THE CANCER LETTER

PO Box 9905 Washington DC 20016 Telephone 202-362-1809

Vol. 38 No. 3
Jan. 20, 2012

The Cancer Centers: Permanent Reinvention

Is a New Cancer Center Always a Good Thing?

UCSD To Buy Las Vegas Center at Bankruptcy Sale

This is the second installment in a series of articles that examines the fundamental challenges to the cancer centers as they chart their future beyond 2012. Last week, The Cancer Letter focused on the National Comprehensive Cancer Network, an umbrella group formed by cancer centers two decades ago. Now, we focus on the aftermath of a backfired effort to create an NCI-designated cancer center in Las Vegas.

By Paul Goldberg

A bankruptcy judge in Las Vegas earlier this week approved the sale of a part of the Nevada Cancer Institute to the University of California, San Diego, Health System.

The center, which once aggressively recruited scientists in an ambitious quest for the NCI designation, is being reorganized under Chapter 11 of U.S. Bankruptcy Code. The reorganization would reduce the center's outstanding debt by over $50 million.

Few cancer care insiders in the area claim to understand what UCSD intends to do with its Nevada outpost, and the principals aren't answering questions. The answers will come after the deal closes later this month, they say.

The purchasing price is $18 million, which covers the center's main building. However, the founders of the Las Vegas institution took on the obligation to raise another $15 million for NVCI over the next five years, and backed the obligation by attaching a $15 million endowment set up by a private foundation.

(Continued to page 2)

PSA Screening

New Jersey Legislature Votes to Oppose USPSTF PSA Screening Downgrade

By Conor Hale

The New Jersey Legislature voted unanimously to oppose the evidence-based recommendations of the U.S. Preventive Services Task Force.

The independent task force proposed downgrading its rating of prostate-specific antigen screening for prostate cancer—from "I" for inconclusive, to "D," for no benefit for men under 75. The task force held a public comment period, and is expected to deliver its final recommendation to Congress this spring.

(Continued to page 7)

UCSD Agrees to Pay $18 Million For Las Vegas Cancer Center

(Continued from page 1)

The money was originally donated by the Engelstad Family Foundation with the stipulation that only the interest would be used to fund lung cancer research. However, the foundation has now agreed to use the principal to secure the deal, court documents show.

The sale to UCSD was approved by U.S. Bankruptcy Court Judge Mike Nakagawa on Jan 14. The court documents are posted at: http://www.cancerletter.com/categories/documents.

The Cleveland Clinic Foundation reportedly also considered setting up a center in the desert, but in the end there were no bidders besides UCSD.

When the contours of the purchase by UCSD were first revealed last month, the center's boosters portrayed the development as fulfillment of their dram for Las Vegas.

"The sale of NVCI's operations and treatment facility to UCSD, along with the debt restructuring, are great news for NVCI, our patients and the community, and if approved, will preserve NVCI's important mission and ensure that Nevadans will continue to receive comprehensive and innovative cancer care," Michael Yackira, chairman of NVCI's board of directors, said in a statement Dec. 2. "UCSD, one of our nation's leading health systems, is particularly renowned in the field of cancer through the UCSD Moores Cancer Center, and will continue NVCI's tradition of excellence."

THE CANCER LETTER

® The Cancer Letter is a registered trademark.

Editor & Publisher: Paul Goldberg
Copy Editor: Conor Hale

Editorial, Subscriptions and Customer Service:
202-362-1809 Fax: 202-379-1787
PO Box 9905, Washington DC 20016
General Information: www.cancerletter.com

Subscription $405 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd.

NVCI co-founder and board member Heather Murren said the purchase by UCSD is consistent with her plan to bring an NCI-designated cancer center to Las Vegas.

"While the path was very different, perhaps than we originally envisioned, we are very pleased that we'll be able to offer that kind of service to the people here," Murren said to Las Vegas Sun at the time.

Murren founded the center with her husband Jim, the chairman and CEO of MGM Resorts International. The Murrens continue to serve on the NVCI board, which will become advisory after the sale, court documents show.

Statements by Yackira and Murren notwithstanding, it remains to be seen whether the UCSD outpost would be focused on cancer, insiders say.

Also, the center's founders had to promise to raise money that would finance the purchase by UCSD. It's difficult enough to raise money for an ongoing effort to build a cancer center. Raising funds for the aftermath of a failed effort to build a cancer center in an area where there is no shortage of cancer care requires extraordinary salesmanship.

In the beginning, the story of NVCI was about big plans and big money to match it. Now, it's about dashed hopes, broken promises, unused square footage and unanswered questions.

One of these questions is whether building a new cancer center is always a good thing. The Las Vegas center is a case study in the aftermath of failure to create a cancer center. It's a story of buildings that didn't need to go up, careers that didn't need to be disrupted, and promises that didn't need to be broken.

The NVCI business plan was particularly gutsy. Most centers have used patient care revenues to support at least some of the research infrastructure. In Las Vegas, patient care revenues had to be generated from a medium-sized outpatient clinic. Land use restrictions precluded the center from constructing a hospital.

And then there was debt—lots and lots of debt—some of it short-term debt, the sort you use to build a casino.

It's unclear what will happen to all the square footage along the short stretch of road wistfully named Breakthrough Way, beneath the red cliffs of the Summerlin area of Las Vegas. The Engelstad foundation also donated money for a 184,000-square-foot research building, named after Ralph Engelstad, owner of the Imperial Palace hotel and casino and lot of other real estate, who died of lung cancer in 2002.

Only a part of the Engelstad research building

was used by the center, and some portions were never finished. Now, the structure stands empty, and since it's not a part of the sale to UCSD, and empty it will remain until it finds a new use. The Engelstad foundation didn't respond to a call from a reporter.

The NVCI administrative building and the 600-car parking deck haven't been used for some time, either.

Despite these grim events, the center is trying to project a happy, hopeful outward appearance.

Two days after the bankruptcy ruling, it sponsored something called the "Bottles of Hope" workshop:

"With colorful polymer clay and a little imagination, participants will transform empty chemotherapy bottles into unique gifts offering encouragement and smiles to Nevadans living with cancer. Finished bottles are gift wrapped along with inspirational messages and presented to cancer patients receiving treatment… Bottles have been decorated with intricate patterns and abstract splashes of color, and been molded into signature sculptures from flower vases and animals to sports equipment and cartoon figures."

"I Wish UCSD Well"

"I wish UCSD well," said John Ruckdeschel, the former CEO who on April 1, 2011, was told to pack and be gone within the hour (The Cancer Letter, May 20, 2011).

Ruckdeschel has moved on to become the medical director of the oncology clinical program at Intermountain Healthcare in Salt Lake City.

"The supply of medical oncologists is adequate currently," said Nicholas Vogelzang, another former NVCI director, who had been recruited from the University of Chicago, ultimately landing at the Las Vegas US Oncology operation.

Vogelzang is a member of the US Oncology research executive committee, chair of the organization's developmental therapeutics committee, co-chair of the genitourinary committee, and the Las Vegas site research leader.

The US Oncology volume in Las Vegas has grown by about 23 to 28 percent over the past two and a half years, since Vogelzang's departure from NVCI.

However, it's difficult to attribute this growth to the ungluing of the cancer institute, said Vogelzang. "It's hard to make a one-to-one correlation, because we have also picked up a contract from one of the managed care organizations," he said.

"The US Oncology practice, which has 30 physicians, four surgeons, three pediatricians, eight radiation oncologists and 22 medical oncologists, really has a substantial majority of the practice of medical oncology in the valley," Vogelzang said. "I don't know of anyone who is unable to get medical oncology services."

About two million people live in the valley surrounding Las Vegas.

Care is widely available. Only the uninsurable patients, usually undocumented immigrants, and public aid patients, who are restricted to certain providers, have difficulty getting treatment.

"We do some, but the biggest problem for most of these folks isn't the doctor fee," Vogelzang said. "The biggest problem is the drugs."

For the most part, Las Vegas residents receive care close to home, usually at community practices, medical insiders say. Those who opt to go to academic cancer centers are more likely to head to Los Angeles than San Diego.

Vogelzang is puzzled by UCSD's potential role in the valley's oncology market. "I think you have to match up UCSD's strengths with what where they want to grow," Vogelzang said. "They are very big on liver and GI cancers. They are very big in interventional radiology and radiology in general. They have a big GI surgery. They also have historical strengths in melanoma and breast cancer. I know enough of the folks there to know that they are outstanding docs, but there is not a large number of them, so we are not dealing with an MD Anderson."

Some of the care provided by US Oncology includes clinical trials.

"I just looked at our numbers for the year here, and we accrued 309 patients to clinical trials," Vogelzang said. The site is number two in accruals within US Oncology. "I want to be number one," Voglezang said. "Baylor [Health Care System] beat us this year. I have another 40 patients to get before I can get the accrual title from Baylor."

Las Vegas patients are getting accrued to the NCI Community Clinical Oncology Program trials, the UCLA trials, and drug company-sponsored trials.

It's not even clear that UCSD would use the center as an outpost of cancer care.

A UCSD statement recently didn't mention providing cancer care:

"We are excited about the prospect of bringing Nevada Cancer Institute into the UC San Diego Health System family. We've been impressed with the facilities and quality of staff and the model of supportive care. Anticipating closure of the sale early next year, we are looking forward to becoming a partner in Nevada's

health care community."

A UCSD spokesman declined to discuss the institution's plans until the deal is finalized later this month.

In the Shadow of Collapse

In court documents, NVCI founder Heather Murren blames the center's collapse on the "protracted decline in the economy, decreases in medical reimbursement rates from managed care payor entities, increases in operational costs, decreases in the amount and availability of charitable donations, a reduction in research funding opportunities and increased competition."

Murren wrote that in late 2009, the board decided to hire an investment banking firm with expertise in the health care field, ultimately hiring Cain Brothers.

The firm focused on 11 providers of cancer care nationwide, and some of them engaged in negotiations.

"Unfortunately, none of these efforts resulted in an agreement, including because of expressed concern that the land use restrictions to which the debtor's real property is subject were incompatible with the interested parties' business strategies, as those restrictions would not permit the provision of certain additional health care services that currently are not offered by NVCI," Murren said in the filing.

By March 2011, NVCI was facing what Murren described as "an acute liquidity shortfall and the prospect that the debtor would default under both its credit agreement and the indenture governing certain outstanding public bonds."

At this point, the center replaced Cain Brothers with a not-for-profit healthcare unit of J.P. Morgan Securities LLC.

As a result of J.P. Morgan's efforts, two entities conducted due diligence and presented NVCI with written expressions of interest in late July 2011. The debtor, with the assistance of J.P. Morgan, engaged both parties in negotiations aimed at improving the terms of their proposals, throughout August.

"After considering the merits of the proposals, the advice of the debtor's professionals, and the views of the Debtor's lenders and their agent, the Board determined to proceed with the acquisition proposal presented by The Regents of the University of California on behalf of its UC San Diego Health System ("UCSD"), pursuant to that certain executed Letter of Intent dated August 30, 2011 (the "Letter of Intent"). The Letter of Intent indicates the parties' mutual interest in negotiating a transaction under which UCSD would acquire the Flagship Building and substantially all of the personal property of the Debtor used in connection with the operations, for $18 million in cash (subject to higher and better offers), pursuant to Bankruptcy Code section 363. The Letter of Intent contemplates that UCSD will use those assets to operate a nonprofit cancer center, consistent with the philanthropic mission of the Debtor."

"The Campus is Beautiful"

Cancer geneticist Sheri Holmen wasn't the sort of researcher any institution wants to lose.

During her four-and-a-half years at NVCI, Holmen received three R01 grants and one American Recovery and Reinvestment Act grant. The indirect costs she brought to NVCI added up to $600,000.

Holmen's husband, Matthew VanBrocklin, was receiving private foundation money and was also applying for R01s.

The couple loved NVCI.

"The campus is beautiful," Holmen said recently. "The facilities are outstanding. It had everything that I needed to do, including a small-animal MRI, and core facilities. The hope was always to get in on the ground floor and help build this place become an NCI-designated cancer center. My goal was to get funding, and I was the first person to get an NIH grant."

The schools were great, the couple's two children were on a nationally-ranked swim team. They bought a house in late 2007, just as real estate prices in Las Vegas started to drop. "We couldn't have predicted that it was going to keep coming down as far as it did," Sheri said. "You never know where the bottom is."

Problems at NVCI were hard to miss. First, Vogelzang, the director who recruited Holmen from Van Andel Cancer Institute, was gone. The couple believed that Ruckdeschel, who has built a reputation on rescuing distressed cancer centers, would make NVCI a success.

But then Ruckdeschel was ousted, along with 150 of the center's 330 employees. "I highly respected Jack," Holmen said. "I thought he was doing a good job in trying to make it work. I got really concerned when leadership changed.

"We realized that the worst case scenario was bankruptcy and loss of research, and that wasn't an acceptable option for us at that stage in our career. We decided to start looking elsewhere."

The couple found jobs at the University of Utah. VanBrocklin is an assistant professor at the department of surgery at the university's school of medicine. Holmen is an associate professor in the same department and an investigator at the Huntsman Cancer Institute.

"We were offered fabulous positions," Holmen

said. "With three R01s it's not hard to find a job somewhere else."

In fact, Holmen and VanBrocklin were the only funded investigators at the time they left for Utah. It was a difficult move. The kids were unhappy to go, and the house sits unsold. But at least they were able to get good jobs.

"The folks who didn't have funding had a lot harder time finding alternatives," Holmen said. "And they kept on the hope that UCSD would come in and rescue the place and that they would be okay."

Now, these investigators were told that their time is up.

"What we have heard is that research is finished," Holmen said. "UCSD is not going to continue basic research there.

"The investigators there have until the end of this month to wrap up."

PSA Screening

Similar Opposition Measures In N.Y., Pennsylvania, Maryland

(Continued from page 1)

The task force has already given a D rating to PSA screening for men over 75.

The state legislature passed a joint resolution "memorializing the Congress of the United States to seek the withdrawal of the United States Preventive Services Task Force recommendation against prostate-specific antigen-based screening for prostate cancer for men in all age groups."

The resolution was signed by Governor Chris Christie on Jan. 17 and sent to the presiding officers in Congress, as well as each member of New Jersey's Congressional delegation. New Jersey is the first state to pass such a bill since the task force made its recommendation public in October of last year (The Cancer Letter, Oct. 7, 2011).

The resolution criticized the USPSTF for not having a urologist or oncologist on the task force when they made their recommendation.

According to the resolution, the USPSTF recommendation "puts the men who are most at risk in harm's way: specifically, the underinsured, those who live in areas where health care is not readily available, those who have a family history of prostate cancer and African-American men who have a substantially higher prostate cancer incidence rate than white men and more than twice the prostate cancer mortality rate of white men."

The measure was supported by the New Jersey Patient Care Access Coalition, led by David Taylor, chairman of the coalition's board and a practicing urologist in New Jersey. "Hopefully this will send a loud and clear message to Washington that this flawed recommendation should not stand," Taylor said in a statement.

A D rating from USPSTF means that there is "moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits."

The task force's draft paper concluded that "PSA-based screening results in small or no reduction in prostate cancer-specific mortality and is associated with harms related to subsequent evaluation and treatments, some of which may be unnecessary."

Members of the Large Urology Group Practice Association "have already developed similar measures to the New Jersey resolution in Maryland, Pennsylvania and New York, and will continue to work on both state and federal levels to increase public awareness of this issue," said Deepak Kapoor, president of the association.

David Penson, health policy vice chair of the American Urological Association, said, "Other states should take notice of New Jersey's impressive and decisive stand against the USPSTF recommendations and the positive step forward in ensuring coverage of the PSA test for men in New Jersey."

FDA News

FDA Proposes New User Fees For Generics and Biosimilars

By Conor Hale

FDA recommended the creation of two new user fee programs, aimed at generic drugs and biosimilars, in an effort to increase the approval rate of these products.

The program recommendations were sent to Congress by the HHS Secretary Kathleen Sebelius, to be considered alongside the fifth reauthorization of the Prescription Drug User Fee Act, which will expire by the end of September.

FDA plans to collect $299 million annually for five years from the generic pharmaceuticals industry, beginning Oct. 1 of this year. The money would be used to hire additional scientific reviewers for the administration, helping FDA meet its goal of reviewing 90 percent of applications in under 10 months.

These new programs come at a time when generic drugs—especially injectable drugs used in oncology—are in short supply. The new programs will be modeled after PDUFA, which has been FDA policy for 20 years.

According to FDA, fees paid by the industry under the Generic Drug User Fee program would support a timely review of prescription drugs, advance drug development for rare diseases, enhance communication with small or emerging companies, increase the use of standardized electronic data, and foster the use of new clinical endpoints that improve drug development times.

Although drug supplies are low, applications for new generic drug are on the rise. FDA receives between 800 and 900 new applications annually—and generics account for over two-thirds of all prescriptions dispensed in the U.S.

The proposed Biosimilar and Interchangeable Products User Fee program is intended for products approved through a new, abbreviated pathway for biological products shown to be biosimilar or interchangeable with a FDA-licensed product.

These products have minor differences in clinically inactive components and have no meaningful differences from the licensed product in terms of safety, purity or potency. The abbreviated approval pathway was established by the Affordable Care Act healthcare reform law.

"These final recommendations offer a great example of what can be achieved when the FDA, industry and other stakeholders work together on the same goal," said FDA Commissioner Margaret Hamburg. "At a time of greater budgetary constraint, user fees provide a critical way for leveraging appropriated dollars, ensuring that FDA has the resources needed to conduct reviews in a timely fashion."

"We look forward to working with members of Congress in the weeks and months ahead to ensure that the final program is one that expedites access to low-cost, high-quality generic drugs for Americans and further safeguards the quality and accessibility of our nation's drug supply," said Ralph Neas, president and CEO of the Generic Pharmaceuticals Association.

A subcommittee of the House Committee on Energy and Commerce will hold a hearing Feb. 1 to discuss the reauthorization of PDUFA. Hamburg is expected to testify. The committee will hold another hearing Feb. 7, focused on the proposed user fees for generics and biosimilars, as well as on the FDA's backlog of generic drug applications.

Follow us on Twitter: @TheCancerLetter

In Brief

MSKCC Receives $50 Million For Surgery Center, Investigators

MEMORIAL SLOAN-KETTERING Cancer Center received a $50 million commitment from **The Robertson Foundation** for two new initiatives in honor of Josephine "Josie" Robertson: a surgery center and an investigators program.

The Josie Robertson Surgery Center will be a 16-story, 179,000-square-foot building built in Manhattan's East Side, featuring 12 operating rooms. It is scheduled for completion in 2015.

The Josie Robertson Investigators Program will recruit ten young physicians and scientists in the first five years of the program. Each appointment will last for five years.

Robertson was elected to Memorial's board of overseers in 2004 and worked as a director and member of the Breast Cancer Research Foundation. She died in 2010.

ANTHONY ZIETMAN began his tenure as editor of the International Journal of Radiation Oncology·Biology·Physics Red Journal, the **American Society for Radiation Oncology**'s primary research journal.

Zietman and his team of nine senior editors and 38 associate editors follow James Cox, who stepped down last year after 15 years of service to the Red Journal and ASTRO.

"Jim Cox and his staff and senior editors have done a remarkable job over the past 15 years, raising the number of submissions to nearly 2,000 per year and increasing the impact factor to more than 4.5," Zietman said. "I am humbled yet incredibly excited to take the helm of this journal."

Under Zietman's management, the journal is making several changes: switching to double-blind review; enhancing disclosure statements; instituting a $75 submission fee for clinical manuscripts; improving page layout; enhancing online features; featuring cover art submitted by team members; and highlighting articles outside the Red Journal.

The editorial offices of the Red Journal will be moved from MD Anderson Cancer Center to the ASTRO headquarters in Fairfax, Va., where ASTRO has hired a full-time editorial staff to assist Zietman's team as well as to support the society's new complementary clinical practice journal, Practical Radiation Oncology.

THE BONNIE J. ADDARIO Lung Cancer Foundation awarded over $1 million in grants for lung cancer research, immediate results-oriented projects and programs focusing on early detection, genetic testing, drug discovery or patient-focused outcomes.

The awardees are:

• **Guoan Chen**, assistant research professor in thoracic oncology at the University of Michigan, for "Discovery and Validation of Serum Micro-RNAs for Lung Cancer Diagnosis and Prognosis," with the primary objective to detect lung cancer earlier and reduce the mortality of NSCLC.

• **Rolf Craven**, associate professor in the Department of Molecular and Biomedical Pharmacology at Markey Cancer Center College of Medicine, for "S2R (Pgrmc1): sigma-2 receptor as a therapeutic target in Lung Cancer," with the primary objective to develop new therapeutic and diagnostic strategies for erlotinib-resistant lung cancer.

• **Carlo Maley**, associate professor and director of the Center for Evolution and Cancer at the University of California, San Francisco and Natalie Lui, surgery resident in the university's Thoracic Oncology Program, for "Within Tumor Genetic Diversity in Lung Cancer," with the primary objective to determine whether genetic diversity at treatment predicts survival in patients with adenocarcinoma, ultimately leading to a greater understanding of lung cancer's response to therapy.

• **Jiantao Pu**, assistant professor at the University of Pittsburgh School of Medicine, for "Diagnosis-by-Search: Enabling Early Detection & Accurate Diagnosis of Lung Cancer," with the primary objective to develop a novel computer-aided diagnosis system.

The funding includes young investigator awards through the foundation's advisory board, "Jill's Legacy":

• **James Kim**, assistant professor at the Harmon Center for Therapeutic Oncology Research, for the "Role of Hedgehog pathway activity in human Lung Cancer with mutant K-ras," with the primary objective of determining the relationship between mutant K-ras and the Hh pathway and identify other Hh-dependent proteins that may be important for tumor growth.

• **Naveen Kommajosyula**, research fellow at Dana-Farber Cancer Institute, for "PARP Inhibition in NSCLC," with the primary objective of determining the basis of PARP inhibitor sensitivity, and to identify NSCLC appropriate for PARP inhibitors in clinical trials, characterize these mutations, and discover lung cancers harboring deleterious ATM mutations sensitive to PARP inhibitors.

ST. JUDE CHILDREN'S RESEARCH HOSPITAL launched a website for published research results from the Pediatric Cancer Genome Project, a collaboration between St. Jude and **Washington University School of Medicine in St. Louis**. The project aims to sequence the entire genomes of normal and cancer cells from pediatric cancer patients and compare the differences in the DNA.

The website, http://explore.pediatriccancergenomeproject.org, is designed to expand access to the genomic data, accelerate discovery and hypothesis testing, provide comprehensive visualizations of the data, and allow clinical and basic researchers to search published results.

The project began in January 2010, and has sequenced more than 250 sets of pediatric genomes to date. The work has been featured in two papers recently published in Nature: one focusing on the genetic basis of early T-cell precursor ALL, and one on retinoblastoma.

"The entire research community will now be able to mine this rich set of findings," said Clayton Naeve, chief information officer at St. Jude. "Access to the genome project's user-friendly data website is a step in that direction."

Funding Opportunities

AACR Accepting Applications In Carcinoid, pNET Research

THE AMERICAN ASSOCIATION FOR CANCER RESEARCH is accepting applications for the 2012 Caring for Carcinoid Foundation-AACR Grants for Carcinoid Tumor and Pancreatic Neuroendocrine Tumor Research.

At least two two-year grants of $125,000 a year are open to independent, institution-affiliated junior and senior investigators to study approaches that have direct application and relevance to carcinoid tumors or pancreatic neuroendocrine tumors.

Proposed research may be in any discipline of basic, translational, clinical or epidemiological cancer research. Applications will be accepted from researchers currently in the field and those with application experience in other areas of cancer research.

Applications are due Feb. 1, by 12:00 p.m. ET. For more information, visit: http://www.aacr.org/CFCF.