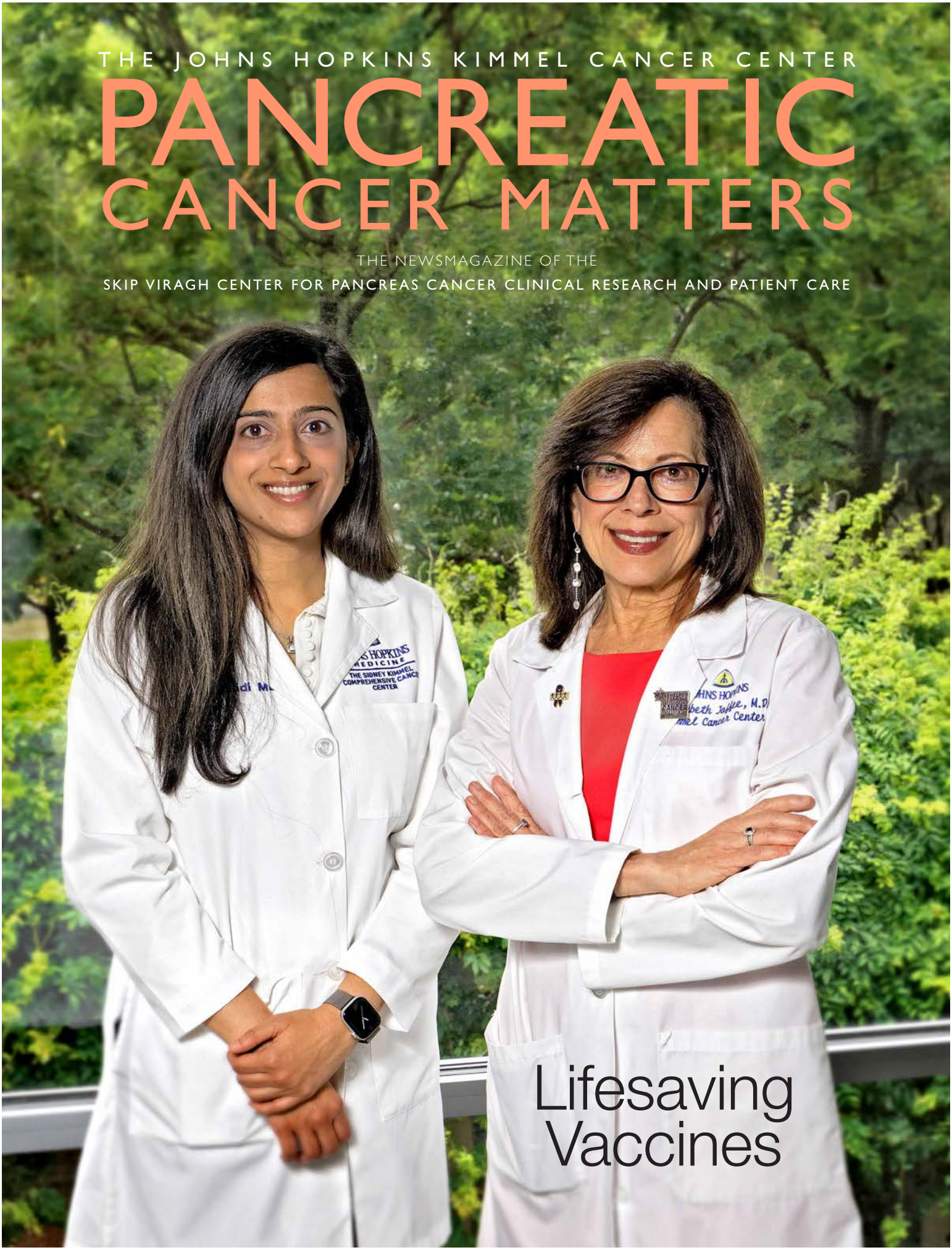
THE JOHNS HOPKINS KIMMEL CANCER CENTER

PANCREATIC CANCER MATTERS

THE NEWSMAGAZINE OF THE

SKIP VIRAGH CENTER FOR PANCREAS CANCER CLINICAL RESEARCH AND PATIENT CARE



Lifesaving Vaccines

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Lifesaving Vaccines

Using KRAS to harness the power of the immune system

Navigating Pancreatic Cancer

Helping to track patients through their cancer journey

Transformational

The promise of KRAS inhibitors becoming a reality

REBB's Rebellion

Determination and immunotherapy helped her to beat the odds

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• *The McGlothlin Fellows to Faculty Fund*
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• *Kelly's Heroes*
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Advances

The latest in cancer treatments and innovation

In the News

The Skip Viragh Center for Pancreas Cancer Clinical Research was featured in a recent segment of *CBS This Morning with Ted Koppel*

PANCREATIC CANCER MATTERS

THE SIDNEY KIMMEL COMPREHENSIVE CANCER CENTER AT JOHNS HOPKINS

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Neeha Zaidi, M.D., left, and Elizabeth Jaffee, M.D.

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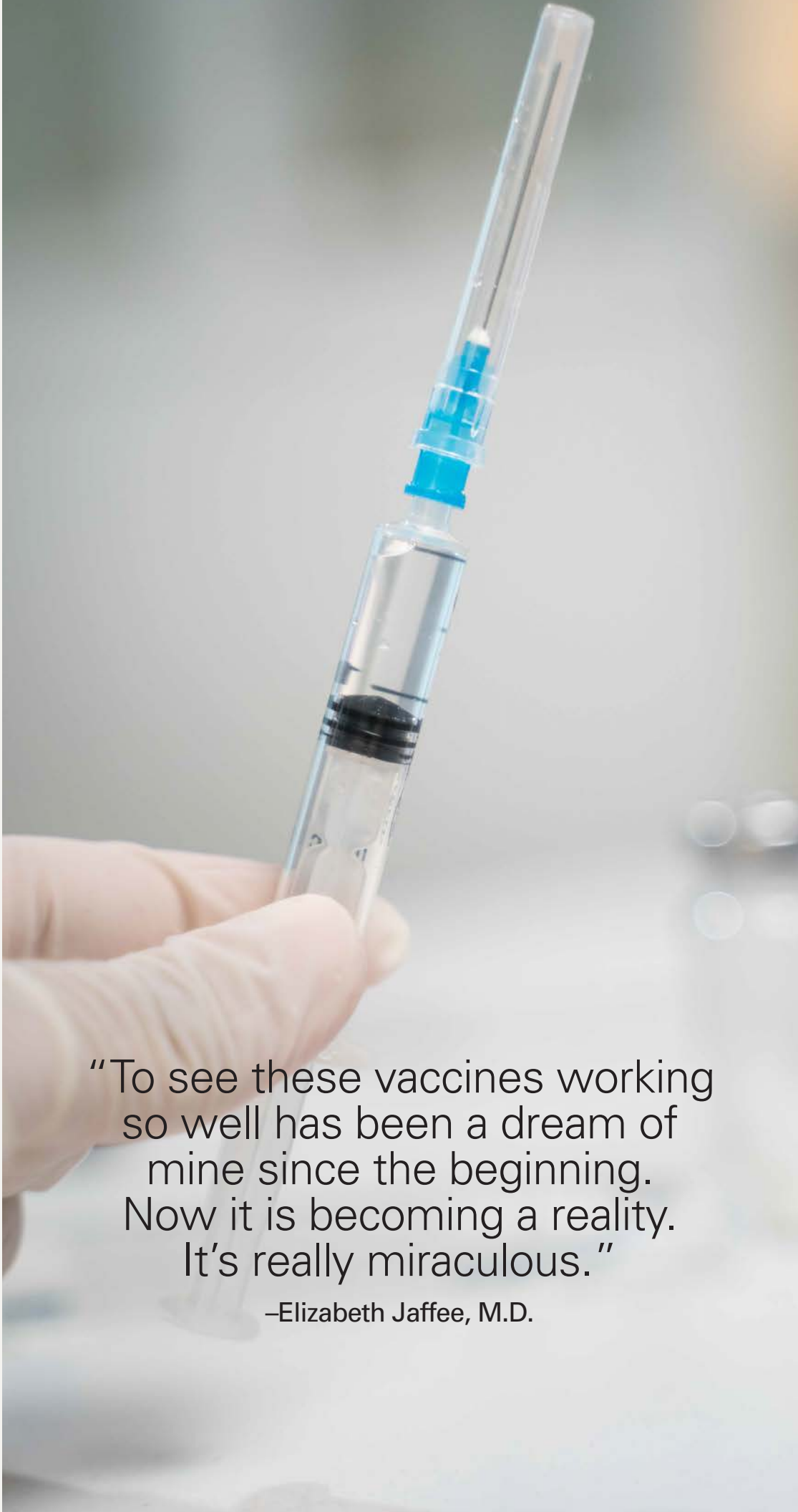


"To see these vaccines working so well has been a dream of mine since the beginning. Now it is becoming a reality. It's really miraculous."

–Elizabeth Jaffee, M.D.

Lifesaving Vaccines

Using KRAS to Harness the Power of the Immune System

Neeha Zaidi, M.D., is turning the tables on pancreatic cancer. Mutations to a gene called KRAS — a cancer driver common to almost all pancreatic cancers — are now a target for prevention and treatment.

Dr. Zaidi, an immunotherapy and pancreatic cancer expert, is studying KRAS mutation-targeted vaccines to harness the power of the immune system against this aggressive cancer. One of the most exciting aspects is its potential to stop cancer from ever developing in patients at high risk for pancreatic cancer.

"KRAS is an early mutation in pancreatic cancer. It occurs at least a decade before cancer develops, so this is a huge opportunity for interception and intervention," she says.

"KRAS is an early mutation in pancreatic cancer. It occurs at least a decade before cancer develops, so this is a huge opportunity for interception and intervention."

The vaccine uses peptides — protein fragments from the mutated KRAS gene — to send signals to the immune system. In one of the most recent clinical trials, patients who had pancreatic cancer surgery received the vaccine in combination with drugs known as immune checkpoint inhibitors with the aim of killing off any remaining cancer cells and keeping the cancer from coming back.

Immune checkpoints are the natural on and off switches of the immune system, but cancer cells often exploit these controls to turn immune cells away. Using checkpoint inhibitors in combination with the vaccine allows the immune cells the vaccine brings to the cancer to complete its job of killing cancer cells.

The new studies are built upon the pancreatic cancer platforms developed by internationally renowned pancreatic cancer and cancer immunology expert **Elizabeth Jaffee**, M.D., Deputy Director of the Kimmel Cancer Center, Co-Director of the Skip Viragh Center for Pancreas Cancer Clinical Research and Patient Care, and the Dana and "Cubby" Broccoli Professor of Oncology.

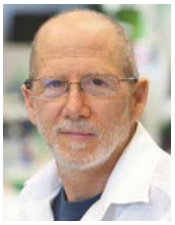
Origin Story

Dr. Jaffee began her pioneering work at the laboratory bench in the 1980s. Her pancreatic cancer vaccine was designed to supercharge the immune system, causing immune cells to seek out and kill cancer cells, including hunting down and cleaning up surviving cancer cells or newly appearing cancer cells anywhere in the body. The first version of the vaccine was called GVAX.

After a decade of laboratory discovery, clinical trials of this first-of-its-kind vaccine began in the early 1990s. Although it was first tested in kidney cancer in 1992, its greatest success was in pancreatic cancer.

Dr. Jaffee created the pancreatic cancer-specific version of the vaccine in her laboratory and also led the first patient studies, even opening a GMP (Good Manufacturing Practice) facility at the Kimmel Cancer Center to produce the vaccine for clinical studies.

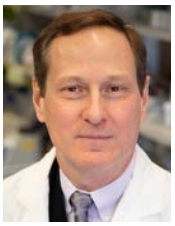
With few treatments for advanced pancreatic cancer, the vaccine attracted worldwide attention. News reports of the vaccine led to over 1,000 calls to the Kimmel Cancer Center, which was the only place doing this kind of research at the time. Patients with pancreatic cancer were desperate to receive the promising new treatment.


VOGELSTEIN

There were amazing success stories. Kathy, one of the first patients to receive the vaccine, saw a response after two doses. Twenty-six years later, she remains cancer-free and credits Jaffee's work with giving her the time to see her grandchildren grow up.

Kathy, now 76, had one grandchild at the time of her diagnosis with pancreatic cancer that had begun to spread and could not be cured with surgery.

"I didn't think I'd live to see her grow up," says Kathy.


KINZLER

Since then, she has welcomed three more grandchildren. Years later, Kathy still gets emotional when she thinks about her cancer battle.

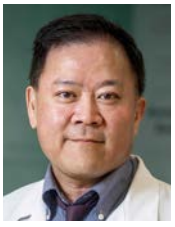
She says she is grateful for Dr. Jaffee's research and the wonderful care she received from her oncologist, **Dan Laheru**, M.D., who co-directs the Skip Viragh Center for Pancreatic Cancer Clinical Research and patient care, and her nurse **Beth Onners**, M.S.N.

"They are wonderful, top notch," says Kathy.

Kathy was part of the first study of the vaccine in 60 patients. Almost all of the patients survived one year, and about two-thirds were alive after two years. A few, like Kathy, had long-lasting responses.

Just Getting Started

Dr. Jaffee was just getting started. She continued her research with the goal of making the vaccine work in more patients and to keep it working for a longer time.


LAHERU

Cancer is complicated, and after three decades of research, Dr. Jaffee recognized that the immune system was equally complicated. To advance therapeutic cancer vaccines, she had to be an expert in both.

The primary problem is that as many as 80% of cancers do not attract the attention of the immune system, Dr. Jaffee says. As a result, the cancer-fighting immune T cells — the foot soldiers of the immune system — do not show up. This is particularly true in pancreatic cancer, she says.


ONNERS

In GVAX, Dr. Jaffee used a molecule called GM-CSF to lure immune cells to pancreatic cancer. Later vaccine iterations used the bacterium listeria to draw the attention of immune cells.

Another early attempt explored a drug that blocked the protein mesothelin, which was found by Dr. Jaffee's collaborator, Dung Le, M.D., to play a role in advancing the growth and spread of pancreatic cancer cells.

As cancer genetic discoveries were made, including the discovery of the genetic blueprint of pancreatic cancer by Ludwig Center investigators **Bert Vogelstein**, M.D., **Kenneth Kinzler**, Ph.D., and team, Dr. Jaffee began using the new genetic information to improve the vaccine. The genetic discoveries revealed gene mutations common to pancreatic cancer, but also showed that mutations often varied from patient to patient.

Armed with new information, Dr. Jaffee and collaborators began developing personalized vaccines that used peptides — a table of contents of sorts displayed on the cell surface to reveal the internal structure of a cell — to prime the immune system to recognize cancer.

The ultimate goal was to create an "off-the-shelf" approach that would work in most patients and could be a more economical option to the personalized vaccines specific to each individual patient's cancer.

KRAS Emerges

One mutation quickly emerged as an optimal target: KRAS. Since KRAS mutations are present in upward of 90% of pancreatic cancers, it was the perfect choice.

One vaccine — using peptides from the mutated KRAS gene — could be the perfect formula to work in almost every patient.

In 2017, Dr. Zaidi started to work with Dr. Jaffee to bring the KRAS vaccine to patients. The first study in 12 patients showed that the vaccine was safe and that it significantly increased the cancer-fighting immune T cells in the blood of patients.

"The vaccine was doing what we wanted it to," says Dr. Zaidi. "It was safe, and it was generating a robust immune response."

In the following years, Drs. Zaidi and Jaffee collaborated on clinical trials of the KRAS vaccine in a variety of scenarios.

As in the early vaccine work, researchers explored obstacles to the vaccine's effectiveness. Ongoing research revealed that the immune system did not just tolerate cancer cells because they were versions of normal cells, but that cancer cells actually hijacked the natural on and off switches of the immune system to shut down an immune response to cancer.

The KRAS vaccine could attract immune cells to the cancer, but the cancer cells would hit the off switch and send them away.

Another advance in cancer immunology research, however, paved the way for removing this obstacle.

Checkpoint Inhibitors

The immune system's on/off switches are immune checkpoints that serve an important purpose. They turn on the immune system when a foreign invader is sensed, or an injury occurs, and shut it down when the invader is neutralized, or the body is healed.

Cancer cells, because they are of our own cells, have access to all of the natural processes and mechanisms normal cells have, and they used immune checkpoints to shut down the immune response being generated by the KRAS vaccine.

However, in the Kimmel Cancer Center's Bloomberg-Kimmel Institute for Cancer Immunotherapy, for which Dr. Jaffee is the associate director, researchers were identifying the immune checkpoints and testing drugs, known as checkpoint inhibitors, that reignited the immune response that cancer cells shut down.

"We are doing a lot of work in early detection and prevention."

In 2020, Dr. Zaidi first tested a vaccine that targeted six of the most common KRAS mutations in combination with two immune checkpoint inhibitors. The combination was given to patients who had surgery to remove as much of their cancer as possible.

One of the best features of using the immune system as a medicine is that it has the potential to work against all cancers, early and advanced. In patients with pancreatic cancer that cannot be cured with surgery because it has spread outside of the pancreas, the vaccine/checkpoint inhibitor combination brings new hope.

A new study of the KRAS vaccine in combination with two checkpoint inhibitors — known as Bal-Bot, for the two drugs used: "Bal" balstilimab and "Bot" for botensilimab — is ongoing in collaboration with **Nilo Azad**, M.D.

With dramatic response in patients who already had cancer, Drs. Jaffe, Zaidi and collaborators wondered if it could also prevent pancreatic cancer from developing.

Prevention

Working with **Michael Goggins,** M.D., a gastroenterologist specializing in pancreatic cancer and markers of high risk, Dr. Zaidi began a study of the vaccine in 20 patients with predisposition, including BRCA mutations, a gene alteration known to increase the risk of developing pancreatic cancer.

"The results were promising," says Dr. Zaidi. "All of the patients had an immune response, and after two years, T cells were still present."

Another prevention study is aimed at patients with IPMNs, intraductal papillary mucinous neoplasms, or pancreatic cysts. In some patients, these growths may become pancreatic cancer. In studies of precancers that appear to be transitioning to cancer, researchers found that immune T cells decreased in numbers the closer an IPMN was to becoming cancer.

Dr. Zaidi is giving the vaccine to 10 patients with IPMNs to see if it can keep T cells engaged and prevent them from transitioning to pancreatic cancers. In laboratory models, the vaccine slowed the growth of these precancers. Her clinical trial will prove if it can also work in people.

Some IPMNs create such a high risk for pancreatic cancer that they are surgically removed. Zaidi is studying whether giving these patients the KRAS vaccine before surgery will provide clues to how the vaccine is working.

With tissue removed at surgery, Dr. Zaidi says, they could see if immune cells got into the tissue and if there was any immune system suppressing activity that might keep the vaccine from doing its job to prevent the cancer. In that case, other immunotherapies, such as checkpoint inhibitors, might be required to hold the cancer at bay.

"We are doing a lot of work in early detection and prevention," says Dr. Zaidi.

Dr. Jaffee, who has spearheaded the evolution of the vaccine from its first iteration for patients with advanced pancreatic cancers, is eagerly anticipating the findings from the latest gene-targeted versions that have shown the promise to prevent pancreatic cancer from developing.

Bringing Hope

As Drs. Jaffee, Zaidi and their colleagues continue to harness the immense power of the immune system, these therapies are bringing unprecedented hope to patients. Cancers that would have most certainly killed are now being reined in by the immune system. (see "REBB's Rebellion," page 00). It was what Dr. Jaffee hoped for when she began her research at the Johns Hopkins Kimmel Cancer Center in the 1980s.

Currently, however, her optimism is tempered by the threat of cuts to federal research grants. She says it is the only thing standing in the way of future cures for patients with pancreatic cancer and other types of cancer. Already, just 8% of studies get funded by the National Cancer Institute. Any further cuts would devastate research and the vital progress being made against cancer, she says.

"To see these vaccines working so well has been a dream of mine since the beginning," says Dr. Jaffee, who has dedicated her career to finding cures for this deadly cancer. "Now it is becoming a reality. It's really miraculous."

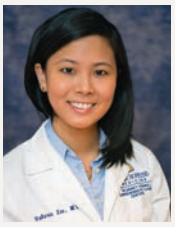
GOGGINS

RESEARCH SAVES LIVES

WEB EXCLUSIVE: Read the *Baltimore Banner* feature on vaccine studies conducted by Drs. Jaffee and Zaidi and the implication of research cuts at **bit.ly/3G6UtWb**.

Navigating Pancreatic Cancer

PISHVAIAN



LEE

THE NUMBERS AREN'T GOOD. Only 4% of patients with pancreatic cancer get referred for a clinical trial, says **Michael Pishvaian**, M.D., Ph.D., Director of Gastrointestinal Developmental Therapeutics and Clinical Research Programs for the Kimmel Cancer Center in the Greater Washington area. This is despite the fact that experimental therapies aimed at improving the survival rates of this lethal cancer can extend survival by one year or more.

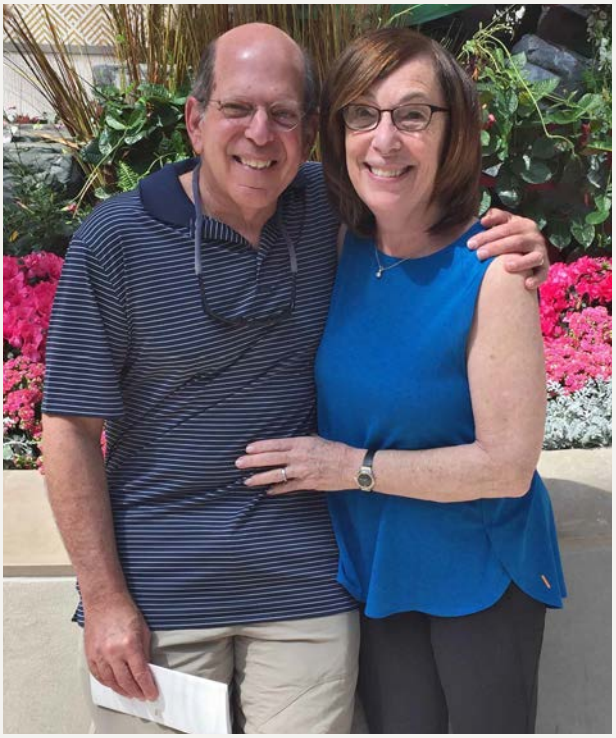
Many of these promising new therapies are directed at gene mutations present in the cancer. Almost all patients with pancreatic cancer have gene alterations in their cancers that could be targeted with therapy, but there again, Dr. Pishvaian says, just 30% of patients receive the genetic profiling of their tumors needed to identify these gene targets. For patients with advanced pancreatic cancer that has spread beyond the pancreas and cannot be treated with surgery, clinical trials are often the best option.

Dr. Pishvaian and **Valerie Lee**, M.D., at the Kimmel Cancer Center at Sibley Memorial Hospital are working to change these numbers, in partnership with the Sibley Memorial Hospital Foundation to raise funds for a new Gastrointestinal Oncology Clinical Trial Navigator.

The navigator will ensure every patient gets molecular testing as soon as possible after diagnosis, facilitate and expedite enrollment in clinical trials and track patient outcomes. The navigator will also catalog tissue samples, particularly those that turn out to be resistant to treatment, to help guide additional therapy and learn more about the mechanisms of pancreatic cancer behavior.Their goal is to boost these numbers from 4% to 25% for clinical trials enrollment and from 30% to 90% for genetic profiling of tumors.

Elliott and Evonne, donors to the patient navigator position, understand the need firsthand. Elliott was diagnosed with advanced pancreatic cancer in November 2024, the day before he and his wife Evonne were to leave for a family vacation with their 15 children and grandchildren.

"We were happy to kick off this fundraising campaign," says Elliott. "We hope this will catch on, and there will be others who will want to help."



Elliott is receiving chemotherapy, and is being considered for a clinical trial of drugs that target the KRAS gene, a common gene mutation fueling pancreatic cancer, and one profiling showed his cancer contains.

"I want every patient to have the opportunity to get into a clinical trial and to expand their treatment options," says Elliott. "To have a full-time associate who could focus solely on matching clinical trials will be a huge benefit to the patients and their doctors."

"The navigator will play a complementary role that parallels the work of the clinical team, tracking patients through their cancer journey."

The navigator will coordinate across all Johns Hopkins Kimmel Cancer Center sites, and will work in conjunction with a national program called the Canopy Cancer Collective, which is designed to improve the quality of care and outcomes for patients with pancreatic and other gastrointestinal cancers.

"The navigator will play a complementary role that parallels the work of the clinical team, tracking patients through their cancer journey," says Dr. Pishvaian. "We think someone focused only on testing and trials could make a major impact."

For additional information or to make a donation to help fund the navigator position, contact **Sarah Jane Keegan** at 202-370-6531 or sjkeegan@jhmi.edu.

Transformational

The Promise of KRAS Inhibitors Becoming a Reality

MUTATIONS IN KRAS genes are the most common gene alteration in pancreatic cancers, occurring in about 90% of the cancers. However, this gene target was long considered undruggable because of its molecular makeup.

For 30 years, researchers have been working tirelessly to figure out a way around this challenge to target the KRAS enzyme, a central figure in the development and spread of pancreatic cancer and other cancers, including colorectal and lung cancers.

This research is finally paying off. Over the past 10 years, a new class of drugs, called KRAS inhibitors, were developed and are now being studied in clinical trials around the world for their ability to latch onto the protein and disrupt its cancer-causing signal.

This represents a significant advance in the treatment of GI cancers, says pancreatic cancer expert **Michael Pishvaian,** M.D., Ph.D., Director of Gastrointestinal Developmental Therapeutics and Clinical Research Programs for the Kimmel Cancer Center in the Greater Washington area.

"They have tremendous promise, and we are hopeful they will work significantly better than chemotherapy," he says.

Elizabeth Jaffee, M.D., Deputy Director of the Kimmel Cancer Center and Co-Director of the Skip Viragh Center for Pancreas Cancer Clinical Research and Patient Care, echoes his enthusiasm, pointing out that this breakthrough illustrates the value of continued research and the need for stable funding.

"Major advances in therapy, like this, don't happen overnight. They often take decades to go from the laboratory to the bedside, and this is a perfect example of the value of government investment in medical research and its ability to help Americans," says Dr. Jaffee.

About 20 variations of KRAS inhibitors are being studied, Dr. Pishvaian explains. Some, called pan KRAS inhibitors, are designed to work across all KRAS mutations, and others target specific KRAS mutations.

One inhibitor being studied in clinical trials at Johns Hopkins Sibley Memorial Hospital and around the world targets KRAS G12D, the most common KRAS mutation in pancreatic cancer.

Results are looking very promising. In a study of the Pan-KRAS drug in 100 patients with pancreatic cancer whose cancers did not respond to chemotherapy, tumor size was reduced in 30% of patients, and the cancer was controlled overall in 80% of patients treated in the study, he says.

"That is triple what we see in chemotherapy," says Dr. Pishvaian.

With chemotherapy, about 5% to 7% of patients get tumor reduction, and about 30% will see their cancer stabilized for about four months, Dr. Pishvaian explains.

Dr. Pishvaian points out that it is still early in the studies, but the data show better responses for a longer time than standard therapies. Still, researchers continue to look for ways to improve them even more and to combat resistance to the drugs. Combination therapies is one approach.

"The effectiveness of KRAS inhibitors is opening up a new horizon for treating pancreatic cancer," says Dr. Pishvaian. "It is also opening the door to combination therapies. Research of these combinations is just getting started."

Combining KRAS inhibitors with drugs that target other gene alterations and adding immunotherapies — drugs that boost the immune response to cancer — are among the combination treatments being explored.

The first studies were in patients with advanced pancreatic cancer who were not candidates for surgery. Newer studies are exploring the drugs following surgery to reduce the chance of the cancer coming back. As many as 60% of patients suffer recurrences of their pancreatic cancer after surgery.

Not surprising, the favorable results have sparked great patient interest in the KRAS inhibitor clinical trials, which Dr. Pishvaian says are filling quickly. He is hopeful that the promising findings will lead to a fast-track FDA approval of the drugs as early as 2026.

"Transformational" is the word Dr. Pishvaian says best describes the promise of KRAS inhibitors for pancreatic cancer.

"By next year, all therapy will be viewed through the lens of KRAS inhibitors," he says. "All patients with pancreatic cancer will likely receive this therapy at some point in their cancer journey."

JAFFEE

REBB (RIGHT) WITH
NURSE MAUREEN BERG

REBB's Rebellion

Determination and Immunotherapy Help Her Beat the Odds

THE PAIN WAS getting worse. Roberta — REBB, as she is known to her family and friends — instinctively knew something was wrong. The discomfort in her abdomen was not going away. An endoscopy and colonoscopy did not reveal the cause, and despite her doctor's insistence there was nothing medically wrong, REBB was not reassured.

If nothing was wrong, why was the pain worsening? REBB demanded to know. Still, REBB's doctor near her home in Arizona dismissed her complaints. By now, the pain was excruciating, and REBB was desperate for relief. Her doctor suggested painkillers, but REBB refused to take medication without knowing the source of her pain. Frustrated by her doctor's unwillingness to get to the bottom of the problem, REBB turned to an Eastern medicine specialist and acupuncturist she and her husband John saw from time to time. Almost immediately, he sensed a problem with her gallbladder or pancreas, REBB says, and he urged her to get a scan taken right away.

Reluctantly, her doctor agreed to order the scan. The source of REBB's pain was instantly recognizable and shocking. The scan showed a large mass on REBB's pancreas. The reality was beyond anything REBB could have imagined.

It's Cancer

A few years earlier, REBB lost her daughter Valerie to breast cancer at just 42. Now, REBB was facing a cancer diagnosis of her own.

REBB says she felt Valerie guiding her. When she searched on the internet for pancreatic cancer experts, Johns Hopkins came up first.

"I could hear my daughter say, 'It's time to go to Johns Hopkins,'" says REBB.

At this point, the pain was becoming intolerable. On June 20, 2021, REBB and John got on a plane and flew from Arizona to Johns Hopkins. They would make that trip many more times over the next years.

REBB met with **Jin He**, M.D., Ph.D., the Paul K. Neumann Professor of Pancreatic Surgery, who ordered additional imaging. The tumor was larger than revealed by the earlier scan REBB received in Arizona. Typically, chemotherapy and radiation therapy would be the first line of treatment, aimed at shrinking the tumor before surgery. However, seeing how toxic these treatments had been to her daughter, REBB refused. Dr. He and team respected her decision and proceeded with a type of surgery called a Whipple.

Treatment Begins

This Whipple procedure, perfected at Johns Hopkins, involves removing the head — and sometimes the body — of the pancreas, a part of the small intestine called the duodenum, a portion of the bile duct, the gallbladder, associated lymph nodes and sometimes a small portion of the stomach.

Dr. He was able to remove most of the tumor. REBB refused any chemotherapy or radiation following the surgery.

A frequent international traveler and an avid reader, REBB stays abreast of the latest medical and research advances in Europe and the U.S.

"I felt that if I was going through this, there was a reason, and research needed to be a part of it," says REBB. "I told my doctors, any test they wanted to run, I was up for it. If we can learn from this, let's do it."

Research Options

REBB knew her situation was serious. She awaited approval of a new Kimmel Cancer Center clinical trial that combined a therapeutic vaccine with two drugs called checkpoint inhibitors, which unleash the immune system to attack the cancer.

Pancreatic cancer vaccines were first developed and studied in patients in the early 1990s by **Elizabeth Jaffee**, M.D., one of the world's leading pancreatic cancer experts and co-director of the Kimmel Cancer Center's Skip Viragh Center for Pancreas Cancer Clinical Research and Patient Care. In 2022, Jaffee collaborated with pancreatic cancer and immunotherapy researcher **Neeha Zaidi,** M.D., on a new iteration of the vaccine that targeted KRAS mutations — gene alterations that were common among pancreatic cancers. REBB's tumor had these mutations.

ZAIDI

HE

In clinical trials of the vaccine alone, Dr. Jaffee and colleagues found that it worked to drive immune cells to pancreatic tumors, which on their own did not attract immune cells. However, another component of the immune response was dampening the effect of the vaccine. The on/off switches of the immune system — natural controls called immune checkpoints, that turn on an immune response and shut it down when it is no longer needed — were exploited by cancer cells. The cancer was shutting down the immune cells drawn to the cancer by the vaccine before they could go to work against the cancer.

Drs. Zaidi and Jaffee were about to launch another clinical trial, combining the KRAS mutation-targeted vaccine with two immune checkpoint inhibitors.

In 2015, researchers at the Kimmel Cancer Center's Bloomberg~Kimmel Institute for Cancer Immunotherapy identified and helped develop a drug that targeted the anti-PD-1 immune checkpoint. They found that drugs that block the checkpoint release restraints placed on the immune system by cancer cells. Remarkable results were seen among cancers that contained large numbers of mutations that attracted immune cells into the tumor, such as lung cancers and melanoma skin cancers. In pancreatic cancer, however, few immune cells were naturally drawn to the cancer, so checkpoint inhibitor immunotherapy was not enough to achieve a therapeutic immune response to the cancer.

Drs. Jaffee and Zaidi thought combining the KRAS vaccine with checkpoint inhibitors might be the solution, and they developed a clinical trial to study the combo. Since REBB's pancreatic cancer contained KRAS mutations, she was a good candidate for the experimental therapy.

Research nurse **Maureen Berg** had already discussed the vaccine with REBB and was working to get her started on the clinical trial.

Ready and Waiting

REBB was passionate about this kind of medical research, and she was eager to get started.

However, as she was waiting for the study to get up and running, her health was declining. The major surgery and cancer had taken a toll. REBB, 65, was getting weaker. By December 2021, she used a wheelchair when going any prolonged distance.

"I was so ill, I started a book for my children and grandchildren titled *My Days Are Numbered*," with stories about the family and Valerie that her children did not know. I wanted them to know the legacy they belong to," says REBB.

Yet, in a strange way, REBB considered her diagnosis a blessing. Since 2012, when she began exploring treatments for her daughter, REBB had been reading about the promise of immunotherapy in treating cancer.

She believes she was in the right place at the right time. This new study of a treatment that caused the immune system to attack cancer cells, rather than poisoning them with chemotherapy or breaking their DNA with radiation therapy, was exactly the kind of treatment REBB was searching for, and she was eager to give it a try. She hoped it could stop the two remaining cancerous lesions on her pancreas from growing and spreading.

Healing Begins

At last, in January 2022, REBB started the vaccine/checkpoint inhibitor treatment. She and her husband John flew weekly from Arizona to the Kimmel Cancer Center for treatment. Over time, the frequency of her visits decreased to every other week, then every three weeks, and finally monthly. They were often accompanied — and always supported — by a host of family and friends, to whom REBB expresses immense gratitude.

"These are the people who supported me each and every day. They are as healing as my treatments," says REBB.

"I am so grateful for my husband, John, who continues to be my caregiver, my son SeanRobert, grandson Tristen and granddaughter Lauren, the dozens of friends and caregivers, the flight crews and customer service representatives, and the incredible staff at Johns Hopkins, who provided not just medical care, but patient care," says REBB. "We could have gone to a major hospital system right down the street, but my gut told me Johns Hopkins was the right choice, and John never questioned my decision. He made all of the necessary travel arrangements and has been by my side throughout it all."

REBB believes each of these people, who she says "had her back when the chips were down," played an important role in getting her to the moment when she could begin immunotherapy.

Better Days

"Almost immediately I started feeling better. My immune system was destroying the cancer. By April, I was running through the airport, and by December 2022, I was cancer-free," says REBB, who adds, "Because of Johns Hopkins physicians' research and this clinical study, I was there in February 2024 to welcome my granddaughter Vaelyn, named in memory of her Aunt Valerie."

In the Winter of 2022, as REBB was finishing her immunotherapy treatments, she began writing a new book, *My Days Were Numbered*.

In her book, she was writing about all of the people she met along her cancer journey — the delightful guy at the car rental place, whom she nicknamed Mr. Joy; the car service driver who took her back and forth to Johns Hopkins and whose watchful eye may have saved a young child from being taken by a stranger; and the kind receptionist from the hotel where REBB and John stayed, stopping traffic on a busy street for a group of Johns Hopkins physicians. These experiences gave REBB a different vantage point, she says, of seeing all of the pieces that came together to allow her to battle the cancer that was trying to take her life.

Today, REBB feels healthy and full of energy. She continues to travel, and loves evening gowns and voyages on the Queen Mary 2. She enjoys reading — especially to her granddaughter Vaelyn — meeting people, and teaching women and children about investing. Since her diagnosis, she has become a vocal advocate for second opinions.

"I always strongly suggest to anyone and everyone, after receiving an initial diagnosis, especially a diagnosis of something serious like cancer, that they should get a second opinion at a research institution like Johns Hopkins before having anything done," says REBB. "In my opinion, going to a medical research teaching hospital and university specializing in the diagnosis the person has received is the only way to go. These places are on the cutting edge, and you want minds like that, who are always searching, when you have a diagnosis like pancreatic cancer. Johns Hopkins touches so many lives, and I credit the experts there and this immunotherapy trial with saving mine."

Supporting Patients

A MONTHLY SUPPORT group is available to patients with pancreatic cancer. The group meets via Zoom and is facilitated by social worker **Madison Hankin**, M.S.W., L.G.S.W. She says all patients with pancreatic cancer are welcome to attend, and the group currently includes patients at all phases of their cancer journeys, from the newly-diagnosed to long-term survivors. For questions or to join the support group, email Madison Hankin at mhanki13@jhmi.edu.

BACK, FROM LEFT: DRS. HUFF, MARU, HANDLER, ZAIDI, JAFFEE, ARIF, NAKAZAWA, WANG, LIANG. FRONT. FROM LEFT: FRAN AND JIM MCGLOTHLIN, DR. LAHERU

The McGlothlin Fellows to Faculty Fund

Ensuring the Future of Pancreatic Cancer Research and Treatment

JIM AND FRAN MCGLOTHLIN have a long history of supporting "young people of promise." For more than 30 years, they have helped disadvantaged students achieve success through full college scholarships for graduates of the Mountain Mission School, located in Jim's hometown of Grundy, Virginia. Students of the school, which does not charge fees or tuition, also receive onsite housing, food, clothing, and other services. The McGlothlins also provide full college scholarships to students in the business graduate school and law school at their alma mater William and Mary and established the McGlothlin Leadership Forum, which unites students at the university with leaders in business and law to inspire them and promote their success. Further, students of need attending the Medical College of Virginia receive scholarships through the generosity of the McGlothlins and graduate debt free.

It is unsurprising, then, that after Jim's battle with pancreatic cancer and treatment at the Kimmel Cancer Center, Jim and Fran decided to show their gratitude by establishing the Fellows to Faculty Fund to support the next generation of pancreatic cancer researchers.

The inspiration for the McGlothlin Fellows to Faculty Fund began in 2015 when a CT scan revealed that Jim had a tumor in his pancreas. The cancer was detected early and appeared to be limited to the part of his pancreas, known as the tail. The tail was removed through surgery, and the McGlothlins were optimistic.

From Patient to Patron

The surgery was deemed a success, leaving the McGlothlins shocked when an oncologist entered Jim's hospital room and matter-of-factly told Jim that he had little chance for survival.

"He told me death was inevitable; that I had maybe a year to live," Jim recalls.

The news was overwhelming for the McGlothlins.

"I was destroyed," says Fran.

Jim was scheduled to begin chemo- therapy the next month near their home in Virginia. A friend suggested that Jim and Fran seek a second opinion.

They traveled to the Kimmel Cancer Center and met with leading pancreatic cancer expert **Daniel Laheru,** M.D., the Ian T. MacMillan Professor of Clinical Pancreatic Cancer Research and co-director of the Skip Viragh Center for Pancreatic Cancer Clinical Research and Patient Care.

A Plan

Dr. Laheru saw things differently. He had a plan.

"If it were my family member, this is what I would do," Dr. Laheru told Jim and Fran, detailing a chemotherapy regimen that, although grueling, could save Jim's life.

"Dr. Laheru was compassionate and reassuring. We left feeling hopeful," says Jim.

Dr. Laheru met with Jim's doctor in Virginia to go over the plan and they worked together throughout the treatment.

Jim's doctor in Virginia was amazed. He called it a "storybook prescription," the McGlothlins recall.

Jim and Fran say Dr. Laheru did not exaggerate when he explained the intensity of the chemotherapy regimen. Jim lost 60 pounds and some days could barely get out of bed, but he fought on, and the plan worked.

Today, ten years later, Jim remains cancer free.

Giving Back

The McGlothlins were grateful and felt they had a responsibility to give back.

"Dr. Laheru saved Jim's life. What price can you put on that?" says Fran. "Johns Hopkins is a special place, and we felt like we had an opportunity to help others."

After donating $4 million to advance the pioneering cancer vaccine research of **Elizabeth Jaffee**, M.D., the Dana and Albert "Cubby" Broccoli Professor of Oncology and co-director of the Skip Viragh Center for Pancreas Cancer Clinical Research and Patient Care, they established the Fellows to Faculty Fund. It supports research of young pancreatic cancer investigators just getting started. Investing in these bright young doctors, the McGlothlins say, ensures that progress against pancreatic cancer continues.

"They will change the way pancreatic cancer is treated," says Jim.

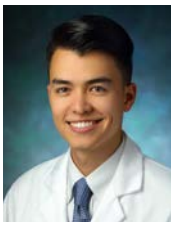
The Fund was launched in 2023 with five young investigators supported. An additional five received funding in 2024. The McGlothlins hope to expand the Fund to support more young investigators.

"We believe in mankind, and these bright and talented young people are the future of our country," says Jim.

This year's McGlothlin Fellows are deciphering and developing immunotherapies that capture the power of the immune system and reveal its promise for prevention, long-lasting responses, and cures for pancreatic and other GI cancers.

The 2024 McGlothlin Fellows


ARIF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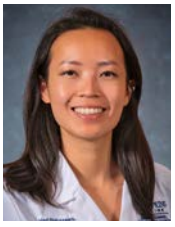

NAKAZAWA

Waqar Arif, M.D., Ph.D.
Dr. Arif is focusing on a type of liver tumor, called hepatic adenomas that typically affects young women. These tumors are usually benign, but about 5% become malignant and transform into hepatocellular carcinoma (HCC). His goals are to understand the genetic and epigenetic changes that govern the transformation of these benign lesions into cancer with hopes to identify novel therapeutic targets.

In addition, Dr. Arif is studying fibrolamellar hepatocellular carcinoma (FLC), a very rare form of liver cancer that usually affects children and young adults and has no standard treatment. A vaccine/immune checkpoint inhibitor combination was developed at the Kimmel Cancer Center to ramp up an immune attack against the cancer. In a clinical trial of the immunotherapy, some patients who initially responded to the treatment, saw their cancer come back and spread a few years later. Dr. Arif is utilizing the latest spatial transcriptomic techniques on samples from FLC patients to study the changes between primary lesions before starting therapy and metastatic lesions post immunotherapy. The goal is to understand the molecular and cellular changes that occur between the original onset of the cancer and when the cancer spreads to look for treatments to stop the cancer's return and spread.

"I am grateful for Mr. and Mrs. McGlothlin's generous support of our department's vital, ongoing cancer research. Their contributions not only advance our mission but also strengthen my dedication to discovering better ways to improve the lives of our patients," says Dr. Arif.

Amanda Huff, Ph.D.
Dr. Huff is working to decipher how cancer vaccines developed in the Kimmel Cancer Center attract immune T cells to cancer.

She is particularly interested in the KRAS vaccine. KRAS mutations are common among pancreatic cancer, and this vaccine causes immune T cells to traffic to tumors. Dr. Huff will study the T cell responses generated by the vaccine to decipher the specific characteristics of the immune cells and how T cell behavior differs among patients.

Dr. Huff says this research will expand the understanding of the mechanics of how immune cells recognize antigens—those things that trigger immune responses—and contribute to the development of better vaccines.

"I am deeply honored and grateful to be named a McGlothlin Fellow. This award is not only a tremendous encouragement but also a vital support in my research developing new and better immunotherapy treatments for patients with pancreatic cancer," says Dr. Huff. "This fellowship will allow me to deepen my scientific exploration, grow as a researcher, and hopefully, ultimately contribute meaningful advancements to the field.

Kai-Li Liang, M.D.
Dr. Liang is helping lead clinical trials of the KRAS mutation-targeted vaccine. KRAS mutations are present in approximately 90% of pancreatic cancer patients, and since these mutations are only found in cancer cells, it makes them a vaccine target. The vaccine currently targets six of the most common mutations and is aimed at increasing immune recognition by the immune system.

One of the clinical trials is studying this vaccine in patients who are at high risk of developing pancreatic cancer. Since the same KRAS mutations found in pancreatic cancer are also found in pre-cancerous pancreatic cysts, the goal of this trial is to activate the immune system to intercept the development of pancreas cancer in high-risk individuals.

Another trial is aimed at patients who have advanced pancreatic cancer and is studying the KRAS vaccine in combination with two immunotherapy drugs, known as Bal-Bot. Balstilimab or "Bal" and botensilimab or "Bot" target the PD-1 and CTLA-4 immune checkpoints respectively, to help harness the power of the immune system against cancer cells. Immune checkpoints are natural on/off switches for the immune system that cancer cells exploit to avoid detection by the immune system. The goal of this trial is to alter the tumor microenvironment—the cells in and around pancreas tumors—and to activate the immune system to seek out and destroy cancer cells.

Dr. Liang will also be studying both blood and pancreas tissue samples to determine whether immune cells are infiltrating into tumors and if these cells can help create a more immune responsive environment.

"I am deeply honored and humbled by the generous gift by Mr. and Mrs. McGlothlin. This award provides invaluable support to address the unmet need for improved therapies in pancreatic cancer," says Dr. Liang. "From their generosity, I hope to help design personalized cancer treatments that minimize toxicity and improve quality of life."

Mari Nakazawa, M.D.
Dr. Nakazawa is interested in understanding why some tumors respond to immunotherapy with checkpoint inhibitors while others do not. She has observed that patients with the same disease at the same age can have completely different responses, with one passing away in months and the other responding after multiple cycles of immunotherapy and returning to normal life.

She is using an immunotherapy biobank started in 2021 that contains serial blood samples from 300 patients receiving immunotherapy. She hopes by studying these samples, she may uncover indicators of response and resistance to therapy.

Dr. Nakazawa will collect data on all of the features of immune cells and tumor cells, including spatial features and changes in DNA. She will integrate all of information, using computational models that can integrate large data sets beyond the capacity of the human brain, to understand the complex system from many different angles and to chip away at the causes of treatment resistance.

"I am deeply honored to be named a McGlothlin Fellow in pancreatic cancer research and to continue this important work with the support of Mr. and Mrs. McGlothlin for a second year," says Dr. Nakazawa. "Their unwavering commitment over multiple years has not only sustained my research but has also reinforced the collective determination to advance therapies for this devastating disease. I joined the GI group because I was inspired by the pioneering work of Drs. Jaffee and Laheru in harnessing the immune system to fight pancreatic cancer, and I am profoundly grateful for the opportunity to build upon that legacy."

H. Henry Wang, M.D., Ph.D.
Dr. Wang is studying the KRAS mutation-targeted vaccine in pancreatic and colorectal cancers. He is tracking immune T cells stimulated by the vaccine in tumor samples and blood samples to learn more about their characteristics and identify features that indicate a likely immune response against the cancer.


WANG

What Dr. Wang is learning could lead to improved versions of the KRAS vaccine and help identify patients most likely to respond to the therapy.

"I am deeply honored to receive the McGlothlin Fellows to Faculty Award," says Dr. Wang. "This generous support from Mr. and Mrs. McGlothlin enables me to pursue my goal of becoming a physician-scientist dedicated to advancing immunotherapy for pancreatic and colorectal cancer. It is a true privilege to contribute to the McGlothlin legacy in the fight against these devastating cancers."

Kelly's Heroes

Bringing Hope and Clinical Trials to Patients Fighting Pancreatic Cancer


DUNG LEE WITH KERRY KELLY


STEVE KELLY

STEVE KELLY BELIEVED in the power of clinical trials. "Someone is going be the breakthrough patient," he told his family and friends when his world was rocked by a diagnosis of advanced pancreatic cancer.

Following the diagnosis, he made two key decisions. He chose to come to the Kimmel Cancer Center for treatment and opted to participate in two clinical trials of promising new therapies. The first was a five-drug combination and the second was a therapeutic pancreatic cancer vaccine aimed at getting his immune system to attack the cancer.

Although the research therapies extended his life, says his wife Kerry, he died from the cancer in 2015 at age 55. Determined that Steve's death from pancreatic cancer was not going to be the end of his story, his family and friends started Kelly's Heroes, a 501(c)(3) charitable organization, to "take care of Steve's unfinished business," says Kerry.

Steve, an editor at the *Philadelphia Inquirer* was confident in the research at the Johns Hopkins Kimmel Cancer Center. If he was not the breakthrough patient, Steve believed it was just a matter of time before those breakthroughs would happen for another patient.

Kelly's Heroes raises awareness and funds for pancreatic cancer clinical trials. Contributions come through events inspired by Steve's fun-loving spirit, Kerry says, including an annual golf tournament, St. Patrick's Day party and the Kelly's Heroes running team that follows in Steve's footsteps by competing in marathons and half-marathons. Kelly's Heroes is also now part of the World Pancreatic Cancer Coalition, and Kerry is chair of the planning committee for World Pancreatic Cancer Day.

Over the last five years, Kelly's Heroes has supported the research of leading cancer genetics expert, Dr. **Bert Vogelstein**, who was the first to map the genetic causes of pancreatic cancer, and gastrointestinal cancer clinical researcher Dr. **Dung Le**, who developed and led the clinical trial of the five-drug combination Steve received. The combination initially worked, shrinking Steve's tumors.

"What we learned from patients like Steve, made it possible for other patients to be doing well today," says Dung Le, M.D., Bloomberg-Kimmel Professor of Cancer Immunotherapy.

Like so many patients, Steve was in great shape, a young and active husband and father when cancer changed everything.

"We were devastated," says Kerry. "We were not familiar with pancreatic cancer and what we found online was grim."

Standard treatment doesn't provide long-term survival for many patients with pancreatic cancer. "Our goal is to bring hope to pancreatic cancer patients by making sure they have more treatment options," says Kerry.

"The support we've had for Kelly's Heroes is a testament to Steve and what he meant to people," says Kerry. "He was a dedicated newsman and a wonderful, caring person. Even in the face of cancer, Steve lived with a capital L."

ADVANCES

Getting Right to the Tumor

Innovative Collaboration with Interventional Radiology

FOR PATIENTS WITH pancreatic cancer that remains contained to the pancreas but has begun to invade nearby blood vessels, a new approach delivers the pancreatic cancer-fighting drug gemcitabine directly into the tumor.

Working with interventional radiologists, the drug is given through a blood vessel that is accessed through a leg vein and goes straight into the tumor, as opposed to through an IV, where it circulates through the bloodstream to get to the cancer.

LEE

"It's a different vector of administration we are trying," says **Valerie Lee**, M.D., who treats pancreatic cancer patients at the Kimmel Cancer Center at Sibley Memorial Hospital.

These patients have cancers, termed locally advanced, that often cannot be removed with surgery and have already had systemic chemotherapy without much benefit.

"We think it can intensify the therapeutic benefits of the drug and reduce the side effects caused by systemic chemotherapy," she says.

Dr. Lee is collaborating with **Nikhil Bhagat**, M.D., director of vascular and interventional radiology for Johns Hopkins in the greater Washington area, and interventional radiologists **Andrew Ackman**, M.D., Brian Johnson, M.D., and **Abhishek Srinivas**, M.D.

Surgical Advances

BURNS

ABOUT 30% TO 40% of patients with pancreatic cancer are not candidates for surgery based on current standard of care. However, pancreatic cancer surgeon **Will Burns**, M.D., and colleagues are changing this, developing innovative techniques that are bringing new surgical options — and new hope — to patients.

Dr. Burns, the surgical lead for the pancreatic cancer multidisciplinary clinic, says patients are often excluded from surgery because their cancers are attached to or wrapped around critical structures, such as veins and arteries. The Kimmel Cancer Center is among just a few cancer centers in the world that can take on these challenging cases.

He and his colleagues continue to develop new surgical techniques that are getting more patients to surgery and improving quality of life and survival. With their extensive expertise, the pancreatic cancer surgical team is able to perform complex surgeries that other hospitals are not equipped to try.

For some patients, the cancer is limited to the pancreas, but surgery is not an option because the tumor is attached to a critical vein that controls blood flow between the liver and intestine.

In this case, Dr. Burns say, the surgeon removes the vein to ensure no tumor is left behind and then reconstructs the vein or replaces it with a piece of vein from somewhere else in the body. The team works quickly, usually performing the entire procedure in under an hour to minimize loss of blood flow to the liver and intestine.

Another type of surgery, called arterial divestment, is used when tumors are touching arteries. Arteries are difficult to replace, Dr. Burns explains, so instead of attempting to reconstruct or replace the artery, the surgical team works along the outer edge of the artery walls, meticulously unwrapping the tumor from the artery. In some cases, radiation is delivered to the surgical site via tiny radioactive beads inserted through a catheter, which kill any cancer cells that may remain stuck to the artery wall to reduce the chances of the cancer coming back.

In some instances, the tumor grows into the artery, and then the surgical team removes the artery and rebuilds it using a vein from elsewhere in the patient's body.

Dr. Burns and team are also now helping patients with pancreatic cancer with limited spread to other organs in the abdomen, such as the liver.

"This is the next frontier," says Dr. Burns. "We think we can prolong survival."

Specific patients who are otherwise fit and healthy, and who responded well to chemotherapy, are candidates for surgery to remove the head of the pancreas — a procedure known as the Whipple — as well as tumors that spread from the pancreas to the lung and liver. The primary tumor and spread to the liver are handled in a single operation, with two different surgeons addressing each organ. Cancer spread to the lung is treated in a separate surgery.

In addition to giving patients the chance for longer survival, these new surgical techniques allow researchers to analyze the tumors before and after surgery, providing a better understanding of the biology of the cancer and how the spreading tumor differs from the

primary tumor in the pancreas. This additional knowledge will help them develop better therapies, Dr. Burns says.

He also is working on a new clinical trial of post-surgery immunotherapy combined with a drug therapy that targets the NOTCH pathway. NOTCH is believed to play a key role in the development and progression of pancreatic cancer and in its ability to become resistant to treatment.

The combination therapy worked well in laboratory models, and Dr. Burns is hopeful it will advance to clinical trials in the next year. However, the potential cuts to grants from the National Institutes of Health now have this important next step in question.

These pioneering techniques — all developed by Kimmel Cancer Center surgeons within the past one to eight years — represent major clinical gains. Patients who were previously not considered candidates for surgery or could only have a portion of their cancers removed are now able to have their entire tumor removed.

Treating the Triangle


NARANG

DESPITE THE improvements in surgery for pancreatic cancer, about 40% of patients who have surgery will see their cancer return in close proximity to the pancreas, which is commonly referred to as a local recurrence. The reason why such local recurrences occur remains unclear. Radiation oncologist and pancreatic cancer expert **Amol Narang**, M.D., along with his team of researchers, have been exploring this question and strategies to reduce the local recurrence rate.

In 2020, Dr. Narang's team performed analysis that shed greater light on the answers to these questions. They mapped, in very specific detail, the exact location of the local recurrences that happened over the prior five years and found that the vast majority of local recurrences were isolated to a very specific area — a triangular space sitting above the pancreas between a group of blood vessels and containing fat that was enriched in nerve tracks emerging from the pancreas.

This triangular space has been occasionally referred to as the Heidelberg Triangle, named for German scientists who first described the space as being clinically relevant due to the risk of spread from the pancreas along nerve tracks coursing through this space. The German group has advocated for removing the nerve track tissue in this space in addition to removing the main tumor, in order to decrease the risk of recurrence. While the German group is actively exploring this surgical approach, it is challenging because the nerve tracks may not be visible.

Dr. Narang envisioned a different tactic for getting at cancer cells in this area. He proposed using intra-operative radiation in the triangle during surgery to remove the pancreatic tumor, after also targeting the triangle before surgery with as much radiation dose as the nearby stomach and small intestine will allow.

"We have a one-time opportunity and one-time access to this triangle, and we think we should be treating this area in all patients," says Dr. Narang.

The data back him up. A 2023 analysis found that by modifying the way radiation was delivered before surgery to also include the triangle, the local recurrence rate dropped from 40% to 20%. These data prompted targeting of the triangle to become the international standard for how radiation should be delivered prior to surgery. Still, Dr. Narang thought they could do better, and he believed that increasing the dose of radiation to the triangle by adding intra-operative radiation was key.

"I would love to drop the recurrence rate to zero," Dr. Narang says.

He led a small clinical trial of intraoperative radiation in 20 patients. The therapy delivers a high dose of cancer cell-killing radiation to the triangle via a robotic device that carries small radioactive beads, which are inserted through catheters. The delivery method is precise, protecting nearby tissue and organs, such as the duodenum and small bowel, from radiation damage. His goal was to drop the recurrence rate to zero, and he got very close.

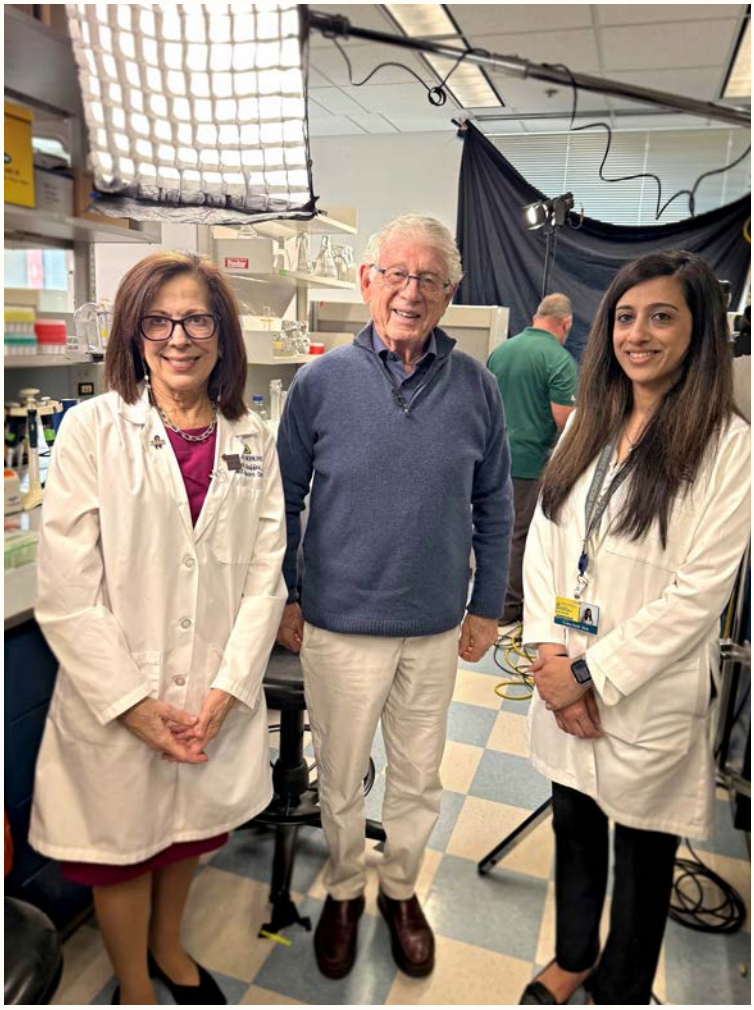
"It's still early, but only one person treated on the trials has had a local recurrence after treatment, and we think we know how we can tweak the therapy in a way that would have prevented that patient from having had a recurrence," says Dr. Narang. "We're optimistic."

Dr. Narang and team showed that they could safely get the radiation to the targeted triangle area without affecting surgery recovery time.

The success of the trial has gained so much interest throughout the U.S. that Dr. Narang believes a name change to the triangle is in order. He suggests the "Baltimore Triangle."

In the News

Elizabeth Jaffee, M.D., (left) Kimmel Cancer Center Deputy Director and Co-Director of the Skip Viragh Center for Pancreas Cancer Clinical Research and Patient Care, and **Neeha Zaidi**, M.D., (right), associate professor of oncology, were featured in a segment of CBS *This Morning with Ted Koppel* (center). Dr. Jaffee, who pioneered therapeutic pancreatic cancer vaccines, and Dr. Zaidi, who is studying her vaccines in clinical trials, shared the research that led to the vaccine development and discussed the importance of federal funding in advancing cancer research. The segment aired on June 29. Watch it here: **http://bit.ly/4lbg3sg**



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Each contribution to the Johns Hopkins Kimmel Cancer Center makes a difference in the lives of cancer patients here at Johns Hopkins and around the world.

Our physician-scientists are leading the way on many of the scientific breakthroughs in cancer, and your donation will support patient care and innovative research that is translated to better, more effective treatments. We are also focusing on ways to prevent cancer and support survivors.

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