

SPRING 2022
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MOFFITT MOMENTUM[®]

DISSECTING DISPARITIES

Breast cancer more
deadly for some

CONTAINING COVID

Vaccine effectiveness
in cancer patients

TAKING THE PLUNGE

Immunotherapy's promise
in lung cancer



®

Leadership Message



Patrick Hwu, MD
President and CEO

Dear Friends,

Here is the latest issue of Momentum magazine, featuring portraits of hope, innovation, ingenuity and perseverance.

Cancer patients lacking a healthy immune system are extremely vulnerable. The common cold becomes dangerous – and a novel coronavirus potentially deadly. Once COVID vaccines became available, Moffitt researchers mobilized quickly to launch a study on how protective the shot is for this population. How long does the protection last, and is it the same for different types of cancer? See how more than 100 team members came together to shed light on the vaccine's effectiveness in cancer patients.

Moffitt continues to pave the way to becoming the cell therapy capital of the universe. Tumor-infiltrating lymphocyte therapy is a type of cellular immunotherapy that has shown success in melanoma. Now Moffitt is testing this in patients with non-small cell lung cancer. The therapy extracts immune cells inside tumors, grows billions of them in a lab and then infuses them back into the patient to attack the cancer. Deborah Barker has had an excellent response for her stage 4 disease thanks to her thoracic oncologist Ben Creelan. More importantly, she's ready to plunge back into scuba diving.

Black women are more likely to die of breast cancer, and Dr. Kimberley Lee wants to know why. Her research focuses on survival for women with hormone receptor positive breast

cancer. Yvette Gray's experience demonstrates large differences in the way in which Black women receive treatment for breast cancer compared to their white counterparts – and how this disparity makes her more likely to die of the disease. Learn more about Dr. Lee's groundbreaking study.

At wellness company It Works! you strive to reach for "a whole 'notha level." It's founder Mark Pentecost's way of motivating his team to dream bigger. When he was diagnosed with multiple myeloma – a cancer with no cure – he was challenged to do the same. With a \$10 million donation to establish the Pentecost Family Myeloma Research Center at Moffitt, the goal is to find a cure within the next 10 years.

You might have seen them across the cancer center, at Miles for Moffitt or on YouTube. Meet The ReMissions! I've been performing in bands for more than 30 years and I knew Moffitt needed our own group. It is so rewarding to make beautiful music with these talented musicians. Learn more about their day jobs and how they each contribute to Moffitt's mission. And check out my Twitter to see The ReMissions' newest releases: @PatrickHwuMD.

We hope you enjoy reading the incredible stories in this issue, which emphasizes Moffitt's ongoing commitment to our patients and the community by contributing to the prevention and cure of cancer through scientific research, innovative patient care and more.

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ON THE COVER:

Yvette Gray is helping Moffitt Cancer Center better understand the differences in survival for women with hormone receptor positive breast cancer.



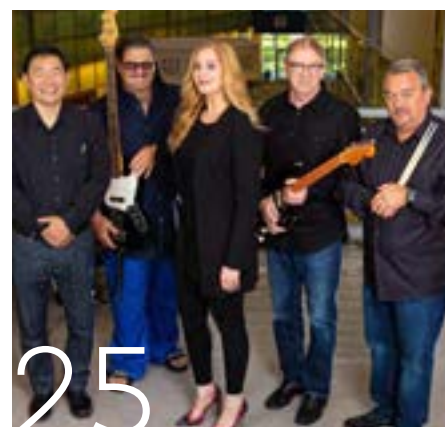
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COVID-19
Coronavirus
Vaccine



STUDYING A FAST-MOVING TARGET

*Moffitt researches
COVID vaccine effectiveness
in cancer patients*

By Ann Miller Baker

Photos by Nicholas Gould

From its earliest days as a novel virus in Wuhan, China, the COVID-19 pandemic has always been a particular threat to cancer patients.

Cancer itself taxes the patient's immune system. When surgery alone cannot eliminate the cancer, treatments like chemotherapy, radiation, transplantation and newer targeted therapies exact a greater toll. Without the defenses of a healthy immune system, the common cold becomes a threat – and a novel coronavirus potentially deadly.

COVID vaccines became available under emergency use authorization in December 2020, and frontline medical staff were first to receive the protective jab. Cancer patients and others with compromised immune systems weren't far behind. Since then, they've been among the first cleared to receive second doses and boosters.

But 18 months later, questions remain. How much protection do the vaccines offer our patients – and for how long? Do they offer equal protection for all regardless of the type of cancer? The answers are vital for patients, caregivers and families struggling to strike a balance between minimizing risks and living their lives.

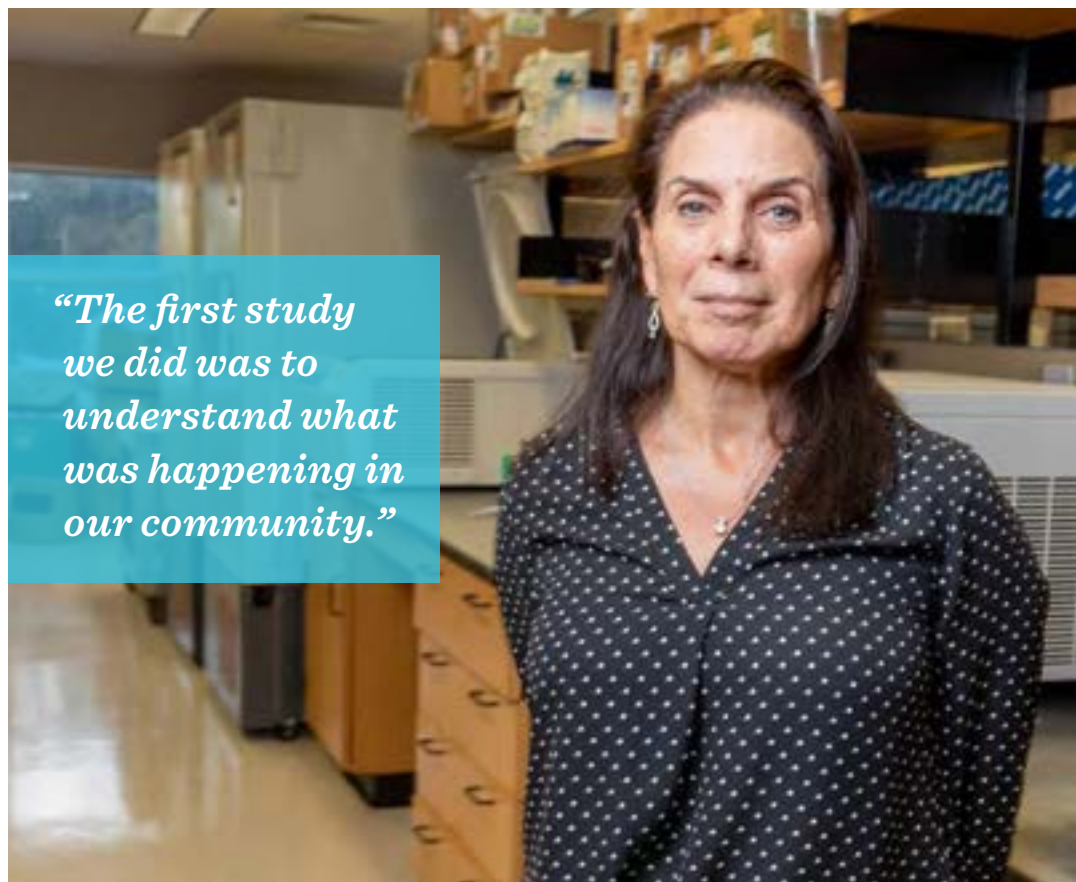
Thankfully, Moffitt Cancer Center has the facilities and personnel needed to find some of those answers, including a world-renowned epidemiologist best known for her work to prevent and eliminate cancers caused by the human papillomavirus through use of the HPV vaccine.

SURVEYING COMMUNITY RISK

Anna Giuliano, PhD, is the founding director of Moffitt's Center for Immunization and Infection Research in Cancer (CIIRC). She was instrumental in turning the cancer center's research attention to the pandemic's potential

impact on our patients, initiating a surveillance study in the fall of 2020 before COVID vaccines were available to the public.

"The first study we did was to understand what was happening in our community," said Giuliano. "We know that what happens in the community strongly influences what happens with our cancer patients." Fifty-thousand Hillsborough County residents were contacted at random by letter, postcard or email to see if they would be willing to answer a questionnaire and come to a Moffitt clinic to contribute a blood sample for the study. Nearly 900 agreed.



"The first study we did was to understand what was happening in our community."

ANNA GIULIANO, PHD
Founding director of the Center for Immunization and Infection Research in Cancer

To examine those samples, CIIRC co-director Shari Pilon-Thomas, PhD, first had to develop a testing mechanism, or assay, to measure COVID antibodies in the blood. “While my lab had the experience needed to develop the assays, we faced several challenges including finding and generating the reagents needed to develop the new assays at a time when many of Moffitt’s research facilities were shut down due to COVID,” noted Pilon-Thomas. Fellow Moffitt researcher Ernst Schonbrunn, PhD, contributed a protein critical to creating the new assay. Then, while continuing their other research efforts, team members in the Pilon-Thomas and Giuliano laboratories went to work testing nearly 900 blood samples.

The results showed roughly 20% already had traces of COVID antibodies in their blood, evidence of a past COVID infection. That’s twice the prevalence of confirmed COVID infections reported by state health agencies at the time – a significant risk for the county’s immunocompromised citizens.

VACCINES CAUSE QUICK RESEARCH PIVOT

Before the surveillance study was even completed, the first COVID vaccines were being distributed to frontline health care workers nationwide. In January 2021, Gov. Ron DeSantis ensured Moffitt Cancer Center was among the first to receive thousands of doses of vaccine – a boon to our staff and an opportunity for our patients.

“With that amount of vaccine availability, [Moffitt President and CEO] Dr. Patrick Hwu and [Moffitt Chief Medical Officer] Dr. Bob Keenan decided that we also needed to start vaccinating our cancer patients,” recalled Giuliano. “But at that point, we had no idea how they would respond to vaccine – who would respond well and who wouldn’t. There was nothing available in the literature.”

Giuliano saw an opportunity to change that with a study that would capture Moffitt patients’ data before and after they received the vaccine. But setting up this type of research study can often take months, and our patients needed any protection the vaccines might afford as soon as possible.

“With Dr. Hwu’s support, we were able to get the Moffitt machinery working as fast as I think it has ever worked in

getting contracts, institutional research board approvals and all the procedures in place,” said Giuliano.

Moffitt had an advantage in making things happen quickly, an ongoing research protocol called Total Cancer Care® (TCC). Developed at Moffitt in the early 2000s, TCC has been enrolling cancer patients nationwide to share blood and tissue samples, as well as medical information over the course of their lifetimes. The data are used to help researchers and physicians improve cancer prevention, detection and treatment.

As patients came through Moffitt vaccination clinics in mid-January of 2021, those who had already consented to be part of the TCC protocol were asked to provide a blood sample before their first dose of vaccine, as well as periodically post-vaccination – potentially for as long as two years – to track the level of COVID antibodies over time. In total, 515 patients with a variety of cancer diagnoses agreed and qualified to be part of the study.

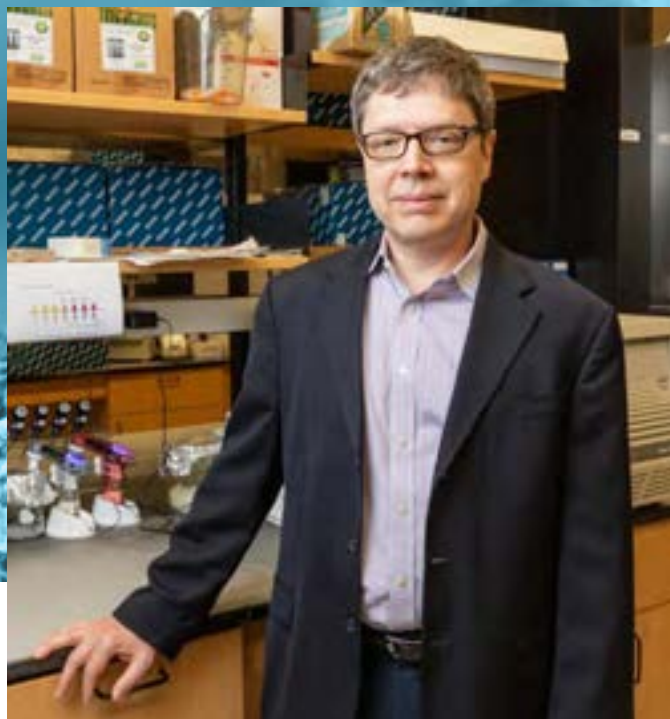
Getting those patients enrolled was the easy part, said study co-investigator Jeffrey Lancet, MD, a blood cancer specialist and researcher who chairs Moffitt’s Department of Malignant Hematology. “Our diverse patient population is very well educated in their disease and risks. People were literally knocking down the doors trying to find a way to get this potentially lifesaving vaccine.”

The trickier part was designing the research protocol to capture information about the many variables in such a diverse group of cancer patients. “We went into this thinking that the vaccine may have very different effects on patients based on the type of cancer they had, the extent of that cancer, the treatment that they’re receiving, the time that they’d been receiving treatment and many other factors that could play into it,” said Lancet. “We were very careful about identifying all the variables that could impact the efficacy of a vaccine so that we’d be better able to understand, in the end, which patients are most likely to benefit and those least likely to benefit.”

In particular, Lancet wanted to be sure this study would address a question critical to the blood cancer patients he treats. How does their particular diagnosis – lymphoid or myeloid cancer – affect response to the COVID vaccine?

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JEFFREY LANCET, MD
*Chair of the Department
of Malignant Hematology*

It's already established that patients with lymphoid or B-cell diseases in particular are less likely to mount a response to vaccines. “That’s no surprise because you need B cells to make antibodies,” said Lancet. “And if you’re suppressing your B cells, either through the disease process itself or through treatments, chances are you’re not going to make antibodies. But we didn’t know if that would be the case with myeloid cancer patients. We also knew that patients with myelodysplastic syndromes (MDS) or acute myeloid leukemia (AML) had high rates of morbidity and mortality once infected with COVID. So, the logical question to ask was does the vaccine do anything to protect these patients?”

To get some answers, the study ensured a significant number of patients with MDS and AML would be enrolled. The data would become part of a separate research abstract on this patient population, which was presented at the American Society of Hematology conference in December 2021.

PRELIMINARY RESULTS SHOW PROMISE, PITFALLS

By the summer of 2021, the preliminary data were already beginning to show the differing vaccine responses. Overall, most participants (over 70%) produced some level of antibodies after the first vaccine. Even more (90%) did so after a second dose.

But the level of antibodies in their blood couldn’t match the amount produced by healthy adults. Only those cancer patients whose pre-vaccination blood samples contained COVID antibodies (presumably from an earlier infection) responded to the two-dose vaccine regimen with nearly as robust antibody levels as healthy controls. And in all cases – healthy or immune-compromised – antibody levels peaked within weeks after vaccination, then declined over time.

Patients with solid tumors were more likely to develop antibodies after two shots than those with blood cancers. The rates were lower for those with lymphoid blood cancers, particularly among patients with B-cell non-Hodgkin lymphoma and chronic lymphocytic leukemia who were on active treatment. The majority of study participants with myeloid blood cancers were positive for antibodies after their second vaccination. However, most of these patients were in remission or on lower intensity therapy at the time of vaccination. Further study will be required to see if those undergoing more aggressive treatment respond as well.

Types of treatment and their timing relative to vaccination also seem to matter. Patients taking anti-CD20 medications like Rituximab that are used to deplete B cells showed no antibody response to the vaccines. Other treatments like BTK inhibitors or CD19 CAR T therapies reduced the vaccine response.

To Giuliano, the greatest concern was that even after two doses of vaccine, few if any of the study participants had produced as much antibody as healthy adults. And even the healthy adults’ antibody levels weren’t enough to stave off breakthrough infections with a then-emerging variant called omicron.

MORE VARIABLES MEAN MORE RESEARCH

When booster shots were approved in September of 2021 for those over 65 or immunocompromised, Giuliano knew there wouldn’t be time to develop another research trial focused on third-dose response. She could see that participants in Moffitt’s ongoing study were already showing declining antibody levels. They needed a third dose, and their responses would have to be tracked in another observational

study. This additional third dose study would also give Lancet an opportunity to track some outliers who hadn't developed antibodies after two shots – but did respond after three.

The list of variables to take into account for each research study continues to grow: boosters, new variants like omicron, past COVID infections and even the use of new therapeutics like monoclonal antibodies to prevent or treat COVID infections. Lancet offered just one example: “What is the importance of future vaccinations in people who were infected with the omicron variant? You could probably bring together a thousand researchers and assign each of them a different variable to study and you'd have hundreds of highly publishable papers in the end.”

“One of the frustrations in working with coronavirus research is that every month, something dramatically changes,” noted Giuliano. “It's very hard to keep up with that and move the research machinery to be able to respond.”

Amid the uncertainties of the COVID era, Lancet said one thing seems certain. “This is not going away. We need to devote more resources to its study, but we can't do that by simply extending everyone's bandwidth at the expense of other duties. People are still getting cancer and needing treatment from us.” He said it's entirely possible cancer

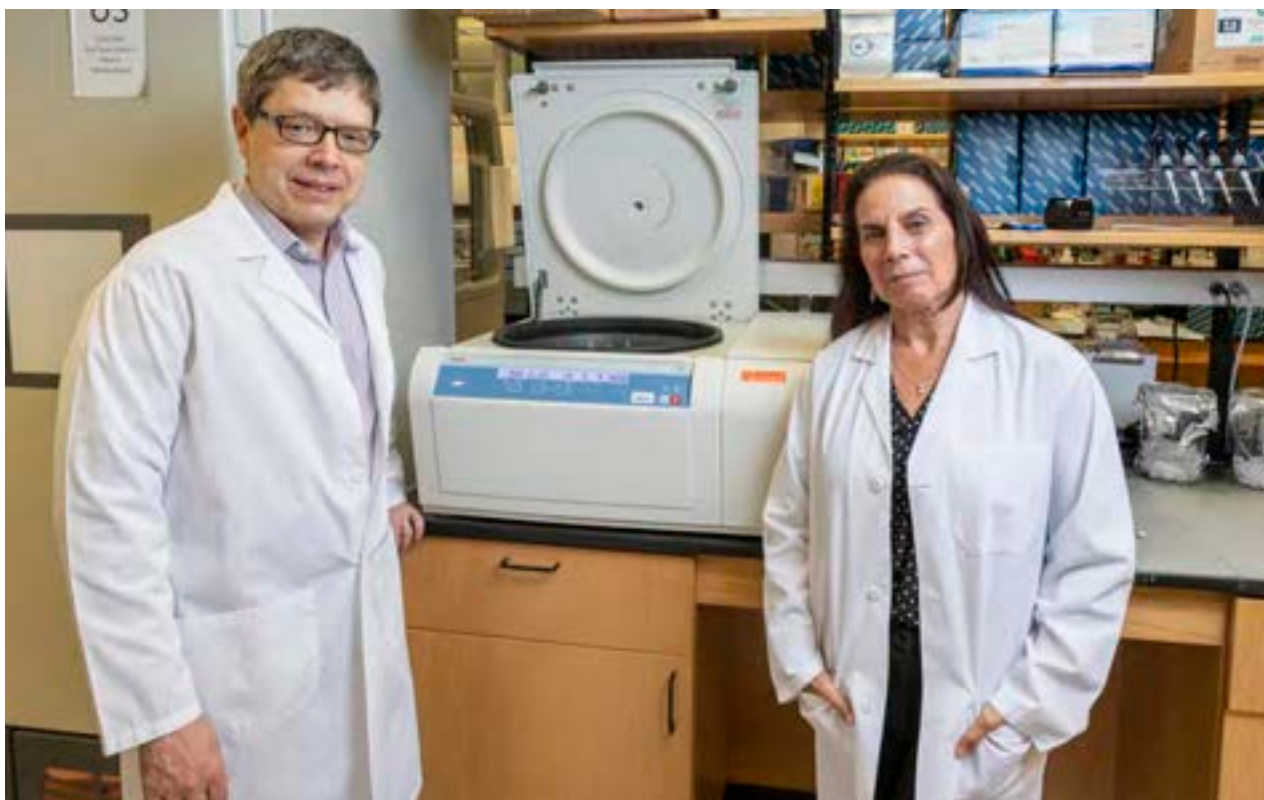
centers will need to create specific positions devoted solely to developing COVID protocols and vaccine strategies for patients.

Giuliano remained hopeful that evolution theory will play out. “Viruses evolve. They're just like humans, they want to propagate. The best way to do that is to actually cause some disease (sneezing, coughing) that helps to spread the virus. But it doesn't really pay to kill the patients. So, if you look at viral evolution, the pattern is to become less and less disease-promoting and more and more transmissible, like omicron.”

In the meantime, Moffitt will continue to research vital information for both patients and providers to guide their decision-making. Giuliano noted that the studies to date have drawn together more than 100 Moffitt team members from phlebotomists drawing blood samples and vaccinators in clinics, to research staff who developed testing assays and those in the Immune Monitoring Core who continue to use them processing samples.

“It felt like we were all working with the same mission in mind,” said Giuliano. “And I can tell you when people believe in something, it's amazing what can happen.”

“It felt like we were all working with the same mission in mind.”



Most cancer patients produce antibodies after the first and second dose of the COVID vaccine, but not to levels produced by healthy adults, according to a study designed by Dr. Jeffrey Lancet and Dr. Anna Giuliano.



YVETTE GRAY
Cancer Survivor

WHY IS BREAST CANCER MORE DEADLY FOR BLACK WOMEN?

Researcher focuses on care delivery
in hormone receptor positive disease

By Steve Blanchard

Photos by Ray Reyes

Yvette Gray knew she needed to schedule a mammogram when she discovered a suspicious lump in her breast during a self-exam. The assistant federal defender sought the care of specialists near her home in Fort Myers, but soon discovered she had an additional battle to face alongside her cancer: racial bias.

Gray, 55, a Black woman, said she has run into bias before in health care but was still disappointed when communication surrounding her diagnosis was sporadic and incomplete. She said when she interacted with her local doctors, she felt more like a statistic than a patient.

“I wasn’t pleased after that initial meeting,” Gray said. “The doctor never looked me in the eyes, didn’t explain much to me

and I felt rushed. We all know there are stereotypes and implicit bias in society, but it’s especially prevalent in health care.”

Unfortunately, Gray’s experience isn’t unique. According to Kimberley Lee, M.D., a medical oncologist in Moffitt Cancer Center’s Department of Breast Oncology, there are large differences in the way in which Black women receive treatment for breast cancer compared to their white counterparts. In fact, the disparities are so great that Black women are more likely to die of breast cancer, specifically HER2 negative breast cancer, even though it is more treatable.

LEE WANTS TO KNOW WHY.

“My current work is to understand what is happening with the treatment,” Lee said. “Are Black women getting appropriate treatment for this cancer? Are they responding the same way?”



Dr. Kimberley Lee's research is focused on survival for women with hormone receptor positive breast cancer, such as Yvette Gray, right.

FOR LEE, IT'S PERSONAL

Lee has a very good reason for being so involved in disparities research and breast cancer in particular.

"I'm Black," she laughed. "I think it spoke to me in a way that had me wondering why skin color determines how women deal with a breast cancer diagnosis."

"Why am I more likely to die because of the color of my skin?"

While she has been a team member at Moffitt for about a year, Lee has studied disparities for years. Prior to arriving at Moffitt, she worked in Baltimore, where she studied disparities and saw firsthand how neighborhoods segregated by race saw different survival rates.

"That was in general health care terms," Lee said. "When I got into oncology, I saw similar data around breast cancer, and I found it personally appalling. Why am I more likely to die because of the color of my skin? That just doesn't make sense."

CARE DELIVERY'S ROLE IN DISPARITIES

Lee chose to focus her racial disparities research on survival for women with hormone receptor positive breast cancer. Some breast cancers express receptors for hormones such as estrogen and progesterone. These types of cancer feed off hormones in the body. Endocrine therapy using hormone-blocking medications decreases the levels of these hormones, essentially starving the cancer of the food it needs.

"My work is focused on care delivery, on the science of how we get appropriate care to all people," Lee said. "We know that Black women are more likely to be undertreated or mistreated and less likely to get the drugs or surgery that they need. I am focusing on how we give them the things we know that work and focusing on that care delivery piece."

And that starts in the clinic. "I'm a researcher and a doctor and knowing what is happening in the clinic means I can intervene as an MD and help narrow this gap in terms of outcomes," Lee said. "That's where the health care delivery focus of this study comes from."

“We all know there are stereotypes and implicit bias in society, but it’s especially prevalent in health care.”

PILLS AND THEIR SIDE EFFECTS

According to Lee, the disparities among Black breast cancer patients start in the prescription of pills. After surgery, breast cancer patients are given medication to reduce their risk of recurrence and are prescribed to take it for five to 10 years. However, Black women are less likely to start these life-saving medications. Those who do are less likely to take it every day and stay on it for the recommended time. The reason behind this is unclear, Lee said, but it could be linked to the side effects.

The medications cause symptoms similar to menopause, as well as others. This can be distressing if not managed appropriately. Some studies have shown that Black women have worse symptoms from the medications than white women, but Lee says this has not been fully borne out.

“Deciding to quit the medication early could be linked to side effects and coping with those or a lack of communication with the patient’s health care team is contributing to that,” Lee said. “If you can’t get the help you need or you can’t communicate, you might decide to stop taking the treatment.”

Another piece could be that some patients simply don’t understand the importance of taking the medication. They may assume that because they are no longer actively being treated for cancer – as in chemotherapy or radiation – any kind of oral treatment just isn’t necessary.

“Some women just may not want to think about breast cancer anymore and say, ‘I’ve been treated, I want to be done,’” Lee said. “Pills are a reminder of that experience, so that could contribute to them stopping.”

COLLECTING THE DATA

The current phase of Lee’s study involving in-depth interviews with 30 patients and 10 providers will continue through 2023. But the research won’t stop there.

“When this current study ends, we’ll move into intervention,” Lee explained. “That will take three to five years, so it’s a very long process.”

“My work is focused on care delivery, on the science of how we get appropriate care to all people.”



Dr. Kimberley Lee, medical oncologist

Intervention, she explained, involves coming up with a solution for providers to be more culturally aware when treating Black women and ensuring different viewpoints are considered to assist in treating a wider range of patients.

“Then we test that,” Lee said. “We ask the patients again, ‘How was that for you?’ And even after that, we could refine it again. So, it is a process that takes some time.”

But Lee believes the time spent on the study will be worth it. Already, she has found that the patients participating in the study have had similar experiences when it comes to their encounters with health care providers. The room for improvement is large, she said.

“This is qualitative research,” Lee said. “It’s overarching to understand the barriers Black women encounter and to make sure we provide care for all women with breast cancer. This specific study just happens to be HER2 positive focused.”



PATIENTS AND PROVIDERS SHED LIGHT

Lee’s in-depth conversations in this phase of the study have already shed light on the issue of disparities. She has found that clinicians especially are thankful for the research and are eager to participate.

“The clinicians have all agreed that this work is important,” Lee said. “One factor contributing to disparities in the Black community is distrust in the health care experience. Many think that researchers are experimenting on them and not including them in the conversation. I think this kind of study on this group can help with that sense of ‘here is an institution trying to do something for us.’ ”

When asked to be part of the study’s patient cohort, Gray was more than happy to assist Lee with her research – especially if it will help other Black women, and patients in general, receive the information and treatment they deserve.

“Dr. Lee asked me questions about being a Black woman and having this happen and the experience I’ve had so far,” Gray said. “Both she and my surgeon, Dr. [Nazanin] Khakpour, have called me personally to check in and to update me. This research is so important, not only for patients like me, but for the doctors who are treating us. They need to see and hear and read this research and understand it so they can do better.”

“This research is so important, not only for patients like me, but for the doctors who are treating us.”

Gray has since completed her active treatment and is essentially cancer free. But she understands the importance of continuously monitoring her condition and following the directions of her health care specialists. It’s important, she said, that Black women in general also understand this and stresses that treating Black women in a supportive and nonjudgmental environment is the best first step to overcoming disparities in this area.

“We fear that judgment and we fear that our concerns are minimized by doctors at times,” Gray said. “Too often they just overlook treating us as a person and as a woman and discount some of our unique situations as Black women.”


Once health care professionals understand that and listen to individual patients rather than assuming any type of bias, health equity will finally be in sight.

“When your doctor does better, it’s better for the patient,” Gray said.



Treating Black women in a supportive and nonjudgmental environment is the best first step to overcoming disparities, says Yvette Gray, left, a breast cancer patient of Dr. Kimberley Lee.

***“When your doctor does better,
it’s better for the patient.”***

A woman with long brown hair and glasses is standing outdoors by a body of water. She is wearing a white short-sleeved shirt with a black floral pattern and black pants. She has a black life vest on her back with a yellow scuba mask attached to the front. She is holding a black scuba mask in her right hand. The background shows green trees and water.

DEBORAH BARKER
Cancer Survivor

Dividing into Hope

Cellular therapy gave scuba diver Deborah Barker a new option for beating non-small cell lung cancer

By Sara Bondell

Photos by Nicholas Gould

Deborah Barker feels most at home in the water. She could swim before she could walk growing up in Florida. She became scuba certified as a teen, and as an adult, she has traveled the world – the Galápagos Islands, Cuba, Belize, the Philippines and the Red Sea to name a few – diving and taking underwater photographs.

“I Zen out when I am underwater,” said Barker. “I have a reputation when I go on trips. The guys who fill our tanks always say I use the least amount of air so I am very comfortable. It’s very peaceful for me.”

“I Zen out when I am underwater.”

But in the fall of 2017, Barker lost that peace. She noticed a weird back pain, and thinking it was related to a previous injury, requested an MRI. The scan showed a concerning lesion near her spine, and a biopsy revealed Barker had stage 4 non-small cell lung cancer (NSCLC).

Barker was anxious to start treatment immediately. Her wetsuit and dive equipment were stored, the possibility of another trip hanging in limbo.

“I wasn’t sure if I was even going to be alive.”

FINDING NEW OPTIONS

While shocked to hear about her own diagnosis, Barker was familiar with cancer. The women in her family have a history of breast cancer and her father died from lung cancer in 2000.

“I went through it with him. From diagnosis to death it was about six months and I watched him feel miserable in treatment to only get about an extra month of life,” said Barker. Because of that experience and the advanced stage of her own cancer, Barker did not want to undergo the standard treatment regimen of chemotherapy.

According to the National Cancer Institute, NSCLC makes up about 80% to 85% of lung cancers. While it is the most common form of lung cancer, current treatment options do not cure the disease for most patients. There is only about a 25% five-year survival rate for NSCLC.

Barker started radiation for the tumor on her spine, but genetic testing of her cancer showed no mutations that could be treated with newer targeted medications. So, she began looking for a clinical trial.

“My sister went through a clinical trial for acute aplastic anemia and I was her stem cell donor in 2006,” said Barker. “I was very impressed with it all and was biting at the bit to get on a trial myself.”



A strange back pain led to Barker’s diagnosis of stage 4 non-small cell lung cancer. She wanted to start treatment so she could get back to her love of scuba diving.

After being disqualified at the last minute for a trial because doctors couldn't get a big enough biopsy of her tumor, Barker came to Moffitt Cancer Center in February 2018. There, she found hope in a new clinical trial for tumor-infiltrating lymphocyte (TIL) therapy, a type of cellular immunotherapy that has shown success in melanoma and was being newly tested in patients with NSCLC. It extracts immune cells present inside tumors, grows billions of them in a lab and then infuses them back into the patient to attack the cancer.

T cells are a type of white blood cell that helps the immune system fight off infections. They can recognize cancer cells as abnormal and work to kill them, however, sometimes the tumor can weaken the immune system so much it prevents T cells from doing their job. Checkpoint inhibitor drugs were developed to release the brakes cancer can put on T cells and allow them to attack tumors.

"We have had a lot of great milestones for stage 4 NSCLC, but most of the new treatments, such as checkpoint inhibitor chemotherapy combinations, work for months, not years," said Barker's thoracic oncologist Ben Creelan, MD. "The gold standard for Deborah's cancer has a median progression-free survival of seven months. So, I think TIL therapy is an attractive option to seriously consider for patients like her."

A new unapproved treatment option didn't scare Barker. She was a groundbreaker – one of the first women to work outside the administrative offices in a Florida brewery. After starting as a lab technician at what was then the Joseph Schlitz Brewing Company in Tampa in 1974, she went back to school for a degree in chemical engineering and eventually became the brewery's first female brewmaster. That experience taught her a thing or two about perseverance.

"I didn't carry any fear with me," said Barker of her decision to join the clinical trial. "I didn't hesitate for a moment because I felt like I didn't have a choice."

UNLOCKING IMMUNE RESPONSE

Once Barker was enrolled in the trial, the first step was to harvest the immune cells inside her cancer. While she wouldn't be a candidate for surgery in other circumstances because of her progressed disease, she underwent robotic surgery to remove cancerous lymph node tissue and a small portion of her lung that contained her primary tumor.

The T cells collected were sent to a lab to be multiplied, and Barker started receiving infusions of immunotherapy drug nivolumab. She responded so well to the initial treatment that doctors decided to hold off on TIL therapy.



"I didn't hesitate for a moment because I felt like I didn't have a choice."

“Deborah’s immune cells were locked away inside her tumor so they weren’t able to completely eradicate the cancer on their own. But by pulling them out, growing them in large numbers and re-infusing them she’s clearly had an excellent response.”



Dr. Ben Creelan, thoracic oncologist

“I was very happy I responded, but I was disappointed I wasn’t getting my cells right away,” said Barker.

However, after a year of stability, a scan showed disease progression in January 2019. Doctors told Barker it was time for her to receive her T cells.

After a round of inpatient chemotherapy, Barker was ready for her TIL infusion. She pulled from her experience with her sister’s transplant to get through the tough spots, but says she had very few severe side effects. After, she was placed back on nivolumab for another year, and besides a small disease progression that was treated with radiation, Barker has had clean scans ever since.

“Deborah’s immune cells were locked away inside her tumor so they weren’t able to completely eradicate the cancer on their own,” said Creelan. “But by pulling them out, growing them in large numbers and re-infusing them she’s clearly had an excellent response.”

Of the 16 patients on the trial, two – including Barker – had a complete response after TIL therapy. One theory why TIL works is because it spurs the growth of memory T cells, which stay in the body for decades to help patrol and prevent future cancer infections.

“With TIL therapy, there is a chance you can hit a home run. Obviously, Deborah has done that.”



Barker, the first female brewmaster at Joseph Schlitz Brewing Company, is no stranger to being a groundbreaker.

“I didn’t carry any fear with me.”

“Because there aren’t many good second-line treatment options for NSCLC, it’s hard to look a patient in the eyes and tell them standard treatment is worth doing when there isn’t a giant upside and we will probably be having the same discussion again in six months,” said Creelan. “Whereas with TIL therapy, there is a chance you can hit a home run. Obviously, Deborah has done that.”

TIL therapy is also a one-time treatment, reducing the length of time patients have to cope with intense therapy and unwanted side effects. Another benefit is that because the T cells come directly from the tumor, they can recognize many targets on cancer cells, making it even harder for cancer to hide or evade treatment. In Barker’s case, her T cells were able to recognize five unique mutations within her tumor.



TIL therapy is awaiting U.S. Food and Drug Administration approval in melanoma. Since Barker’s trial was the first to study the treatment in stage 4 NSCLC, a lot more research is needed in the lung cancer space. New data has shown TIL therapy response is better in NSCLC patients who have not had prior treatment and when it is combined with checkpoint inhibitors. For patients whose tumors cannot be easily removed, Moffitt is opening a trial that will use peripheral blood cells instead of T cells harvested from tumors for TIL therapy.

LAND OF THE LIVING

The COVID-19 pandemic and becoming a caregiver for her mother delayed Barker’s return to the water, but after five years, she’s ready to put her scuba gear back on.

After her longtime dive partner, who Barker met at Schlitz in the ’70s, lost her own battle with cancer, Barker became involved with the Old Broads Dive Club out of California. She has scheduled two trips with them this spring: one to Cozumel and one to Little Cayman Island. Barker is more anxious about traveling than she is about the actual diving. She knows her lungs are ready.

“I felt like I had one foot in this world and one foot out,” said Barker. “Now, I feel like I am going to be around awhile so I need to get back to the land of the living.”

“I need to get back to the land of the living.”

Taking Multiple Myeloma Care to 'Another Level'



**A \$10 million donation from It Works! founder establishes
Pentecost Family Myeloma Research Center**

By Sara Bondell

Photos by Nicholas Gould

Mark Pentecost was on top of the world one Friday night in March 2016.

THE FOUNDER OF WELLNESS COMPANY IT WORKS!

was playing in a company fundraiser football game with celebrity quarterback Tim Tebow. He felt good – strong, athletic and healthy.

That all changed Monday morning when his doctor called him with the results of some routine tests. Pentecost had multiple myeloma, a type of blood cancer involving plasma cells. The disease was aggressive and he needed treatment immediately.

“I went from, ‘I am still athletic and pretty good’ to Monday, when I am like, ‘What?’ ” said Pentecost. “Three of my four grandparents lived to their mid-90s, so that was the plan I thought I was on.”

The news sent immediate shockwaves through Pentecost’s family, especially his wife, Cindy, who has watched multiple family members and close friends die from cancer.

“My concern was here we go again,” she said.



Despite being diagnosed with multiple myeloma, which has no cure, Mark Pentecost knew not beating cancer wasn't an option.

The call had come just minutes before stepping onto a plane to travel to an It Works! event, giving the couple little time to process the news and decide how to tell their three children. At the event, Mark Pentecost spoke in front of hundreds of his sales force, trying to give the keynote motivational speech, while in the back of his mind knowing he had to face the lifechanging news he just received.

He didn't know what his next steps would be. But he knew not beating cancer wasn't an option.

LOOKING FOR A CURE

Multiple myeloma is a relatively uncommon cancer, making up about 1% of all cancer diagnoses. While the disease can be successfully managed in some patients for years, there is no cure.

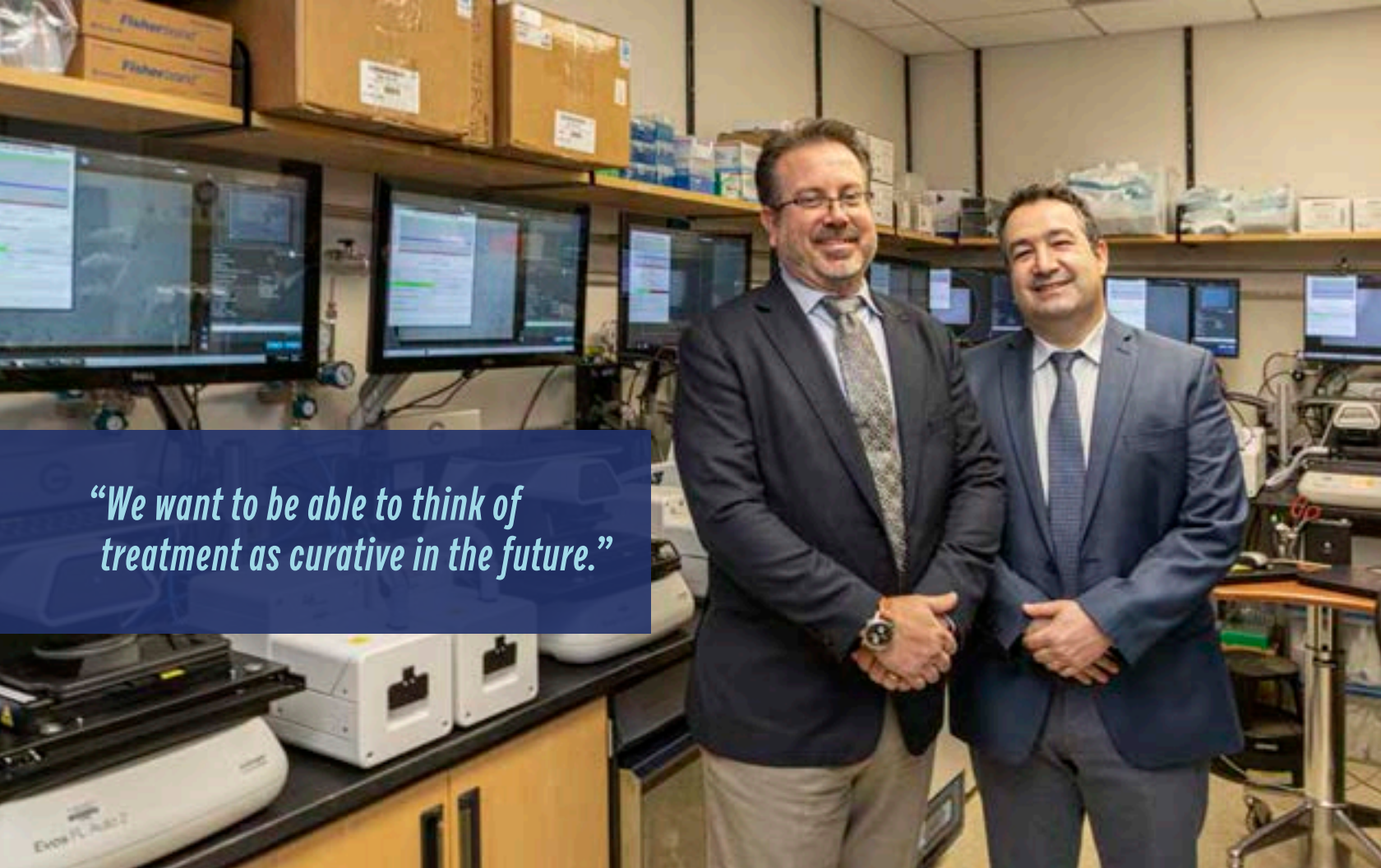
“Multiple myeloma is very heterogeneous, meaning it's very different from patient to patient,” said Kenneth Shain, MD, PhD, a medical oncologist and scientific director of the Moffitt Myeloma Working Group. “And even with a given patient the disease can change over time and those changes lead to treatment resistance.”

This has caused hematologists to look at multiple myeloma differently than other cancers that are treated with curative intent. Instead, multiple myeloma can be considered more of a chronic disease, where patients often face an unending cycle of successful treatments followed by relapse.

“Eventually, myeloma wins,” said Shain. “But if we have more options and better options, that means more ways we can keep our patients chronically controlled over many, many years.”

Decades ago, the average survival rate for multiple myeloma was two to three years. However, recent treatment advances such as stem cell transplants, antibody therapies and CAR T therapy have increased survival rates to about seven to 10 years and likely even better with contemporary treatment strategies.

“Despite these improvements, there is still a lot of work to be done,” said Rachid Baz, MD, section head of Myeloma in



“We want to be able to think of treatment as curative in the future.”

Dr. Kenneth Shain, left, and Dr. Rachid Baz are spearheading the Moffitt Myeloma Working Group to find innovative treatments to help prevent relapse in patients. “We want to develop new therapies that are a bit more personalized and aim at curing the disease,” says Baz.

Moffitt’s Department of Malignant Hematology. “We want to be able to think of treatment as curative in the future.”

With that cure in mind, Moffitt’s Myeloma Working Group was established to find new, personalized treatment options for patients that can prevent future disease relapse.

When Mark Pentecost learned he had been diagnosed with a cancer that had no cure, he and his family refused to believe it.

“We are aware there isn’t a cure, but baloney,” said Cindy Pentecost. “We never believed that and we wanted everyone else to get to the point where they realized, too.”

Mark Pentecost started chemotherapy at Moffitt and began traveling around the country seeking multiple medical opinions. He went through the grueling process of a stem cell transplant, losing all his hair and muscle tone.

“I’d see myself in the mirror and be like, ‘Who is that?’ and then ‘Oh, that’s me,’ ” he said.

After his transplant, he realized he felt most at home at Moffitt Cancer Center and chose to continue his treatment under Baz’s care. He started a maintenance program, which he continues today, taking a chemotherapy pill three weeks

out of each month. His disease has remained stable for six years, and the special relationship he has built with the Multiple Myeloma Program inspired him to start giving back.

The Pentecost family donated \$3 million to the program in 2018, resulting in the creation of Moffitt’s Ex Vivo Mathematical Myeloma Advisor, or EMMA. The tool can test a cancer patient’s sensitivity to dozens of drugs at one time to determine the best treatment.

“At the core of what we are doing is to try and figure out what is different about patient Y versus patient X, and can we give the right therapy at the right time for the right patient?” said Shain. “EMMA helps us find the best path.”

“I find it a shame that people get cancer and they have to guess which treatment they are going to take, and it may or may not work,” said Cindy Pentecost. “I would like to get to the point where they take your blood and say, ‘OK, this one is going to work for you. At least if you have a chance, this is the one.’ ”

Since its creation, more than 700 patient samples have been analyzed by EMMA and tested with more than 200 different drugs. Not only does this help predict best treatment options



Mark and Cindy Pentecost have donated \$13 million to establish the Pentecost Family Myeloma Research Center at Moffitt.

The research center will tackle myeloma from multiple levels, including finding better ways to predict which patients with precursor diseases, like monoclonal gammopathy of undetermined significance, are at highest risk for developing multiple myeloma. It also will utilize clinical trials to continue work in determining which treatments work best for certain patients at certain times, help accelerate drug discovery, boost translational research and promote community education outreach.

for those patients, but now physicians can use the data to try to identify new treatment biomarkers and determine the best way to sequence therapy.

DREAM BIGGER

At It Works! team members are often told to reach for “a whole ‘notha level.” Whether it’s adding another story to the corporate headquarters building or finding new ways to elevate ideas, Mark Pentecost motivates his team to always dream bigger.

Last year, Mark Pentecost’s team at Moffitt asked him to do the same. Was he willing to go up “a whole ‘notha level?”

“And I said, ‘How can I not support that when they use my own language against me?’ ” he said. “That’s when they said they want to find a cure and that got us really excited. For me, I always wanted to know there’s a cure. I wanted to have something to fight for, an end to the race.”

The Pentecost family and the Multiple Myeloma Program are now dreaming bigger than ever, thanks to a second donation of \$10 million to establish the Pentecost Family Myeloma Research Center at Moffitt. The goal is to leverage existing expertise from across the cancer center to find a cure for multiple myeloma within the next 10 years.

“We want to try and develop therapies that are not just the cookie-cutter approach,” said Baz. “We want to develop new therapies that are a bit more personalized and aimed at curing the disease.”

“Multiple myeloma is a tough disease to say we are going to cure tomorrow, but if we continue to drive change, we hope that this will translate to increased numbers of patients in whom we actually are invoking curative intent therapy, meaning we never have to treat them again or we develop enough ways to maintain their disease long enough that multiple myeloma doesn’t take them from us,” said Shain.

A MARATHON, NOT A SPRINT

If his cancer journey has taught Mark Pentecost anything, it’s patience.

“I had to be patient and literally a patient,” he said. “I realized I couldn’t just sprint to the finish line. It’s not just go to the doctor, get some medicine and get well. I had to go through the entire process.”

Going through that process reminded him how important his spirituality and relationships are and how much he leans on his wife and kids. He may not know where his finish line is and when he will get there, but he knows with new funding and resources, Moffitt will continue to be at the forefront of advances in myeloma.

“Selfishly, I want to see a cure for multiple myeloma, but I am excited to see how this plays out because if we can get people to use the ‘cure’ word and we are eventually finding cures, that is amazing,” he said.

*“I always wanted to know there’s a cure.
I wanted to have something to fight for, an end to the race.”*



From left, President and CEO Dr. Patrick Hwu, registered nurse Jeff Leighton, breast radiologist Dr. Dana Ataya, researcher Dr. James Mulé and security officer Ron Zalva.

The ReMissions

Music Inspired by Moffitt

By Amanda Sangster and Ann Miller Baker

Photos by Nicholas Gould and Kevin Kirby

When Dr. Patrick Hwu left Texas for Florida, he bid adieu to many friends including the local band he played in for years. It wasn't his first musical gig – Hwu has been playing in bands for more than 30 years. It's become a meaningful creative outlet for him while dealing with a high-pressure career.

Shortly after Hwu arrived in Tampa, the new Moffitt Cancer Center CEO began recruiting fellow team members to form a new band: The ReMissions. Named in honor of the one thing that every cancer patient hopes for – their disease to be in remission – these musical team members want their positive message to highlight the great work Moffitt is doing to fight cancer.

“Being in a band is really about teamwork,” said Hwu. “As opposed to being a solo performer, the role in a band isn't to just play, but to hear and listen to everyone else. That's what we do here that makes Moffitt so special. We're a team. We listen to each other, work together and make harmony together.”

Whether playing an intimate rooftop concert or performing for a crowd of patients and staff, The ReMissions are ready to share their sound with the world.



Meet The ReMissions

DR. DANA ATAYA

Breast Radiologist, Vocals

- Learned piano at age 5, acoustic guitar at 12, currently learning harmonica
- A songwriter/composer, she recorded an album of original tracks while in medical school
- Favorite vocalists range from Etta James to Adele

Music was a huge part of Ataya's family life growing up. As a child, she sang along with her maternal grandmother who was also a talented vocalist. Taking note of those natural gifts, Ataya's mother introduced her to piano at age 5. She's been playing ever since.

Today, music plays a therapeutic role in Ataya's day job as a breast radiologist. Specially trained in interpreting mammograms, ultrasounds and MRIs of breast tissue, Ataya is also the expert called upon to perform additional image-guided tests when cancer is suspected. “One of the scariest things

is facing the unknown with the knowledge – this could be breast cancer,” noted Ataya. She routinely asks her patients if they have a favorite type of music they'd like to hear in the background during biopsies. “And overwhelmingly, the answer is absolutely yes,” said Ataya. With help from her ultrasound technician “deejays,” Ataya has been able to accommodate some pretty diverse musical tastes – even bamboo flute relaxation tracks. And they've found it really does have an impact.



Dr. Dana Ataya, vocals

“Music, spirituality, that human connection to what makes us individuals is something that I think is so important to share with my patients when I'm caring for them,” said Ataya. And



You've probably seen The ReMissions perform at Moffitt Cancer Center and events such as the 2021 Miles for Moffitt in downtown Tampa.

what those patients share with her sometimes gets poured back into Ataya's music. "So many of the songs I've been writing have been inspired by something my patients will confide in me or just say." Look for The ReMissions to perform some of those inspired originals soon.

Follow her on Twitter: @DanaAtayaMD

DR. PATRICK HWU
*President and CEO, Medical Oncologist,
 Researcher, Keyboard*

- Plays keyboard, piano, guitar and trumpet
- Favorite song to jam to: "Stormy Monday," The Allman Brothers Band's version
- Favorite concert: Queen

Raised by parents who loved classical music and musicals, Hwu grew up listening to their vast record collection. He began formal piano lessons in third grade but started playing rock 'n' roll and blues in high school. That's also when he made

"Being in a band is really about teamwork."

his first trip to Tampa, playing trumpet with his high school marching band in the 1981 Gasparilla Parade.



Dr. Patrick Hwu, keyboard

Since moving to Tampa 18 months ago as Moffitt's president and CEO, Hwu has spent his days immersing himself in the culture of the cancer center. He's hosted more than 40 listening tours with various departments, learning about the organization and engaging in meaningful conversation with team members and leaders to develop priorities

“Music, spirituality, that human connection to what makes us individuals is something that I think is so important to share with my patients.”

for the years to come. His leadership helped Moffitt to survive – and thrive – through the COVID-19 pandemic by putting patients first with more than 15,000 individuals vaccinated since COVID vaccines became available in December 2020, a 5,000% increase in virtual visits and our first curbside clinic offering select services to patients in their vehicles at the McKinley Campus.

He’s kept his eye on expanding Moffitt, both physically, with a new location in Wesley Chapel, a new expansion hospital under construction and plans to develop a 775-acre parcel in Pasco County; as well as reputationally, with his vision of making Moffitt a world-leader in cell therapies for cancer treatment. It’s a goal guided by his work as an internationally recognized tumor immunologist, pioneering research and clinical efforts to better understand the interactions between tumors and the immune system. Hwu’s research efforts focus on vaccines, adoptive T-cell therapies and immune resistance.

Orchestrating the efforts of Florida’s top-ranked National Cancer Institute-designated Comprehensive Cancer Center along with his own research only adds to Hwu’s appreciation for playing in a band. “It nourishes your creative side, inspires and enhances resiliency,” said Hwu. “Our No. 1 rule for The ReMissions is to have fun!”

Follow him on Twitter: @PatrickHwuMD

JEFF LEIGHTON

Registered Nurse, Intensive Care Unit, Bass

- Plays bass and guitar
- Has been playing in bands for 45 years
- Favorite bass players: Stanley Clarke and John Paul Jones (Led Zeppelin)



Jeff Leighton, bass

Leighton remembers watching “American Bandstand” with his mother every afternoon when he was a kid growing up in Detroit. He also credits Detroit radio for igniting his passions for all types of music, especially blues, R&B, Motown and soul. Like many bass players, he seems unflappable onstage. “My favorite skill is that I keep my cool when everybody else is losing theirs,” he said.

That also helps in his role at Moffitt as the Code Blue nurse for the McKinley Campus. “To do phase 1 clinical research [drug trials] at McKinley, we have to have a dedicated code team and that’s who I am,” Leighton explained. In addition to responding to all emergencies, he helps with screenings, starts IVs and also covers shifts in the ICU on Moffitt’s Magnolia campus. He came to the cancer center 13 years ago with two decades of critical care experience under his belt, working in emergency centers, ICUs and critical care units for open heart and neurosurgical patients.

“Thirty years of experience will give you a lot of knowledge, so I just try to pass on what I know to the newer people. And in the meantime, I make sure that everyone stabilizes on my watch.”

Leighton admits to a bit of nervousness when his email to Hwu about joining the new band garnered an invitation to band practice and a list of songs to learn. “One of the songs they wanted to do is Queen’s ‘Bohemian Rhapsody.’ That might as well be Beethoven! I was like, you’re kidding, right?” (Not if you know Hwu’s favorite musicians!)

“There is no joy in the world like making music,” Leighton said. “Running a code is great when things turn out well. And I do get a lot of satisfaction out of my job. But playing music is a whole ‘nother realm. It amazes me how a group of people can make magic out of thin air.”

Follow him on Twitter: @JeffLeightonRN

DR. JAMES MULÉ

Researcher, Associate Center Director of Translational Science, Guitar

- Plays electric guitar, acoustic guitar and the lute – all solely by ear
- Has a collection of 29 guitars
- Favorite jam: Led Zeppelin’s Jimmy Page on “Kashmir”

Mulé was introduced to music at a very young age, spending Sundays with his grandfather at the New York Metropolitan Opera. Years later, he wound up listening to a different set of great artists: an eclectic mix of punk, rock and folk bands at the famous music club CBGB.

When it comes to research, Mulé is a recognized “great.” He’s been designated a Master of Immunology by the American Association for Cancer Research’s journal Cancer Immunology Research for his research and clinical trial contributions

“Our No. 1 rule for The ReMissions is to have fun!”

to cancer immunotherapy, particularly in solid tumors. In his role as Moffitt’s associate center director of Translational Science, Mulé oversees the directors and co-directors of four transdisciplinary Centers of Excellence (comprising clinicians, scientists and staff), the Cell Therapies Facility, as well as the Office of Innovation and Industry Alliances. In short, he’s in charge of ensuring laboratory-based research gets translated into viable treatments and prevention strategies for cancer patients’ benefit. Fostering a collaborative environment among laboratory scientists and physicians is essential to this work.



Dr. James Mulé, guitar

Funny, then, that it took so long to form a musical collaboration with his longtime friend Hwu. The two met early in their careers at the National Institutes of Health, talking music almost as much as research. “We’ve always kept in touch about music,” said Mulé. “Every time I would get a new guitar, I’d send him a picture of it to get his thoughts.”

Now that Hwu has joined Mulé at Moffitt, the two can finally jam regularly through The ReMissions. But it’s still a challenge for Mulé, who plays solely by ear. “Patrick [Hwu] is so good on the piano and reads music so well,” he explained, “but whenever he changes the key of a song, I joke and say just play it and I’ll figure it out!”

Mulé says playing music is good for the soul because it challenges and relaxes him.

Follow him on Twitter: [@DrJamesMule](#)



Ron Zalva, drums

RON ZALVA

Security, Drums

- Plays drums, conga drums and timbales
- Loves jazz, rock, blues, soul and Latin music
- Favorite drummer: Buddy Rich

When he first started playing at age 5, Zalva fell in love with the drums and has been hooked ever since. By age 12, he already had his own band, The Shantelles. That’s him gigging out at the Palma Ceia Country Club in the photo. Playing in bands throughout central Florida has been a huge part of his life, but never his career.



Zalva spent 27 years with the Hillsborough County Sheriff’s Office as a beat cop and a detective, much of it patrolling the Town ‘N’ Country area near Moffitt. After two years of retirement, he needed something to keep him busy. His oldest brother, who’d worked at Moffitt, suggested it might be a good fit. The family already had their own cancer story. Zalva was another brother’s donor for a bone marrow transplant in 1980 before Moffitt even opened. For the past six years, he’s been patrolling Moffitt’s multiple campuses, doing whatever it takes to help patients, families and staff feel safe and secure.

The job keeps him moving, which is partly why Hwu had to track him down to offer a spot in The ReMissions. Another Moffitt security officer had mentioned Zalva’s many bands and love of the drums to Hwu, but it took a couple of tries before Hwu connected with him. “I thought I’d done something wrong!” Zalva joked. “But he’s a very nice man, very down to earth.”

“I’ve never been in a smarter band in my life,” said Zalva. “They’re brilliant people. It’s amazing how they love to play, especially Dr. Hwu.” As for Zalva, he still plays for relaxation every day and even has his own studio at home.

Zalva believes that music feeds the soul and says his favorite quote is “Music is what feelings sound like.”

Follow him on Twitter: [@RonnyZ85728502](#)

ABOUT MOFFITT CANCER CENTER

Moffitt Cancer Center in Tampa, Florida, has made a lasting commitment to the prevention and cure of cancer, working tirelessly in the areas of patient care, research and education.

MISSION

To contribute to the prevention and cure of cancer

VISION

Create revolutionary breakthroughs and innovations that rapidly impact and save more lives

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