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Colorado Institutions Vying to Build First Carbon Ion Center in the U.S.

By Paul Goldberg

The University of Colorado and Colorado State University are vying to become the first institution to build a carbon-ion radiotherapy research and treatment facility in the U.S. The treatment modality is available in Europe and Japan.

Officials at the two universities are exploring the feasibility of building a \$300 million research and treatment facility at the University of Colorado Anschutz Medical Campus in Aurora.

Their first step is to conduct a \$200,000 feasibility study for the project. (Continued to page 2)

<u>Conversation with The Cancer Letter</u> **Pat White: NIH Funding "Our Only Concern"**

A lobbying campaign will make an effort to secure an immediate, significant funding increase for NIH.

The effort, called ACT for NIH: Advancing Cures Today, seeks to bring together patients, scientists, advocates, and lawmakers on both sides of the aisle. Their objective is to demonstrate the impact of a decade of clamping down on NIH funding. Adjusted for inflation, NIH receives nearly 25 percent less funding than it did in 2003.

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Gonzalez-Angulo Found Guilty In MD Anderson Poisoning Case

By Leonard Zwelling

HOUSTON—Ana Maria Gonzalez-Angulo, a 43-year-old breast cancer specialist at MD Anderson Cancer Center, was found guilty of poisoning her lover, George Blumenschein, another medical oncologist at MD Anderson.

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NCI Hoping to Study Carbon Ion Before it Reached U.S. Shores

(Continued from page 1)

They have signed a memorandum of understanding to pursue the project with University of Colorado Health's Poudre Valley Hospital in Fort Collins and with the National Institute of Radiological Sciences in Japan.

According to industry estimates, carbon ion radiation therapy centers cost twice as much to construct as proton beam centers.

The NCI Board of Scientific Advisors recently approved a concept to conduct a randomized controlled trial to determine the safety and efficacy of carbon ion therapy at existing facilities in Japan, before such centers are constructed in the U.S. (The Cancer Letter, July 3).

"Cancer experts at CSU have worked for several years with colleagues at the CU School of Medicine and NIRS to explore the possibility of a carbon-ion research and treatment facility in Denver," Mark Stetter, dean of the CSU College of Veterinary Medicine and Biomedical Sciences, said in a statement. "It's clear that our collaboration offers distinct advantages for an international carbon ion center that would provide truly needed help for animal and human cancer patients."

The project would have the following features:

• Partnership with Japanese experts;

• Expertise at the CU Cancer Center;

• A home base on the Anschutz Medical Campus, which provides adult and children's oncology research and treatment;

• A patient transfer pilot project between Poudre Valley Hospital and NIRS;

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• Radiation research and training programs at CSU; and

• Animal oncology work at the CSU Flint Animal Cancer Center.

"As we've seen since 2008, when the CU Anschutz Medical Campus became fully up and running, stateof-the-art medical research and treatment facilities are an advantage to the entire region because they help patients while also generating scientific knowledge, innovation and economic development," Richard Krugman, vice chancellor for health affairs for the University of Colorado Denver and dean of the CU School of Medicine, said in a statement. "We're excited to be part of a collaboration that will offer one-of-a-kind carbon-ion research and treatment here in Colorado."

Money for the feasibility study comes from CU, CSU and key university units involved in the project, officials said.

"The program will allow us to send our patients that qualify to Japan for this treatment," Miho Scott, medical oncologist with University of Colorado Health and team lead for patient transfer, said in a statement. "Once approved, travel and medical care are coordinated through our program."

NCI to Conduct Randomized Trial of CIRT

Data coming from single-arm studies of CIRT in unresectable pancreatic cancer show a potential twoyear survival rate of 54 percent. With standard therapies, the two-year survival rate is less than 10 percent.

There are no randomized controlled trials of CIRT underway.

By conducting the trial outside the U.S., where no CIRT centers are in operation, NCI also seeks to head off the problem now observed with proton beam, a technology being rapidly adopted throughout the U.S. ahead of conclusive evidence from randomized trials (The Cancer Letter, <u>Aug. 1</u>; <u>June 20</u>; <u>Oct. 25</u>, 2013).

The proposal approved by BSA at the June 22-23 meeting sought to conduct a five-year randomized trial in Japan—a country heavily invested in carbon ion radiation therapy but with no previous or planned randomized trials—at a cost of \$2 million per year.

Though the board supported the study and unanimously approved it, comparative data are needed for all radiation modalities, several BSA members said.

"Should we consider doing this with photons, protons, and carbon?" BSA member Kevin Cullen, director of the Marlene and Stewart Greenebaum Cancer Center at the University of Maryland, said at the BSA meeting. "Because if you don't, if the trial is positive, people are going to say, 'Aha! We should build carbon facilities on every corner of the block.' And if it's negative, then people will still say, 'Maybe protons are better.' So you leave big questions that are going to have seismic implications in terms of how we're spending our resources building facilities."

"My concern would be that the results from this single study might be used to fill machines with patients with breast cancer or prostate cancer, where, in fact, there may be harms associated with the treatment, let alone lack of benefit," said BSA member Ethan Basch, director of the Cancer Outcomes Research Program at the University of North Carolina Lineberger Comprehensive Cancer Center.

Tessa Vellek and Will Craft contributed to this story.

<u>Conversation with The Cancer Letter</u> White Left NIH To Lobby For It

(Continued from page 1)

When appropriations were high, one in three research proposals was funded. Now, the success rate is one in six, the lowest in history. In some areas, the success rate is as low as one in ten.

The campaign is coordinated by Pat White, who recently left the position of associate director for legislative policy and analysis at NIH.

The advisory committee members are:

• <u>David Baltimore</u>, president emeritus of the California Institute of Technology,

• <u>Ronald DePinho</u>, president of MD Anderson Cancer Center,

• Jennifer Doudna, professor at the University of California, Berkeley,

• <u>Bernadette Gray-Little</u>, chancellor of the University of Kansas,

• <u>Michael Milken</u>, advocate for research innovation and public health,

• <u>Ronald Petersen</u>, director of the Mayo Alzheimer's Disease Research Center and professor of neurology at the Mayo Clinic College of Medicine.

The ACT for NIH campaign is underwritten by Jed Manocherian, founder and chairman, who is a member of the MD Anderson Cancer Center Board of Visitors. His brother, Greg Manocherian, is vice chairman. The Manocherians are real estate investors and developers.

Announcing White's departure from NIH in July, NIH Director Francis Collins said:

"Pat has the opportunity to lead a new and profoundly important advocacy effort on behalf of the NIH. Pat and his team will push for an immediate reversal in the last decade's decline in NIH's resources, making instead a compelling case for long-term, stable growth."

The campaign's website is <u>www.ACTforNIH.org</u>.

White spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

Paul Goldberg: *What are you doing that no one else is doing?*

Pat White: We are running a very tightly focused effort to try and restore the lost purchasing power from the last ten years of a flat and declining NIH budget.

PG: *How are you doing it in a way that no one else is?*

PW: First of all, it's our only goal. While other very effective actors in the community have NIH as one of their priorities, they also often have other objectives. Our only concern is NIH funding.

PG: *What are the sources of your funding?*

PW: Our campaign is being funded by Jed and Greg Manocherian. They are real estate investors and developers. And Jed is on the Board of Visitors of the MD Anderson Cancer Center, and that is how he learned about the crisis in biomedical research funding, and determined to act to try to fix it.

PG: *How much money have they committed?*

PW: He hasn't made a commitment yet. He has been very generous. A lot of what we end up doing will be dictated by what our strategy and tactics are. So right now there's not a top-line dollar figure.

PG: You're a long-time Washington hand. How did they talk you into doing this?

PW: Well, first of all, the zenith of my career has been working at the right hand of Francis Collins for the last almost five years.

But what I realized is that no matter how hard Francis worked, no matter how hard we at NIH worked, we were not going to be able to influence the policy and funding discussion—in a way that my leaving government and taking up this effort would allow me to do.

PG: So what are you going to do?

PW: We've retained a lobbying firm, we've retained a PR team, and the idea is to, essentially, start a dialogue and work with any member of Congress, on a bipartisan basis, to try and make NIH a priority.

PG: *How will you do this?*

PW: We are approaching potential NIH champions—people who have either spoken up or

acted on behalf of NIH over the last couple of years and raised with them the possibility that, either in the upcoming lame duck session or next spring as the budget and perhaps reconciliation process gets underway, that NIH should be made a priority.

PG: *Do you have a constituency beyond these individuals?*

PW: No I don't, and that's actually a very important thing about this campaign.

First of all, it's complimentary to all the good work that other groups in town are doing, and we have reached out to people like FASEB, AAMC, AAU, APLU, and Research!America to ask their help and advice.

People are already working with us, and there was an explosion today in social media with our friends and colleagues from other advocacy organizations helping amplify our message and our launch.

We're all in this together and I'm try to provide new and additional help.

PG: Who is "we," by the way? Who's working for you?

PW: We've retained Cornerstone Government Affairs as our lobbying firm, and they are probably the top firm in the health appropriations arena.

We have one additional person on staff—his name is Mike Zwolinski, and you can read about him on our webpage. He was at the Association of Schools and Programs of Public health before joining ACT for NIH.

Gonzalez-Angulo Found Guilty In MD Anderson Poisoning Case

(Continued from page 1)

A jury at the Harris County 248th District Criminal Court found Gonzalez-Angulo <u>guilty of aggravated</u> <u>assault</u> Sept. 26. The court immediately went into the penalty phase of the proceedings.

The jury reached its guilty verdict after deliberating for a total of four hours spread over two days.

The case against Gonzalez-Angulo was largely circumstantial. Prosecution was able to establish that Blumenschein was poisoned with ingested ethylene glycol on the morning of Jan. 27, 2013. However, the case circumstantially connected the poison to the coffee that may have been served to him by Gonzalez-Angulo.

Much was been made of the Fatal Attraction-like portrayal of the case—it's tabloid fodder, slimy yet solid and even instructive. Of course, office romance involving peers isn't against the law, but in some situations it can be corrosive. Long before the alleged poisoning, this was one such situation, witnesses said.

Over the past two weeks in this courtroom, prosecutors have, in effect, demonstrated the corrosive effect of this office romance and the manner in which it affected the conduct of business at MD Anderson.

Here in the courtroom, we saw that many smart, caring people—many of whom were doctors, and some of whom were friends of both the victim and the defendant—knew about this affair. It wasn't difficult to grasp the effects of this relationship on those in the work place and more importantly, the toll it was taking on both physicians.

At least two faculty members sensed the high probability of a catastrophe and even tried to stop it from occurring. One confronted each of the two investigators and asked whether they were having an affair. According to court testimony, both Gonzalez-Angulo and Blumenschein lied.

Another senior faculty member was suspicious that some of the work the two were doing was competing with the well-established phase I program at MD Anderson (The Cancer Letter, <u>Sept. 19</u>).

Yet no supervisor intervened.

Friends were aware of the defendant's inner turmoil. She was losing weight and was becoming more emotional, agitated and angry, witnesses said.

Before Blumenschein's poisoning, Gonzalez-Angulo claimed that she had been mugged. Details of the incident struck many as suspicious as her accounts seemed to be inconsistent, witnesses said.

Her bruises didn't fit the story either, and her friends—all of them physicians—said in court that they knew it.

Yet no one said or did anything. No one tried to turn the tide.

Also, there were anonymous letters and accusations of conflicts of interest aimed at Blumenschein.

Even after the poisoning, a cascade of anonymous letters pointed out that Blumenschein was a principal investigator on studies sponsored by GlaxoSmithKline, the employer of his live-in girlfriend, who has a Ph.D. in clinical epidemiology. (According to testimony, the two were trying to start a family.)

Many of these letters had Gonzalez-Angulo's first name and Blumenschein's last name consistently misspelled.

According to testimony, a GSK investigator compared the voice on audiotapes Blumenschein made of Gonzalez-Angulo's calls to him after his near-fatal poisoning to calls into the GSK hotline for conflicts of interest. The GSK investigator identified the caller as

Gonzalez-Angulo.

It is not clear whether Blumenschein will have the career he seemed certain to enjoy for another 20-ormore years before this dalliance. His life expectancy is altered because his renal function is still only 43 percent of what it was.

The toll on Gonzalez-Angulo was visible to the naked eye even before the jury reached the verdict. Her complexion, her hair, and her suits all match: all are grey.

The author, a former physician-scientist and administrator at MD Anderson, covered the trial on his blog, lenzwelling.blogspot.com.

<u>Guest Editorial</u> "Gizmo Idolatry" and Marketing Da Vinci's Radical Robot

By Richard Ablin and Ronald Piana

In America, cutting-edge inventions are seen as the gateway to the future. However, the hazard of credulously accepting new technology into medical practice was warned against in a 2008 Journal of the American Medical Association editorial "Gizmo Idolatry."

The term "gizmo idolatry" describes the conviction that a high-tech approach is better than a low-tech approach, even if there's no evidence to support that view. A glaring example of medical "gizmo idolatry" is the da Vinci Surgical System. Without credible data to prove its safety and benefit in complex surgeries, this costly robotic machine has been promoted into near ubiquitous use in hospitals across the nation.

The da Vinci surgical robot; however, is merely a symptom of the larger malady in our fee-for-service healthcare system, which is inundated with exorbitant drugs and medical technologies of unproven value.

Developed by Intuitive Surgical, the da Vinci Surgical System was approved by the FDA in 2000 for soft-tissue surgery. The approval was based on a trial conducted by Intuitive Surgical. Aside from the obvious conflict-of-interest, the trial had another problem: When 113 men who had da Vinci robotic surgery were compared to 132 men who had standard laparoscopy, the

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robotic surgery was no more effective than laparoscopy. More disconcerting, the surgery used in the study was gallbladder removal. This simple procedure is as far removed as can be imagined from the incredibly complex challenge of radical prostatectomy, for example, with its devastating side effects of incontinence and loss of sexual function.

After gaining FDA approval, da Vinci's marketing team sought out a target-rich environment: men with prostate cancer who were encouraged by their urologists to have radical prostatectomies. Using glowing website testimonials, talking-head doctors, and seductive radio and billboard ads, the da Vinci robotic prostatectomy was promoted as a "minimally invasive" procedure. True, a robotic prostatectomy involves smaller incisions, so there's usually less blood loss and a faster recovery time. But for the big three outcomes—saving lives, urinary control, and sexual function—there were no data proving that da Vinci robotic surgery was any better than traditional laparoscopy for prostatectomy.

Lack of data didn't deter Intuitive Surgical. They had a marketer's dream: a robot, which connotes exacting precision, named after Leonardo Da Vinci, one of history's inventive titans. Equally important, being the only FDA-approved robotic system for soft tissue surgery, Intuitive Surgical had a monopoly on the prostate cancer market.

During the decade since its approval, use of the da Vinci Surgical System for radical prostatectomy has skyrocketed. According a National Cancer Institute Cancer Bulletin, by 2011, four of five radical prostatectomies in the U.S. were performed by the da Vinci robot. The NCI also stressed that da Vinci's cornering of the market "had numerous consequences, including a mass migration of prostate cancer patients to hospitals with robotic systems and an overall increase in the number of prostatectomies performed each year... the trend has raised some concern because it coincides with a period during which prostate cancer incidence has declined slightly."

Given the financial reality of da Vinci, mass migration to hospitals seems an intended consequence. Each da Vinci robot costs close to \$2 million, plus a \$150,000 per year service contract. Some hospitals have several units. In order to amortize the loans, pay the huge service contracts, and turn a profit, hospitals need to create their own supply and demand chain, using the radical prostatectomy as their cash cow.

And they do.

Fox News medical contributor, Dr. David B. Samadi, chief of robotic surgery at Lenox Hill Hospital,

gloats of doing an astounding 15 robotic radical prostatectomies a week. To date, the globe-hopping urologic surgeon has done close to 6,000 robotic prostatectomies. Samadi's claims of cures and better side effects outcomes are not backed up by convincing evidence. The logic used to push radical prostatectomies comes from a mountain of skewed and debatable data, such as large retrospective studies out of the troubled and corrupt Veterans Health Administration system.

Also, since the vast majority of prostate cancers are non-threatening, there's a lack of benefit to treating screen-detected prostate cancers. The U.S. Preventive Services Task Force has validated this; however, the American Urological Association and the FDA lack the fortitude to address this public health issue.

One fact remains irrefutable: Only 3 percent of all men diagnosed with prostate cancer will die of the disease; the other 97 percent will die of another cause, such as old age. The lasting damage done to 97 percent of men in an effort to save 3 percent using a procedure with uncertain benefits is simply unconscionable.

We should divert our wasted resources into finding a cure.

The da Vinci Surgical System is a boondoggle for healthcare. The FDA's own product safety system, MAUDE (Manufacturer and User Facility Device Experience), has pages of self-reported harms associated with da Vinci. A quick Google search turns up dozens of product-liability lawsuits filed against Intuitive Surgical. A class action suit may follow.

America's healthcare system needs innovative ideas and new technologies. What our overburdened system does not need is vastly expensive technologies that dazzle us with their futuristic appeal, but offer little to no benefit. We have far too much of that, and the da Vinci Surgical System is proof.

Richard Ablin is professor of pathology at the University of Arizona College of Medicine, The Arizona Cancer Center and the BIO5 Institute, and, with Ronald Piana, is the author of the recently published book The Great Prostate Hoax: How Big Medicine Hijacked the PSA Test and Caused A Public Health Disaster.

Piana is a science writer specializing in oncology.

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MD Anderson Expands Reach Into Florida, Georgia, Ohio

By Paul Goldberg

Two institutions said they are in varying stages of completing partnerships with MD Anderson Cancer Center.

The two deals are a part of an expansion strategy that essentially means that the MD Anderson logo can light up almost anywhere, establishing the Houstonbased cancer center as a potential competitor to almost any cancer center in the U.S.

• Baptist Health of Jacksonville and MD Anderson announced on Sept. 24 that they have signed a letter of intent to create a joint cancer center in North Florida next year, and, separately,

• Columbus-based OhioHealth announced that the system is Ohio's first certified member of MD Anderson Cancer Network

The Florida deal would make Baptist Health a partner member of MD Anderson Cancer Network, the highest level of linkage offered by the Houston-based cancer center.

As a partner, Baptist Health will be operationally and clinically integrated with MD Anderson, the parties said. There are currently two other MD Anderson partners in the U.S.: the Banner MD Anderson Cancer Center in Arizona and MD Anderson Cancer Center at Cooper in Camden, N.J.

The Ohio deal doesn't entail such close linkage. The health system will become one of <u>15 MD Anderson-</u> <u>certified sites</u>.

"This is truly a game-changer," Hugh Greene, president and CEO of Baptist Health, said in a statement. "MD Anderson is recognized as the leader in cancer care in our nation and across the globe. With such an incredible partner, we intend to transform cancer care in our region and provide even more hope and courage for our cancer patients and their families."

Baptist Health includes five hospitals with 1,154 licensed beds, 1,658 medical staff and more than 250 outpatient facilities throughout northern Florida and southern Georgia.

"With Baptist Health, MD Anderson found an already-strong cancer program that is committed to enhancing its care and contributing to our mission," Thomas Burke, executive vice president of MD Anderson Cancer Network, said in a statement.

The new collaboration gives MD Anderson a new foothold in Florida. Earlier this year, another hospital system, Orlando Health ended its 23-year long-distance relationship with MD Anderson and forming a bond with the University of Florida in Gainesville. The two institutions are integrating their cancer programs to form the UF Health Cancer Center (The Cancer Letter, Jan. 10).

When MD Anderson's affiliation with OhioHealth is completed, eight OhioHealth hospitals and more than 100 OhioHealth medical oncologists, radiation oncologists and oncology surgeons will be certified members of MD Anderson Cancer Network.

"This collaboration will help advance cancer care in the communities that OhioHealth serves while still keeping that care local for patients and their families," Dave Blom, president and chief executive officer of OhioHealth, said in a statement.

The Ohio collaboration places an MD Anderson sign squarely in the territory of a premier NCIdesignated comprehensive cancer center: the Ohio State University Comprehensive Cancer Center-James Cancer Hospital and Solove Research Institute.

Similarly, the Florida deal would place MD Anderson in competition with the NCI-designated H. Lee Moffitt Cancer Center.

The Camden facility, too, is in close proximity of three NCI-designated comprehensive cancer centers: the University of Pennsylvania, Fox Chase Cancer Center, and Thomas Jefferson University (The Cancer Letter, June 21, 2013).

MD Anderson's aggressive branding strategy is guided, at least in part, by a business plan created under a \$1.6 million contract with McKinsey & Company, a consulting firm often engaged by financial institutions, pharmaceutical companies, and multinational corporations (The Cancer Letter, Feb. 7).

In a PowerPoint presentation marked "CONFIDENTIAL AND PROPRIETARY" and obtained by The Cancer Letter earlier this year, McKinsey described a "robust national strategy" aimed primarily at non-academic hospitals and health systems.

The schema describes tiers of affiliation that has a clear take-home message: an MD Anderson network institution—possibly sporting the MD Anderson sign on the building—can pop up anywhere in the U.S.

The proposal would place four to eight new partner institutions into top-tier markets, with up to 30 affiliates over a decade.

The business strategy presentation, dated March 12, 2012, is posted <u>on The Cancer Letter website</u>.

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NCI Starts "Exceptional Responders" Study

By Paul Goldberg

NCI has launched a pilot study to investigate the molecular factors of tumors associated with exceptional treatment responses of cancer patients to drug therapies,

The <u>Exceptional Responders Initiative</u> seeks to identify the molecular features of tumors that predict whether a particular drug or class of drugs will be beneficial.

The observational study would seek to recruit 300 patients, all of them at NIH. To be eligible for the study, patients must have documented exceptional response, defined by the following criteria:

• Received a treatment in which less than 10 percent of patients are expected to have a complete response, or a durable (at least 6 months) partial response; the proportion of objective responses for the trial or clinical setting in which the patient's response was observed should be expected to be less than 10 percent (in the patient's cancer type).

• Achieved either a) a complete response, or b) a partial response with duration at least 6 months, as defined by Response Evaluation Criteria in Solid Tumors criteria for solid tumors or response criteria for tumors where RECIST is not commonly used, when treated with the particular agent.

• Patients exceptional response was observed while enrolled on a completed clinical trial of an investigational agent, investigational combination, or standard therapy that is not considered effective for greater than 10 percent of the population with the patient's tumor type.

• Required tumor samples must exist and be able to be submitted; investigators wishing to submit samples must not have made agreements that would prohibit this submission.

• Tumor tissue from prior to administration of the drug to which the exceptional response occurred is required; ideally this sample will have been collected just prior to treatment, but other prior tissue will be considered; tissue may be fresh frozen or formalinfixed paraffin embedded.

DNA and RNA from tissue samples will be isolated at the Biospecimen Core Resource at Nationwide Children's Hospital, in Columbus, Ohio. Those isolates will then be shipped to a DNA sequencing and analysis center at Baylor University in Houston. "The feasibility of this approach is supported by reports in the literature of relevant mutations in tumor specimens from patients who experienced an exceptional response to a drug in a clinical trial, even though that drug failed to meet the trial's endpoint for clinical benefit," Louis Staudt, director of the NCI Center for Cancer Genomics, a co-leader of the study, said in a statement.

"The increasing ability of molecular technologies to stratify tumor types by prognosis or response to treatment will result in many common cancers being separated into specific subtypes that may respond to drugs in very different ways," co-lead investigator Barbara Conley, of the NCI Division of Cancer Treatment and Diagnosis, said in a statement. "The ability to identify molecular markers that are able to predict a clinical response in these subsets of patients will provide us with the tools to further advance our ability to conduct studies consistent with the principles of precision medicine."

The study will also examine the feasibility of conducting a larger exceptional responder study. The output of this initiative might include a list of plausible mutations, possible mutations, or simply all the mutations found in the exceptional responder cases.

A Q&A about the study <u>is available on their website</u>. Additional questions from investigators, physicians, and hospitals looking to contribute tumor samples can be sent by email to <u>NCIExceptionalResponders@mail.nih.gov</u>.

Exceptional Responders Initiative is one of a new generation of studies started by NCI. Others include:

• Lung-MAP, a clinical trial for second-line treatment of non-small cell lung cancer. The trial, also called Lung Cancer Master Protocol or SWOG S1400, uses the patients' tumor characteristics to select one of five targeted therapies, comparing them with active control in each arm (The Cancer Letter, June 20).

• ALCHEMIST, or Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial, which will test an ALK inhibitor and an EGFR inhibitor in patients with selected mutations who have early stage, resectable lung cancer. The trial will screen over 7,000 patients nationwide over the next five years. Those who don't have the select mutations will be followed and their genomes studied (The Cancer Letter, <u>Sept. 5</u>).

• The Molecular Profiling based Assignment of Cancer Therapeutics trial, or M-PACT, was initially launched at NCI. The trial will eventually be opened to researchers in the institute's <u>Early Therapeutics Clinical</u> <u>Trials Network</u> (The Cancer Letter, <u>Feb. 21</u>).

<u>In Brief</u> Doug Ulman Named CEO Of Fundraiser Pelotonia

DOUG ULMAN was appointed president and CEO of **Pelotonia**, a cycling fundraiser that has raised more than \$61 million for cancer research. Ulman is president and CEO of the LIVESTRONG Foundation.

A three-time cancer survivor himself, Ulman will also work on behalf of The Ohio State University Comprehensive Cancer – James Cancer Hospital and Solove Research Institute. He also plans to be involved in the academic, business and health communities of Columbus.

The new \$1.1 billion, 21-level James Cancer Hospital and Solove Research Institute will open in December 2014. Every dollar raised by Pelotonia riders will fund the research at the OSUCCC – James, according to a statement from Pelotonia.

"With cuts in federal funding for cancer research, Pelotonia has been critical to the mission of the OSUCCC – James," said Michael Caligiuri, director of university's cancer center.

MARGARET FOTI, chief executive officer of the American Association for Cancer Research, received the Ellen V. Sigal Advocacy Leadership Award from **Friends of Cancer Research** at its Cancer Leadership Awards Reception in Washington, D.C.

During her long tenure as CEO, AACR membership has grown from 3,000 to more than 35,000 laboratory, translational, clinical, and population scientists; other health care professionals; and cancer advocates in 97 countries.

The organization opened its Washington, D.C. office in 2007 to engage with policymakers on Capitol Hill. Under Foti's direction, the organization spearheaded a Rally for Medical Research in downtown Washington, D.C. in April 2013.

CITY OF HOPE and **Wilshire Oncology Medical Group** have reached an agreement in which Wilshire physicians will join City of Hope Medical Group in California, delivering care to patients through new community practice sites in Glendora, Pomona, Rancho Cucamonga, West Covina and Corona.

The five new locations opened on Sept. 22.

The agreement extends City of Hope's geographic footprint east of its main Duarte, Calif., location. Current patients of Wilshire Oncology Medical Group physicians should not see any disruption in their care during the transition. THE WEST CLINIC received the National Committee for Quality Assurance Recognition as a Patient-Centered Specialty Practice for its responsiveness to patients and medical colleagues, cooperation and integration with other health care groups, and dedication to continuous improvement.

The West Clinic met or exceeded national standards for: communicating with primary care clinicians and establishing coordinated care plans; providing timely access to care and clinical advice based on patient need; using a systematic approach to track referrals and coordinate care; and measuring and improving performance over time.

PCSP recognition is modeled on and complements NCQA's Patient-Centered Medical Home Recognition program. PCSP recognition highlights the "neighbors" in medical specialties that surround and inform the medical home and colleagues in primary care.

FDA awarded **The Critical Path Institute** \$2.1 million for the first year of funding of a five-year grant.

The grant offers a potential \$10.5 million over five years. This is the second five-year grant that the institute has received from FDA under the Critical Path Initiative program.

The institute is an independent, non-profit organization established in 2005 with public and private philanthropic support from the Arizona community, Science Foundation Arizona, and FDA. It has focused on developing biomarkers to more accurately predict organ-specific toxicity; establishing databases with standardized, aggregated, and integrated data; advancing biomarker and clinical outcome assessment tools in disease areas such as Alzheimer's disease, Parkinson's disease, multiple sclerosis, non-small cell lung cancer, rheumatoid arthritis, and others; and developing and publishing therapeutic area data standards.

BETH ISRAEL DEACONESS MEDICAL CENTER and **Cancer Genetics Inc.** entered into a collaboration to correlate genomic profiles to outcomes in diffuse large B-cell lymphoma.

Additional genetic markers validated in the

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study will be incorporated into CGI's proprietary test and genetic signature for the prediction of outcome in DLBCL.

Approximately 200 DLBCL tumors from patients previously treated with current frontline immunotherapeutic regimens will be evaluated. The biomarkers assessed will include genomic rearrangements, copy number changes, and mutations.

Copy number changes will be detected by CGI's proprietary MatBA array, which is commercially available as a laboratory developed test and is CLIA and NYS approved. Mutation analysis of a panel of genes known to be altered in DLBCL will be performed by next-generation sequencing.

THE FEDERATION OF AMERICAN SOCIETIES FOR EXPERIMENTAL BIOLOGY published <u>a detailed factsheet</u> about federal research funding in nearly 400 congressional districts.

According to FASEB, each district factsheet presents the number of institutions receiving funding, the total amount of funding, the number of grants received from the NIH, the National Science Foundation, the Department of Energy Office of Science, and the Agriculture and Food Research Initiative of the U.S. Department of Agriculture.

"Federally-funded research has improved health, increased national security and prosperity, and led to the development of innovative technologies," FASEB President Joseph Haywood said in a statement. "These factsheets are a unique resource that demonstrates the direct impact of NIH, NSG and other federal research dollars in each congressional district. This is important information for supports of research to have, whether they are talking with their neighbor or members of Congress."

LISA STOCKMON joined **City of Hope** as chief marketing and communications officer.

Stockmon is currently chief marketing officer and executive vice president of The Leukemia & Lymphoma Society. She will lead City of Hope's branding; advertising; government and community relations; media relations; marketing; publications; events and visitor services; speakers' bureau; public relations; and external and internal communications.

Prior to her role at The Leukemia & Lymphoma Society, Stockmon served as managing director for Time Inc. Content Solutions and as corporate vice president for Brand Planning & Development for Time Warner Cable.

THE FDA DRUG SHORTAGE ASSISTANCE AWARD... There is such a thing!

The agency created it to reward companies for cooperating with regulators to "prevent drug shortages and minimize their impact on public health."

The first winners are:

• The Guerbet Group, a company that worked with FDA to help alleviate the shortage of ethiodized oil injection, an important imaging agent for a variety of patients with certain forms of liver cancer. The company's work included acquiring the new drug application for Ethiodol, a form of ethiodized oil; submitting the relevant applications to restart its manufacture under the trade name Lipiodol; and gaining additional approval for a medically necessary indication that was of critical concern during the shortage.

• The Clinigen Group, a company that helped ensure supplies of a medication needed for patients with AIDS who also have a serious eye condition called cytomegalovirus retinitis. The company's work included acquiring the NDA for Foscavir (foscarnet sodium) injection, and submitting the relevant applications to return the product to market.

THE EUROPEAN HEAD AND NECK SOCIETY and the European Cancer Patient Coalition called for the implementation of a Europewide head and neck cancer early diagnosis awareness program in the European Parliament.

The meeting, hosted by European parliament member Ciprian Tanasescu, is taking place during the second annual Make Sense Campaign Head and Neck Cancer Awareness Week, and will be attended by members of the European parliament, representatives of the European Commission and a panel of European head and neck cancer experts.

"There is a concerning lack of awareness of head and neck cancer and its signs and symptoms, despite it being the sixth most common type of cancer globally. Consequently, over half of patients are diagnosed in the late stages when the survival rate is just 60 percent," said Tanasescu.

QVC and The Fashion Footwear Association of New York presented \$240,000 for breast cancer research to the University of Pittsburgh Cancer Institute and UPMC Cancer Center.

The contribution came from the proceeds of the 20th annual QVC Presents "FFANY Shoes on Sale" event, held last fall to benefit several cancer research centers across the country, including UPCI for the second year in a row. The association gala will be held Oct. 8 in New York City, and the charitable shoe sale is scheduled to air on the QVC network Oct. 16.

The grant will fund metastasis research being led by principal investigators Adrian Lee, Nancy Davidson, and co-investigators Steffi Oesterreich, and Adam Brufsky.

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