THE CANCER LETTER

Feb. 19, 2016 • www.cancerletter.com • Vol. 42 No. 7

Should ODAC Vote? Yes? No? Undecided?

By Paul Goldberg

At its most recent meeting, in July 2015, the FDA Oncologic Drugs Advisory Committee voted…

No, it *didn't* vote!

Breaking with a long-standing tradition, the agency asked ODAC members to "discuss" the key questions of risk vs. benefit of an experimental therapy instead of reducing their answers to a yea-or-nay vote (The Cancer Letter, July 10, 2015). Agency officials are mum on the subject of whether not voting has become a thing.

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News Analysis

Rejected Therapy Reveals Inconsistency of FDA Procedures for Drugs, Immunotherapies

By Paul Goldberg

Reform of the FDA oncology program is emerging as the immediately tangible element of the Obama administration's moonshot program.

With a modest $75 million commitment, the administration may be able to standardize the manner in which elements of modern cancer care are reviewed and approved by the regulatory agency (The Cancer Letter, Feb. 12).

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Slamming the Door

Part IV: Nobel Laureate in Crosshairs

By Paul Goldberg

In early 2012, Gilman was under the impression that CPRIT was functioning smoothly.

Then, to his surprise, the first of a series of controversies surfaced.

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Should ODAC Vote? Yes? No? Undecided?

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If it has, the agency would be able to focus on the substance of discussion and wouldn't have to worry about especially vocal ODAC members leading the rest of the committee into the wilderness. A vote is a great equalizer.

Is the opinion of a specialist in a specific disease worth more than that of an expert in an entirely different disease? Is a clinician's opinion worth as much as a statistician's? Or a patient's?

The agency generally thinks hard before disregarding a unanimous vote, but a split vote doesn't predict the agency's ultimate decision.

I asked a group of former and current ODAC members whether they think the committee should continue to be asked to vote. This was literally a vote on a vote. ODAC veterans were also asked to explain their reasons for voting the way they did.

I tallied the numbers and got five votes for the vote, and three against. The split is a regulatory maybe—it creates the need to pay attention to the rationale for casting the votes.

A former industry representative disregarded the instructions and voted "it depends." His comments appear below, but his vote was not counted in the total, as per ODAC rules.

The limitations of these findings are vast. There is bias. It's possible that people who believe that the vote is a good thing chose to respond while those who thought voting is absurd didn't. I didn't think it was nice to collect data on people who declined to participate or ask them to explain their reasons for not playing.

There was no starting rule and no stopping rule. Also, those who responded served on ODAC at very different times, including the times when drug applications were weak and consensus of the committee members looked like it was better than admitting to flying by the seat of one's pants.

Here is my questionnaire:

"During the most recent meeting of ODAC, FDA staff didn't ask for a vote on the approval question. There was discussion, but no vote. I have been covering ODAC for many years, and I find this change fascinating. So I decided to contact several former and current ODAC members and—in the spirit of ODACs past—ask for a vote and an explanation.

"**Voting Question (Yes, No or Undecided):** Should there be a vote on approval questions?

"**Your Reasons for casting this vote:** The answer can be as long as you wish. If anecdotes from ODACs past are useful, please feel free to cite them."

Here are the votes and the explanations in the order in which they were received:

Richard Simon
Chief, Biometric Research Branch
NCI Division of Cancer Treatment & Diagnosis

Vote: Yes

Why: I think it would be better for ODAC to retain their vote structure. They can get good advice with or without a vote, but voting forces the members to give their opinion on the hard choice. The human mind tends to avoid making those hard choices.

I know I always had a headache at the end of the day when I was on ODAC. Without a vote, I think ODAC loses something.

Wyndham Wilson
Senior Investigator, Lymphoid Malignancies Branch
Head, Lymphoma Therapeutics Section
NCI Center for Cancer Research

Vote: No.

Why: I think that scientifically the vote is unnecessary. It puts the FDA in a position when they go against ODAC of somehow justifying it. I just see how the vote is helpful in the overall scientific process. I understand how it's helpful in the political process. They can ask the questions, they can get discussions going.

They record all that stuff. They know exactly what each person said, so they can tally up, but they can also

Editor & Publisher: Paul Goldberg
Associate Editors: Conor Hale and Matthew Bin Han Ong

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

Subscription $405 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.

weigh what people said based on the merits of their arguments and based on the expertise of each individual.

If somebody has a lot more experience in a disease and makes cogent arguments, I would take their view far more seriously than those of someone who doesn't have these qualities vis-à-vis that particular drug. The other problem is that it's used by the companies instantaneously as a thumbs-up or thumbs-down Coliseum type of thing right there, and it goes on newswire, and then all of a sudden stock goes up, stock goes down, etc. That's an effect of having an absolute vote.

If I were FDA, I would move away from the vote.

Maha Hussain
Cis Maisel Professor of Oncology
Professor of Medicine and Urology
Associate Director for Clinical Research
Co-Leader, Prostate Cancer/GU Oncology
Univ. of Michigan Comprehensive Cancer Center

Vote: Yes.

Why: It's a short unequivocal answer for what the ODAC member thinks of the agent after hearing the full story. The discussion happens anyway, but the vote distills the discussion, and the FDA can consider whichever portion of the discussion and the vote.

Mikkael Sekeres
Director of the Leukemia Program and vice-chair for Clinical Research
Cleveland Clinic Taussig Cancer Institute
Deputy Associate Director for Clinical Research
Case Comprehensive Cancer Center

Vote: Yes.

Why: Most drugs that come before ODAC do not have a clearly delineated risk/benefit profile—otherwise, a committee to advise the FDA would not need to be convened.

The most important component of these meetings are the questions asked by ODAC members and the replies to the questions provided by the sponsor and by FDA. These questions are posed by members with a variety of backgrounds and sundry areas of expertise, and thus ideally reflect the many issues that need to be considered by FDA in whether or not to approve a drug. In this respect, the questions and answers themselves provide guidance to FDA.

So why the need for a vote?

No member of ODAC is allowed the time to express all of his or her views on the relative risk/benefit balance. Comments that are voiced may not represent the totality of thoughts about a given product.

A vote is a summary statement to FDA. It also pushes each ODAC member to weigh the risks and benefits as FDA has to weigh them and decide as an individual, and as an individual representing the hematology and oncology community, whether he or she would feel comfortable having this drug widely available, and offering it to patients.

Kathy Albain
Professor of Hematology/Oncology
Co-leader, Cardinal Bernardin Cancer Center Breast Cancer Research Program**,**
Co-director of the multidisciplinary Breast Oncology Center
Director, Thoracic Oncology Center and Research Program**.**

Vote: Yes (with some caveats, see below.)

Why: In the era I served on ODAC (1998-2002… the first approval of trastuzumab, the approval of tamoxifen for the prevention indication, the angst about PFS as a primary endpoint, etc.), our meetings consisted of either review of an indication with a vote, a review of an issue with advisory comments only, or a combination of both.

I found that the indications that required us to individually state our "vote" and reason for the vote raised the bar for accountability among us and informed the direction of the subsequent discussion.

By that I mean that to state for the public record on behalf of all our patients whether to recommend the drug be approved by the FDA or not demanded a heightened level of pre-meeting study, attentiveness to all the evidence, sponsor and ODAC colleagues' discussions, and a most serious consideration of risk-benefit ratio.

Participating in discussion-only advisory questions was also highly valuable for those situations in which either the evidence for approval was somewhat murky, or where the drug might not be quite ready for approval, or if the issue for which the Agency was soliciting our advice was not amenable to a yes-no vote. I actually found the meetings that combined both were the most valuable to all parties.

If there is a concern regarding "influence" of other voters' decisions before his/her turn to vote, perhaps taking a closed ballot first, and then asking in public each advisor the reason for their vote would address that issue.

Also, I am not certain going forward how necessary/valuable an advisory committee such as ODAC would be to the agency if it is always restricted

to a "discussion only" when a new drug approval or indication is at stake.

I am not clear, though, that that is the agency's intent from reading the transcript you provided.

My vote is to keep the vote with added discussion time.

Gregory Curt
Co-chairman, Life Sciences Consortium Task Force
Executive Director for External Relations in US Medical Affairs, AstraZeneca

Vote: It Depends.

Why: Inevitably, in industry, when someone asks a "yes or no" question to a regulatory affairs team member, the answer is, predictably, "it depends."

I suspect that the same perspective prevails within the agency. So my answer is not "undecided," but rather "it depends," and we need to recognize the difference and why it is so important today.

ODAC needs to evolve with the changing milieu of the science of cancer drug development, and I really believe that FDA has been at the proactive and informed forefront of this these changes.

Think about it. Not so long ago, large phase III studies costing hundreds of millions of dollars and thousands of patients were the coin of the realm. Success or failure depended on incremental benefits in a histologically defined patient population and which regimen was less toxic.

Indeed, that reality remains for other therapeutic areas outside of oncology, but oncology is evolving beyond that model and I predict that other therapeutic areas will follow. It's great for both the field and for patients.

Today, using molecular characterization, it is sometimes possible to identify a subset of patients who will benefit substantially from new targeted agents with increasingly less toxicity.

What does the agency do with that information? We've already seen approvals based on impressive single arm trials with post-marketing commitments for verification of the results in confirmatory studies. This brings new agents of real value to patients earlier than ever before. But the challenge doesn't end there.

What do the post marketing trials in this brave new world need to look like? What is the importance of exploring alternative dose-schedules, something relatively unaddressed to this point, but potentially very important? Should phase I trials be expanded to hundreds of patients when an activity signal is identified? What is the safety responsibility for an IRB and when does a formal DSMB need to assume this role? How does one bring early access into the mix?

FDA is proactively addressing all of these important issues in oncology, and I believe they are at the vanguard of future medicine in other areas. A dialog with industry, potentially within the context of ODAC or other venues will be important to progress.

David Steensma
Senior Physician, Dana-Farber Cancer Institute
Professor, Harvard Medical School

Vote: A qualified No.

Why: While the votes were a useful barometer, not all questions posed to ODAC require a vote or benefit from one. In fact, in committees I served on, the votes often seemed somewhat artificial after what was a nuanced and in-depth discussion of data or policy. And close votes also put the agency in a potentially challenging situation politically—8 to 5, 9 to 7, etc.

Ultimately the agency has to make decisions about approvals, labels and REMS based on many factors, and ODAC's role is only advisory. I think that ODAC's "highest and best use" is to bring out perspectives for the agency that they might not have considered.

Conversely, I had the sense while serving on ODAC that the agency sometimes called an ODAC meeting not so much because they wanted committee members' opinions, but because the agency wanted a discussion about a drug, efficacy assessment, or safety concern aired in a public forum. This was a smart way for the agency to provide support for decisions they had already decided to make. I also envisioned that sometimes there had been many discussions behind closed doors and that the OHOP staff were finding a sponsor difficult to deal with, and decided that calling an ODAC would be a good way to have a sponsor hear concerns voiced by experienced oncologists who didn't work for the government.

The conflict of interest paranoia that we operate under today means that only a small proportion of voting ODAC members know a drug or disease area in depth, and this could influence votes. (Not that being uninformed ever stopped anyone for voting for politicians…)

For instance, I was excluded from ODAC committee meetings due to perceived COI where my relationship with the sponsor was a mystery to me or tangential at best (e.g., a co-investigator on a multisite trial in a different disease area, sponsored by a competitor in a different disease area of the sponsor of the drug before ODAC.) I was allowed to serve on other committees for diseases where I hadn't seen a patient

since fellowship and knew the disease area only from weekly conferences and JCO papers, yet my vote carried equal weight to a true expert in the disease.

At the end of the day, it was an honor to serve on ODAC. Although ODAC service required a lot of time to try to do it properly—time away from the practice for the committee meetings, and time carefully reviewing briefing materials from the agency and the sponsor—for the most part I felt that was time well spent and a genuine public service. I also learned a lot from it.

Helen Schiff
Breast Cancer Patient Advocate
Working with the National Breast Cancer Coalition and SHARE

Vote: No.

Why: I agree with the FDA in changing its policy about not asking ODAC members to vote on recommendations to the FDA. Why? First and foremost, on my years on ODAC and my years testifying or following ODAC meetings, I found that I am more in agreement with FDA decisions than with the outcome of votes taken at ODAC meetings.

I think the FDA has more expertise on what drugs should be approved and which should not. In reality, since ODAC meetings are advisory, a vote up or down is kind of hypocritical. It doesn't carry much weight, but can be used by interested parties as a foil against an FDA decision.

In addition, I think there will be a more honest give-and-take and a more nuanced discussion if ODAC members are not forced to defend an up or down vote.

Derek Raghavan
President of the Levine Cancer Institute
Carolinas Healthcare System

Vote: Yes

Why: The issues that face ODAC and the FDA are often complex and convoluted. The quality of data presentations and of the data varies, and there is often considerable wind and rhetoric.

At the end of the day (which is often a long and tortured one), it is helpful for the committee members to finalize their opinions into a composite. It also holds FDA staff accountable for either adhering to, or deviating from, the strength of the recommendation. Thus deviation against a structured, unanimous advisory opinion from ODAC is quite different from a decision with a 55:45 split.

News Analysis

Rejected Therapy Reveals Inconsistencies at FDA

(Continued from page 1)

As it stands, immunological and cellular cancer therapies as well as diagnostics don't go through the same review procedures as cancer drugs and biologics.

The administration is proposing to address this inconsistency by creating a "virtual" oncology center at the agency, but no one seems to be able to understand how a virtual center would be defined and whether it would be able to synchronize the agency's functions in oncology.

In today's FDA, the type and quality of review can vary dramatically. The pathways to which a therapeutic or diagnostic is assigned can determine:

• The type and quality of guidance received through the development process,

• The chances of the application being referred to an advisory committee,

• The level of expertise of the advisory committee, and

• The chances that committee members would be asked to vote on an application.

Consider the recent application by Telesta Therapeutics Inc. for the approval of Mycobacterium phlei Cell Wall-Nucleic Acid Complex, or MCNA, for intravesical use in the treatment of non-muscle-invasive bladder cancer at high risk of recurrence or progression in adult patients who failed prior bacillus Calmette-Guérin immunotherapy—i.e., in patients who are BCG refractory or BCG relapsing.

Earlier this month, the company got bad news from the agency: an additional phase III clinical trial for MCNA would be necessary to adequately establish MCNA's efficacy and safety.

"We are very disappointed with the FDA's decision," Michael Berendt, the CEO and chief scientist, said in a statement. "Since we began our dialogue with the FDA in February 2014, we have clearly communicated that we believe that MCNA is a safe and efficacious agent for the treatment of high risk non-muscle invasive bladder cancer patients who have failed front line BCG therapy. The FDA decision, at this point, to require an additional clinical trial, is a setback for under-served bladder cancer patients, our dedicated staff, and our investors who have funded our efforts to obtain MCNA approval in the U.S."

The agency's decision follows on a meandering all-day meeting of an advisory committee, which voted 18-6 against approval (The Cancer Letter, Nov. 20, 2015).

Publicly available information doesn't make it possible to assess the quality of guidance the company received from the FDA Center for Biologics Evaluation and Research and compare it with the type of guidance it would have received at the agency's Center for Drugs Evaluation and Research.

However, when the matter came to the attention of the advisory committee, the lack of focus in the presentations by the company and the agency was difficult to miss.

Had the drug gone to CDER's Office of Hematology and Oncology Products, the application would have been a candidate for being bounced to the FDA Oncologic Drugs Advisory Committee, which usually consists of about a dozen members, most of whom are focused on cancer drugs.

The CBER group formed a massive advisory committee that included all of ODAC and the entire Cellular, Tissue, and Gene Therapies Advisory Committee. That's 25 voting members.

With the committee taking a vote, people who don't know cancer could have easily drowned out those who understand the disease. This method of soliciting advice differs from what would have happened before the agency took the first stab at consolidating its oncology units more than a decade ago.

Before that consolidation, small-molecule compounds went to one administrative unit—CDER—and biologics, including monoclonal antibodies and growth factors, went to another—CBER.

Nonetheless, both small-molecule drugs and biologics went to the same advisory group: ODAC.

One might have surmised that by the time FDA asks an advisory committee to vet an application, the questions would deal primarily with clinical utility of the therapy in question. By that stage in the game, advisors would be asked to discuss the outcomes, as opposed to the biological mechanisms for achieving them. Yet, the biological mechanism was very much on the table.

It's unlikely that MCNA would have made it to an advisory committee at CDER. The company's single-arm trial missed its primary endpoint and was stopped prematurely.

Worse, it was unclear what kind of patients benefited and what the characteristics of their disease were.

"At the end of the day, I thought there was a handful of patients, maybe even less than the number of committee members [here], that we could say had clear and durable benefit from the drug," said ODAC member Brian Rini, associate professor of medicine at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University.

ODAC appears to have moved away from asking its advisors to vote. The latest thinking at the oncology office suggests that a committee vote can be misleading and a discussion has greater value.

Also, at ODAC meetings, committee members who exhibit a lack of understanding of laws and regulations are given quick reminders. This didn't happen at the MCNA deliberations, when the chair of the joint committee, Timothy Cripe, professor of hematology, oncology and bone marrow transplantation at Nationwide Children's Hospital at Ohio State University, expressed disappointment with the outcome.

"We're still losing the war on cancer in general, and we need all the help we can get," Cripe said. "And with immunotherapies on the rise, if this were approved, I'm sure there would be a lot more trials and combinations that would augment its activity."

Actually, FDA's functions don't include encouraging development of approaches to therapy. The agency's function is to approve indications for therapies.

Before the vote was taken, Cripe floated a proposal to take an informal straw poll before the binding vote, presumably to determine how many committee members were opposed to the application.

And when a voting patient representative noted that approval is important because it would lead to reimbursement, neither Cripe nor FDA staff members stepped in to point out that FDA has no authority to consider the cost of therapies.

Over the past decade, the agency has been pushed by oncology groups to consolidate its cancer operations, thus making it possible to place cancer drugs, biologics, vaccines, diagnostics and devices all under the same regulatory roof (The Cancer Letter, July 9, 2004, July 23, 2004, Feb. 18, 2005, March 4, 2005, April 22, 2005).

This drive is visibly intensifying as the agency's Office of Hematology and Oncology Products is changing the structure of drug development—and approving more drugs than any other part of FDA (The Cancer Letter, Feb. 14, 2014).

This is happening in part because, likely more so than at any other time in the history of oncology, all participants understand the approval criteria and as the Obama administration is seeking to make progress against cancer.

"The moonshot creates a framework that builds upon the incredible oncology research taking place all across the country," Ellen Sigal, chair of Friends of Cancer Research, a Washington group spearheading

FDA reform, said to The Cancer Letter last week (The Cancer Letter, Feb. 12)

"By finding ways to streamline the FDA it creates a more collaborative ecosystem across all sectors to expedite scientific discovery. Specifically, it calls on Congress to update FDA's structure to better reflect 21st century science by creating Centers of Excellence within FDA. The centers will improve coordination within and between FDA medical product centers and break down decades-old silos within FDA and make for a more efficient agency. This coordination will allow the agency to expedite the development of novel combination products, as well as support an integrated approach in product evaluation, support continued development of combination products, and develop and promote precision medicine methods.

"Most importantly, the proposal enhances FDA's ability to execute their vital role in translating scientific discovery into new therapies for patients."

The most spectacular snag in CBER's operations involved the drug Provenge, which was approved by the advisory committee in 2007, only to encounter a backlash from cancer experts who had been outvoted by non-oncologists on the committee (The Cancer Letter, April 13, 2007, April 27, 2007, May 4, 2007).

Slamming the Door

Part IV: Gilman in Crosshairs

(Continued from page 1)

CPRIT's peer reviewers had evaluated 40 applications for Multi-Investigator Research Applications, the largest CPRIT grants designed to fund team science, recommending that seven of these project receive funding. This was no small undertaking. The applications described multiple projects and core facilities.

Proposals for these projects—abbreviated as MIRAs—take a long time to write and a long time to review. The CPRIT committees worked hard to complete the review, but committee members were enthusiastic. There was a lot of good science on the table. In fact, one of the grants received the best score ever for an application of that type.

The projects were distributed all over the state and most of the proposals were inter-institutional, but five of the seven principal investigators were at UT Southwestern. This was understandable. UT Southwestern is, hands-down, the leader in biomedical research in the state. And, not surprisingly, it received the highest proportion of CPRIT grants.

By way of comparison, MD Anderson's strength is in clinical research and clinical care. The institution has been building its basic science, and the focus on basic science was likely one important reason the regents selected DePinho to lead that institution.

Cumulatively, since CPRIT's formation through 2011, UT Southwestern received $173.6 million in funding for 91 grants. MD Anderson was second, with $128.7 million in funding for 81 grants.

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The fact that some institutions got more money than others seemed to upset some Texas politicians.

Documents I would later obtain under the Texas Public Information Act show that at CPRIT, an oversight committee member named Mark Watson, from San Antonio, constantly raised questions about the amounts of research funds going to UT Southwestern as well as about the cost of peer review.

Watson ran an insurance office and a ranch. He had previously served as chairman of the board of the Cancer Therapy and Research Center and assisted in the CTRC merger with The University of Texas Health Science Center at San Antonio. Gilman was surprised to learn that CPRIT's executive director, Bill Gimson, decided to give in to Watson by unilaterally removing the seven approved MIRAs from the research slate that was to go to the oversight committee in March 2012.

This cut the total awards for research by two-thirds.

CPRIT management's eagerness to appease Watson by changing funding requests outraged Gilman. Some politico out there was second-guessing peer review of grant proposals conducted by some of the best scientists in the world. What did Watson want? Regional quotas?

"One person (as best I know) is turning us on our heads," Gilman wrote in a March 9 email to Gimson. "Nobody I know has ever heard of this guy before. Because of him, you are suggesting cutting just about 50 percent of our recommended requests for research, including nearly two-thirds of that destined for UTSW, almost half of that for Baylor, 100 percent for UT Dallas, etc.

"If we don't fight back, rather than try to sneak around the situation, we are not worthy of our jobs."

Though furious, Gilman refrained from raising hell—not publicly, and not yet.

He decided to hold back, because Gimson had assured him that the MIRAs would be funded later in the year, in July 2012. Basically, the executive director

was asking for three months during which he would socialize and educate Watson.

Gilman had to sell this to the scientific council, assuring its members that delay was caused by political budgetary problems and that the grants would be funded.

This made Gilman uncomfortable, but he did it anyway, he said.

Had he known what else was about to happen, he would have been unwilling to compromise, he told me later.

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In early March 2012, another CPRIT official, Jerry Cobbs, who ran the commercialization program, asked Gilman to look over a six-and-a-half-page proposal submitted by the Institute for Applied Cancer Science, Lynda Chin's institute at MD Anderson. The proposal was sent directly to Cobbs via email.

Gilman looked at the thing and immediately determined that it contained no scientific content.

There were no targets mentioned, no molecules, no diseases, no intellectual property. Nothing to review.

Gilman said he had heard of that proposal before, and that the proposal should be submitted as a MIRA, accompanied by sufficient detail. Cobbs concurred, telling Gilman that the Chin proposal would go nowhere, at least for now. Wrote Cobbs: "Much too complicated as presented. Will just focus on Rice/TMC INCU. Will revisit the pipeline build opportunity with MDA at later date." Based on the Cobbs response, Gilman assumed that this issue was dead for the time being.

But the Cobbs email warrants unpacking. Cobbs was referring to the incubator that was proposed by Rice University. That institution had made what Gilman regarded as a well-formulated and somewhat more modest request—about $4 million per year. The proposal received thumbs-up from reviewers and was heading toward approval by the CPRIT Oversight Committee.

Gilman was still unable to see what was coming.

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Internal documents I obtained under the Texas open records law make it possible to see the things Gilman couldn't have known at the time.

For starters, he couldn't have known that DePinho and Chin were working with Charles Tate, a venture capitalist who served on the executive committee of CPRIT's oversight committee, chaired the economic development and commercialization subcommittee, and served on the MD Anderson Board of Visitors, a group composed of wealthy supporters.

Tate had advocated the loophole for incubators, making them subject to review based on their commercial, as opposed to scientific, promises. He did not seem to understand that weak science would not be the progenitor of great products, Gilman would say to me later.

Documents show that, unbeknownst to Gilman, Tate was working on a plan to combine Chin's incubator with the incubator proposed by Rice. The two proposals would be combined and sped through to oversight committee for approval.

In an email to Cobbs, the CPRIT commercialization officer, on March 14, 2012, Gimson writes that Tate had warned him about considering the Rice proposal first, to be followed by the MD Anderson proposal: "Jerry: Charles just called me—he is concerned about timing and bifurcated approach of the Rice/IACS Incubator. Let's talk tomorrow early. Bill."

Other emails similarly identify Tate as the author—or at the very least a co-author of the plan to combine the Rice and MD Anderson proposals.

A March 12, 2012, email from Gimson traces that idea to around March 2011. "[Tate] was very engaged (and vocal about the proposed structure of the incubator and more specifically the decision-making process for potential projects—he wanted a "one time" approval for the incubator with individual projects (to be funded from incubator's grant) to be approved by a 'strategic steering committee.'"

On April 23, Chin, reported that she had gone through her calendar and found that "the date at which point we decided to definitively move forward with putting the two [proposals] together occurred on Dec. 1, 2011, through two meetings…first with Charles Tate, at which point he indicated that IACS would fit very well with the incubator concept."

Why were these behind-the-scenes activities necessary?

Possibly, giving money to Chin's institute was a part of the deal—formal or not—that may have been struck at the time of DePinho's and Chin's couple's arrival in Texas. Indeed, $75 million over three years would have given IACS a healthy start. Had it been funded, the purported incubator could have become a powerful tool for dispensing money by methods less cumbersome than peer review.

The money would have been placed in a black box, which IACS leadership would control.

Tate understood the complex interplay of government and industry in Texas. He also understood how lucrative such arrangements can be.

The financier has contributed $465,000 to the political campaigns of Texas Lt. Gov. David Dewhurst. Three years earlier, an investigation by The Dallas Morning News found that Tate and other donors to Gov. Rick Perry benefited from investments from the Texas Emerging Technology Fund. http://dallasne.ws/dNtkZ0

Tate appeared to be well compensated for his generosity.

A Tate company, called ThromboVision Inc., received $1.5 million in state funds, almost four times the amount Tate had contributed to Perry.

The company has since declared bankruptcy.

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In the afternoon of March 22, 2012, a week before the CPRIT oversight committee meeting, Gilman's administrative assistant walked into his office to tell him that CPRIT had just put up the slates for the oversight committee, and that the slates included a $20 million incubator grant for one year to Rice and MD Anderson.

"Bullshit," said Gilman. "You are crazy."

She said, "No, I am not."

"That can't be."

"Take a look."

She wasn't crazy.

The grant to Rice was expanded to include MD Anderson. Actually, the way Gilman saw it, the title page of the Rice proposal remained unchanged and the six-and-a-half-page business plan describing Chin's institute was fused to the rear of the Rice proposal. The Rice proposal was unchanged: it requested $12 million over three years.

The two documents didn't refer to each other. They were completely independent; they were simply fused.

Suddenly, everything became clear to Gilman.

The delay in funding the seven approved Multi-Investigator Research Applications was directly related to the MD Anderson incubator. In fact, the desire to fund IACS without proper peer review had caused a delay in funding excellent research projects that went through review.

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There were other problems with the way the incubator proposal was handled:

• The MD Anderson portion of the proposal was, in fact, submitted without review by *any* provost. Officials at Rice said that they reviewed only their own portion of the proposal. Rice officials said they "saw" the MD Anderson portion of the proposal only after it was first submitted to CPRIT.

• After bypassing standard institutional review, the MD Anderson portion of the proposal was submitted to CPRIT in a way that bypassed the procedures specified in the state agency's request for proposals. The proposal was submitted by an official of Chin's unit of MD Anderson directly to CPRIT chief commercialization officer via email, completely omitting the signature of MD Anderson Provost Raymond DuBois.

• The CPRIT official then turned around and, bypassing the electronic filing procedures, forwarded the email over to the contractor that manages grant awards for the state agency, knowledgeable sources said. The contractor then forwarded the application to the commercialization reviewers.

• In another departure from rules, a meeting of outside advisors who reviewed the commercialization proposal was convened by the CPRIT general counsel, rather than the contractor, sources said.

• At that meeting, which was held March 21, 2012, a reviewer who recused himself—citing his role on the board of directors of a company founded by Chin and DePinho—was nonetheless invited to address the committee and describe the track record of the individuals involved.

• The chair of the five-member review committee and one member of the board figured on the Rice portion of the application, which had been reviewed earlier. The committee's chair didn't cast a vote, but the conflicted committee member voted on the MD Anderson portion of the application, state officials confirmed.

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Gilman went ballistic.

He arranged a meeting with Texas Speaker of the House Joe Strauss, but that accomplished little.

Also, he approached Francisco Cigarroa, the chancellor of the UT System. Cigarroa, who got an undergraduate degree from Yale and an MD from UT Southwestern, had the authority to stop the project.

Gilman and others had extensive conversations

with Cigarroa. "Well, I just don't think there is anything I can do about this," Cigarroa said to them.

Later, Cigarroa would turn up at MD Anderson events, expressing support for DePinho and his Moon Shots.

Kenneth Shine, the executive vice chancellor for health affairs, found an ingenuous way to appease Gilman, yet not get in the way of approval of the giveaway of state funds to Chin. "Bill, I just received this email (from Gilman)," he wrote to Bill Gimson on March 28, the day before the CPRIT board approved the incubator. "It does suggest that postponing action and obtaining additional scientific review of the proposal makes sense. Ken."

This choice of recipients is fascinating, because Gimson didn't report to Shine. DePinho and Chin did.

Had he really wanted to stop this project, Shine would have sent instruction to them.

Gilman spoke with members of the CPRIT review council. There would be no way any member of the committee would stay in the job if the CPRIT higher-ups so blatantly disregard peer review.

The situation would be particularly egregious if the seven MIRAs remain unfunded while the IACS incubator would get a massive handout.

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Internal documents later obtained from CPRIT made it possible to watch state officials make sure that the grant to the incubator cleared all the hurdles to final approval.

As they try to deliver $18 million to MD Anderson, officials sound a bit like car salesmen in a dealership's smoking lounge.

"As a cautionary note, nothing is a done deal until it's in the 'hip-pocket-national bank' but taking an optimistic view of tomorrow's Board meeting, I would like your input on the announcement," CPRIT Chief Commercialization Officer Jerry Cobbs wrote in a March 28, 2012, email to Chin.

This exchange is all the more remarkable because it shows high-level CPRIT and MD Anderson officials focusing on chiseling the language of the press announcement of the Chin incubator *before* it went to the CPRIT board for final approval.

In another email the next day, Gimson asks Chin for a strong quote for use in a press release.

"We are experiencing some internal pushback that the [Institute of Applied Cancer Science] proposal is not an incubator—and should have a 'science' review," Gimson writes. "I would like a quote from you in this release to show strong support."

Later that morning, Chin emails him this quote from her husband, DePinho:

"The cancer drug development system is broken. Today's biotech paradigm of driving academic discoveries to effective clinical endpoints suffers a 95 percent failure rate. The IACS is a novel organizational construct designed to dramatically increase success by bringing together the best attributes of academia and industry to yield targeted drugs with clear applications in specific cancers. IACS comprises industry-seasoned professionals with proven capabilities in developing drugs, crating highly successful companies and forging productive alliances with biopharma. CPRIT support for this effort will catapult Texas to the forefront of the biotech industry in the decades to come."

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Many strings of emails begin with Gilman's morally outraged discourses on what he sees as the obvious illogic of deviating from rigorous peer review or bowing to political pressures.

As these emails bounce around CPRIT and its governing board, state bureaucrats and advisors add in disrespectful remarks.

"I believe Al is upset because he wants these [incubator] proposals to come as MIRA proposals so that he has control over it…If this is accurate, then once again Al is operating from improper motives," writes Jimmy Mansour, chair of CPRIT's oversight committee and a telecommunications entrepreneur. His March 22 email, addressed to oversight committee member Joseph Bailes, was prompted by Gilman's objection to the effort to approve the MD Anderson incubator without considering the assessing the scientific projects it would undertake.

As Gilman continues to disagree, Mansour instructs CPRIT chief executive Gimson and CPRIT attorney Kristen Doyle March 31: "I would simply tell Al that we must follow the rules in this matter. CPRIT policies and procedures and consistent application thereof are essential to the health and credibility of those [sic] organization."

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Other events were occurring outside Gilman's purview included the approval of $11 million to Peloton Therapeutics. The decision to award these funds was made without any peer review by CPRIT.

Later this would lead to criminal charges against Cobb. Cobb, who was acquitted, had rushed the application through approval without arranging peer review. This case—the only criminal prosecution to result from the CPRIT scandals—surprised Gilman.

The funding was approved on June 18, 2010. The company—which grew out of research by Steven McKnight, UT Southwestern's Department of Biochemistry chair—didn't seek special treatment. And, presumably, it would have easily withstood rigorous review. Gilman made CPRIT aware of the McKnight proposal and the interest from the Column Group, a California-based venture capital firm. That was the end of his involvement.

When we discussed Peloton, Gilman said the Peloton grant was outside his purview. Review procedures were not well established for commercialization applications, particularly for nascent companies that did not have a previous track record. CPRIT never asked Gilman or the scientific reviewers to examine the Peloton application, and he never had a reason to see it—and never did.

He had no idea the application had not undergone formal review, but he told me that the review it clearly did get from Column Group was as good as it gets. The scientific leadership of the partnership included David Goeddel, a founder of Genentech. Other advisors included David Baltimore, a Nobel laureate; former NCI Director Richard Klausner; Columbia University's Thomas Maniatis, one of the founders of modern molecular cloning; and Mike Brown and Joe Goldstein, both Nobel laureates from UT Southwestern.

The Column Group was putting its own millions of dollars into the venture.

"Peloton was the best investment CPRIT ever made," Gilman said to me after that scandal started to emerge.

That said, he had no idea why anyone would skip peer review and thought that Cobbs didn't deserve to face criminal charges for what was at worst a screw-up.

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After CPRIT made the decision to fund the Rice-MD Anderson incubator grant, Tate made a fascinating statement:

"One of the biggest obstacles to getting life-saving treatments to patients is not a lack of good ideas or good science, but a lack of business expertise," he said in a Rice press release, suggesting that there are plenty of good cancer drugs, and that commercializing them is all that needs to be done.

Of course, Gilman and his team of scientists regarded this statement as outrageous.

Venture capitalist Robert Ulrich, chair of the CPRIT commercialization panel, appears to be at least as pleased as Tate.

In an email, Ulrich projects that CPRIT would now spend 40 to 45 percent of its funds on such projects. "Incubators are just getting off the ground," he writes in a May 2 email to Gimson. "In the near term, I suspect their funding requirements will be two to four times what they are for the first incubator… Bottom line, I can see an allocation of 10% Administration, 10% Prevention, 40% Research, and 40% Commercialization."

On May 15, a week after announcing his plans to resign, Gilman prods Gimson to produce meaningful guidelines on incubators.

"It's a simple question, I think: how much local autonomy on the amount of money to be handed out to any project or nascent company? And how do you judge the total amount that should be awarded to an incubator?

"$4M a year is really quite a lot. A related question: what is the density of the science in the area served by the incubator? An incubator in Houston should get more than one in Lubbock.

"It's frankly hard to imagine an incubator in Lubbock."

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In internal memos, Gilman appears to be an alone, and often despised, advocate of science at a state agency suddenly gone political. Trust appears to be a deficit commodity on all sides. Pressure and isolation appear to get to Gilman.

"So I'm not a complete jerk," he vents to CPRIT colleagues in an email March 8. "I just like to bay at the moon and yell at the jerks and otherwise make a complete pain in the ass of myself. I've become a curmudgeon. Or, as the old cigarette ad used to say, I would rather fight than switch."

In an effort to get Gilman to leave voluntarily, Gimson starts pressuring him to leave the UT Southwestern campus.

In an email dated April 19, Gimson updates the oversight committee members Mansour and Joseph Bailes on the progress of that operation.

"[Gilman] is aware that peer review process will change and he must leave the UTSW campus if he is to continue at CPRIT."

On May 5, three days before handing in his letter of resignation, Gilman writes:

"One of the things that has annoyed me the most over the past while is having Mark Watson and perhaps others question the integrity of the peer review system.

"Its establishment has been the one thing of value that I have accomplished over the past nearly three years."

In a May 8, 2012, email to CPRIT scientific council member William Kaelin, a Dana-Farber Cancer Institute scientist, Gilman writes: "There are some really evil people on the [CPRIT] Oversight Committee now. Can they be taken out? I will not continue to work for them or with them. There are the 'UT Southwestern is getting too much money' people and there are the 'we should spend much more money on commercialization' people."

Though decisions made at MD Anderson were contributing to the turmoil at CPRIT, officials at MD Anderson say the CPRIT emails weren't reaching them.

"I don't think, quite frankly, that anyone here at MD Anderson, including Ron, was aware of the level of discussion that was going on internally at CPRIT at that point in time. I don't think there's any question that we became more aware of this as it played out," Fontaine said to me during a January 2016 interview.

"But in terms of Dr. Gilman's view of what should be apportioned to basic science research or pure research versus commercialization; versus some of the other things that CPRIT was supposed to be doing in prevention, and getting companies to relocate to Texas, I don't think anybody here—I can't speak for 18,000 folks—but I would be surprised if anybody here was knowledgeable about what was going on there as other may have been that were more closely involved.

"I do believe that there had been some discussions kind of generally out there, amongst our faculty and others, that the number of awards that were going to MD Anderson versus other institutions, but I don't think it ever got to the granular level of commercialization versus research, on our radar screen, until this story started coming about."

Report: Medicare Pays 340B Hospitals Less Part B Drug Reimbursement

By Matthew Bin Han Ong

A group advocating for the 340B Drug Discount Program examined the widely held belief that health care organizations enrolled in the controversial federal program receive significantly higher reimbursement for drugs than institutions that do not take part in the program.

Previously, a July 2015 study by the Government Accountability Office found that, per beneficiary, Medicare Part B drug spending was indeed higher at 340B hospitals than at non-340B hospitals.

The GAO concluded that, on average, beneficiaries at 340B hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at other hospitals.

But the Feb. 10 study, funded by 340B Health, found that—contrary to what the GAO report stated—hospitals enrolled in the program receive 13 percent less in Medicare Part B reimbursement than non-340B hospitals and physician practices. 340B Health is a Washington, D.C. association advocating for hospitals enrolled in the federal discount program.

Other studies by pharmaceutical companies and economists have found that the program is spending more than the original legislation intended, and that wealthier patients are more likely to benefit from the drug discounts (The Cancer Letter, Oct. 10, 2014).

The 340B Health study focused on "separately payable" Medicare Part B drug utilization and spending, and compared 340B-enrolled hospitals to all other providers in the Part B market.

"The 340B program gives hospitals with high volumes of low-income and other vulnerable patients discounts on pharmaceuticals," said 340B Health President and CEO Ted Slafsky. "This study confirms that hospitals accessing 340B savings are treating significantly higher numbers of vulnerable patients and that 340B hospitals are not providing more drugs or more expensive drugs than non-340B providers."

According to the 340B Health study, Part B spending in non-340B hospitals represents 18 percent of all Part B drug spending. Physician offices that do not qualify for 340B represent 56 percent of Part B drug spending.

The GAO did not include that latter group of providers in its review, the study's authors said.

"A more complete analysis of Medicare Part B spending differences would include those other non-340B providers," said Dobson DaVanzo & Associates, the firm that conducted the study.

"Separately Payable" Drugs

Part B-covered drugs generally fall into three categories: drugs furnished incident to a physician's service, drugs explicitly covered by statute, and drugs used in conjunction with durable medical equipment.

The Centers for Medicare and Medicaid Services divide payment for these drugs into two categories: separately payable drugs and packaged drugs. Separately payable Part B-covered drugs are reimbursed when estimated per-drug, per-day costs are greater than $60.

Packaged drugs are inexpensive Part B-covered drugs that do not exceed the $60 threshold—CMS does not make separate payments for these drugs, which include payment for the treatment during which the drug is administered.

Congress established the 340B program in 1992 in response to escalation of drug prices, which limited access to treatments for low-income and uninsured patients.

Under this popular but controversial program, health care providers—including safety net hospitals and clinics that receive federal grants—get discounts in pricing of 20 to 50 percent on outpatient drugs. The discounts have to be provided by manufacturers participating in Medicaid or Medicare Part B programs.

To get 340B discounts, institutions usually have to demonstrate that Medicaid or Medicare covers about 30 percent of their patients, which are referred to as disproportionate share hospitals.

In recent years, many key players in oncology have been questioning the 340B program's expansion and the eligibility criteria it uses to enroll these institutions. Critics say the program is poorly defined, and is increasingly abused by entities that can fend for themselves without help from the government.

The Health Resources and Services Administration issued a draft guidance that would provide stricter definitions for which patients and entities should be covered. The public comment period ended Oct. 27, 2015, and stakeholders are anticipating the final guidance. (The Cancer Letter, Sept. 11, 2015.)

The guidance's redefinitions have generated much debate: pharmaceutical companies and academic health care economists say that the guidance would prevent unnecessary expenditure, while 340B supporters argue that it would severely limit access to drug discounts for low-income patients (The Cancer Letter, Oct. 16, 2015).

Study: A Full Range of Providers

Comparing 340B hospitals to the full range of providers reimbursed for Part B drugs, including private practices rather than non-340B hospitals alone, yields a "more complete analysis of Medicare Part B spending differences," the study says.

"Not only do 340B DSH hospitals treat a more vulnerable population…[they] have lower Medicare spending per patient for Part B separately billable drugs than patients who receive care at non-340B covered entities," 340B Health's study concludes.

After including physician offices in the analysis, average spending per beneficiary was lower in 340B DSH hospitals than in non-340B providers, according to the study.

"Among beneficiaries who received at least one of the top 50 drugs provided by 340B covered entities (ranked by total Medicare spending), drug spending per beneficiary was 60 percent lower than spending in non-340B covered entities ($240.92 versus $556.02)," the study's authors said.

Across all drugs, 340B spending was $112.15 compared to $128.91 for patients treated in non-340B covered entities. The study analyzed differences in reimbursement for the top five Part B drugs and found that average spending per beneficiary was lower in 340B DSH hospitals than in non-340B providers for all five drugs.

The study compared Medicare beneficiary demographics in 340B hospitals against non-340B providers. It found that 340B hospitals are:

• Nearly four times as likely as non-340B providers to treat patients with end-stage renal disease

• More than twice as likely to treat patients dually eligible for Medicare and Medicaid

• More than twice as likely to treat patients who are disabled

• More than twice as likely to treat Black, Hispanic, and North American Native patients

Slafsky, of 340B Health, said that private-practice cancer clinics—vocal critics of 340B-enrolled hospitals—do not treat many low-income patients.

"The bottom line is that our hospitals provide care to an entirely different patient population, one that is often sicker and has more complicated health conditions," Slafsky said. "Without 340B discounts, we shudder to think what would happen to our most vulnerable patients."

According to the Community Oncology Alliance, over 30 percent of all cancer drugs reimbursed under Medicare Part B are discounted by 340B, and in

hospital outpatient facilities, over 60 percent of the cancer drugs are discounted by 340B.

"The Government Accountability Office—the government's own independent watchdog—concluded that 340B hospitals have a huge financial incentive that is having a direct adverse impact on seniors with cancer, Medicare, and taxpayers," said Ted Okon, executive director of COA.

340B hospitals are reimbursed at upwards of Average Sales Price plus 100 percent, with up to 50 percent in 340B discounts for cancer drugs, COA said.

"The 340B program has seen incredible growth with no signs of slowing down, despite a dramatic reduction in the number of uninsured and underinsured Americans in the country that originally its need," COA said in a statement.

"If the administration is truly interested in addressing the increasing costs of cancer care, it must start with the ballooning 340B drug discount program in hospitals."

In Brief

Arnold Foundation Gives $7.2M To Drug Pricing Programs

THE LAURA AND JOHN ARNOLD FOUNDATION delivered $7.2 million in grants to address the rising cost of pharmaceutical drugs.

The research projects will focus on analyzing how regulatory policies and programs impact drug pricing, drug development, and patients' access to medication. The pilot projects will test new drug pricing and purchasing models that take into account a drug's value to patients.

The grants include:

$4.7 million to Memorial Sloan Kettering Cancer Center to support the Evidence Driven Drug Pricing Project. The three-year initiative, led by Peter Bach, will research, pilot, and evaluate alternative value-based payment structures for specialty drugs that link a drug's price to evidence of how well it works and for which patients. Bach and his team will also analyze other payment models and policy proposals that have the potential to reduce patient costs.

$1.6 million to the Center for Evidence-based Policy at Oregon Health and Science University to support a 15-month project that will include two phases. First, researchers will analyze the prescription drug development pipeline, the federal and state regulations that govern Medicaid drug purchasing, and best practices for alternative purchasing models. Second, the center will work with participating states to design a set of pilot programs. The pilots will test the feasibility and effectiveness of alternative purchasing models that tie Medicaid reimbursement to improved patient health and seek to support sustainable state Medicaid budgets.

$748,445 to Brigham & Women's Hospital in support of the Program on Regulation, Therapeutics, and Law. The grant will fund a yearlong project led by Aaron Kesselheim and Jerry Avorn to evaluate the effectiveness of federal regulatory programs designed to incentivize innovation in drug development. The researchers will evaluate how policies have improved patient outcomes, reduced drug approval times, or led to more breakthrough discoveries. Researchers will analyze programs and incentives such as tax breaks, market exclusivity protections, and FDA fast-track approval pathways.

$200,000 to the National Academy of Sciences Institute of Medicine to support a two-year research project that will examine patient access to effective and affordable therapies. Researchers will create a set of policy recommendations aimed at making drugs more affordable while spurring development.

These grants follow a $5.2 million commitment to the Institute for Clinical and Economic Review announced in July 2015. ICER is producing public reports on new drugs, released near the time of the drug's FDA approval, including an analysis of its comparative effectiveness, cost-effectiveness, and potential budget impact.

In addition, the foundation has committed $318,000 to Johns Hopkins Bloomberg School of Public Health to conduct policy research that will aid in the development of fair pricing solutions for expensive specialty drugs.

Spending on prescription drugs has reached record highs in recent years. According to the foundation, more than a half-million patients had medication costs in excess of $50,000 in 2014, a 63 percent increase over the previous year in the number of people paying that amount.

JOAN SCHILLER was named deputy director of clinical investigation of the **Inova Dwight and Martha Schar Cancer Institute**.

Schiller is the former division chief of Hematology/Oncology at UT Southwestern Medical Center where she lead UTSW's process to become an NCI-designated cancer center and then an NCI-designated comprehensive center in 2015. She was also deputy director of the Simmons Comprehensive Cancer Center in Dallas.

While in Texas, Schiller served as an editor for the Journal of Clinical Oncology. She is a board member for the International Association for the Study of Lung Cancer, and the principal investigator on several national clinical trials for lung cancer.

Schiller currently serves on the NCI Board of Scientific Counselors and has authored or co-authored more than 200 publications, including articles, abstracts, book chapters, books, reviews and invited manuscripts about the diagnosis and treatment of lung cancer. She is the founder and president of Free to Breathe, a national advocacy organization aimed at raising awareness and funding for lung cancer.

JEANNIE LEE is the 2016 winner of the **Lurie Prize in Biomedical Sciences** for uncovering the functions of long, noncoding RNA in epigenetic regulation. Her work was selected by the Foundation for the National Institutes of Health for accelerating the understanding of mechanisms driving epigenetic regulation, which involves changes in gene function without changing the DNA sequence.

Specifically, Lee's work investigates how a whole sex chromosome can be shut down and how "X-chromosome inactivation" can be leveraged to treat congenital diseases, such as Rett, CDKL5 and Fragile X Syndromes in addition to numerous cancers such as breast, ovarian, blood, intestinal and male germ cell tumors where there is often an extra x-chromosomal copy. The Lurie Prize will be presented to Lee May 18 in Washington, D.C.

Lee is a professor of genetics and pathology at Harvard Medical School and at Massachusetts General Hospital, as well as a Howard Hughes Medical Institute Investigator.

"Dr. Lee's work has revolutionized the field of epigenetics," said Charles Sanders, chair of the foundation. "Her research has led to groundbreaking contributions, and we now have a better understanding of the unique role that long non-coding RNAs play in gene expression, which could lead to the development of new therapeutics."

The Lurie Prize recognizes outstanding achievement by a promising scientist age 52 or younger, and includes a $100,000 honorarium, endowed by philanthropist and FNIH board member Ann Lurie, president of the Ann and Robert H. Lurie Foundation, and president of Lurie Holdings.

Lee is a recipient of the Molecular Biology Award from the National Academy of Sciences as well as a Member of the National Academy of Sciences, American Association for the Advancement of Science the Genetics Society of America.

THE CANADIAN CANCER SOCIETY announced four winners of its most prestigious cancer research awards, The Awards for Excellence.

Mary Gospodarowicz received the O. Harold Warwick Prize for outstanding achievements in cancer control research. Gospodarowicz is the Princess Margaret Cancer Centre's medical director and the first Canadian immediate past president of the Union for International Cancer Control. Early in her career, she pioneered research into treatment for testicular cancer, clinical trials in prostate and bladder cancer, Hodgkin lymphoma, and late effects of radiotherapy. Through her involvement in committees of the Canadian Cancer Trials Group, she guides high impact cancer research. She has also advocated for access to radiotherapy in low- or middle-income countries.

Catherine Sabiston, from the University of Toronto, received the William E. Rawls Prize, given to a young investigator whose outstanding contributions have led to important advances in cancer control. Sabiston's study on the psychosocial experience of breast cancer survivors involved in team paddle boating was published in the top exercise psychology journal.

Poul Sorensen was awarded the Robert L. Noble Prize for outstanding achievements in basic biomedical cancer research. A molecular pathologist from the BC Cancer Agency and University of British Columbia, Sorensen's research focuses on molecular abnormalities that underlie childhood sarcomas and brain tumors, and adult cancers of the breast, brain and prostate.

Uri Tabori received the Bernard and Francine Dorval Prize. This prize is given to a young investigator whose outstanding contributions to basic biomedical research have led to improved understanding of cancer treatments and/or cures. Tabori, of The Hospital for Sick Children and the University of Toronto, has made contributions to foundational cancer research

in pediatric oncology and advanced the scientific community's understanding of childhood brain tumors. In particular, Tabori has helped explain the molecular basis of the most common brain tumor found in children.

The awards, which come with a $20,000 contribution to each recipient's research program, will be presented at a ceremony in Toronto later this year.

MARCIA MCNUTT was elected to a six-year term as president of the **National Academy of Sciences**. McNutt is editor-in-chief of the Science family of journals.

William Press, the Warren J. and Viola M. Raymer Professor in the departments of computer science and integrative biology at UT Austin, was elected treasurer.

Also, four members were elected to the academy's governing council: **Susan Amara**, scientific director of the , Intramural Research Program at the National Institute of Mental Health; **Fred Gage**, the Vi and John Adler Professor at the Salk Institute for Biological Studies; **Evelyn Hu**, the Tarr-Coyne Professor of Applied Physics and Electrical Engineering at Harvard University; and **Laura Kiessling**, the Steenbock Professor of Chemistry and Laurens Anderson Professor of Biochemistry at the University of Wisconsin-Madison.

McNutt succeeds Ralph Cicerone, who is completing his second term as president, the maximum allowed by the Academy's bylaws. Their terms begin July 1. The treasurer will serve four years, and the councilors for three years.

McNutt became the 19th editor-in-chief of Science in 2013. As editor-in-chief she led the effort to establish Science Advances, an open access, online-only offspring of Science.

McNutt was elected to the National Academy of Sciences in 2005 and has served on more than 30 committees and boards of the National Academies of Sciences, Engineering, and Medicine. Most recently, she chaired an expert panel that evaluated options for slowing or offsetting global climate change. She is currently a member of the advisory committee for the Division on Earth and Life Studies and the Forum on Open Science.

McNutt's research concentration is in marine geophysics, where she has used a variety of remote sensing techniques from ships and space to probe the dynamics of the mantle and overlying plates far from plate boundaries on geologic time scales. She is the author or co-author of more than 100 peer-reviewed articles and has made contributions to the understanding of the rheology and strength of the lithosphere.

She has demonstrated that a deep-seated, large-scale mantle thermal anomaly has been very persistent. It is not only producing midplate volcanoes in the island chains above its location deep beneath the central Pacific, but also has produced older volcanic chains now submerged in the northwest Pacific that erupted as the Pacific plate drifted over the central Pacific over the last 100 million years.

McNutt began her faculty career at MIT, where she became the Griswold Professor of Geophysics and served as director of the Joint Program in Oceanography and Applied Ocean Science and Engineering sponsored by MIT and the Woods Hole Oceanographic Institution.

She later served as president and chief executive officer of the Monterey Bay Aquarium Research Institute and as professor of geophysics at Stanford University. From 2009 to 2013 she was the director of the U.S. Geological Survey. While at the USGS, she helped lead the response to the Deepwater Horizon oil spill, for which she was awarded the Meritorious Service Medal by the U.S. Coast Guard.

MEDICAL ONCOLOGY & HEMATOLOGY ASSOCIATES of Northern Virginia joined the **Inova Medical Group**.

The practice, which brings five physicians, four nurse practitioners or physician assistants, and more than 50 support staff members, will have a brand new outpatient infusion clinic, outpatient pharmacy and lab, and outpatient research facility.

The newly named Inova Hematology Oncology will have office locations in Falls Church and at Inova Fair Oaks Hospital, offering specialty care for many forms of cancer including skin cancers, brain tumors, cancers of the gastrointestinal tract, head and neck cancer, and genitourinary cancer.