood into supermedicine

Spirulina is a superfood with a story. The world's greatest source is the shores of Lake Chad in Central Africa, where 200 women work tirelessly harvesting and processing the blue-green algae. Spirulina is loaded with vitamins, minerals and antioxidants — and 15 grams of it has as much protein as 100 grams of beef. NASA has even sent it into space as a nutritional supplement.

“Many mornings, I’ve had it in my smoothies,” says Scott Dessain, MD, PhD, a researcher for the Lankenau Institute for Medical Research (LIMR). “I think it’s pretty good with banana.”

Now the director of LIMR’s Center for Human Antibody Technology (CHAT) sees a path for the superfood to become supermedicine. CHAT has succeeded in developing a genetically modified spirulina that can create an antibody used in molecular biological research. That successful experiment opens the path for Dr. Dessain to develop a spirulina that will produce another antibody — to treat polio.

“This whole project started with George Prendergast, LIMR’s CEO and President,” Dr. Dessain says. “CHAT clones many antibodies for biomedical research and treatments. He asked, ‘Why don’t you think about delivering antibodies straight to the intestine?’ It makes sense. It’s complex to deliver antibodies through an injection. And if you take the treatment orally, the stomach acid digests it, so it never gets to where it needs to be.”

But if you could eat a tasty food and treat intestinal viruses like polio at the same time, that’s a game-changer, he says.

“Instead of having to create treatments with antibodies that cost hundreds of dollars per dose, you could create a strain of spirulina inexpensively that expresses the same antibody,” Dr. Dessain says. “Spirulina protects the antibodies as they pass through the stomach but then releases them after digestion in the intestine.”

Dr. Dessain has long focused on polio. The World Health Organization approved the usage of antibodies cloned in his lab as the standard for quality-control testing of all inactivated polio vaccines worldwide in late 2022. The new test increases assurance of the vaccines working properly when administered. Polio resurged in public consciousness after a baby in Gaza developed the disease, prompting a campaign to vaccinate tens of thousands of children there.



Dr. Scott Dessain

If successful, spirulina could be the drug delivery method that ties together several seemingly disparate branches of LIMR research. Dr. Prendergast hopes it can deliver indoleamine 2,3 dioxygenase (IDO1) antibodies that he worked to develop to treat cancer and inflammatory disease. Other

antibody candidates include anti-Bin1 antibody to treat inflammatory bowel disease and perhaps Alzheimer’s disease (Sunil Thomas, PhD, and Dr. Prendergast); anti-RhoB to treat autoimmune disease (Lisa Laury-Kleintop, PhD); and anti-IDO2 to treat rheumatoid arthritis (Dr. Laury-Kleintop and Laura Mandik-Nayak, PhD).

“There’s so much potential here,” Dr. Dessain says. “Spirulina would be inexpensive to grow. And the Food and Drug Administration review process could take years less than for a drug because it would probably fall under the classification of genetically modified food. I think an exciting future lies ahead for spirulina and the treatment of disease.” ✨



Spirulina is a blue-green algae that Scott Dessain, MD, PhD, modifies in the lab to create antibodies.

Advanced imaging sets LIMR apart in cardiac research

One of the pillars of premier cardiac research sounds as basic as can be: the ability to see. But in this instance, seeing refers to magnification and crisp clarity that can only come from advanced imaging — and the experts who know how to maximize the technology. This imaging plays a crucial role in establishing Lankenau Institute for Medical Research as a leader in research and clinical trials for novel cardiac procedures and devices.

“Companies will only allow you to participate in the clinical trials they sponsor if you have three components,” says Sandra Abramson, MD, FACC, FASE, Director of Cardiovascular Imaging at Lankenau Medical Center. “You need a good cardiothoracic surgeon for open procedures. You need a good interventional cardiologist for minimally invasive procedures. And you need advanced cardiac imaging because if they can’t visualize the pathology, they can’t fix it.”

The work of LIMR and Lankenau Medical Center, both part of Main Line Health, is intertwined to the patient’s benefit. Basel Ramlawi, MD, Chief of Cardiothoracic Surgery, and William Gray, MD, Chief of Cardiovascular Diseases, not only conduct surgical and minimally invasive procedures but are LIMR resident faculty members. Other cardiac physicians also are affiliated with LIMR. That close relationship fosters a variety of novel clinical trials, including many aimed at treating diseases of the tricuspid and mitral valves. Other trials are of devices to close off a pouch in the heart where blood clots usually form and often cause stroke in those with atrial fibrillation.

“Advanced cardiac imaging gives us the capability to see visual detail that other centers might not — and to do so in real-time as we perform procedures,” Dr. Ramlawi says. “These imaging procedures allow us to place devices more precisely where they need to be.”

Advanced imaging consists primarily of three modalities: echocardiography, cardiac MRIs and cardiac CT scans.

Echocardiography, known commonly as an echo, is a screening tool to determine the ability of the heart to pump blood and if valves are functioning properly, Dr. Abramson says. Patients with regurgitation of the mitral or tricuspid valves (backward flow of blood) may experience symptoms including fatigue and shortness of breath.

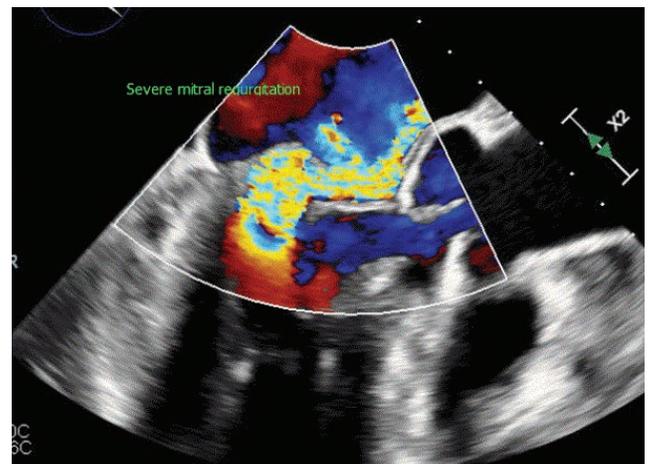
If valvular heart disease is suspected, the patient likely would undergo a transesophageal echocardiogram, which involves inserting a tube down the esophagus and stomach — right behind the heart — allowing for even more precise images. If necessary, greater detail can come from an intracardiac echo — an ultrasound probe inserted into the heart.

Katie Hawthorne, MD, who leads the cardiac MRI program at Lankenau Medical Center, uses the test to precisely evaluate the heart’s blood volumes and pumping ability.

“Cardiac MRI is the gold standard,” Dr. Hawthorne says. “We can see what goes on in the heart muscle itself. It’s almost like the heart is under a microscope.”

The cardiac CT, adds Dr. Abramson, not only provides visualization of the heart and its vessels but is used to ensure access is unobstructed from the groin to the heart for catheter-based procedures.

Says Dr. Gray: “We leverage the multimodality advanced imaging that we have developed at Main Line Health to advance our abilities in the research realm. It is absolutely an integral part of our cardiac research program. It really sets us apart from many centers in the region and the country.” ✨



Images of mitral transcatheter edge-to-edge repair. The color yellow in a transesophageal echocardiogram demonstrates a severe leak of the mitral valve before intervention (top) and mild mitral regurgitation after successful intervention (bottom).

Dr. Matt Finley becomes Vice President, taking over LIMR day-to-day operations

Matt Finley, PhD, MBA, who has assembled an exceptional track record overseeing key departments at Lankenau Institute for Medical Research (LIMR), was promoted in July to Vice President, assuming day-to-day leadership of Institute operations.

George Prendergast, PhD, President and CEO for the last 20 years, promoted Dr. Finley as part of a realignment that allows Dr. Prendergast to focus solely on bolstering LIMR's regional presence as the Institute's 100th anniversary approaches.

"At this stage of my tenure, I feel I can best serve LIMR by going out into the community to talk about our many successes and conduct fundraising to accelerate our growth," Dr. Prendergast says. "Matt's record of excellence over the last four years convinced me that now is the right time to hand him the day-to-day responsibility of running our ACAPRENEURIAL™ program with its unique blend of academic and entrepreneurial pursuits."

Dr. Finley, who joined LIMR as Director of Research Administration in 2020, is now responsible for the day-to-day administration of all scientific, educational and operations management. Operations management includes oversight and administration of all infrastructure, physical plant, equipment, operational departments, programs/policies/procedures, training and entrepreneurial activities in the LIMR biotech company incubator. He works directly with supervisors, managers and directors within LIMR to build engagement.

LIMR, which will turn 100 in 2027, has accelerated its ACAPRENEURIAL program in innovative directions in recent years under Dr. Prendergast and Dr. Finley. Among its recent initiatives are:

- The novel SYNC-T combination therapy whose early clinical trial results offer hope for treating metastatic prostate cancer
- A suture and a drug-hydrogel under development to deliver scarless wound healing
- A potential drug for treating the earliest stages of two conditions that can result in blindness: diabetic retinopathy and wet age-related macular degeneration
- A program of Main Line Health healthcare-worker-invented products as part of the Lankenau Ventures joint venture, including the Rogers Limb Support device
- A cardiovascular clinical research program with Main Line Health researchers serving in lead roles in first-in-human trials in valve replacement, stroke prevention and more



Dr. Matt Finley

"I'm excited about working with George to help LIMR achieve new heights," Dr. Finley says. "We have an incredible team of researchers and I'm proud to have a chance to make an even greater impact in supporting their successes."

FDA approves novel carotid stent system after successful trial led by LIMR professor



Dr. William Gray

The Food and Drug Administration (FDA) has given premarket approval for a device that Main Line Health-led clinical trials indicated would reduce the risk of stroke among patients undergoing a procedure to treat cholesterol blockages in the carotid artery.

Clinical studies of the Neuroguard IEP® system, including the PERFORMANCE I trial and PERFORMANCE II FDA investigational device exemption trial, have consistently recorded no major strokes or neurologic deaths at 30 days postprocedure and robust durability through one year. The three-in-one carotid stenting system combines a high-performance, purpose-built stent and an integrated balloon and filter.

William Gray, MD, Chief of Cardiovascular Diseases at Main Line Health, LIMR professor and national co-principal investigator of the pivotal PERFORMANCE II trial, said in *Endovascular Today*: "FDA approval confirms the results of the clinical studies. The innovative Neuroguard IEP system performs exceptionally well with the lowest one-year stroke rates ever shown for any type of carotid revascularization, thereby establishing a new standard of care for meaningfully reducing the risk of procedural and long-term stroke among patients with carotid artery disease."

Bringing commitment and scientific know-how to advance LIMR

The innovative scientific research at Lankenau Institute for Medical Research (LIMR) has turned Jonathan Fox, MD, PhD, and Suzanne Markel-Fox, PhD, into long-term supporters. For over 20 years, they have given unrestricted support and directed gifts toward specific scientific endeavors because they believe in LIMR's mission and expertise.

Jonathan, Chief Medical Officer for Cardiovascular and Renal Diseases at BridgeBio Pharma, Inc., a clinical-stage biotechnology company developing novel, genetically targeted therapies, and Suzanne, a psychologist/health information technology expert, had experienced Lankenau Medical Center's clinical excellence and LIMR's research excellence firsthand before Jonathan joining LIMR's Board in the early 2000s. When he was asked to join the Board, having served as faculty at renowned academic medical centers and worked in big pharma, he says, he was "very intrigued by the idea that here was this little David of a medical research institute sitting among the Goliaths of the Philadelphia medical research scene."

Though Jonathan and Suzanne moved to the San Francisco Bay area 12 years ago, they have remained committed to Lankenau Medical Center and LIMR. Shifting his career to the biotech research field has given Jonathan even more appreciation for LIMR's ACAPRENEURIAL™ model, merging academic and entrepreneurial approaches, and he praises George Prendergast, PhD, LIMR President and CEO, for his forward-thinking leadership.

"Seeing what Lankenau Medical Center and LIMR are doing is similar to what I try to do in my main work — develop therapies for people in need and extend and improve their lives," Jonathan says. "That's what I try to do in terms of my work in BridgeBio, that's what LIMR is trying to do in terms of its research, and that's what Lankenau Medical Center is doing in terms of being a cornerstone of the Main Line and providing great care for the community. The fact that Lankenau's always been so involved in research to me is what makes it special."

Jonathan feels highly engaged Board members must be at least one of the following: "a doer, a donor or a door opener." He has risen to the occasion on all fronts. He asks challenging questions, advises on science and growth opportunities, and makes important industry connections. Also, critically, he and Suzanne are committed philanthropists.



They have recently supported a novel combination therapy called SYNC-T™, developed by Syncromune, a company with ties to LIMR, that involves freezing part of a tumor and then conducting an infusion of four types of immunotherapy drugs. The therapy targets metastatic castrate-resistant prostate cancer. LIMR will be conducting trials of SYNC-T.

The couple has chosen a small number of beneficiaries for their philanthropy and voices pride in including LIMR among them. Over the years, their contributions have grown significantly. They make meaningful annual contributions — largely through tax-advantageous gifts of appreciated stock — and have elected to include LIMR as a residual beneficiary of their estates, leaving a legacy that will support LIMR for years to come. Their thought leadership and philanthropic partnership play a key role in propelling LIMR's upward trajectory. ✨

For more information on ways to structure tax-advantageous gifts, please contact Katie Beddis at beddisk@mlhs.org.

Your investments in research at LIMR can have a significant impact

You can designate one of the following funds to direct your contributions and support research that is important to you.



Biotechnology Innovation Fund

This fund supports work on biological molecules engineered by LIMR scientists that can enhance the diagnosis, prognosis and treatment of disease. Your generous contributions to this fund can help advance the work of our researchers including our studies on targeted nano-carrier therapeutics as experimental treatments for cancer and our work on cloned human antibodies as treatments for infectious disease, cancer and neurological illnesses.



Cardiovascular Breakthrough Fund

Cardiovascular disease accounts for nearly 800,000 deaths in the United States every year, or about one of every three deaths. Additionally, about 92 million American adults are living with some form of heart disease or the aftereffects of stroke. LIMR is home to world-renowned cardiovascular researchers. Your gift to this fund will further research that could benefit the lives of millions of heart disease and stroke patients.



Immunotherapy Pioneer Fund

Immunotherapy entails the prevention or treatment of disease with substances that manage the immune system's capabilities to clear disease rather than attack the disease itself. LIMR has spearheaded unique studies of disease modifier pathways that impact immunity and cancer progression, developing new drugs to target them. Your generous contributions to this fund will help us to continue to advance these innovative directions.



Regenerative Medicine Vision Fund

Regenerative medicine deals with new processes of replacing, engineering or regenerating human tissues to restore or establish normal function. LIMR is privileged to have one of the pioneers in regenerative medicine, Professor Ellen Heber-Katz, PhD, who has discovered an experimental drug approach that may eliminate a need for stem cell transfer. Your contributions to the Regenerative Medicine Vision Fund will help further her research.

LIMR Unrestricted Fund

Unrestricted gifts to LIMR enable opportunities to target your gift where our doctors and scientists believe it can have the greatest impact.

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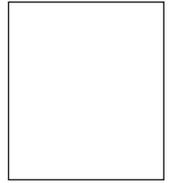
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ABOUT MAIN LINE HEALTH

Main Line Health is an integrated health system serving the Philadelphia region, with more than 2,000 physicians, one quaternary and three tertiary care hospitals, a wide network of patient care locations and community health centers, specialized facilities for rehabilitative medicine and drug and alcohol recovery, a home health service, and a biomedical research institute. Collectively, Main Line Health's physicians, care teams, healthcare facilities and researchers provide patients with primary through highly specialized care as well as access to clinical trials.