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The Raghavan Experiment

With \$500 Million to Draw On, An Iconoclast Invents Rational Care for a Gigantic System

This is the first story in a two-part series exploring an attempt by one regional health care organization to devise a better system for delivery of cancer care to 14,000 new patients a year.

By Paul Goldberg

CHARLOTTE, N.C.—The job offer presented to Derek Raghavan late in 2010 had the look of a dare.

A vast health system in North and South Carolina was asking him to create a better way to practice oncology.

Raghavan, a medical oncologist who came to the U.S. from Australia in 1991, sees this country's healthcare system with clarity of an outsider. His public persona here is shaped largely by years of service on the FDA Oncologic Drugs Advisory Committee, where he established himself as the sort of guy you don't want to match wits with.

The job offer had the feel of Raghavan's own precisely aimed, lethal, Australian-accented remarks.

It boiled down to this:

So Derek, you have, on numerous occasions, trashed the way America treats cancer. You have cast ridicule and moral indignation at the cooperative groups, pharmaceutical companies, the NCI.

Now, create a system that meets your own exacting specifications, old mate.

(Continued to page 2)

Fiscal Cliff

Sequestration Delayed for Two Months While Congress Debates Debt and Budgets

By Conor Hale

Through a series of hurried negotiations and late-night bills, lawmakers in Washington narrowly avoided the worst punishments of the fiscal cliff—but set up another crisis by postponing the automatic federal budget cuts until March 1.

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Capitol Hill

Pres. Obama Signs Recalcitrant Cancer Bill

By Matthew Bin Han Ong

President Barack Obama signed a bill Jan. 2 requiring NCI to develop scientific frameworks for "recalcitrant" cancers.

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The Challenge of a Clean Slate: Raghavan Designs Cancer Care That Functions Rationally

(Continued from page 1)

Raghavan wasn't looking to change jobs. As director of the Cleveland Clinic Taussig Cancer Center, he was expanding that institution's reach. After seven years in Cleveland, the ranking of the clinic's cancer center by US News & World Report went up from No. 46 to No. 9. (It's now No. 6.)

The opportunity Raghavan saw down south was of a different order of magnitude. He was being asked to build rather than rebuild.

Presented with a big empty lot, he could work from the ground up. And the Carolinas Health System was willing to bankroll Raghavan's vision.

It committed \$500 million over ten years.

"For someone who comes from Australia, having a \$500 million budget to draw on is absolutely ample," Raghavan said to me recently. "It enables us to do big things when justified." An audio recording of a conversation with Raghavan is posted on [The Cancer Letter website](#).

The health system's Levine Cancer Institute, which Raghavan now directs, isn't a massive place, and his corner office on the third floor is yet to acquire a lived-in look. The furniture is unassuming wood-grain Formica, dark brown, trending toward red. There are a few family photos around, but the bookshelves are empty.

The Carolinas Health System serves a massive

area around Charlotte and stretches into North and South Carolina.

There are no direct competitors in oncology, except on the boundaries. Duke University, the University of North Carolina and Wake Forest University are to the northeast; the Medical University of South Carolina and Emory University are to the south; and Vanderbilt University and Sarah Cannon Research Institute lie to the west.

The system has 33 hospitals, 6,200 licensed beds, 1,900 physicians, and nine million patient encounters a year. In 2011, the system's combined net operating revenues exceeded \$6.7 billion. After the recent merger with the Moses Cone Health System in Greensboro, the cancer caseload will likely reach 14,000 new patients a year.

The \$20 million gift for the center from which Raghavan directs his cancer empire came from Leon Levine, founder of Family Dollar, a chain of stores that sell food, clothing and household products.

Few of Raghavan's peers claim to understand why he left the Cleveland Clinic for an unknown place down south. Fewer still claim to understand why he has been uncharacteristically low-profile for a year and a half. The answer may be very simple: Raghavan has been busy.

As he seeks to provide rational care for 14,000 new patients, his to-do list looks something like this:

1. Take out the perverse incentives that influence the doctors' selection of clinical trials vs. standard care.
2. Select only the clinical trials that ask questions that matter.
3. Create clinical pathways that include access to world-class experts when they are needed.
4. Hire those experts.
5. Remove the barriers that make the underserved underserved. (That would be particularly appropriate at the Carolinas, a system that operates safety net hospitals.)
6. Create methods for guiding all people—rich and poor—through cancer prevention strategies.

How does Raghavan intend to accomplish all this—or even a part of this?

"It's simple," he says.

"Sure, like $E=mc^2$ is simple?" I answer with a question.

After all, these aren't novel goals, in the same way that world peace isn't a new concept.

"No, it's not $E=mc^2$ simple. It's simple simple."

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An Irrational System

"I think the opportunity to start with a blank slate and design the foundation and the systems on top of that foundation is what's unique about this," said Clifford Hudis, president-elect of the American Society of Clinical Oncology and chief of the Breast Cancer Medicine Service at Memorial Sloan-Kettering Cancer Center.

Few people dispute the notion that cancer care in the U.S. could use fundamental restructuring.

"If you wanted to design an inefficient system that would hold us back, inhibit communications, slow down scientific advance, you couldn't do much better than what we've got," Hudis said.

Like other observers, Hudis immediately focuses on the bioinformatics component of Raghavan's experiment.

"If you started from a clean slate—and this is something I think about almost every day—I would have a system where a patient could push a button to transmit everything from one experience to another," Hudis said. "We've got barriers to efficient care. They cost us money and time. They cost us money in terms of duplicating tests and duplicating conversations, for that matter."

Consider the experience of a patient as he goes from an abnormal finding on a routine medical test administered by an internist to eventual cancer diagnosis and treatment.

"Not one part of that path is transportable electronically right now," Hudis said. At every step, "everybody is re-documenting, introducing errors, miscommunicating, and so forth. I wouldn't have a system where a patient on one side of a busy avenue in

New York has to print out a 500-page chart and carry it across the street to the specialty hospital on the other side of the street. It's insane."

Is it possible that Raghavan's war chest would enable him to succeed where others have not?

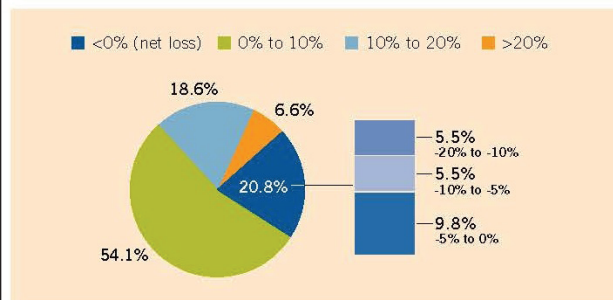
And, clearly, his timing is good. The system is changing radically as the new reimbursement structures are rapidly forcing a massive volume of oncology services to move from the doctors' offices to the hospitals.

Genentech publishes an illuminating document called The Oncology Trend Report. Based on a survey of 183 oncologists, the most recent version of the report points to financial difficulties these doctors experience:

- Oncologists most frequently estimated net practice income between 0 percent and 2.5 percent of total revenue; smaller and community-based practices were most likely to report negative earnings.
- 39.3 percent of oncologists reported a decrease in their individual net income in the previous 12 months; 37.7 percent reported no change; and 22.9 percent reported an increase.
- Parenteral drug margins decreased for more than half of oncologists.
- 53.6 percent of respondents plan to make practice changes in the next two to three years to improve financial performance; approximately half plan to implement electronic health record systems and/or e-prescribing systems, and a fourth plan to reduce or restrict services to uninsured patients.

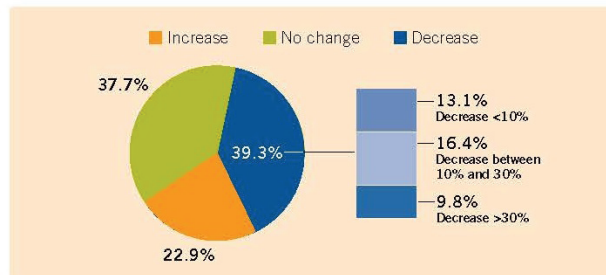
Many doctors are selling their practices, and hospitals are buying. Though accounts of this shift are for now mostly anecdotal, they come from all over the U.S.

Practice Net Income as a Percentage of Total Revenue in 2010



The majority of practices' earned net income was equal to 0% to 10% of their total revenue.

Change in Oncologists' Individual Net Income, 2010 to 2011



Much like the previous study period, about 40% of oncologists saw their individual incomes drop in 2011. Most of those (16.4%) experienced a decrease between 10% and 30%.

Source: The 2012 Genentech Oncology Trend Report: Perspectives from Managed Care, Specialty Pharmacy Providers, Oncologists, Practice Managers, and Employers. 4th ed. South San Francisco, CA: Genentech; 2011.

“Anecdotally, we are certainly seeing some movement of hospital acquisition of oncology practices,” said Patricia Goldsmith, executive vice president and chief operating officer of the National Comprehensive Cancer Network. “Some of it is outright acquisitions, others are more affiliations than acquisitions.”

NCCN plans to conduct a survey of its member institutions to gain a better understanding of the trend.

“One of the major motivating factors for contributing to this trend is the complexity of delivery of oncology care,” Goldsmith said. “Physicians have gone to medical school to practice medicine.

“But, increasingly, what they have to do in order to run a successful practice is be a business manager. They have all of the challenges of reimbursement. They have the additional complexities of precertification, pathway companies, challenges in terms of collection, covering the drug float in their practices.

“When we look at the cost of drugs and biologics, the drug float for physician practices can be very, very daunting. For a lot of community oncology practices, particularly the smaller ones, the ability to have the resources and infrastructure that the hospitals bring becomes attractive.

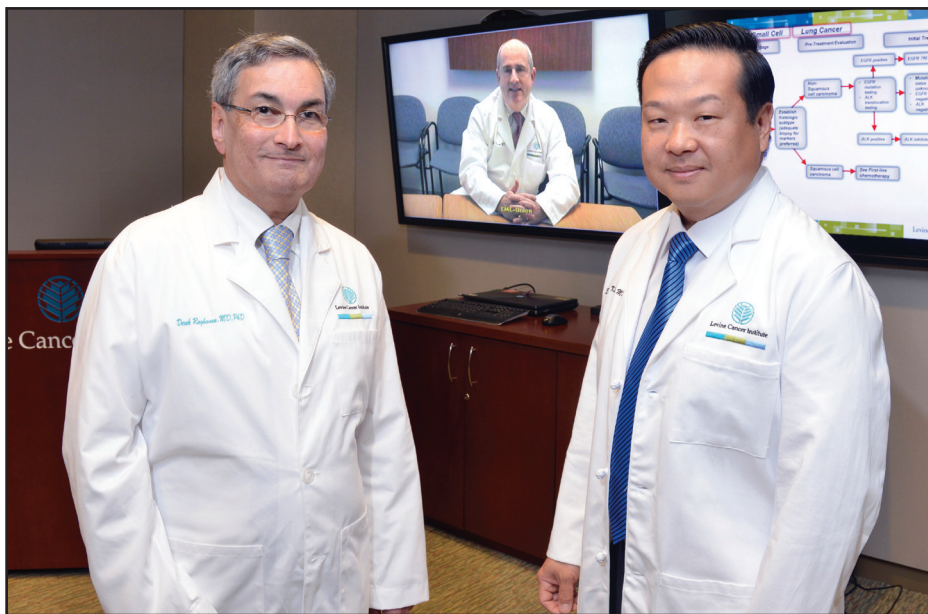
“I think, in some ways, it allows physicians to get back to practicing medicine, which is what they went to medical school for.”

Moreover, health care industry insiders predict that the Affordable Care Act will drive even more business toward the hospitals and health systems.

Raghavan isn’t alone in banking on the potential of clinical pathways and bioinformatics systems to make the new structure of cancer care click into place.

ASCO is building a knowledge-generating computer network that would collect and analyze cancer care data from patient records, clinical trials, biomarker data, and clinical practice guidelines.

The system, [called CancerLinQ](#), is intended to provide real-time, personalized guidance and quality



It takes a big conference room and a wall-full of screens to run Charlotte’s Levine Cancer Institute. Center director Derek Raghavan and his lieutenant Edward Kim, chair of solid tumors and investigational therapeutics, confer with Greg Brouse, medical director of Edwards Cancer Center at CMC-Union Hospital in Monroe, N.C.

feedback to physicians.

The market for clinical pathways and decision support and review systems is competitive.

NCCN, McKesson Specialty Health, and the US Oncology Network recently announced a collaboration to create clinical pathways delivered through decision support technology that will allow physicians to assess treatment options consistent with evidence-based standards. These enhanced solutions will also allow providers to consult coverage policies mandated by payers.

Other players include the P4 Pathways owned by CardinalHealth, Via Oncology Pathways, Eviti Inc., and ICORE Healthcare. Content libraries and software from these firms are used by a number of regional and national payers. IBM has also announced plans to develop a decision support system using Watson technology (The Cancer Letter, [Nov. 30, 2012](#)).

However, Raghavan seems to be designing a much broader experiment.

What he has in mind is comprehensive, spanning the conduct of clinical trials, delivery of care and development of bioinformatics. And he stands alone in staging his experiment in part as a teaching exercise.

The experiment is all the more compelling because Raghavan talks.

“Our motto—and it’s kind of twee, and I apologize—is it’s a cancer institute without walls,” Raghavan says. “What it means is you can walk into Stanly Regional Medical Center in the town of Albemarle, N.C., 40 miles northeast of here, or you can go into Northeast Hospital, which is 40 miles north—you can go to any of our places and get shown to the Levine Cancer Institute unit.”

Recognition of absurdity and inequity of the U.S. health care system is Raghavan’s starting point. The existing system doesn’t perform well and is resistant to learning.

“How can we do a better job?” Raghavan said. “This is bullshit. If there are only five to six percent of patients getting into our clinical trials, there is something fundamentally wrong.

“If we could cure everybody, it would be fine. But we can’t. Therefore, how can we be comfortable sitting in our offices saying, ‘I am giving standard of care treatment,’ when the standard of care results in less than 70-80-90 percent cure rate?

“How can you possibly justify giving a patient with pancreatic cancer single-agent Gemzar or FOLFOX or something else that doesn’t work outside the context of a trial where you are trying to build something? It’s nuts. The thought that so few patients have access drives me nuts.”

What, then, is the right proportion for clinical trials accrual?

“I think a reasonable percentage is 25-30 percent,” Raghavan said.

Otis Brawley, chief medical officer of the American Cancer Society, is hoping to see Raghavan build something that works.

“Derek is the ideal person for this kind of a challenge,” said Brawley, an author of a recent book, *How We Do Harm: A Doctor Breaks Ranks About Being Sick in America*.

“There are tremendous inefficiencies in how oncology is practiced, because there is a lack of coordination among specialists, and—among some practitioners—an appalling lack of respect for science,” Brawley said. “The salvation of oncology is through a coordinated effort to give medical care, respecting the science and developing the science.”

Raghavan’s panoramic grasp of incongruences in oncology positions him to engineer a better system, Brawley said. Moral indignation and compassion help, too.

“I’ve been in conversations with this guy, and his commitment on health disparities issues and getting

treatment right is so deep that I actually question the depth of my own commitment,” Brawley said.

The Question of Cost

On the day I visited Raghavan, he was grumbling about a story that appeared on the front page of the hometown newspaper, the *Charlotte Observer*.

The story—an investigation—showed that the same health care services cost more at hospitals than at doctors’ offices.

“North Carolina patients are likely to pay more for routine health care if their doctors are employed by a hospital, an investigation by the *Observer* and the *News & Observer* of Raleigh has found,” said the story published on the front page Dec. 17. “It’s true for services ranging from heart tests to routine office visits. And it’s part of a national shift that experts say is raising costs but not quality.

“Hospitals are increasingly buying doctors’ practices, then sending bills for routine services that are significantly higher than those charged by independent doctors.”

In recent months, one Charlotte-based practice was acquired by the Carolinas Health System, which now employs all its doctors; another of the CHS hospitals has invited Raghavan to create its oncology unit by new recruitment.

To a great extent, the problem lies in the way the U.S. has paid for cancer care.

Most of cancer care was deliberately taken out of hospitals and was provided by oncology practices. This system was created in the sixties and seventies in order to save money on administration of chemotherapy.

To pay for equipment and work required to administer chemo, doctors were allowed to keep the “spread” between the price at which they bought the drugs and the price that ended up on the patients’ bills. For years, oncologists argued that they were underpaid for the services they provided, but the spread allowed some practices to generate considerable revenues.

Critics argued that this system created the incentives for doctors to sell more drugs, which led to overtreatment. The government and insurers have been cutting into the spread for years, and oncology practices found themselves less viable and have become more willing to accept being acquired.

Hospitals, meanwhile, have been able to charge more than oncologists in private practice. And they are able to take part in the federal 340B drug pricing program, which requires drug manufacturers to provide outpatient drugs at significantly reduced prices.

“Aren’t the charges at hospitals indeed higher?” I ask Raghavan. “Does this make the story fair?”

Raghavan responds with a tirade:

“What I believe is that most private practices don’t do indigent care, don’t offer clinical trials, don’t have navigators, genetic counselors, provide urgent care for sick patients, don’t provide interpreters for folks who don’t speak English.

“They don’t provide one-stop shopping for multi-disciplinary care, they don’t provide routine tumor board discussion of all or even complex cases. They mostly don’t provide special attention for the elderly, they don’t generally take care of pediatric patients, and so on.

“Those that do offer clinical trials usually only offer low-risk studies—either phase IV (post-marketing and well-paying pharma trials or the cooperative group trials, the latter being very important but usually pretty low risk).

“What we are doing is trying to get a larger menu out there via all the pieces that you see here. Practice doctors have neither the time, inclination or mechanism to offer ‘navigator academies,’ ‘emergency department liaison programs,’ internet-linked standard pathways, tumor boards, consensus driven standard algorithms of care, phase I trials, easy access to BMT, educational programs for the indigent and under-served, participation in community oncology fairs, education of nurses and students, etc.

“It is absolutely correct to state that it is cheaper to get a regimen at a private practice *if* you are insured, intelligent, can cooperate easily, *if* you are mobile, etc. Our operation has always taken care of the indigent, and continues to do so; where we can recoup funds, we do; when it is not possible, we do not withhold care.

“The panoply of services must somehow be paid. We have a robust business model and have made some money in the not-for-profit sphere, which has been ploughed back into the business. In truth, it’s a very complex algorithm, and I think that what we do is worthy because we do it, rather than just plan and consider; we take risk; we provide care; we take on projects that others won’t touch.

“That’s why the Charlotte Observer articles are so annoying to me—they just ignore what they wish to ignore.

“Give me a break!”

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Deadpan Truth-telling

Raghavan’s brand of humor would be better described as aggressive truth-telling.

His delivery is perfectly deadpan.

Indignation seems to affect his face like a dose of Botox. It’s possible that the guy laughs, but this has not been observed in public.

Raghavan claims to be unable to retrain himself when an absurdity materializes within striking distance.

“I am deficient in self-control,” he says, and if you believe him, you might also want to consider acquiring shares in the Sydney Harbour Bridge at a discount rate. As any decent performer, he wants to create the illusion of jeopardy. He wants you to think that he is about to say something so impolitic that he will be expelled from civilized society.

He clowns rarely, but well.

At ODAC in the 1990s, Raghavan called for time-outs and asked for an interpreter “from Southern into English” whenever another committee member, David Johnson, then of Vanderbilt Ingram Cancer Center, quoted his grandfather’s Southern sayings and parables, which often involved turtles, squirrels, pigs and other fauna.

“What does it mean, ‘A turtle on top of a fence post didn’t get there by accident?’” Raghavan would inquire. (It usually meant that the events brought to ODAC’s attention were non-random and the possibility that somebody cooked the data or tried to explain away clinically significant events couldn’t be dismissed.)

Raghavan, who is 63, was born in Argentina. His father, an Indian diplomat, was half-French. His mother was a Jewish Australian. Google a photo of his uncle on the Australian side, an investment banker and former president of the World Bank, James Wolfensohn, and you will see essentially the same face.

Soon after coming to work at Roswell Park Cancer Institute, Raghavan ended up on ODAC.

Though his term has ended long ago, the agency keeps inviting him to return, usually when it wants the committee to send a forceful message to the industry and the medical profession.

Indeed, Raghavan says stuff most people would rather not.

“One of the attractive features about ODAC is it doesn’t have lawyers on it and so we can actually think about patient welfare,” Raghavan said at a recent meeting of ODAC (The Cancer Letter, [Jan. 30, 2009](#)).

Raghavan is a skeptic on prostate cancer screening. This position that didn’t win him many friends within his subspecialty, but the data showed what the data showed,

and that harm was being done.

The fact that Raghavan was asked to serve at a recent ODAC meeting on something called “non-metastatic, castrate-resistant prostate cancer” in 2011 was widely interpreted as a signal of the agency’s misgivings about that proposed indication. (The indication is created when men are found to have prostate cancer through PSA testing, which isn’t approved by FDA, and treated surgically and then—off label—with hormones.)

Indeed, Raghavan put the problem in a nutshell:

“A very significant part of this is the advocacy community and the patient community that find it untenable to sit by and watch PSAs rise,” he said at the Sept. 14, 2011, meeting of ODAC ([The Cancer Letter, Sept. 23, 2011](#)).

“And that may be a function of the fact that we’ve educated them poorly. More likely, it’s a function of the fact that there isn’t unanimity among the medical profession. The urologists will tend to be much more PSA-driven than the medical oncologists. I don’t want to open the can of worms, but let’s all remind ourselves that we still can’t agree on screening and the utility of PSA. So that just trickles down at each stage of disease.”

Convergence of Academic & Community Practice

Raghavan isn’t the first academic to attempt to forge collaborations between academic institutions and community oncologists.

He wasn’t yet a teenager when University of Pittsburgh surgeon Bernard Fisher did something similar more than a half-a-century ago, by creating the National Surgical Adjuvant Breast & Bowel Project.

Raghavan was three years out of med school in 1977, when the Mayo Clinic oncologist Charles Moertell built the North Central Cancer Treatment Group, which drew on Mayo-trained Minnesota oncologists to accrue patients to studies.

However, the Raghavan experiment in the Carolinas is fundamentally different. He is creating an unusual cultural crossroads. Local oncologists are joining the health systems as employees at the same time as academic stars are more willing to leave prestigious academic institutions to join his team.

Also, advances in bioinformatics could tie the chaotic, unwieldy enterprises of cancer research and cancer care into a single entity. How can you have a center without walls unless you also have informatics, clinical guidelines and clinical pathways?

Another broad, system-wide change appears to play into Raghavan’s hands. The number of reasons

for patients to travel to comprehensive cancer centers is shrinking, as some diseases can be effectively treated in the community.

Even clinical trials are becoming easier to conduct close to home.

“There was a time when there wasn’t a good understanding of cancer, so it made pretty good sense to have small, exquisitely well organized centers doing what they could to improve things,” Raghavan said to me. “Research was done in centers of excellence by a small number of people, and the people who weren’t interested in research just did standard of care to whatever quality was available.

“Now, the game has changed. We’ve got the molecular prognosticators. We now have spawned a series of targeted therapies that are rationally driven, and a lot of these therapies are relatively easy to administer by an experienced oncologist out in the community. They just don’t have easy access to get into those trials. They have access to corporate-driven trials that are not by nature necessarily very innovative. They are about selling product.”

The reasons for patients living in the Carolinas catchment area to travel to academic centers may shrink further if the system continues to attract academic stars and offer increasingly advanced treatments.

Raghavan said that over his year-and-a-half in Charlotte, the system has spent \$50 million to build a cancer center and another \$20 million on renovations and recruitment.

The roster of people he has recruited includes:

- **Edward Kim**, a lung and head and neck cancer expert, formerly of MD Anderson Cancer Center, now serves as chair of solid tumor oncology and investigational therapeutics at Levine Cancer Institute. Kim’s projects include putting together the clinical pathways for solid tumors.

- **Edward Copelan**, formerly a professor and deputy chief of hematology/oncology at the Cleveland Clinic, who now serves as chair of hematologic oncology and blood disorders at Levine. He is putting together the pathways for hematological malignancies and constructing a stem cell transplantation unit.

- **Belinda Avalos**, former associate professor of hematology/oncology at Ohio State Comprehensive Cancer Center, is now the deputy chair of hematologic oncology and blood disorders at Levine.

- **Ram Ganapathi**, former head of cancer pharmacology at the Cleveland Clinic Taussig Cancer Institute, became chair of cancer pharmacology at Levine.

• **Steven Akman**, a phase I expert at Wake Forest School of Medicine, became medical director at Roper-St. Francis Hospital in Charleston.

• **Mahrukh Ganapathi**, a cancer pharmacologist from Taussig, became head of pharmacologic specimen procurement.

• **James Symanowski**, former director of biostatistics at Nevada Cancer Institute, heads cancer biostatistics at Levine.

• **Zvonimir Milas**, a head and neck cancer surgeon from MD Anderson (Florida), starts at Levine in March.

• **Megan Forster**, a surgical oncologist, is moving from the Moffitt Cancer Institute.

• **Lejla Hadzikadic**, a breast surgical oncologist, will come from University of Pittsburgh Cancer Institute in July.

• **Robert Fraser**, who remains at South East Radiation Oncology, also was named chair of radiation oncology at Levine.

• **Josh Hill**, a fellow in surgical oncology at MD Anderson, became a surgical oncologist.

• **Ashley Sumrall**, a fellow in neuro-oncology at Duke Cancer, became a neuro-oncologist.

• **Steve Riggs**, assistant professor of urologic oncology at Eastern Virginia Medical School, became a urological oncologist.

• **Rebecca Elliott**, former chief hematology/oncology fellow at MD Anderson, joined Levine as a faculty member.

• **Allison Prinz**, physician in practice in Johnson City, Tenn., joined Levine at one of the outlying practices.

• **Carol Farhangfar**, an administrative officer and scientist in translational research, is moving from MD Anderson in February.

• **Meredith Mullins**, former associate director for administration at the Nevada Cancer Institute, was named vice president for administration at Levine.

• **Bob Battista**, former finance director from Taussig Cancer Institute, followed Raghavan.

• **Erinne Dyer**, deputy chief of public relations at Cleveland Clinic, became vice president of public relations, media, marketing and corporate affairs.

A Change to Academic Standards

At a recent protocol review meeting at the Levine Cancer Institute, Kathryn Mileham presented a protocol for the Boehringer Ingelheim drug afatinib (BIBW2992), an irreversible EGFR/HER2 inhibitor.

Levine Cancer Institute is vying to take part in



Kathryn Mileham joined a Charlotte community practice after fellowship at Vanderbilt three years ago. Now a staff oncologist at Levine, she is subspecializing in lung cancer—and starting an academic career.

the afatinib expanded access program.

This was one of the protocols intended to help the cancer center get up to speed, to challenge the faculty to work as a clinical trials organization.

At the same time, community oncologists, including Mileham, are focusing on developing subspecialties, starting their academic careers, and restructuring their practices.

Changes in oncology affected Mileham profoundly.

She joined a Charlotte oncology practice in 2009, after completing a fellowship at the Vanderbilt Ingram Cancer Center, where she was interested in lung cancer and seriously considered it as a subspecialty.

“I had a passion for lung cancer during the fellowship,” Mileham said. At Vanderbilt, she worked with David Johnson, a former ASCO president and Raghavan’s partner in comedy on ODAC, who has since move to the University of Texas Southwestern Medical Center.

Mileham was so interested in the academic track that she considered getting an additional degree, a master’s of science in clinical investigation.

Ultimately, Mileham, who was born in Charleston, S.C., chose to move to Charlotte to be closer to her family. She joined the Mecklenburg Medical Group, a multi-specialty organization.

"I chose this job because it was located in Charlotte, and although there is not a university association, the offerings within Carolinas Medical Center are outstanding," Mileham said. "I did not feel like I needed an academic institution to provide both standard of care and excellent patient management."

In her practice, Mileham treats solid tumors, hematologic malignancies and benign hematological cases.

"Given the direction of my career in the community setting, a subspecialty in lung cancer wasn't something that I could develop," she said.

This changed last May, when all the oncologists at the practice joined the Levine Cancer Institute.

The merger occurred in part because Raghavan was about to bring in academic stars, which would have made it difficult for any community practice to compete with the cancer center.

After joining the cancer center, the practice physicians met with Raghavan and Edward Kim, chair of solid tumor oncology and investigational therapeutics, to discuss their preferred career paths.

"They gave us the option to mold our future," Mileham said. "Each physician had an opportunity to say, 'I have an interest in a particular cancer,' or, 'I prefer to maintain my community focus and my ability to see all parts of cancer without having to subspecialize' or, 'I would like to expand our survivorship and integrative medicine programs.'"

"We were given the opportunity and support to make those decisions on our own. Without being unwillingly channeled toward a particular focus, it is easy to maintain the energy and the excitement and the drive to succeed in providing all aspects of excellent patient care."

Mileham chose lung cancer, and now Kim is building a subspecialty group around her and several of her colleagues. The center's plan is to have oncologists practice within their subspecialties several days a week and fill the gap time by practicing general oncology.

The transition is difficult, Mileham said.

"Our schedules are changing, our careers are changing," she said. "I am trying to maintain the same practice I had and then add the academic on top of it. It's very, very hard to balance the time. I work most nights and weekends, either catching up with dictations or trying to write a paper or review potential clinical

trials.

"As my clinic shifts more toward lung and I phase out hematology and other tumor types, I think I will be able to manage more efficiently the needs of the lung team while still maximizing my clinical space."

Though Mileham is playing catch-up as an academic oncologist, she has no regrets about the three years she spent as a community doc.

"One of the advantages that I bring is that I have the community background," she said. "I have the clinical background with a few years of patient care; yet I am still not too long separated from my fellowship and the academic mindset. When one transitions straight from fellowship into an academic career, the clinic volume is unlikely to be as robust as what we see in the community setting because there is more dedicated time toward research pursuits. Now I have the opportunity to take my clinical experience back to research, rather than attempt to design research without much background."

Mileham acknowledged that her income has decreased. "We were open to a reduction in our overall reimbursement with the opportunity to pursue this part of our careers," she said.

The earnings of starting oncologists can drop by 5 to 10 percent when they become employees of his cancer center, Raghavan said. Doctors who are well into their careers have to take pay cuts of 30 percent or more.

"This system was not designed to line the doctors' pockets," Raghavan said. "It was designed to get better care for patients and to make the job more interesting for the doctors who join us."

Next Week: Writing the clinical pathways and laying the foundation for clinical research program.

Disclosure: Goldberg and Brawley are co-authors of *How We Do Harm: A Doctor Breaks Ranks About Being Sick in America*.

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Fiscal Cliff

Sequestration Delayed For Two More Months

(Continued from page 1)

The sequester—or \$110 billion in instant, across-the-board cuts for the 2013 fiscal year—is now scheduled alongside Congress' debate to raise the debt ceiling and the need to pass a federal funding bill before the government runs out of money March 27.

On Capitol Hill, all three of these issues will be surrounded by loud calls for cutting federal spending. On its own, the sequester represents an approximate 8.6 percent cut to the NIH's \$30 billion budget.

The last-minute compromise, named the American Taxpayer Relief Act of 2012, was technically passed after the fiscal cliff's midnight Jan. 1 deadline. Congress agreed to raise taxes for the wealthy to Clinton-era levels. The bill does not address the debt ceiling.

The bill also postponed a scheduled 26.5 percent cut to doctor reimbursements through Medicare for one year.

"A last-minute patch to the Sustainable Growth Rate formula...averted massive cuts to oncologists who care for and treat Medicare patients," said Clifford Hudis, president-elect of the American Society of Clinical Oncology. "This end-of-year crisis management once again demonstrates the critical need for fundamental reform of the Medicare reimbursement system."

In a statement regarding the federal budget continuing resolution's March 27 deadline, the NIH reiterated that the institutes would continue to "issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90 percent of the previously committed level).

"This is consistent with our practice during the [continuing resolutions] of FY 2006-2012. Upward adjustments to awarded levels will be considered after our FY 2013 appropriations are enacted but NIH expects institutions to monitor their expenditures carefully during this period."

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Capitol Hill

President Obama Signs Recalcitrant Cancers Bill

(Continued from page 1)

Formerly known as the Pancreatic Cancer Research & Education Act, the bill was attached to the \$633-billion 2013 National Defense Authorization Act.

The Recalcitrant Cancer Research Act mandates NCI to identify, within six months, two or more cancers with a five-year survival rate of less than 20 percent. The director of the institute will then convene a working group of experts to identify research questions and recommend, within 18 months, actions that should be taken to advance research on these cancers.

The version signed by the president watered down the original controversial measure, which, according to critics, threatened to touch off a "disease olympics" and dilute NCI's authority to set research strategy.

"In my view, the bill can be tolerated, but it's not a particularly useful bill," said NCI Director Harold Varmus to the NCI Board of Scientific Advisors Nov. 5 (The Cancer Letter, [Nov. 16, 2012](#)). "As it is currently written, we'd be required to do studies of pancreatic cancer and something that's called 'lung cancer,' but my own view is that we need to pay more attention to categories of cancer that conform to the cell of origin and the nature of the genotype. Lung cancer is certainly not one disease, just as pancreatic cancer is not one disease."

"Recalcitrant cancer" is defined in the bill as a cancer for which the five-year relative survival rate is below 50 percent. The five-year survival rates of pancreatic and lung cancer are 6 percent and 16 percent, respectively.

It took nearly two years for the legislation, which was originated by the Pancreatic Cancer Action Network, to be passed in its current form.

An early version of the bill drew the ire of critics in the cancer community—many were concerned about the measure's earmarked authorization of \$887.8 million in NCI funds to be used specifically for pancreatic cancer research. The bill would have roughly doubled the institute's spending on the disease, which has already increased by 300 percent in the past decade (The Cancer Letter, [Aug. 3](#), [Aug. 10, 2012](#)).

"It would basically have taken away from the NCI the responsibility of deciding what grants that address pancreatic cancer would be funded," Varmus said Nov. 5.

Such measures targeting specific diseases are a slippery slope, said Varmus at the National Press Club in Washington, D.C., on Sept. 25.

“One thing that I would very much object to that was part of the original bill is an effort to take decision-making about grant-making out of the hands of the NCI and putting it in the hands of advocacy groups, not just because inherently it’s wrong, but very quickly, every other advocacy group would say, ‘I want that too!’ and then we have chaos.”

The political momentum led various research advocacy associations as well as individual oncology professionals to wage a letter-writing campaign in opposition to the original legislation. The Subcommittee on Health of the House Committee on Energy and Commerce promptly rewrote the bill, returning control of the budget and research process to NCI, requiring only regular progress reports besides the mandatory identification of lethal cancers.

“The adoption of the Recalcitrant Cancer Research Act is a historic victory in the fight against deadly cancers—particularly pancreatic cancer—as it is the first legislation designed specifically with the disease in mind,” said PanCAN CEO Julie Fleshman in a press release Jan. 3, celebrating the signing of the act.

In their early campaign materials, PanCAN proclaimed that the bill isn’t “disease-specific” and proceeded with advertisements and lobbying efforts, which included leaving morgue toe tags at congressional offices.

“This achievement would not have been possible if not for the leadership of the bill’s lead sponsors, Rep. Anna Eshoo (D-Calif.), Rep. Leonard Lance (R-N.J.) and Sen. Sheldon Whitehouse (D-R.I.),” said Fleshman. “In addition, we applaud our partners at the Lung Cancer Alliance for their efforts in passing this important legislation.”

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In Brief

Menendez and Allison Move From USC to Cedars-Sinai

LAWRENCE MENENDEZ and **DANIEL ALLISON** joined the **Cedars-Sinai Orthopaedic Center**.

The two surgeons specialize in metastatic bone disease, sarcoma cancers of the bone and soft tissue, invasive skin cancers and melanomas.

Menendez and Allison came from the University of Southern California—Menendez served as chief of the Metastatic Bone Clinic, the Multidisciplinary Sarcoma Center and the Center for Orthopaedic Oncology.

Allison was assistant chief of the USC Center for Orthopaedic Oncology at the USC Norris Cancer Hospital.

YALE CANCER CENTER received a \$1 million gift from the **Milbank Foundation for Rehabilitation** to support palliative care services, research, and fellowships at Smilow Cancer Hospital at Yale-New Haven and Yale Cancer Center through its Palliative Care Program.

The gift will also provide support to build the palliative care training programs at Yale School of Medicine.

WILLIAM KIM and **JAMES MIER** will each receive grants for kidney cancer research from the **American Association for Cancer Research** and **Kure It**. The two-year 2012 AACR-Kure It Grant awards \$250,000 grants to support translational kidney cancer research.

Kim is an assistant professor in the departments of medicine and genetics at the University of North Carolina School of Medicine in Chapel Hill. Mier is associate professor at Harvard Medical School in the division of hematology and oncology at Beth Israel Deaconess Medical Center.

They will receive complementary registration to the AACR’s annual meeting in April in Washington, D.C., and will be recognized at the Annual Grants Reception and Dinner on April 9.

Kim’s project, “Defining the RCC [Renal Cell Carcinoma] Kinome for Target Discovery and Individualized Therapy,” aims to personalize kinase therapy based on the patient’s kidney tumor.

Mier’s research will explore the mechanism by

which HDM2 antagonists and vascular endothelial growth factor-targeted drugs act together to block tumor angiogenesis and induce disease regression in renal cell carcinomas in his project, "HDM2/HDMX as a Therapeutic Target in Renal Cell Carcinoma."

BANNER MD ANDERSON CANCER CENTER on the Banner Gateway campus plans to break ground this month on an expansion of its outpatient cancer facility.

The 111,000-square-foot expansion will add: three linear accelerators; 30 additional clinic exam rooms, for a total of 60 rooms; 13 additional infusion bays; The Cox Center for Integrative Oncology and Cancer Prevention, funded in large part by a grant from the James M. Cox Family Foundation; and dedicated space for the Stem Cell Transplantation and Cellular Therapy program.

The \$62.6 million expansion will open in spring 2014.

DANIEL COSTA received the Translational Lung Cancer Research Fellowship by the **Lung Cancer Foundation of America** and the **International Association for the Study of Lung Cancer**.

Costa is a medical oncologist at Beth Israel Deaconess Medical Center and an assistant professor of medicine at Harvard Medical School.

His work focuses on a specific sub group of epidermal growth factor receptor mutations, exon 20 insertions. EGFR exon 20 insertion mutations could account for up to 5-10 percent of all EGFR mutations.

He will receive \$150,000 for up to two years. The second year of support is based on demonstrating satisfactory progress.

FDA News

FDA Awards Premarket Approval To Breast Tissue Assessment Tool

FDA awarded premarket approval to an intra-operative tissue assessment tool for early-stage breast cancer surgery.

The MarginProbe System, developed by Dune Medical Devices Inc., can improve surgeons' ability to intra-operatively identify "cancer on the margin" and reduce pathologically positive margins following a patient's initial lumpectomy surgery.

Approval was based on a 664-patient prospective, multi-center, randomized, double arm study to evaluate the effectiveness of MarginProbe in identifying cancerous tissue along the margins of removed breast tissue during initial lumpectomy procedures. MarginProbe, which uses electromagnetic signatures to identify healthy and cancerous tissue, was found to be over three times more effective in finding cancer on the margin during lumpectomy compared to traditional intra-operative imaging and palpation assessment.

It is estimated that 30 to 60 percent of early-stage breast cancer patients who have an initial lumpectomy procedure will undergo a repeat surgery. This is because cancerous cells are found to be present on the rim or edge of the removed tissue.

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