THE CANCER LETTER

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Turmoil in Texas

Margaret Kripke Comes out of Retirement To Become Chief Scientific Officer at CPRIT

By Paul Goldberg

Margaret Kripke must have a penchant for long odds.

That's the only explanation that friends and colleagues can offer for the former MD Anderson Cancer Center provost coming out of retirement to become the chief scientific officer of the Cancer Prevention and Research Institute of Texas.

It's a challenge to follow in the footsteps of a Nobel laureate who left in disgust over violation of principles of peer-reviewed science, taking almost the entire peer review structure with him.

If that's not enough, the Travis County district attorney's public integrity unit opened a criminal investigation of the state agency's award of an $11 million grant to a company called Peloton Pharmaceuticals without any peer review. The state attorney general has zeroed in on the same matter, and the state auditors have been scouring CPRIT's books, and are expected to issue an audit report in January.

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CPRIT Executive Director Bill Gimson is Out As Scandal Grows, Investigations Begin

By Paul Goldberg

About two weeks elapsed between Margaret Kripke committing to take the job as chief scientific officer at the Cancer Prevention and Research Institute of Texas and the public announcement that she had accepted the job.

During that period, the institute took a brutal pummeling, as Texas law enforcement agencies started investigations, legislators asked questions and new allegations of impropriety emerged.

If the allegations stick—which is far from certain—they could move the epicenter of CPRIT's troubles from MD Anderson to UT Southwestern.

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In Brief

Haile Named Stanford Cancer Institute Associate Director of Population Sciences

ROBERT HAILE was named associate director of population sciences at the **Stanford Cancer Institute**. He will also have a faculty appointment in the Department of Medicine (Oncology).

The institute's Population Sciences Program spans several academic departments including epidemiology, genomics, disparities research, and community-based participatory research, among others.

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The Cancer Letter Will Return Jan. 4, 2013

Kripke: "I Am in The Dark About What's Happening"

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And state legislators are asking the agency that hands out $300 million a year for cancer research and prevention to justify its continued existence.

Another obstacle: the resignation of CPRIT's chief commercialization officer, Jerry Cobbs, who proposed giving an $18 million grant to a biotech incubator co-directed by Lynda Chin, an MD Anderson scientist and the wife of that institution's president, Ronald DePinho.

Cobbs quit just ahead of the announcement that he had recommended another $11 million grant with no peer review whatsoever.

As the good people of Texas and the state's generally hands-off legislature started to demand answers, recruiting Kripke looked like a way to break the momentum of devastating events.

Kripke, who is 69, is a former member of the President's Cancer Panel and a former president of the American Association for Cancer Research. She retired from MD Anderson in 2007, and has the gravitas needed to restore the organization's credibility.

Just after 11 a.m. on Dec. 11, CPRIT sent out a press release announcing Kripke's hiring. A little more than an hour later, the same office sent out another bit of news: the resignation of Bill Gimson, CPRIT's executive director, the official ultimately responsible for the MD Anderson and the Peloton fiascos.

In his letter of resignation, Gimson accepts no blame for the events that caused CPRIT to bleed out its scientific credibility and brought it to the edge of a precipice (The Cancer Letter, May 25, Oct. 12, Oct. 19, Oct, 26).

"The last eight months have been extremely difficult for those at CPRIT—during this time they have not been able to do their jobs due to wasted efforts expended in low value activities that do nothing to advance cures for cancer," Gimson wrote. "Unfortunately, I have also been placed in a situation where I feel I can longer be effective. After considerable thought, and in the hope that my fellow CPRIT workers will finally be able to get back to what is important, I hereby tender my resignation as CPRIT Executive Director."

A couple of hours after this epistle was released to reporters, Kripke took questions in a telephone press conference, arranged by CPRIT officials. The first question was entirely predictable: what can you say about Gimson resigning?

"Since I learned about it a few minutes ago, I haven't had an opportunity to digest it yet," Kripke said. "I am, of course, sorry to hear it, because he seemed to be doing a reasonably good job, and I am waiting to see what the board is going to do about his letter."

"So, Dr. Kripke, whom are you reporting to?" asked another reporter.

"I have no idea at this juncture," Kripke said. "Until Jan. 17, I am reporting to Mr. Gimson, because he will stay on until then. After that, I don't know what happens. As you know, I haven't started yet, so I am in the dark about what's happening."

Kripke is expected to start work on Jan. 7.

What prompted Kripke to accept the job?

"I have to tell you, there has been more turmoil since I accepted the position than there was at the time I did accept a couple of weeks ago," Kripke said. "I think the whole concept of CPRIT is fabulous. I've been a big fan of CPRIT since it was first instituted. I think it has the potential to put Texas on the map in terms of cancer research. It's a wonderful thing for the citizens of Texas, and a generous thing that they've done.

"I feel that it's being beleaguered at the moment, and I want to do whatever I can to help. I just think it's too great an opportunity to waste."

Kripke is a professor emeritus at MD Anderson, and she hasn't gone to the institution. "After I retired, I spent two years part-time as a special assistant to the provost," she said. "Since that—for the past three years—I had no role at MD Anderson at all."

In the past, CPRIT sought to fund proposals judged most meritorious during peer review. At least, this has

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been the goal of the scientific branch of the state agency. There have been no quotas for distribution of funds to specific institutions. Similarly, there were no quotas to direct how much of CPRIT's money needed to do to research or commercialization.

Internal CPRIT records obtained by The Cancer Letter earlier this year showed that the absence of pre-specified rules created deep schisms within the organization and its oversight board. In this battle, Kripke's predecessor, Alfred Gilman, championed the cause of relying on peer review to fund the best science. When it came to receiving CPRIT dollars, UT Southwestern was ahead of MD Anderson.

The fact that Gilman, a former UT Southwestern dean, ran CPRIT's peer review from a rented office at that institution had become a controversial matter at the state agency.

Kripke said a geographic distribution of funds isn't being considered. However, the idea of targeting funds for specific uses is under discussion.

"I don't think there would be geographic distribution quotas," Kripke said. "That hasn't been part of the mandate of my role here. In terms of other uses of the funds, there is discussion about some kind of targets for how much money would go to product development vs. how much would go to research.

"That's, actually, in early stages of discussion, and I don't know how it will play out eventually."

Some quotas would be reasonable, Kripke said. "One of the reasons things got into trouble was because there wasn't clarity about how much money was going to go to commercialization," she said. "I think it would make sense to put some parameters around that, but I just don't know what those should be. Some clarity in that regard would be helpful."

Kripke said her work on the President's Cancer Panel convinced her that "there are things that could be done to accelerate the pace of cancer research," she said. "I would like to try my hand at accomplishing that."

Kripke said she would seek to broaden the research portfolio and seek "better balance" between clinical, translational and basic research was well as putting more emphasis on prevention and "less focus on trying to cure established, advanced cancers." However, the portfolio would be shaped by the proposals that would be submitted, she said.

Asked whether she agrees with the criticism of the agency put forth by Gilman and others, Kripke said she was uncertain. "It's actually hard for me to say, because I wasn't involved in any way in CPRIT at that time," she said. "I know what the concerns are and what the allegations are.

"I don't think people would resign frivolously, so there must be something to their concern."

Kripke said it will be challenging to construct a peer review structure. At least 30 resignations were received from the current roster, and all but one member of the scientific review council have resigned.

"My first challenge would be to try to restore the credibility of review process and to bring new reviewers into the mix," she said. "I don't know how difficult it will be. I haven't started yet."

Kripke rejects the idea of using an existing peer review structure put together by a non-profit organization or a professional society.

"My intention is to try to restore the system that Dr. Gilman has set up," Kripke said. "I think the peer review system that he initiated is really terrific. It is highly respected, and the structure was innovative. I would hope to rebuild that structure."

Kripke said she doesn't foresee playing any role in re-reviewing either the MD Anderson incubator grant that is expected to be submitted to CPRIT or the Peloton grant. "Neither of those comes under my bailiwick," she said. "I am the chief scientific officer and am responsible for the review of scientific grants."

This is no small matter.

The MD Anderson incubator, which was proposed as a collaboration with Rice University, served as the direct cause of CPRIT's troubles. Critics argued that the incubator was going to engage in early-stage drug discovery research that was never described and that would be labeled as "commercialization." The proposal was six-and-a-half pages long and contained no scientific content, critics said.

"First of all, commercialization was a very bad choice of terms," Kripke said. "I think what they are really trying to do is develop products that would be beneficial for cancer patients. I am supportive of it in that sense. I am not supportive of using all of the money to support all of the product development activity."

The process for subjecting commercialization grants to scientific review would have to be rebuilt, Kripke said. "I am not quite sure what that would look like, and I don't really know what my involvement would be. I certainly would have some suggestions for how it should be done, but that would come under the direction of the [chief commercialization officer]."

Kripke said she would prefer not to involve the reviewers she would assemble in reviewing commercialization proposals. "It would be better to have dedicated scientific reviewers who worked in the same

committee at the same time as people who are reviewing the business end of things," she said.

Kripke said her experience on the President's Cancer Panel prepared her for the CPRIT job—the panel looks at a different aspect of the cancer problem every year. "It really changed my thinking about what's needed in cancer research," she said. "I came to the conclusion that just doing more basic science is not going to get us there. That's why I am very committed to broaden the portfolio of research to move things from the laboratory into patients, and that's probably going to be my focus."

When a reporter asked Kripke whether she has an opinion about the Moon Shots Program, the signature program of the MD Anderson President Ronald DePinho, she laughed and said no.

"I know exactly what you know, which is what I've read in the papers," she said. "I wasn't a part of that administration which has brought that forward. If I understand the program correctly, it's a broader approach to cancer research, for example, taking a particular cancer and looking at causative agents, looking at prevention, looking at methods for early detection, right down through to treatment and survivorship.

"So it's a somewhat different way of looking at cancer research that people have done in the past. I think it's a very exciting way of looking at things. How quickly it can happen is one of the difficult issues here."

An audio recording of the conference can be found at: http://www.cancerletter.com/categories/documents.

Scandal Expands as Probes Focus On CPRIT's Funding of Peloton

(Continued from page 1)

As it stands, the implosion at the state agency can be traced directly to the agency's handling of an $18 million grant for MD Anderson scientists including Lynda Chin, the wife of MD Anderson President Ronald DePinho, to establish a biotech incubator. CPRIT violated its own rules in an effort to fund this project, a subsequent audit found.

In recent weeks, CPRIT disclosed that it had given an $11 million grant to a Dallas company without conducting any peer review. The company, Peloton Pharmaceuticals, was founded by Steven McKnight, chairman of the Department of Biochemistry at the UT Southwestern Medical Center (The Cancer Letter, Nov. 30).

In addition to the investigations, this revelation appears to have triggered the departures of CPRIT's chief commercialization officer, Jerry Cobbs, and its executive director, Bill Gimson.

However, no information has emerged to suggest that Peloton officials have sought special treatment or that the company's science wouldn't have withstood scrutiny. In fact, the company has withstood due diligence performed by the Column Group, a venture capital firm that led a Series A financing investing $18 million in the start-up. Peloton's application, funded in 2011, is being re-reviewed. Efforts to reach the company were unsuccessful.

Also, the Houston Chronicle has picked up on the fact—which has never been hidden—that Texas billionaire Peter O'Donnell, whose foundation picks up a portion of the salaries of CPRIT officials and pays for dinners of peer reviewers, was among those investing in Peloton.

However, sources point out that O'Donnell bought Peloton stock a year after the company was funded, then transferred stock ownership to UT Southwestern.

Here is a chronology:

• **Nov. 16:** Chief Commercialization Officer Cobbs resigns, stating that he plans to return to the private sector. The agency officials declined to elaborate on the departure, initially describing it as a "personnel matter."

• **Nov. 29**: The Peloton problem is announced in a press release. CPRIT officials state that, in the course of a compliance review, they discovered that the company's proposal received $11 million without any peer review. The state agency said it has notified Peloton and placed a hold on future funding.

• **Nov. 30.** Two state legislators who wrote the legislation that created CPRIT write a letter to express "deep concern" about the agency funding a grant to Peloton without formal peer review.

"As the authors of the original CPRIT statute—and subsequent legislation to strengthen the institute's guidelines to ensure transparency and prevent conflicts of interest—we require an explanation in writing as to how this occurred. That explanation should include a description of what occurred, when and how the problem was discovered, what actions have been taken to rectify the situation, and how CPRIT proposes to prevent such oversight from occurring in the future," wrote Sen. Jane Nelson (R-Flower Mound) and Rep. Jim Keffer, (R-Eastland) in a letter to CPRIT.

• **Dec. 7:** The Travis County district attorney opens a criminal investigation of the "award of grants" by CPRIT. No grant is specified. The matter is assigned to the Public Integrity Unit. The letter, which instructs CPRIT officials to retain documents, is posted at http://www.cancerletter.com/categories/documents.

• **Dec. 8:** CPRIT Oversight Committee Chairman Jimmy Mansour asks for an investigation by the Texas attorney general and an audit by Deloitte Touche. His email to Gimson reads: "Please contact the Attorney General's office and request that he direct his attorney's to seek affidavits from all individuals related to or associated with Peloton past and present. Please encourage them to return to us as soon as possible.

Please contact the Governor's Office requesting an emergency waiver approval for an audit of CPRIT by Deloitte Touche. Please contact DIR and request forensic assistance in recovering all lost email between Gerry Cobb, Al Gilman and Bob Ulrich relating to Peloton/Damascus. Also, please send this note to the Board."

A subsequent email reads: "We need to know if they have any financial interest in Peloton or benefited in some related way from it receiving approval."

Attorney General Greg Abbott is a member of the oversight committee.

• **Dec. 10:** Gimson offers his letter of resignation, which praises the MD Anderson Moon Shots Program.

• **Dec. 10:** Kripke's acceptance of the job of chief scientific officer is announced.

• **Dec. 10:** The state attorney general informs CPRIT that it has opened an inquiry into "the flawed grant that [CPRIT] awarded to Peloton Therapeutics." The letter states that "the review will include—but is not limited to—any financial interest CPRIT staff or any other individual may have had in the Peloton grant award."

Gimson's resignation letter, the announcement of Kripke as chief scientific officer, and the state attorney general's letter to CPRIT are each available at: http://www.cancerletter.com/categories/documents.

Gilman: Peloton Problem is About CPRIT, not Peloton

In an interview with The Cancer Letter, Gilman said that as former CPRIT Chief Scientific Officer he played no role in awarding a grant to Peloton.

"My total dealing with Peloton was to recommend to Jerry Cobbs that he look into it, because it looked like a good deal," Gilman said to The Cancer Letter. "Calling it to CPRIT's attention was a part of my job.

"It was early on, it was excellent science, and it brought California high-quality venture capital money to Texas, funding a Texas company with California money—that's terrific.

"They were enthusiastic about it. They didn't document the review very well, for sure. People ask, 'Why didn't Gilman review the thing?' Well, first of all, I was never asked to. Secondly, I wasn't aware of what was going on. I was never sent the proposal. I didn't see it.

"My understanding now is that Peloton submitted a business plan that included scientific details to CPRIT and the Column Group. The Column Group, who made a co-investment with CPRIT, was supremely qualified to review the Peloton proposal.

Column's managing partner is David Goeddel, who was the first scientist hired by Genentech, and who moved on to co-found Tularik.

Column's scientific advisory committee includes three Nobel Laureates—Michael Brown and Joseph Goldstein, both of UT Southwestern, and David Baltimore, of the California Institute of Technology, as well as former NCI Director Richard Klausner.

Science partners also include Tom Maniatis, chairman of the Department of Biochemistry and Molecular Biophysics at the Columbia University Medical School, who pioneered the development of gene cloning technology and its application to the study of eukaryotic gene regulation. Maniatis is a co-author of the Molecular Cloning Manual, which was instrumental in the world-wide dissemination of the technology.

"This was a high-powered review group; it's unparalleled," Gilman said to The Cancer Letter. "They were the ones that not only reviewed it scientifically, but then agreed to put their skin in the game to co-fund it. So did it get a good scientific review? I'd say it got superb scientific review, though CPRIT didn't do its own scientific review. I don't know what Cobbs did, but apparently it wasn't documented."

CPRIT funded Peloton in June 2010, and private financing was finalized in July 2011.

Gilman said he has no financial involvement with either Peloton or the Column Group.

Recent news coverage has focused on the role of philanthropist Peter O'Donnell in the Peloton matter is similarly misguided, Gilman said.

O'Donnell, the philanthropist who had been the chairman of the Texas Republican Party, played a key role in getting $3 billion in taxpayers money to fund CPRIT.

Over the years, O'Donnell has given at least $135 million to the UT System, most of it anonymously. (He is known variably as Mr. Anonymous and Mr. O'Nonymous.) Though in 2009, the foundation's 990 tax forms listed $106.1 million in assets, its website is so spartan that it looks like it cost less than $20 to build.

O'Donnell doesn't seek to get buildings named

after himself or his wife Edith. However, after donating $32 million to build the UT Austin Applied Computational Engineering and Sciences Building, he allowed the cafeteria located in the building to serve something called the Peter O's Burger.

In 2009, CPRIT Foundation received $500,000 from the O'Donnell Foundation.

O'Donnell's money supplements the salaries of CPRIT employees, including Gilman and Gimson, who earned more than the state maximum. The foundation also paid for dinners for peer reviewers, who came to Dallas for two-day meetings. Gilman also contributed funds for these dinners.

These were modest events for up to 20 people, at places that included Mike Anderson's BBQ in Dallas, where "dinner plates" can be had for $12.50, and if you want something stronger than an iced tea, you bring it yourself, which Gilman's crew did.

"The fact that he gave $1 million or $1.5 million to the CPRIT foundation compared to other stuff is peanuts, and he did it solely with the notion of helping CPRIT be better," Gilman said. "Peter's contribution to CPRIT has nothing to do with the Peloton grant getting funded."

O'Donnell foundation officials didn't respond to requests for an interview. Speaking with the Houston Chronicle, a foundation official said the philanthropist didn't profit from the arrangement. According to the official, O'Donnell invested $900,000 on July 25, 2011, more than a year after the CPRIT Oversight Committee ratified funding for Peloton. He donated all his Peloton shares, as well as the rights to future shares, to UT Southwestern on Dec. 13, 2011.

"The important thing is that it happened after the CPRIT grant was funded. Had it been before, he could have profited from that. But it was one year after. He did it because he has enormous faith in Steve McKnight. He provided a large amount of money to recruit Steve McKnight to Texas."

Gilman said that in December 2011, O'Donnell donated all of his Peloton stock to UT Southwestern. "He made no profit from it," Gilman said.

When Gilman, a Nobel laureate, was being recruited from UT Southwestern, where he was the provost and dean of the medical school, his total compensation was equivalent to about $700,000 a year. As CPRIT employee, he could earn no more than the maximum state salary of $212,000.

The O'Donnell foundation stepped in at the request of CPRIT to make it possible to hire Gilman. "I didn't know Peter had made the donation at that time. My salary was negotiated with the head-hunter."

Though Gilman is acquainted with O'Donnell, he learned about the source of the supplement to his salary sometime after accepting the job. "Certainly, Peter never told me," Gilman said. "That's the sort of person Peter O'Donnell is. He is a saint."

During Gilman's first two years on the job, his salary, with the supplement, was at $700,000, but after making peer review function well, Gilman cut his hours and dropped his salary to $500,000 this year.

Had Gilman not resigned in protest over the MD Anderson's incubator proposal, his salary would have dropped to $350,000.

"I was cutting my salary in half voluntarily, because things were functioning smoothly and I didn't need to be there all that time."

Technology Transfer

GlaxoSmithKline Partners With MD Anderson, Fred Hutchinson

GlaxoSmithKline has signed separate research partnerships with MD Anderson Cancer Center and Fred Hutchinson Cancer Center to develop and market therapeutics.

GSK's research collaboration and license agreement with MD Anderson will focus on developing antibodies that promote an immune system attack against cancer. The company's partnership with Fred Hutchinson will explore a small-molecule-based medicine to potentially reverse facioscapulohumeral muscular dystrophy, with implications for cancer immunotherapies.

MD Anderson grants GSK exclusive worldwide rights to develop and commercialize antibodies that activate OX40 on the surface of T cells. They were discovered by Yong-Jun Liu and colleagues when he was professor and chair of MD Anderson's Department of Immunology.

OX40 is a secondary or co-stimulatory receptor protein. Liu and colleagues found that when it's activated, it enhances immune attack and blocks suppressors of immune response. MD Anderson's Institute for Applied Cancer Science will collaborate with GSK to conduct preclinical research on the antibodies.

Under the terms of the agreement, MD Anderson will receive an upfront license payment and funding for IACS research collaboration activities, as well as payments for reaching development, regulatory and commercial milestones. In addition, MD Anderson will also be entitled to royalties deriving from the commercial sales of products developed under the collaboration.

The goal of the new agreement with Fred Hutchinson is to potentially reverse FSHD by inhibiting the activity of a protein that is incorrectly expressed by the DUX4 gene. The protein activity is what damages muscle cells and leads to progressive muscle weakness and atrophy in FSHD patients.

Researchers also discovered that DUX4 regulates cancer/testis antigens. Cancer/testis antigens are encoded by genes that are normally expressed only in the human germ line but are also abnormally expressed in various tumor types, including melanoma and carcinomas of the bladder, lung and liver.

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Research Funding

Stand Up To Cancer Launches Immunology "Dream Team"

Stand Up To Cancer and the Cancer Research Institute announced the formation of a Dream Team project dedicated to cancer immunology—"Immunologic Checkpoint Blockade and Adoptive Cell Transfer in Cancer Therapy."

The team's project will focus on increasing the effectiveness of adoptive cell therapy and decreasing tumor resistance to immunotherapies. The project is estimated to start in the spring of 2013, with the first clinical trials scheduled to open in early 2014.

The SU2C-CRI Cancer Immunology Translational Research Dream Team will receive $10 million in funding over three years for this translational cancer research project that will unite laboratory and clinical efforts leading to the immunological treatment, control and prevention of cancer. The team will be led by James Allison and Antoni Ribas.

Allison is chairman of the department of immunology, director of the immunotherapy platform and co-director of the David H. Koch Center for Applied Research of Genitourinary Cancers at MD Anderson Cancer Center.

Ribas is professor of medicine, surgery and molecular and medical pharmacology, director of the tumor immunology program area at the Jonsson Comprehensive Cancer Center, and member of the Eli and Edythe Broad Center for Regenerative Medicine and Stem Cell Research at the University of California, Los Angeles.

Co-leaders of the Dream Team are Drew Pardoll and Cassian Yee. Pardoll is director of the division of immunology and Abeloff professor in the departments of oncology, medicine, pathology and molecular biology and genetics at the Sidney Kimmel Comprehensive Cancer Center. Yee is a member of the Clinical Research Division and program in immunology at Fred Hutchinson Cancer Research Center; a professor of medicine at the University of Washington School of Medicine; and an attending physician at the Seattle Cancer Care Alliance.

Scientists on this Dream Team represent eight institutions: MD Anderson Cancer Center, UCLA, The Johns Hopkins University, Fred Hutchinson Cancer Research Center, Dana-Farber Cancer Institute, California Institute of Technology, Memorial Sloan-Kettering Cancer Center and the Netherlands Cancer Institute.

Other Dream Team principal members include: David Baltimore, California Institute of Technology; Glenn Dranoff, Dana-Farber Cancer Institute; Philip Greenberg, Fred Hutchinson Cancer Research Center; Michel Sadelain, Memorial Sloan-Kettering Cancer Center; Ton Schumacher, Netherlands Cancer Institute; and Jedd Wolchok, Memorial Sloan-Kettering.

The team also includes the following advocates: Robert Behrens, REB Investments Inc.; Debra Black, Melanoma Research Alliance; Roy Doumani, cancer survivor; Valerie Guild, Aim at Melanoma; Jonathan Simons, Prostate Cancer Foundation; and Mary Elizabeth Williams, Salon.com.

In Brief

Haile Moves to Stanford Institute; Swanson Takes Job at Northwestern

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Since 2007 he has led the University of Southern California's Norris Cancer Center's Program in Cancer Causes and Prevention. He joined the University of Southern California in 1994 as professor and director of the Genetic Epidemiology Program.

KRISTIN RAE SWANSON was named professor and vice chair of research for neurological surgery at **Northwestern University** Feinberg School of Medicine.

Swanson comes to Feinberg from the University of Washington, where she served as the James D. Murray Endowed Chair of Applied Mathematics in Neuropathology as part of the Nancy and Buster Alvord Brain Tumor Center.

MICHAEL THUN, vice president emeritus of the American Cancer Society Surveillance and Epidemiology Research program, will retire at the end of 2012.

Thun began working at the society in 1989. He says he plans to use retirement "to travel, refuel, and explore opportunities for the next phase of life."

He has overseen the analyses of the society's large cohort studies, including Cancer Prevention Study 2. Thun's work has produced groundbreaking data on many issues, spanning aspirin as an anti-cancer agent, the adverse effects of obesity, and the evolving risks of smoking in the U.S. and worldwide.

"One of the most appealing aspects of my position is working with the extraordinarily gifted cancer scientists at the American Cancer Society," said Otis Brawley, the society's chief medical officer. "Michael Thun is one of most talented among those folk. He has also recruited many other exceptional researchers, building a department that is the envy of the leading schools of public health in world. He and his colleagues have had tremendous impact, literally defining how to control cancer."

"Michael's contribution to our understanding of cancer risk is hard to overstate," John Seffrin, CEO. "For the last few decades, he's been the caretaker of an enormously valuable public health tool: the Cancer Prevention Studies. Millions of Americans volunteered for those studies, and Michael made sure their contribution was treated with respect, while unselfishly sharing this data to improve life for countless others."

Thun has worked for 30 years in epidemiology and disease prevention, first as a medical officer at the New Jersey State Health Department investigating toxic exposures, then as an epidemic intelligence service officer and staff scientist for the Centers for Disease Control and Prevention at the National Institute for Occupational Safety and Health.

He became director of analytic epidemiology for the American Cancer Society in 1989, and in 1998 became vice president of epidemiology and surveillance research. He has served on numerous advisory groups for the Institute of Medicine, World Health Organization, International Agency for Research on Cancer, National Research Council, NCI and the CDC, and is an adjunct professor at Emory University, Rollins School of Public Health and the Winship Cancer Center. In 2010, he received the American Association of Cancer Research-American Cancer Society Award for Research Excellence in Cancer Epidemiology and Prevention.

LÁSZLÓ TABÁR and his colleagues were presented the first Alexander Margulis Award for Scientific Excellence by the Radiological Society of North America.

He is professor of radiology at the University of Uppsala School of Medicine and medical director of the Department of Mammography at Falun Central Hospital in Sweden.

Tabár and colleagues were honored for the article "Swedish Two-County Trial: Impact of Mammographic Screening on Breast Cancer Mortality During 3 Decades," published in Radiology in September 2011. This new annual award recognizes the best original scientific article published in RSNA's journal.

The award was accepted on behalf of Tabár

and the research team by study coauthor Stephen Duffy, professor of cancer screening at Queen Mary, University of London.

AMGEN will acquire **deCODE Genetics**, headquartered in Reykjavik, Iceland. The all-cash transaction values deCODE Genetics at $415 million, subject to customary closing adjustments, and was unanimously approved by Amgen's board of directors. This transaction does not require regulatory approval, and is expected to close before the end of 2012.

Founded in 1996, deCODE Genetics analyzes the link between the genome and disease susceptibility. The company has discovered genetic risk factors for dozens of diseases ranging from cardiovascular disease to cancer.

"deCODE Genetics has built a world-class capability in the study of the genetics of human disease," said Robert Bradway, president and CEO at Amgen. "This capability will enhance our efforts to identify and validate human disease targets. This fits perfectly with our objective to pursue rapid development of relevant molecules that reach the right disease targets while avoiding investments in programs based on less well-validated targets."

PHOENIX CHILDREN'S HOSPITAL announced the creation of the **Ronald A. Matricaria Institute of Molecular Medicine**.

Timothy Triche and Robert Arceci were named the institute's co-directors.

Triche is professor of pathology, cancer biology, and pediatrics at the Keck School of Medicine of the University of Southern California, and is the director of the Center for Personalized Medicine at Children's Hospital Los Angeles. Arceci is the King Fahd Director of Pediatric Oncology at the Johns Hopkins School of Medicine.

A founding gift by Ronald Matricaria provided the initial investment to establish the institute. Matricaria is a member of the Phoenix Children's Hospital board of directors and former chairman/CEO of St. Jude Medical, Inc.

Additional funding for the $50 million venture will come from philanthropic contributions and grant revenue. Initially, the institute will employ 50 scientists and other staff.

MEMORIAL SLOAN-KETTERING CANCER CENTER will launch a pancreatic cancer research center, established with a commitment of $10 million from MSKCC board member David Rubenstein. The new program will be called the David M. Rubenstein Center for Pancreatic Cancer Research.

In addition to providing funds for a senior investigator to direct the program, along with a full slate of educational initiatives—including postgraduate fellowships for future leaders in the field—it will sponsor competitive research grants at Memorial Sloan-Kettering.

Rubenstein is co-founder and co-CEO of The Carlyle Group and has been a member of MSKCC's boards of overseers and managers since 2005. He also serves as chairman of the John F. Kennedy Center for the Performing Arts and President of the Economic Club of Washington. He is vice chair of the board of trustees of Duke University, vice chair of the Brookings Institution and vice chair of the Council on Foreign Relations.

JOHN WALTER, CEO of The Leukemia & Lymphoma Society, was presented the 2012 Spirit of Hope Award for Outstanding Health Care Organization by the **Stanford University School of Medicine** in recognition of the society's 35 years of funding support to Stanford researchers.

In the last 15 years, LLS has awarded more than $27 million in research grants to Stanford investigators.

Funding Opportunities

LLS Requests Proposals In Six Areas of Unmet Need

THE LEUKEMIA & LYMPHOMA SOCIETY has issued new requests for proposals from researchers in six critical areas of unmet medical need:

• New immunotherapeutics for patients with acute myelogenous leukemia;

• Novel therapeutics for patients with non-cutaneous T-cell malignancies;

• Introduction of novel agents in the treatment of patients with diffuse large B-cell lymphoma and mantle cell lymphoma;

• Therapies for patients with myelodysplastic syndromes (MDS) who have failed hypomethylating agents;

• Therapies for new targets such as bromodomains, methylation and other epigenetic approaches for patients with high-risk myeloma;

• Research that addresses long-term and late effects of blood cancer therapies.

LLS will award grants under its Translational Research Program. Each grant will be for a three-year duration with a total value of up to $600,000. For more information please visit www.lls.org.

FDA News

FDA Approves ARIAD's Iclusig In Two Leukemia Indications

FDA approved Iclusig (ponatinib), for the treatment of adults with chronic myeloid leukemia and Philadelphia chromosome positive acute lymphoblastic leukemia, under the agency's accelerated approval program.

Iclusig blocks certain proteins that promote the development of cancerous cells. The drug is taken once a day to treat patients with chronic, accelerated, and blast phases of CML and Ph+ ALL whose leukemia is resistant or intolerant to a class of drugs called tyrosine kinase inhibitors.

Iclusig targets CML cells that have a particular mutation, known as T315I, which makes these cells resistant to currently approved TKIs.

Iclusig's safety and effectiveness were evaluated in a single clinical trial of 449 patients with various phases of CML and Ph+ ALL. All participants were treated with Iclusig.

The drug's effectiveness was demonstrated by a reduction in the percentage of cells expressing the Philadelphia chromosome genetic mutation found in most CML patients, or major cytogenetic response. Fifty-four percent of all patients and 70 percent of patients with the T315I mutation achieved the response. The median duration had not yet been reached at the time of analysis.

In accelerated and blast phase CML and Ph+ ALL, Iclusig's effectiveness was determined by the number of patients who experienced a normalization of white blood cell counts or had major hematologic response.

Results showed that 52 percent of patients with accelerated phase CML experienced MaHR for a median duration of 9.5 months; 31 percent of patients with blast phase CML achieved MaHR for a median duration of 4.7 months; and 41 percent of patients with Ph+ ALL achieved MaHR for a median duration of 3.2 months.

Iclusig is being approved with a Boxed Warning alerting patients and health care professionals that the drug can cause blood clots and liver toxicity. The most common side effects reported during clinical trials include high blood pressure, rash, abdominal pain, fatigue, headache, dry skin, constipation, fever, joint pain, and nausea.

Iclusig is marketed by ARIAD Pharmaceuticals.

FDA expanded the approved use of Zytiga (abiraterone acetate) to treat men with metastatic, castration-resistant prostate cancer prior to receiving chemotherapy.

The FDA initially approved Zytiga in November 2011 for use in patients whose prostate cancer progressed after treatment with docetaxel.

Zytiga's safety and effectiveness for its expanded use were established in a clinical study of 1,088 men with metastatic, castration-resistant prostate cancer who had not previously received chemotherapy. Participants received either Zytiga or a placebo in combination with prednisone. The study was designed to measure overall survival and radiographic progression-free survival.

Patients who received Zytiga had a median overall survival of 35.3 months compared with 30.1 months for those receiving the placebo. Study results also showed Zytiga improved rPFS. The median rPFS was 8.3 months in the placebo group and had not yet been reached for patients treated with Zytiga at the time of analysis.

The most common side effects reported in those receiving Zytiga include fatigue, joint swelling or discomfort, swelling caused by fluid retention, hot flush, diarrhea, vomiting, cough, high blood pressure, shortness of breath, urinary tract infection, and bruising.

The most common laboratory abnormalities included low red blood cell count; high levels of the enzyme alkaline phosphatase, which can be a sign of other serious medical problems; high levels of fatty acids, sugar, and liver enzymes in the blood; and low levels of lymphocytes, phosphorous and potassium in the blood.

Zytiga is marketed by Janssen Biotech Inc.

The European Commission approved expanding the label of Thyrogen (thyrotropin alfa) with a wider irradiation dose range for postoperative thyroid remnant ablation.

Thyrogen is used before radioiodine treatment to avoid temporarily discontinuing thyroid replacement therapy for postoperative thyroid remnant ablation.

The revised indication in remnant ablation provides physicians with the option to administer a reduced dose of radioiodine. Previously the amount of radioiodine was specified at 100 mCi, whereas physicians may now select a dose from the range of 30 to 100 mCi.

"The expanded Thyrogen indication provides a new option for many physicians who may be reducing radioiodine use due to uncertainty about impact on recurrences and mortality in low-risk patients as well as short- and long-term safety concerns," said Professor Martin Schlumberger, of the Institut Gustave Roussy at the University Paris Sud, in Paris.

The decision to approve the expanded indication for use of Thyrogen in Europe is based on the results of the two largest studies (HiLo and ESTIMABL) ever conducted in thyroid remnant ablation. The studies, published in the New England Journal of Medicine in May 2012, evaluated whether rates of successful ablation would be similar among patients receiving recombinant human thyrotropin, patients undergoing thyroid hormone withdrawal, and among patients receiving low or high amount of radioiodine.

In the two studies, a dose of 30 mCi of radioiodine was well tolerated and showed similar success rates for low-dose radioiodine plus rhTSH vs. high-dose plus THW or rhTSH. In both studies, patients receiving Thyrogen rather than THW had fewer hypothyroid symptoms and better preserved quality of life.

These findings have been reflected in the updated Summary of Product Characteristics and apply to all 27 EU member states, plus Iceland and Norway. Thyrogen is marketed by Genzyme, a Sanofi company.

Letter to the Editor

Oncologist Convicted In Absentia, Imprisoned in United Arab Emirates

On Oct. 12, after almost nine weeks in the hospital wing of the Al Wathba prison in Abu Dhabi, United Arab Emirates, Dr. Cyril Karabus was released on bail on the fifth such hearing attempted by his attorneys. The doctor had been arrested at the Abu Dhabi airport on Aug. 18 as his family returned from a wedding in Canada to their home in South Africa.

Dr. Karabus, an internationally renowned pediatric oncologist at the University of Cape Town, who aided underprivileged black children in the past, had been tried in absentia without his knowledge. He was convicted of manslaughter in the death of a patient for whom he cared 10 years earlier during a brief locum in the UAE. His sentence was reported to be three and a half years in prison and the payment of "blood money" to the dead child's family.

Dr. Karabus is not allowed to leave the UAE. His passport was confiscated at the time of his August arrest as his family was shuttled out of the country before their short-term visas expired. The doctor is in his late 70's with a heart condition and a pacemaker and has not looked well to the few Western observers present at his many court hearings. Initially, the files supporting the state's allegations against the doctor were not made available to the defense nor has the defense been allowed to contact the family of the deceased who had myeloid leukemia, a disease that is often fatal in the young. The file given to the defense on Nov. 20 lacked entries beyond July 31, 2002. The child in question died in October of that year. Dr. Karabus' trial is not over and he cannot leave the UAE.

Information about this apparent miscarriage of justice might be of value to those American physicians and other medical staff traveling to the UAE in exchange programs related to the many huge UAE gifts to several prominent American institutions of advanced medical care and research such as Johns Hopkins, Children's National Medical Center in Washington, D.C., and The University of Texas MD Anderson Cancer Center in Houston. Clearly, what a physician may have been tried for in this unusual justice system may not be known to him or her when passing through UAE airport security checkpoints. Perhaps some of the recipient institutions of UAE generosity might think very hard about the security of their own faculty members as they jet into—and hopefully out of—the UAE, as well as reflect upon the implications of such donations.

-Bernard Levin
-Leonard Zwelling