THE CANCER LETTER

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*CPRIT Emails*

# Nobel Laureate Gilman Prepares to Leave The Texas Cancer Agency—Can it Survive?

*By Paul Goldberg*

On Oct. 12, Alfred Gilman will leave the $3 billion Texas agency where he oversaw cancer research.

The parting is anything but amicable, and it doesn't look like it will be over quickly.

The Nobel laureate, who spent the past three years as the chief scientific officer of the Cancer Prevention and Research Institute of Texas, says the principles of funding good science at the state agency have been supplanted by political manipulation and greed.

"I built something I am proud of, and now it's being taken apart," Gilman said to The Cancer Letter. "I can't work for people who are pushing their own interests at the expense of the interests of cancer patients."

The institution Gilman built relied on top-level scientists from outside the state to distribute funds, rising above politics of all flavors: academic, parochial, and Texan. Gilman's departure raises an important question: can CPRIT exist as a credible scientific agency without Gilman?

Or, more precisely, can it survive being publicly slammed by Gilman?

As the CPRIT drama plays out, there is little doubt that the state legislature could easily find an alternative use for the $300 million a year it appropriates to the cancer venture.

Changes at MD Anderson Cancer Center play a central role in this battle. CPRIT's decision to award $18 million to a biotechnology incubator run by Lynda Chin, the wife of that cancer center's president, Ronald DePinho, was a principal cause of Gilman's departure.

(Continued to page 2)

*In Brief*

# Carlson Named NCCN Chief Executive

**ROBERT CARLSON** was named CEO of **The National Comprehensive Cancer Network**. He will officially join NCCN Jan. 2, 2013.

Carlson served as professor of medicine in the Division of Oncology at Stanford University Medical Center and Stanford Medical Informatics. He first joined the faculty in 1983. He is the medical director of inpatient oncology and hematology at Stanford Cancer Institute—one of the 21 NCCN member institutions.

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## Top-Level Scientists Likely To Follow Gilman Out The Door

(Continued from page 1)

Moreover, DePinho has said that he would like to use a portion of CPRIT funds for his $3 billion "Moon Shots Program" to eventually eradicate eight cancers (The Cancer Letter, Sept. 7, Sept. 21).

Gilman will not be leaving alone.

There is no question that at least some of the scientists who conduct review will similarly walk out and slam the door behind them. Some of these scientists acknowledge that they have prepared sharply worded letters of resignation.

Insiders say that at least three of the eight members of the scientific review council are certain to resign, but it's entirely possible that everyone will go.

However, at least for now, all of the scientific reviewers are working on completing the final recommendation to fund over $50 million worth of grants, which will be reported to CPRIT's executive director Oct. 5.

Gilman had announced his decision to leave May 8, but in his letter of resignation, he said he would stay on another six months to shepherd the final round of review through the system (The Cancer Letter, May 25).

After the round of reviews is completed next week, each of the eight council members will announce what Gilman describes as their "individual decisions" to stay or go.

Members of the scientific council may well be followed out the door by the rank-and-file reviewers—more than 100 doctors and scientists from all over the U.S.—who spend their time reviewing projects in the state.

With words of condemnation from Gilman and his colleagues already on record, many of these researchers would see no benefit in either playing a role in Texas politics or keeping CPRIT on their CVs.

Gilman and his colleagues regard the award of CPRIT funds to the MD Anderson incubator as a double insult. After splurging on the incubator, CPRIT didn't have $40 million it needed to pay for seven previously reviewed "multi-investigator research awards," abbreviated as MIRAs.

As a result, awards that were slated to be funded in the 2012 fiscal year were funded out of the following year's money.

"I made a decision to resign effective Oct. 12, and the council members agreed not to make their individual decisions until October, because at the time the [incubator controversy] was blowing up, a large number of new applications was to be submitted to CPRIT, and we thought it would be unfair if the review system collapsed when these applications were under review," Gilman said to The Cancer Letter.

The council members aren't the sort of people you want to resign with a splash.

The chair is Phillip Sharp, a Nobel laureate and an institute professor at the Massachusetts Institute of Technology Koch Institute for Integrative Cancer Research.

The members are:

• Clara Bloomfield, the William G. Pace III Professor of Cancer Research at Ohio State University.

• Sanjiv Sam Gambhir, the Virginia and D.K. Ludwig Professor in the department of radiology and bioengineering, chair of the department of radiology, director of the Molecular Imaging Program, and director of the Canary Center for Cancer Early Detection at Stanford University.

• Tyler Jacks, the David H. Koch Professor in the department of biology and director of the David H. Koch Institute for Integrative Cancer Research at MIT.

• William Kaelin, professor of medicine in the department of medical oncology at Harvard University and the Dana-Farber Cancer Institute.

• Richard Kolodner, professor of medicine and member of the Ludwig Institute for Cancer Research at the University of California, San Diego.

• Charles Sherr, co-chair of genetics and tumor cell biology, co-director of the Molecular Oncology

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**Nobel laureate Gilman says his misadventures at CPRIT could have been predicted:**
"A wise and experienced friend said to me: This is always the way it works when you put a large amount of public money on the table. The vultures and the hyenas lie low for two or three years to see how the system really works. And then they come in for their feast."

Program, and Herrick Foundation Chair at St. Jude Children's Research Hospital.

• Everett Vokes, the John E. Ultmann Professor of Medicine and Radiation Oncology, and chair of the department of medicine at the University of Chicago Medical Center.

**"The Hip Pocket National Bank"**

Hundreds of pages of internal emails obtained by The Cancer Letter under the Texas Public Information Act show that rifts at CPRIT ran deep and involved questions of integrity of peer review.

Gilman appears to be a lone, often despised, advocate of science at the state agency, surrounded by bureaucrats and politicians. Trust appears to be a deficit commodity on all sides.

Reflecting on his adventures recently, Gilman says that he should have foreseen trouble.

"A wise and experienced friend said to me: This is always the way it works when you put a large amount of public money on the table," he said. "The vultures and the hyenas lie low for two or three years to see how the system really works. And then they come in for their feast."

The Cancer Letter obtained CPRIT documents surrounding the MD Anderson-Rice technology incubator through Texas freedom of information law, organized them thematically, and has posted them at http://www.cancerletter.com/categories/documents.

"There are some really evil people on the [CPRIT] Oversight Committee now. Can they be taken out?" Gilman writes in a May 8 email to scientific council member Kaelin.

Documents show Gilman fighting two concurrent battles: one against business interests seeking to use more of CPRIT funds for incubator and commercialization work—and one against Texas politicians who objected to seeing the largest number of investigator-initiated research grants go to UT Southwestern, an institution known for the strongest science programs in the state.

These individuals—as well as Gilman's CPRIT colleagues—seem to be particularly concerned about him keeping an office at UT Southwestern, where he had worked for three decades, as a faculty member and a dean.

"I will not continue to work for them or with them," Gilman wrote to Kaelin. "There are the 'UT Southwestern is getting too much money' people and there are the 'we should spend much more money on commercialization' people."

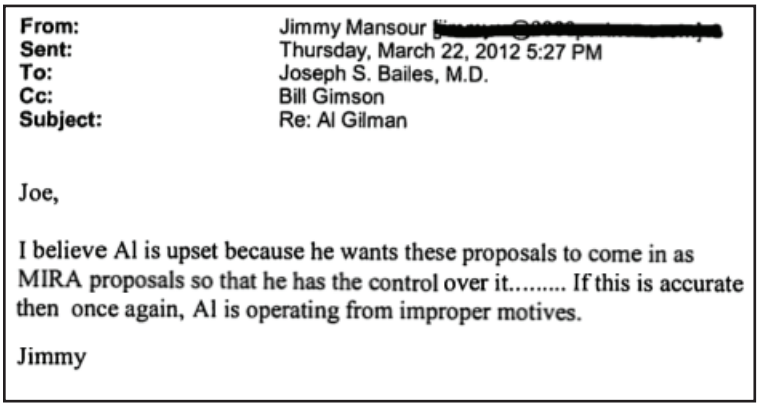
The pressure and the isolation appear to get to Gilman at times.

"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."

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 politicians add in disrespectful remarks.

"I believe Al is upset because he wants these [incubator] proposals to come as MIRA proposals so



**From:** Jimmy Mansour [redacted]
**Sent:** Thursday, March 22, 2012 5:27 PM
**To:** Joseph S. Bailes, M.D.
**Cc:** Bill Gimson
**Subject:** Re: Al Gilman

Joe,

I believe Al is upset because he wants these proposals to come in as MIRA proposals so that he has the control over it..... If this is accurate then once again, Al is operating from improper motives.

Jimmy

**In an email, CPRIT oversight committee chair Jimmy Mansour portrays Gilman's opposition to the MD Anderson-Rice incubator as a power grab.**

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 instructes CPRIT chief executive Bill Gimson and CPRIT attorney Kristen Doyle on 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."

This pronouncement is noteworthy, because a subsequent investigation by the UT System found that CPRIT had deviated from its own procedures in awarding the incubator grant (The Cancer Letter, June 15).

Some CPRIT 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 writes in a March 28 email to Chin.

This exchange is remarkable because of colorful language. It's 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.

In another email March 29, 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. 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."

The incubator grant was awarded and the press releases issued, but the public money never made it into the "hip-pocket-national-bank."

The proposal, which was six-and-a-half pages long, has been withdrawn and is expected to be resubmitted sometime after Gilman's departure.

**Conversation Over Cocktails**

Immediately after coming to Texas, a little more than a year ago, DePinho and Chin became the focal point in the CPRIT controversy, documents suggest.

This is because the MD Anderson power couple, in addition to being academics, are entrepreneurs who focus on commercialization of cancer drugs.

Indeed, DePinho is now seeking a broad waiver from conflict of interest regulations to continue to interact—and receive funds from—a dozen entities (The Cancer Letter, Sept. 21).

This emphasis makes DePinho and Chin natural allies to the entrepreneurs on the CPRIT board, particularly Charles Tate, a venture capitalist who serves on the executive committee of CPRIT's oversight committee, chairs the economic development and commercialization subcommittee, and serves on the MD Anderson board of visitors.

Tate has contributed $465,000 to the political

campaigns of Lt. Gov. David Dewhurst. Two years ago, 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. The story is posted at http://dallasne.ws/dNtkZ0.

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.

According to one of the emails, Tate was involved in generating the idea for Chin's incubator proposal.

In one of the released emails, scientific council member Sherr describes an incident which may explain a lot about the political pressure that was brought down on Gilman.

Sherr's email was never intended to be released. It was addressed to Kaelin, with Gilman on the cc: list.

People who have spoken with Sherr on the subject say that he intended the email to be confidential. People familiar with the situation said that Sherr has told them that he wishes he chose less inflammatory language:

"For what it's worth, here is a brief anecdote that I had previously shared with Al. Last October, Martine was inducted into the American Academy of Arts & Sciences, and I accompanied her to Boston for the annual meeting.

"Over cocktails, I ran into Ron who immediately told me that he was in direct touch with 'the higher-ups' who run CPRIT and that the program and Al would soon be under pressure to change the current approach. (As you know, Ron cannot resist talking about himself, and as a rule, has no shame). My response was that, if he (Ron) were personally concerned, he might speak directly with Al…

"It is my firm belief that Ron has played a direct and important role in helping to orchestrate what is, in effect, a coup d'etat.

"Politically, the only way to get some traction is to go for the jugular and insist that Lynda and Ron's proposal receive a full scientific review rather than the current carte blanche approval. If things continue in the direction that they are headed, I doubt that maintaining a process of conscientious peer review will subvert future initiatives intended to bypass the process.

"Under such circumstances, I could not in good conscience continue to support a corrupt program and would play an active role in suggesting that others follow suit in resigning.

"If Texans choose to insulate themselves from national standards, that is their prerogative as the Lone Star State. But our council members and our respective committee panelists need not yield to the parochial interests of a few politicians and scientific usurpers. I had previously written directly to Bill Gimson to express my concerns and have shared them privately with Al up to this point."

The complete text of the email, as released by CPRIT, is posted at http://www.cancerletter.com/categories/documents. The document can be found in the file titled "Charles Sherr."

**Charles Tate Played Role in Shaping Incubator**

The October 2011 conversation between Sherr and DePinho suggests that the controversy that erupted in the spring of 2012 may have been brewing for at least six months.

This episode, if accurate, also raises questions about DePinho's reasons for revealing these developments to Sherr, a friend of Gilman's. Though Sherr and DePinho have known each other through most of DePinho's career, it would difficult to describe them as friends.

In an interview with The Cancer Letter, DePinho declined to comment on the episode described by Sherr.

"I won't comment on any e-mail that includes inflammatory, derogatory remarks made about me or my family," he said. "I have never, not will I ever attempt to influence a specific award decision by CPRIT or any funding agency, period.

"I will, however, continue to be the most dedicated advocate for great science and drug development that's occurring at MD Anderson, and that is my job. I will continue to advocate the need to repair the broken ecosystem of drug development through greater joint efforts between academic entities and industries—it's vital for patients."

CPRIT emails offer a glance at Tate's role in shaping the ideas that led to creation of Chin's biotech incubator.

Tate appears to have been involved in the idea of creating incubators, where decisions on the future of a project would be made summarily, without convening peers to conduct formal assessments.

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

**Venture capitalist and CPRIT oversight committee member Charles Tate, who helped engineer the incubator proposal. When the proposal was approved, he said:**

"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."

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' similar [to] that used by CTNet."

The six-and-a-half-page plan submitted by Chin's institute was too vague to be interpretable, Gilman would write later.

"It was not a research plan, but rather a general business plan describing intentions of the IACS to conduct ground level laboratory research in the effort to discover new drugs," Gilman describes his initial impression of the plan in an email dated March 28.

"There were no targets mentioned, no molecules, no diseases, no intellectual property. It is not possible to consider this to be a commercialization proposal, because there is nothing to be commercialized other than the hope that products might emerge many years down the road…

"The argument that it does not need to be… reviewed by researchers is abject nonsense. They are hiding behind the trumped up concept that the $18 M award to IACS is really a part of the incubator. It is not a part of the incubator. It is simply intended to be by far the largest basic research award ever made by CPRIT—$18M for one year only—more to follow—made without research peer review. It makes mockery of all the principles that CPRIT has followed for its first two-and-a-half years."

CPRIT documents show that Tate was directly involved in shaping the central piece of the incubator proposal, which combine projects at Rice University and Chin's Institute for Applied Cancer Science at MD Anderson. 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."

Tate appears to have played a role in getting the merged IACS-Rice incubator through CPRIT, apparently personally warning Gimson against considering the Rice proposal first, to be followed by the MD Anderson proposal.

In an email to Cobbs, the CPRIT commercialization head, on March 14, Gimson writes: "Jerry: Charles just called me—he is concerned about timing and bifurcated approach of the Rice/IACS Incubator. Let's talk tomorrow early. Bill."

On March 28, Gilman spells out his objections to approving the proposal, especially at the cost of not going forward with the peer-reviewed MIRAs. However, the CPRIT oversight committee disregards Gilman's objection and approves the incubator.

The committee also disregards the objections from Kenneth Shine, the UT vice chancellor for health affairs.

After seeing a letter circulated by Gilman on March 28, Shine writes to CPRIT's Gimson: "Bill, I just received this email. It does suggest that postponing action and obtaining additional scientific review of the proposal makes sense. Ken."

Shine oversees MD Anderson but has no authority over CPRIT.

The approval of the incubator gave Tate an opportunity to opine on the role of science in development of cancer drugs.

"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 says in a Rice University press release.

"CPRIT is proud to support a center that will ensure the best cancer-fighting technologies can make it to market and into the hands of the people who need them the most." The press release is posted at http://bit.ly/HyeC0d.

Venture capitalist Robert Ulrich, chair of the CPRIT commercialization panel, appears to be similarly pleased.

In an email, he 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."

**The Political Economy of CPRIT**

Parochial politics at CPRIT stem from relative strengths in biomedical research. UT Southwestern is, hands-down, the leader in basic cancer science in the state.

Not surprisingly, it receives the highest proportion of grants.

MD Anderson's strength is in clinical research and clinical care. The institution has been building its basic science in recent years. Focus on basic science was likely the main reason the Board of Regents selected DePinho to lead that institution.

Cumulatively, since CPRIT's formation, UT Southwestern received $173.6 million in funding for 91 grants.

MD Anderson is second, with $128.7 million in funding for 81 grants.

Emails show that at CPRIT, an oversight committee member named Mark Watson, from San Antonio, persistently raised questions about the amounts of research funds going to UT Southwestern as well as about the cost of peer review.

Watson runs an insurance company and a ranch. In the past, he served as chairman of the Cancer Therapy and Research Center and assisted in the CTRC merger with The University of Texas Health Science Center.

The CPRIT management's willingness to appease Watson by changing funding requests clearly outraged Gilman.

"One person (as best I know) is turning us on our heads," Gilman writes 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.

"The only MIRA left unscathed is one that has significant funds for San Antonio. How sad. Why have we been charging ahead with our reviews? To put virtually all of it on the back burner?

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

The projects Gilman alludes to were eventually funded at the oversight committee's August meeting. See table on page 9.

In an April 19 email to oversight committee members Mansour and Joseph Bailes, Gimson suggests that he may have lectured Gilman on the give-and-take required to survive cancer politics Texas-style: "[Gilman] is aware that peer review process will change and he must leave the UTSW campus if he is to continue at CPRIT."

Yet, Gilman doesn't acquiesce.

On May 5, three days before handing in his resignation, he 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."

| Institution/Organization | Number of Awards | Institution/ Organization Totals |
|---|---|---|
| The University of Texas Southwestern Medical Center at Dallas | 91 | $173,580,585 |
| Baylor College of Medicine | 47 | $87,451,746 |
| The University of Texas M.D. Anderson Cancer Center | 81 | $128,688,511 |
| Rice University | 6 | $23,472,111 |
| The University of Texas Health Science Center at San Antonio | 23 | $24,302,787 |
| The University of Texas at Austin | 24 | $35,850,598 |
| Baylor University Medical Center at Dallas | 1 | $2,500,000 |
| Texas Tech University | 5 | $3,492,336 |
| MHMR of Tarrant County | 2 | $2,397,784 |
| Cancer and Chronic Disease Consortium | 1 | $2,177,340 |
| The University of North Texas Health Science Center at Fort Worth | 7 | $4,684,829 |
| The University of Texas Health Science Center at Houston | 16 | $12,810,166 |
| University Health System | 6 | $6,218,267 |
| The University of Texas at Dallas | 3 | $5,909,898 |
| The University of Texas Medical Branch at Galveston | 5 | $7,751,102 |
| Methodist Dallas Medical Center | 1 | $599,574 |
| Texas Nurses Foundation | 5 | $2,107,901 |
| Lance Armstrong Foundation | 2 | $600,000 |
| Mercy Ministries of Laredo | 2 | $608,579 |
| Asian American Health Coalition of Greater Houston (dba Hope Clinic) | 3 | $1,450,887 |
| Angelo State University | 1 | $1,120,825 |
| Apollo Endosurgery | 1 | $5,001,063 |
| Asian Breast Health Outreach Project at Methodist Richardson Medical Center | 1 | $535,540 |
| Asuragen, Inc. | 1 | $6,837,265 |
| Baylor College of Dentistry-TAMU Health Science Center | 1 | $203,244 |
| Baylor Research Institute (MIRA Sub Award) | | $2,108,180 |
| Baylor University | 1 | $200,000 |
| Bellicum Pharmaceuticals, Inc. | 1 | $5,680,310 |
| Caliber Biotherapeutics | 1 | $12,808,151 |
| Cancer Foundation for Life | 1 | $100,000 |
| Cancer Services Network | 1 | $99,581 |
| Cell Medica | 1 | $15,571,303 |
| Centro San Vicente | 1 | $1,937,461 |
| City of Laredo Health Department | 1 | $2,497,500 |
| Clinical Trials Network (CTNET) | 1 | $25,213,675 |
| Daughters of Charity Health Services of Austin (dba SETON Healthcare Network) | 1 | $128,640 |

| Institution/Organization | Number of Awards | Institution/ Organization Totals |
|---|---|---|
| Department of State Health Services | 1 | $335,271 |
| Funding Solutions | 1 | $157,494 |
| Gradalis, Inc. (MIRA Sub Award) | | $748,905 |
| Healthy Tarrant County Collaboration | 1 | $212,535 |
| Ingeneron, Inc. | 1 | $198,111 |
| Kalon Biotherapeutics, LLC | 1 | $7,901,420 |
| Light and Salt Association | 1 | $329,933 |
| LRGV Community Health Management Corporation, Inc. dba El Milagro Clinic | 1 | $149,100 |
| Migrant Clinicians Network | 1 | $473,405 |
| Mirna Therapeutics, Inc. | 1 | $10,297,454 |
| Molecular Templates, Inc. | 1 | $10,600,000 |
| National Center for Farmworker Health, Inc | 1 | $551,221 |
| Peloton Therapeutics, Inc. | 1 | $11,044,931 |
| Pulmotect, Inc. | 1 | $7,126,398 |
| Rules-Based Medicine | 1 | $3,024,432 |
| Scott & White Healthcare | 1 | $3,584,521 |
| SETON Family of Hospitals | 1 | $562,004 |
| Shannon Business Services | 1 | $255,198 |
| South Texas Rural Health Services, Inc. | 1 | $149,971 |
| Texas A&M University | 7 | $2,417,004 |
| Texas A&M University System Health Science Center | 7 | $7,031,810 |
| Texas A&M University System Health Science Center - Institute of Biosciences and Technology | 1 | $12,614,927 |
| Texas A&M University System HSC Research Foundation | 1 | $339,932 |
| Texas Agrilife Extension Service | 3 | $3,410,830 |
| Texas Department of State Health Services | 1 | $2,936,382 |
| Texas Life Science Foundation | 1 | $7,745 |
| Texas Medical Association | 2 | $967,425 |
| Texas Tech University Health Sciences Center | 15 | $16,985,949 |
| The Bridge Breast Network | 1 | $977,603 |
| The Cooper Institute | 1 | $591,384 |
| The Methodist Hospital Research Institute | 8 | $25,283,225 |
| The Rose | 3 | $3,845,471 |
| The University of Texas at Arlington | 3 | $2,285,375 |
| The University of Texas at El Paso (MIRA Sub Award) | | $999,992 |
| The University of Texas at San Antonio | 2 | $898,026 |
| The University of Texas System | 1 | $5,000,000 |
| University of Houston | 6 | $6,869,941 |
| University of North Texas | 1 | $200,000 |
| Visualase, Inc. | 1 | $2,151,776 |
| **Total Awards** | **429** | **760,214,840** |

**Source: CPRIT. Revised 8/2/2012**

*Capitol Hill*

# House Passes Cancer Bill With Mandates for NCI

*By Matthew Bin Han Ong*

A bill that started as an earmark for pancreatic cancer research has made it through the House of Representatives.

Now known as the Recalcitrant Cancer Research Act, H.R.733, the measure would mandate NCI to develop scientific frameworks to conduct and support research on cancers with a five-year survival rate of less than 50 percent.

The Sept. 19 House approval came one week after the Subcommittee on Health amended the bill to eliminate exclusive focus on pancreatic cancer (The Cancer Letter, Sept. 14). A total of 294 house members co-sponsored the measure.

An identical Senate version, S.3560, was approved the same day by the Senate Health, Education, Labor, and Pensions Committee. Altogether, 21 senators have signed on to the amended bill.

If the bill passes both chambers, the director of the NCI would have to identify, within the first six months, two "recalcitrant" cancers with a five-year survival rate of less than 20 percent. These cancers have to be estimated to cause the death of at least 30,000 people per year in the U.S.

This means, despite amendments, the bill mandates that NCI give priority status to pancreatic cancer and lung cancer. The survival rates of these diseases are 6 percent and 16 percent, respectively.

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

"Pancreatic cancer [is a] terrible problem, but it's not the only devastating cancer that we have to deal with," he said. "Comparisons with other cancers are very risky because I don't want to look a patient dying of breast cancer in the eye and say, 'Yeah, you have one of the good cancers.'

"There's no such thing—cancer is a bad disease wherever it takes its toll.

"The directives in the bill do not enable us to do something we would not ordinarily do," he added. "In fact, we already have a group at the NCI that's undertaking what I consider to be a useful exercise—that is, looking back and seeing what we've achieved in pancreatic cancer over the last decade, and scanning horizon for things that we may not have been taking advantage of, just to be sure that everything is probed."

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

A product of aggressive lobbying by the Pancreatic Cancer Action Network, the old version of the bill sought to directly authorize $887.8 million in NCI funds for pancreatic cancer research. If passed, it would reduce NCI's role to that of a minor player and severely undermine the institute's peer review system (The Cancer Letter, Aug. 3, Aug. 10).

Many in the cancer research community were alarmed by the ramifications, and waged a letter-writing campaign in opposition to the original legislation. The Subcommittee on Health promptly rewrote the bill, returning control of the budget and research process to NCI, requiring only regular progress reports besides the mandatory identification of lethal cancers.

"The passage of this bill is a critical step towards reaching our goal to double the pancreatic cancer survival rate by 2020," said PanCAN CEO Julie Fleshman. "Our hope is that the Senate will pass the bill quickly and that President Obama signs it into law, so the NCI can begin implementing an actionable research plan to accelerate progress and improve outcomes for the disease."

At his press club appearance Sept. 25, Varmus said the progress that has been made over the past 30 to 40 years against pancreatic cancer is "considerable," but these advances are confined, so far, to understanding the disease.

"It's a particularly difficult disease to study compared to breast cancer, because of certain attributes of the disease that haven't been sell-ons or mouse models until the last decade or so," he said."The number of people who are now invested in working on pancreatic cancer has enlarged dramatically—the NCI is spending three times as much on pancreatic

cancer," he said. "So, it is a change in environment, but we have to acknowledge that we made almost no progress in early diagnosis or therapy.

"We have a lot of genetic information on the disease, including the incredibly critical piece of information we've had for 30 years," said Varmus. "Virtually every case of pancreatic cancer has a mutation in the KRAS gene.

"If we made some advance against treating cancers with that mutation, whether it is through studying the lung or the breast or the colon, a set of results would be applicable to pancreatic cancer, too, which is a way of saying that not everything that benefits cancer X comes from the study of cancer X, and that's an important thing to remember."

*In Brief*

## Stanford Oncologist Carlson Selected as CEO of NCCN

(Continued from page 1)

He began collaborating with NCCN when the organization was founded in 1995, and has since held numerous leadership roles, most notably representative to the board of directors, chair of the breast cancer guidelines panel, member and founding chair of the breast cancer risk reduction guidelines panel, and chair of the survivorship guidelines panel.

Carlson has chaired numerous task forces at NCCN, has been presented the NCCN Guidelines Achievement Award and the Rodger Winn Award, and has received special recognition and appointment to the NCCN board of producers. He currently serves as associate editor for medical oncology for the Journal of the National Comprehensive Cancer Network and is a member of the editorial advisory board for The ASCO Post.

**MING TAN** was named chair of the Department of Biostatistics, Bioinformatics and Biomathematics at **Georgetown University Medical Center**.

Tan joined Georgetown from the University of Maryland School of Medicine and the Marlene and Stewart Greenebaum Cancer Center, where he was professor of epidemiology and public health and director of biostatistics since 2002. He also headed the Division of Biostatistics and Bioinformatics since 2009.

Tan's research focuses on quantitative modeling and integration of multiple stages of therapeutics and diagnostics development utilizing his statistical and bioinformatics expertise in preclinical discoveries, clinical trials and epidemiological studies.

Prior to his work at Maryland, Tan was a senior faculty member at St. Jude Children's Research Hospital Cancer Center and biostatistics director of St. Jude's Developmental Therapeutics for Solid Malignancies Program.

**CAROLYN BRITTEN** joined the **Hollings Cancer Center** at the **Medical University of South Carolina** and will serve as director of the cancer center's Phase I Clinical Trials Research Program.

Britten, an associate professor of medicine, is a medical oncologist from UCLA's Jonsson Comprehensive Cancer Center, where her leadership positions included serving as director of Protocol-Specific Research Support and associate director of the Signal Transduction and Therapeutics Program.

**THE ALBERT AND MARY LASKER FOUNDATION** announced the winners of the 2012 Lasker Awards: **Michael Sheetz**, **James Spudich** and **Ronald Vale** for basic medical research, **Roy Calne** and **Thomas Starzl** for clinical research, and **Donald Brown** and **Thomas Maniatis** for special achievement.

Sheetz, of Columbia University; Spudich, of the Stanford University School of Medicine; and Vale, of the University of California, San Francisco, will receive the **Albert Lasker Basic Medical Research Award**—for discovering machine-like cytoskeletal motor proteins that transport cargoes within cells.

Calne, of the University of Cambridge, and Starzl, of the University of Pittsburgh Medical Center, will receive the **Lasker~DeBakey Clinical Medical Research Award**—for developing liver transplantation techniques.

Brown, of the Carnegie Institution for Science, and Maniatis, of Columbia University, will receive the **Lasker~Koshland Special Achievement Award in Medical Science**—for discovering the nature of genes while fostering the careers of young scientists.

Cytoskeletal motor proteins are essential for numerous processes including muscle contraction, intracellular movement, and cell locomotion. Sheetz,

Spudich and Vale's discoveries have spurred research on new treatments aimed at cardiac problems, neurological disorders, and cancer.

They used their own invented assays to discover the motor protein kinesin and unveiled key aspects of the process by which molecular engines convert chemical energy into mechanical work.

In the late 1950s, serious liver diseases were fatal and the idea of transplanting any organ from one person to another seemed foolish to most experts. Rejection posed a seemingly insurmountable obstacle.

However, through independent and complementary efforts, Starzl and Calne helped develop the techniques used today. In 1983, a conference convened by the U.S. Surgeon General concluded that liver transplantation had progressed past "experimental procedure" status into a "clinical service."

Brown started in the nascent field of developmental genetics during the mid-1950s by studying frog embryos. He figured out the biological function of an organelle called the nucleolus, co-discovered a process called gene amplification, which later led to an understanding of runaway growth of drug-resistant cancer cells, and made key observations about how cells control gene activity.

Brown's work help paved the way toward the recombinant DNA era, at which point, Maniatis harnessed and applied the new tools to create a set of extraordinarily powerful techniques that have driven key advances in molecular biology.

Brown founded and led the Life Sciences Research Foundation, a partnership with pharmaceutical companies that want to support the academic research that makes their drug-discovery efforts possible.

Maniatis created the Molecular Cloning manual and helped spread technologies into a multitude of laboratories across the world.



*FDA News*

## FDA Approves Stivarga Tablets For Metastatic Colorectal Cancer

FDA approved Stivarga tablets for patients with metastatic colorectal cancer whose disease has progressed after approved standard therapies.

Approval was based on results from a phase III trial that demonstrated improvement in overall survival and progression-free survival. Stivarga (regorafenib) was developed and reviewed under the fast track program and received priority review designation from the FDA.

Stivarga is indicated for the treatment of patients with mCRC who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if KRAS wild type, an anti-EGFR therapy.

Stivarga is an oral multi-kinase inhibitor that inhibits various kinases within the mechanisms involved in tumor growth and progression—angiogenesis, oncogenesis and the tumor microenvironment.

The randomized trial, CORRECT, enrolled 760 patients, and demonstrating that Stivarga plus best supportive care significantly improved overall survival [HR=0.77 (95% CI, 0.64-0.94), two-sided p=0.0102] and progression-free survival [HR=0.49 (95% CI, 0.42-0.58), two-sided p<0.0001] compared to placebo plus best supportive care. Treatment cycles consisted of 160 mg of regorafenib once daily for three weeks on/one week off plus BSC.

Median OS was 6.4 months with Stivarga versus 5.0 months with placebo; median PFS was 2.0 months with Stivarga versus 1.7 months with placebo. No difference in overall response rate was observed. Five patients (1 percent) in the regorafenib arm and one patient (0.4 percent) in the placebo arm experienced partial responses.

The most frequently observed adverse drug reactions in patients receiving Stivarga were asthenia/fatigue, decreased appetite and food intake, hand-foot-skin reaction/palmar-plantar erythrodysesthesia, diarrhea, mucositis, weight loss, infection, hypertension and dysphonia.

The most serious adverse drug reactions included hepatotoxicity, hemorrhage, and gastrointestinal perforation.

Bayer HealthCare and Onyx Pharmaceuticals Inc. will jointly promote Stivarga in the United States.