THE CANCER LETTER

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The Price of Deception: How a Duke Patient was Harmed In Potti's Fraudulent Trials

By Matthew Bin Han Ong

Joyce Shoffner would never have predicted that Duke University, an institution she revered and at one time worked for, would put her in a breast cancer clinical trial testing a fraudulent technology.

Patient Joyce Shoffner describes the aftermath of fraud in Duke trial.

"They advertised publicly that this science offered an 80 percent cure rate," Shoffner said. "To have the type of cancer I had, I was just going to do that, there was nobody that was going to stop me, because this was what I was told and this was what I believed was going to happen."

Anil Potti, in a Duke commercial advertising the trial Shoffner joined.

In July 2008, Shoffner became patient No. 1 in the trial that promised to choose the best therapy for the unique characteristics of her disease. Alas, the groundbreaking genomic predictors pioneered by Anil Potti and his mentor Joseph Nevins, which the trials were testing, would turn out to be fraudulent.

Now, Shoffner—a 68-year-old Raleigh resident, and formerly a biomedical photographer—has the sad honor of being one of only two living plaintiffs in the patients' lawsuit against Duke.

(Continued to page 2)

Watch
The Cancer Letter's Interview with Joyce Shoffner

Shoffner's voice, which combines the monotone of pain with southern lilt, will not be heard from the stand at the Durham County Superior Court.

The case was settled—she is prohibited from disclosing the terms, but now otherwise she is free to talk.

"It's always been about genomics and cell lines and datasets, but not about people. All of it was based on people, but the people were kept in the dark," Shoffner said. "Why did we not at least have honesty? Why was there not some integrity with this when it came to the human life? Why could decent human beings do this to other human beings?"

Shoffner said she did not learn about Potti's fraudulent data until November 2010—over two years after she first joined the trial. Altogether, 117 patients were treated in Duke's three phase II clinical trials. Shoffner was one of the 56 patients in the neoadjuvant breast cancer trial.

Some of these patients were seduced by the televised promise Potti made in a Duke commercial.

"The goal is to be able to tell patients with cancer that I'm not just a cancer doctor, I'm here to treat your particular cancer," Potti said in the ad. "The way to get to that is to do prospective clinical trials. So what I would say to patients is to inquire about prospective clinical trials that use genomic testing to try to determine whether they're getting the right chemotherapy option or not."

Potti and Duke's promises filled Shoffner with hope that her tumor would "melt away."

"The trials and the exciting hope of the groundbreaking science were all presented to me verbally first," Shoffner said. "A researcher, doctor, had come up with a way of treating personal cancer—my own cancer, not general cancer, but mine, my tumor.

"They were going to look at the DNA of my tumor, and from that Duke and Dr. Potti would be able to tell which chemo was correct for my type of cancer. They were saying that with this treatment, these tumors—they used the words—'would just melt away.'

"It wasn't until I had already agreed to be part of this groundbreaking trial that they then brought someone in to have me sign a consent form.

"By that point my mind was already made up."

The promise that she could randomly be placed in the genomically guided arm of the trial was the key reason Shoffner joined the trial, she said.

To get in, Shoffner needed a second biopsy, one that would provide tissue for Potti's genomic analysis.

"These were painful, they went through under my arm all the way up into my neck doing this biopsy," Shoffner said. "But it was going to be worth it.

"They implied that people had been having such wonderful results that they would have to put titanium clips around my tumor, because these tumors were melting away rapidly. And by the time I finished my chemo, there may not be any tumor left, and they would have to go by those nine titanium clips that they inserted into my body to remove the residue.

"I thought, 'Well, this is absolutely remarkable.'"

Before Shoffner was enrolled, signs of trouble were already emanating from Potti's lab. Bradford Perez, a medical student under Potti's tutelage, had blown the whistle about irregularities in handling of the data, and MD Anderson biostatisticians Keith Baggerly and Kevin Coombes had published a letter in Nature Medicine, critiquing Potti's genomic predictor model data.

Unbeknownst to Shoffner, Duke had suspended the trials twice, silenced the whistleblower, and overlooked data from other institutions—while she was in touch with her Duke oncologist, Paul Kelly Marcom.

Shoffner said that Marcom, who was the principal investigator of her trial, never disclosed this information in over two years. When Marcom did talk with Shoffner in November 2010, he said only that there were "problems with the data," and that the trials were terminated, Shoffner said.

Duke officials and Marcom did not respond to questions from The Cancer Letter.

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"I Don't Approve of Lying to Patients"

Even under normal circumstances, communication between doctors and patients is complex—nuance can be lost; anger can flash.

At Duke, Potti's fraud killed every vestige of trust Shoffner had in the institution, leaving her feeling betrayed.

"It's a tragic, tragic event that slows down research," said Jimmie Holland, the Wayne E. Chapman Chair in Psychiatric Oncology at Memorial Sloan Kettering Cancer Center, and founding president of the American Psychosocial Oncology Society.

"Informed consent is based on trust between the patient and the institution and the doctor. It's trust in general; it's a principle that is much wider than medicine," Holland said to The Cancer Letter. "I don't think most oncologists would willfully lie or withhold information—well, obviously that's bad.

"The examples like this that become widely known and discussed have a tendency to reduce the trust in cancer research by protocol, which is very sad, because we need to have research to go forward and improve the care of cancer patients."

Lying, or withholding information from patients is "a very bad idea," said Barrie Cassileth, an integrative medicine specialist and the Laurance S. Rockefeller Chair in Integrative Medicine at MSKCC.

"I don't approve of lying to patients. It has detrimental effects," Cassileth said to The Cancer Letter. "It diminishes what the doctor-patient relationship is about, and there will never be any good to come out of misleading patients."

The research enterprise is the real victim in Shoffner's story, said Jennifer Griggs, a professor of medicine and medical oncology in the Division of Hematology/Oncology at the University of Michigan.

"[Shoffner] refers to being a lab rat or a guinea pig, and what this does is it erodes trust in the biomedical research enterprise and the system. And this makes it harder for all of us to do research," said Griggs, who reviewed the Duke protocols and other publicly available data for The Cancer Letter.

"The Potti group has done harm to research progress worldwide."

Griggs is also a professor in the University of Michigan's School of Public Health in the Department of Health Management & Policy.

"The genomic predictor was clearly bad (everyone agrees), but I don't see that this patient was physically hurt because of this trial per se," said Matthew Goetz, a professor of oncology and pharmacology at Mayo Clinic, who also reviewed Shoffner's case for The Cancer Letter. "It would be understandable, however, that the emotional anxiety of knowing that she was enrolled onto a clinical trial that was testing a bad classifier caused her anxiety and depression—this sort of claim could be justified."

After Shoffner completed her chemotherapy regimen in the trial, she learned that she had been assigned to receive Adriamycin-Cytoxan (AC)—standard chemotherapy for breast cancer—based on Potti's predictor model.

Shoffner's cancer has not recurred, but she has suffered from common adverse consequences of the AC regimen. These include blood clots and diabetes.

After learning about Potti's fraud, Shoffner has been re-examining her treatment at Duke—and wondering whether she was duped into participating in the neoadjuvant trial, whether she received the right chemo, and whether she should have received additional treatment post-surgery.

Shoffner said she is being treated for post-traumatic stress disorder, which she attributes to her experience at Duke.

"For me and for the surviving patients, it's not over," Shoffner said. "Whether the healing process will actually heal, I don't know. It's not resolved for me, it will be a part of my life till the day I die."

Shoffner Questions Treatment Choices

Shoffner remembers the shock of learning that something had gone awry at Duke.

Her oncologist, Marcom, called on the day before Thanksgiving in 2010. He was informing her that the trial, in which Shoffner participated and which he ran, had been terminated.

"The reason that the trials had been canceled, he said there seemed to be some problems with the data, that's all he said," Shoffner recalled.

Unbeknownst to Shoffner, the trials had been suspended in July 2010, after The Cancer Letter reported irregularities in Potti's CV, triggering a broader investigation. In fact, Marcom was making his calls to patients days before the Institute of Medicine's Omics Committee held its first meeting to investigate the Duke scandal.

Shoffner said Marcom did not mention Potti's fraud.

Another aspect of her conversation with Marcom ended up worrying Shoffner even more.

"He said, 'I do wish I had given you Taxol,'" Shoffner recalled. "Being devastated that this holy grail of medicine that was going to cure my type of cancer, which is a bad one—that's all I could think about at that

time. I thought nothing about him saying that about Taxol.

"A couple of days later, we spoke again, and during that conversation, once again, he made a comment that he wished he'd given me Taxol.

"But shortly thereafter, I started thinking about it when I was coming down off my horror, and I thought, 'Well, what is Taxol? And why is he upset that he didn't give it to me?'

"So I looked it up. And I believed from what I read and understood that I should've had Taxol for this type of cancer, and I didn't get it.

"Then I found out that [the fraud] was all over the news.

"I had not heard it, or didn't relate it to me, of course, but it had already been in The New York Times, locally in the news, TV and newspapers," Shoffner said. "I began to feel that I was the last to know."

She found past coverage of the Duke story, and ultimately called Keith Baggerly, a biostatistician at MD Anderson Cancer Center, who had spent hundreds of hours examining the Nevins and Potti data.

Shoffner asked Baggerly whether she was harmed. Baggerly said he wasn't qualified to answer this question.

"[Duke said] that there was no harm done to the patients, that we all got the standard of care anyway," she said. "But I did realize at that time that everybody knew [about the fraud] before I did."

Suddenly, Duke, the place she trusted with her life, no longer seemed safe.

"I was terrified," Shoffner said. "Where was I going to go? What was I going to do?"

University of Michigan breast cancer expert Griggs said Duke should have informed Shoffner and other trial participants about the fraud much earlier.

"It seems that the institution knew things—and The Cancer Letter is intimately involved in this—it looks like there were things that were known well before the institution made it public," Griggs said.

"That information would have been better off being disclosed to the patients earlier than it was."

The Question of Taxanes

Shoffner's disease was HER2 negative, and estrogen receptor (ER) and progesterone receptor (PR) positive.

In an interview with The Cancer Letter, Shoffner said that Marcom was able to determine that she was receiving neoadjuvant Adriamycin-Cytoxan chemotherapy based on the genomic predictor model.

This would mean that Marcom was able to unblind her predictor results.

The protocol reads:

"Both the patient, treating physicians, and research nurses/staff will be blinded to randomization assignment until after the primary treatment endpoint is met. (i.e. progression on therapy; stable disease/minimal response after completing chemotherapy; or proceeding to definitive surgery)."

The protocol is posted here.

"I learned for the very first time in the lawsuit that Dr. Marcom had unblinded my predictor results after my fourth cycle of chemo, but before a decision was made about what further treatment I may receive," Shoffner said. "He saw that I had been placed in the guided AC arm of the trial and that the predictor said I was resistant to taxanes. I also learned that he used the predictor results to go into his judgment not to give me a taxane, either before surgery or after.

"If I hadn't been given the fourth cycle of AC, my treatment couldn't be considered as a data-point in the clinical trial results.

"Dr. Marcom never discussed giving me a taxane before or after he sent me for surgery. I never was given the opportunity to consider whether to take it or not because he never discussed it with me. I would have chosen to take it from what I now know about TAC as the standard of care that I learned in the lawsuit.

"This is why I was surprised when Dr. Marcom even mentioned taxanes in his first telephone call to me in November 2010 nearly two years later, when he said he should have given me a taxane."

If this is correct, Marcom continued to use the faulty predictor model to determine Shoffner's treatment choices after her participation in the trial ended.

According to the Duke trial protocol, she was not precluded from receiving a taxane, or other additional therapy.

After the surgery, Shoffner was found to have 10 positive lymph nodes, which makes her disease Stage IIIC.

Shoffner received an aromatase inhibitor, which is the standard of care for ER-positive patients like her.

Breast cancer experts say that patients like Shoffner would have ordinarily been considered for taxane-based therapy. However, Shoffner's oncologist could have also decided that her toxicity incurred by AC was so severe that additional chemotherapy wouldn't be appropriate.

"An oncologist may believe that, based upon a patient's performance status and complications from AC, that the risks of giving taxanes outweighed the benefit," Mayo's Goetz said. "This is clinical judgment and I have these conversations all of the time with my patients.

"In my mind, even though the classifier was bad, it appears to me that trial design was attempting to answer an important clinical question of whether a genomically-driven test could guide treatment between two regimens that were known to result in similar breast cancer outcomes, but with very different toxicity regimens (e.g. AC causes can result in heart failure in 2 to 5 percent, whereas TC does not)," Goetz said.

"For those patients randomized to the AC arm, it would have been important AFTER surgery that they be at least offered a standard taxane-based regimen (either paclitaxel or docetaxel), which was known to reduce the risk of recurrence for patients that had received AC."

Goetz said that oncologists would usually have a conversation about taxanes with patients like Shoffner, and this would be documented in medical records.

Shoffner said her medical record does not show that Marcom discussed this matter with her. The complaint against Duke states that Marcom "chose not to prescribe" a taxane.

University of Michigan's Griggs said most oncologists would have given Shoffner a taxane.

"I don't think she was given what we would consider the standard of care at the time," Griggs said to The Cancer Letter. "I think pretty much every oncologist would've given her AC followed by a taxane. I would have.

"That the oncologist had the opportunity to treat her with a taxane post-surgery and didn't in somebody with that high a risk of recurrence—10 nodes—most people would say that the benefit is there with a taxane.

"She's free of disease, so I can't say her outcome could have been better. She hasn't had a recurrence. If she had a recurrence, I think there'd be a much bigger concern about the fact that she didn't get a taxane.

"Trial or not, I would've given her both a taxane and an anthracycline, and I think most oncologists—if you polled 100 oncologists, it would be an unusual oncologist who would say, 'No, I'd stop at AC.'

"I think the biggest issue is the fact that she was enrolled in a trial that's based on fraudulent data. And that was the problem that The Cancer Letter was so instrumental in revealing: the fraudulent study and the fraudulent investigator.

"This case, and those of other patients who participated in these trials, demonstrates the importance of the integrity of investigators who conduct clinical research. We can make progress against cancer only through conducting high quality research. If we compromise the trust our patients have in us, we compromise that progress."

Shoffner's Message to Duke

What would Shoffner like to say to Duke—Potti, his mentor Nevins, and the deans who protected them?

"Why didn't you level with us and let us have a choice, instead of just using us for human experiment? Where was your mindset when you overlooked the human factor?" Shoffner said. "I didn't think that human experimentation was possible in this age and time.

"I'd love to say, 'Do you have any regrets about just the human side of it?' I'm sure they all regret that the research didn't come out like they wanted. Oncogenomics didn't come out like they wanted in the end.

"Now, have you had the time to think about the people and what happened to them? At this point, do you have any regrets or concern, or are you so mad at us for filing a lawsuit that you'd wish we'd all die?

"I have felt for a long time like they were waiting to see whether I would die within the five years. And then if I didn't die in the five years, 'Oh, we cured you!'

"If they said, 'I'm sorry,' I don't think I could believe them. I mean, don't need to come to me and tell me, 'Sorry,' because you have shown me—actions speak louder than words—you've showed me that you did not care about me as a human being.

"Someone said along the way, 'Duke sent you a letter of apology, but that it came back. They didn't have your address.'

"And I said, 'Tell them to go to their billing department. They know how to get up with me.'"

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FDA Notifies 300 Medical Practices That They May Have Purchased Unapproved Prescription Drugs

FDA notified more than 300 medical practices that they may have purchased unapproved prescription drugs or injectable devices from a foreign supplier, Gallant Pharmaceutical International.

"Gallant and twelve individuals, including a doctor and an office manager, have been convicted for their roles in distributing drugs and devices that have not been approved or cleared by FDA in the U.S.," the agency's letter to the practices said. "The unapproved drugs and unapproved/uncleared devices sold by Gallant were obtained from foreign sources and shipped and stored outside of the regulated supply chain."

The drugs sold include Avastin, Erbitux, Herceptin, Rituxan, and Velcade.

The agency said that these drugs may be fake, contaminated, ineffective, or otherwise unsafe. Also, they may not have been evaluated by FDA for safety and efficacy and may not contain the appropriate amount of active ingredients; or contain harmful ingredients.

While the last purchases from Gallant were made in 2013, it is not known whether the drugs or devices are still in distribution, FDA said. The agency also made public the list of doctors and medical practices it notified in the letter, which was sent April 1.

Many drugs sold by Gallant were required to carry a black box warning, but the versions sold by Gallant did not meet this or other FDA labeling requirements. Previously, The Cancer Letter explored how fake Avastin made its way through the international drug supply chain and into U.S. hospitals and doctors' offices, paid for by Medicare (Oct. 3, 2014).

In December 2013, Gallant pleaded guilty to two counts of importation fraud, five counts of selling misbranded drugs, and five counts distributing prescription drugs without a license. Co-founder and co-owner Syed Huda also pleaded guilty to one count each of importation fraud, selling misbranded drugs, distributing prescription drugs without a license, and wire fraud, according to the Department of Justice.

Huda was the eighth member of Gallant to enter a guilty plea. Previously, in October 2013, co-founder and co-owner Talib Khan pleaded guilty to selling misbranded chemotherapy and cosmetic drugs, and conspiracy to commit importation fraud, sell misbranded drugs, distribute prescription drugs without a license, and defraud the FDA. Four sales representatives and two office managers also entered guilty pleas.

"Gallant Pharma purchased drugs on the international black market, with no idea whose hands those drugs passed through or what conditions the drugs were stored or shipped in," the FDA special agent in charge, Antoinette Henry, said at the time.

"Gallant Pharma exploited some of our most vulnerable citizens to make a profit, including those suffering from cancer and undergoing intravenous chemotherapy," said Acting U.S. Attorney Dana Boente.

Khan was sentenced in March 2014 to three years in prison, two years of supervised release, and $3.4 million in forfeiture and restitution to victims.

The letter sent by FDA, and the list of 300 notified doctors and practices, are available on the FDA website.

Four Cancer Charities Charged With Fraud in Raising $187 Mil

The Federal Trade Commission charged four cancer charities with fraudulently raising $187 million between 2008 and 2012.

The federal complaint names Cancer Fund of America Inc., Cancer Support Services Inc., their president, James Reynolds, Sr., and their chief financial officer and CSS's former president, Kyle Effler; Children's Cancer Fund of America Inc. and its president and executive director, Rose Perkins; and The Breast Cancer Society Inc. and its executive director and former president, James Reynolds II.

The complaint is posted here. The action was announced May 19.

The four charities didn't fund research. Instead, they claimed to provide direct help to cancer patients.

"Not one of the Defendants has operated a program that provides cancer patients with pain medication to alleviate their suffering, transports cancer patients to chemotherapy appointments, or pays for hospice care," the complaint states. "Moreover, the vast majority of donors' contributions have not directly assisted cancer patients in the United States or otherwise benefitted any charitable purpose. Rather, donations have enriched a small group of individuals related by familial and financial interests and the for-profit fundraisers they hired. This diversion of charitable funds has deceived donors and wasted millions of dollars that could have been spent as donors intended, to help Americans suffering from cancer."

The contributions financed personal loans to insiders, paid for trips to Las Vegas, New York and Disney World, as well as cars, college tuition,

gym memberships, Jet Ski outings, dating website subscriptions, cruises and tickets to concerts and professional sporting events, documents state.

For-profit fundraising companies that were used by the charities got to keep 80 percent or more of the contributions, the complaint states. In some cases, they kept 95 cents of every dollar brought in.

The high fundraising and administrative costs were hidden by using an accounting scheme involving the shipment of pharmaceuticals and other goods to developing countries, the complain states.

"Through this scheme, collectively from 2008 through 2012, Defendants improperly reported over $223 million in revenue and program spending in their financial statements," the document states. "This had the effect of making Defendants appear to be larger and more efficient with donors' dollars than they actually were, deceiving the donating public."

The complaint describes one patient aid program: "sending individuals with cancer boxes of seemingly random items."

These included "a small quantity of Carnation Instant Breakfast drink, adult briefs and bed pads, and a large assortment of what CFA euphemistically described as 'comfort items,'" the complaint states. "In the past, boxes have included things like sample-size soaps, shampoos, and other toiletries, over-the-counter medications, Little Debbie Snack Cakes, toys, disposable plates and plastic cutlery, scarves, batteries, women's makeup, family-themed DVDs, adult-sized clothing, iPod Nano covers, gift wrap, blank seasonal greeting cards, candy, and/or children's coloring books. CFA employees and volunteers pre-packed boxes with an assortment of identical items, until supplies of any given item ran out. Thus, every individual received the same items, regardless of age, gender, clothing size, or personal preference. Individual recipients could also request latex exam gloves, and, on some occasions, box fans and blankets.

"Reynolds' explanation for buying Little Debbie Snack Cakes for cancer patients was because 'they make people happy,'" the complaint states. "He justified a switch to purchasing Moon Pies because they 'make you happier.'"

According to FTC, three of the individuals—Effler, Perkins and Reynolds II—agreed to settle the charges against them. They will be banned from fundraising, charity management, and oversight of charitable assets. Two of the foundations—CCFOA and BCS—will be dissolved. Litigation will continue against CFA, CSS and James Reynolds Sr.

"The defendants' egregious scheme effectively deprived legitimate cancer charities and cancer patients of much-needed funds and support," Jessica Rich, director of the FTC's Bureau of Consumer Protection, said in a statement. "The defendants took in millions of dollars in donations meant to help cancer patients, but spent it on themselves and their fundraisers. I'm pleased that the FTC and our state partners are acting to end this appalling scheme."

In addition to the bans imposed on charity work by the settling individual defendants and the dissolution of two corporations, CCFOA and BCS, the proposed final order against CCFOA and Rose Perkins imposes a judgment of $30,079,821, the amount consumers donated between 2008 and 2012. The judgment against CCFOA will be partially satisfied via liquidation of its assets; the judgment against Perkins will be suspended based upon her inability to pay.

The proposed final orders against BCS and Reynolds II impose a $65,564,360 judgment, the amount consumers donated between 2008 and 2012. The BCS order provides an option, subject to court approval, for spinning off its Hope Supply Warehouses program to a legitimate, qualified charity. BCS's remaining assets will be liquidated and used to partially satisfy the judgment. The judgment against Reynolds II will be suspended when he pays $75,000.

The proposed final order against Effler will impose a judgment of $41,152,231, the amount consumers donated to CSS between 2008 and 2012. The judgment will be suspended upon payment of $60,000. The full judgment amounts against the individuals will become due immediately if they are found to have misrepresented their financial condition.

The Commission vote authorizing the staff to file the complaint and proposed stipulated final orders was 5-0. The documents were filed in the U.S. District Court for the District of Arizona. The proposed orders are subject to court approval.

On the website of one of the charities http://www.breastcancersociety.org, Reynolds II, posted this statement:

"Charities–including some of the world's best-known and reputable organizations–are increasingly facing the scrutiny of government regulators in the U.S. The Breast Cancer Society (TBCS) is no exception. Unfortunately, as our operations expanded–all with the goal of serving more patients–the threat of litigation from our government increased as well.

"While the organization, its officers and directors have not been found guilty of any allegations of wrong doing, and the government has not proven

otherwise, our Board of Directors has decided that it does not help those who we seek to serve, and those who remain in need, for us to engage in a highly publicized, expensive, and distracting legal battle around our fundraising practices."

CPRIT Awards 41 Grants, Totaling About $60 Million

The Cancer Prevention and Research Institute of Texas awarded 28 grants through its academic research program, 11 grants through its prevention program and two grants through its product development research program.

Totaling approximately $60 million, the grants include nearly $31 million for six Core Facilities Support Awards. Additional research grants help support the recruitment of cancer scientists to academic institutions in Texas.

The prevention awards total around $20.6 million. The Evidence-Based service and coalition projects receiving grants will focus on preventing colorectal, breast, cervical and liver cancer through screening, education and clinical services. The Competitive Continuation grants will provide support to previously funded projects, including screening and diagnostic services related to breast, cervical and colorectal cancer.

All 41 research, prevention and product development grants follow:

Core Facilities Support Awards

Six grants, totaling $30,949,575:

• **The Houston Methodist Research Institute**: CPRIT Core for RNA Therapeutics and Research, $4,845,868

• **The University of Texas M.D. Anderson Cancer Center**: Precision Oncology Decision Support Core, $5,999,996

• **The University of Texas Health Science Center at San Antonio**: The Single-Cell Biopsy and Characterization Core (SBCC) at The University of Texas Health Science at San Antonio, $3,277,895

• **The University of Texas Health Science Center at Houston**: Therapeutic Monoclonal Antibody Lead Optimization and Development Core, $5,277,338

• **The University of Texas Southwestern Medical Center**: Bioinformatics Core Facility at UT Southwestern Medical Center, $5,593,882

• **Texas A&M University Health Science Center**: The Combinatorial Drug Discovery Program (CDDP), $5,954,596

High-Impact/High-Risk Research Awards

Sixteen grants, totaling $3,194,510:

• **The University of Texas Southwestern Medical Center**: Dynamin GTPase: A Novel Pro-Apoptotic Cancer Therapeutic Target, $200,000; Acetate May Be a Key Substrate Driving Growth in Early Stage Breast Cancer in Patients, $200,000; Identification of Novel Melanoma Metastasis Driver Genes through Transposon-Mediated Mutagenesis, $200,000; Identifying Inhibitors of Ascl1 to Block Growth of Malignant Neuroendocrine and Neural Tumors, $200,000.

• **Texas A&M Health Science Center**: Efficient Production of IPSC-Derived Mesenchymal Stem Cells to Kill Cancers by Bystander Effects from Suicide Genes, $200,000; Metabolomic Salivary Biomarkers for Oral Cancer Detection, $199,999.

• **The University of Texas Health Science Center at San Antonio**: Inhibition of Breast Cancer Metastasis to the Bone by microRNA Transmission through Gap Junctions, $200,000; Turning on a Novel Tumor-Inhibiting Switch for Colorectal Cancer, $200,000.

• **Baylor Research Institute**: Elevated D-2 Hydroxyglutarate Precedes and Promotes Tumor Progression in Inflammatory Bowel Diseases, $200,000.

• **Rice University**: Non-Invasive Colonoscopy by Molecular Imaging of Mucin Targeted Hyperpolarized Silicon Nanoparticles, $200,000.

• **Texas A&M University**: Small Molecules to Perturb a Novel PPI Target for Chemotherapy, $200,000.

• **Texas Tech University**: Integrated On-Chip Networks for Investigating Exosome-Mediated Drug Expulsion, $200,000.

• **Texas Tech University Health Sciences Center**: Engineered Bone Targeting Nanomedicine for Treatment of Bone Metastases from Breast Cancer, $199,970.

• **The University of Texas at Arlington**: Biomechanical Profiling of Migrating Brain Cancer Genotypes in Tightly-Confined Space for Drug Screening, $199,998.

• **The University of Texas at Dallas:** Identification of Therapeutic Targets on Breast Cancer Stem Cells, $194,543

• **The University of Texas Health Science Center at Houston**: Drug Conjugates of anti-LGR5 Antibodies as Novel Therapeutics for Destroying Cancer Stem Cells, $200,000

Multi-Investigator Research Awards

Two grants totaling $15,922,336:

• **Baylor College of Medicine**: The Texas Hepatocellular Carcinoma Consortium (THCCC), $9,771,157; GATA2 and Steroid Receptor Coactivator-2 Cooperate with Androgen Receptor in Prostate Cancer Progression and Androgen Resistance, $6,151,179.

Recruitment of First-Time, Tenure-Track Faculty

Recruitment grants awarded indicate only approval to negotiate offers; at the time of release candidates have not accepted offers.

• **Maralice Conacci-Sorrell,** Recruitment to The University of Texas Southwestern Medical Center from Fred Hutchinson Cancer Research Center, $2,000,000

• **Andreas Doncic,** Recruitment to The University of Texas Southwestern Medical Center from Stanford University, $2,000,000

• **Natalia Kirienko,** Recruitment to Rice University from Massachusetts General Hospital and Harvard Medical School, $2,000,000

Recruitment of Established Investigators

• **Hongtu Zhu,** Recruitment to The University of Texas M.D. Anderson Cancer Center from University of North Carolina at Chapel Hill, $4,000,000

Competitive Continuation/Expansion Grants

• **Angelo State University**, Access to Breast and Cervical Care for West Texas (West/Central Texas) (ABCC4WT), $1,480,898

• **Texas A&M AgriLife Extension Service**, Increasing Breast and Cervical Cancer Screening and Diagnostic Rates in Rural, Frontier and Border Counties for Uninsured, Underserved Women, $1,500,000

• **The Rose**, Empower Her to Care Expansion: Increasing Access to Breast Cancer Screening and the Continuum of Care for Underserved Texas Women, $1,500,000

• **University Health System**, University Health System Evidence-Based Colorectal Cancer Prevention Screening Program, $1,499,775

• **The University of Texas Southwestern Medical Center,** BSPAN3: Breast Screening and Patient Navigation for Rural and Underserved Women across North Texas, $1,499,993

Evidence-Based Cancer Prevention Services

• **The University of Texas M.D. Anderson Cancer Center**, Alliance for Colorectal Cancer Testing (ACT) in Southeast Texas, $2,588,774

• **The University of Texas Southwestern Medical Center**, The C-SPAN Coalition: Colorectal Screening and Patient Navigation, $4,800,000

Evidence-Based Prevention Programs

• **MHP, Inc. Promoviendo Vidas Saludables**, Cada Paso del Camino: Outreach, Education, Screening, Health Insurance Navigation, and Linkage to Treatment for Breast, Cervical and Colorectal Cancer, $1,498,337

• **The University of Texas Health Science Center at San Antonio**, STOP HCC, Evidence-Based Hepatocellular Cancer Prevention Targeting Hepatitis C Virus Infection, $1,488,294

• **The University of Texas M.D. Anderson Cancer Center**, Media-Rich Mobile Dissemination of a Dysphagia Prevention Program for Head and Neck Cancer Patients during Radiation, $1,263,342

• **Val Verde Regional Medical Center**, FluFIT on the Frontera: Increasing Colorectal Cancer Screening on the Texas-Mexico Border, $1,500,000

Established Company Product Development

Product development funding figures represent the maximum amount to be made available upon successful completion of all milestones.

• **Vermillion Inc.,** Development and Validation of a Second-Generation Multivariate Test for Use in Assessing Risk of Ovarian Mass Malignancy, Austin, three years, $7,533,011

New Company Product Development:

• **Rosellini Scientific LLC,** Wireless Neuromodulation Treatment for Bladder Dysfunction Secondary to Cancer, Dallas, three years, $967,000

In Brief

PCORI Approves $120 Million In Research Studies

THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE approved more than $120 million to fund 34 patient-centered clinical comparative clinical effectiveness research studies on a range of conditions and patient populations.

The new awards include nearly $58.5 million to fund five pragmatic clinical studies focused on radiation therapy for breast cancer, fractures in older adults, and treatments for children with bipolar disorder and Crohn's disease.

Ranging from $7.9 million to nearly $14 million each, the five pragmatic clinical studies will compare:

• The effectiveness of new proton beam therapy versus conventional photon radiation therapy in treating breast cancer and minimizing collateral damage to healthy organs and tissue.

• Whether healthy lifestyle interventions plus the diabetes drug metformin are more effective than lifestyle interventions alone in reducing weight gain and metabolic problems associated with certain antipsychotic medications among overweight and obese youth with bipolar disorders.

• Whether children with Crohn's disease have better outcomes taking a new biological therapy that targets tumor necrosis factor (anti-TNF) alone or taking a combination of anti-TNF plus a low dose of methotrexate, a conventional drug.

• Whether older adults undergoing surgery for hip fracture have greater likelihood of regaining function and independence and experience fewer complications and less pain if they receive nerve blocking regional anesthesia or general anesthesia.

• The ability of an exercise coaching program versus usual care to prevent further injuries and improve health for older adults who have experienced a low-impact fracture as a result of a fall.

The institute also approved 29 other awards, totaling nearly $61.6 million, under broad funding announcements issued in August 2014 under PCORI's five National Priorities for Research. These studies will compare different options for improving outcomes for conditions such as opioid addiction, arthritis, stroke, Parkinson disease, leukemia, chronic kidney disease, and child abuse.

CATHERINE BROWN was named president of the **John Wayne Cancer Foundation**.

A new position for the foundation, Brown will implement key strategies to increase JWCF's presence both nationally and internationally.

"When my dad passed away from cancer in 1979, he asked our family to help the good doctors fight the fight against cancer," said Ethan Wayne, director of John Wayne Cancer Foundation. "We accepted that responsibility and through our efforts, the John Wayne Cancer Foundation was established in his name. We continue the fight and are pleased to bring Catherine onboard to help us with the next phase of the foundation's growth."

Brown most recently served as vice president of the Pacific West Region for the Leukemia & Lymphoma Society. Before that she was executive vice president of ConferenceDirect, president of the Children Affected by AIDS Foundation, vice president of the American Association of Critical-Care Nurses as well as vice president at Anthony J. Jannetti Inc.

THE COMMUNITY ONCOLOGY ALLIANCE and the **Community Oncology Pharmacy Association** appointed its advisory board. **Josh Cox** and **Tommy Harwood** will serve as advisory board co-chairs.

Board members include:

Steve D'Amato, executive director, New England Cancer Specialists

John Clagg, director of pharmacy and admixture services, The Center for Cancer and Blood Disorders

Josh Cox, director of pharmacy, Dayton Physicians Network

Tommy Harwood, deputy director of clinical operations, North Shore Hematology Oncology

Phil Johnson, consultant for Healthsystems;

Stacey McCullough, director of pharmacy, Tennessee Oncology

Michelle Moore, clinical pharmacy manager, Michiana Hematology Oncology

Todd Murphree, manager of the dispensing pharmacy, Clearview Cancer Institute

Bob Phelan, CEO, Cancer Specialists of North Florida

Maryann Roefaro, CEO, Hematology-Oncology Associates of Central New York

The board will meet bi-weekly to address continuity and quality of care issues for community oncology patients receiving oral therapies within physician practices.

The board's priorities include: developing national quality measures for practice-based dispensing and retail pharmacies in conjunction with accreditation recognition; conducting and publishing an independent analysis documenting the quality, compliance, and low costs of patients being treated in dispensing and retail pharmacies within integrated community oncology practices versus disconnected specialty pharmacy providers; establishing a closed listserv enabling information sharing among COPA members on best practices; and creating a website with resources available to practices that have a dispensing or retail pharmacy as well as those looking for resources to assist in establishing a pharmacy.

MERIDIAN HEALTH and **HACKENSACK UNIVERSITY HEALTH NETWORK** signed a definitive agreement for the two health systems to merge and become Hackensack Meridian Health. The agreement follows nearly seven months of due diligence and a thorough review of clinical, regulatory, service, and financial issues.

The merger still requires state and federal regulatory clearance, which the health systems expect within the next nine to twelve months.

"Hackensack University Health Network is pleased to partner with Meridian Health in this historic merger," said Robert Garrett, president and CEO of Hackensack University Health Network.

John Lloyd, president and CEO of Meridian Health, said, "Today marks the first time that two of the state's most innovative healthcare systems are joining to transform the delivery of healthcare and better meet the needs of the communities we serve."

The newly formed organization will share a corporate board comprising an equal number of trustees from each system. The integrated health system will also have co-chief executive officers, Garrett and Lloyd, for a period of two-and-a-half years, after which Garrett would become the sole CEO.

The combined entity will have 11 hospitals: Jersey Shore University Medical Center; Ocean Medical Center; Riverview Medical Center; Southern Ocean Medical Center; Bayshore Community Hospital; Raritan Bay Medical Center; Raritan Bay Medical Center; Hackensack University Medical Center; HackensackUMC Mountainside; HackensackUMC at Pascack Valley; and Palisades Medical Center; as well as two children's hospitals, K. Hovnanian Children's Hospital and Joseph M. Sanzari Children's Hospital.

The system would also include a network of physician practices, ambulatory surgery centers, home care, long-term care and assisted living facilities, ambulance services, fitness and wellness centers, and outpatient centers. The system will employ approximately 25,000 team members and nearly 6,000 physicians on staff.

Drugs and Targets

FDA Grants Fast Track To AG-120

FDA granted Fast Track designation to AG-120 for the treatment of patients with acute myelogenous leukemia who harbor an isocitrate dehydrogenase-1 (IDH1) mutation.

AG-120 is a first-in-class oral inhibitor of the mutated IDH1 protein being evaluated in two phase I clinical trials, one in hematologic malignancies that recently initiated three expansion cohorts, and one in advanced solid tumors, including glioma.

"We look forward to presenting new data from the ongoing phase I study at the EHA Annual Congress next month and remain on track to initiate a global, registration-enabling phase III study in collaboration with Celgene in AML patients who harbor an IDH1 mutation in the first half of 2016," said Chris Bowden, chief medical officer of Agios Pharmaceuticals Inc., the drug's sponsor.

Palmetto GBA issued a draft local coverage determination for the Oncotype DX prostate cancer test developed by Genomic Health Inc. Palmetto is a Medicare Administrative Contractor that assesses molecular diagnostic technologies.

The draft LCD recommends coverage of the Oncotype DX prostate cancer test for qualified Medicare patients throughout the U.S. "to help determine which patients with early-stage, needle biopsy proven prostate cancer, can be conservatively managed rather than treated with definitive surgery or radiation therapy."

The draft will go through Medicare's review process, which includes a public comment period, finalization and notification.

Baylor Research Institute and the Translational Genomics Research Institute extended a collaboration focused on accelerating early detection and treatments for patients with a broad range of cancers.

"We will combine TGen's strengths in genomics and proteomics with BRI's strengths in metabolomics and immune-based approaches, initially focusing on genomic—or molecular—and translational research for oncology," said Robert Pryor, president, chief operating officer and chief medical officer of Baylor Scott & White Health.

The two organizations will perform liquid biopsies, gene sequencing, clinical trials and plan to create personalized vaccines. Operations will be managed from a joint program located at Baylor Charles A. Sammons Cancer Center on the campus of Baylor University Medical Center at Dallas. Research will take place in clinics and labs throughout the health care system, as well as at TGen facilities in Phoenix and Scottsdale.