THE CANCER LETTER

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Intellectual Property

Suit Against Craig Thompson Settled

As Company He Co-Founded Licenses "Newly Identified" Discoveries From UPenn

By Paul Goldberg

The University of Pennsylvania and its former cancer center director, Craig Thompson, settled the lawsuits that claimed that Thompson had formed a company around discoveries he made while working at Penn.

However, two brief press statements—signed by Thompson, the university and the companies involved—provide little insight into events that led to the litigation and the details of the settlement.

The dispute pitted the Leonard and Madlyn Abramson Family Cancer Research Institute and the university against Thompson, who has moved on to become CEO of Memorial Sloan-Kettering Cancer Center.

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Earmarks for Research

"Recalcitrant" Cancers? Committee Rewrite Of Pancreatic Bill Raises New Questions

By Matthew Bin Han Ong

A House committee has completely overhauled a controversial bill that would have directed NCI to focus more of its attention on pancreatic cancer.

The bill, proposed by the Pancreatic Cancer Action Network, has collected the co-sponsorships of 290 House members and 58 Senate members. The new House version of the bill no longer contains features that cancer researchers found least acceptable.

Gone is the earmarked authorization of $887.8 million in NCI funds to be used for pancreatic cancer research.

Gone is the 13-member advisory panel which would chart the direction of this research.

Gone is the threat of bypassing the NCI peer review system.

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In Brief

Howard Fine Becomes Hematology Chief At NYU Langone Medical Center

HOWARD FINE has joined **NYU Langone Medical Center** as chief of the Division of Hematology and Medical Oncology, director of the Brain Tumor Center, deputy director of the NYU Cancer Institute, and the Anne Murnick Cogan and David H. Cogan Professor of Oncology.

Fine's appointment became effective Sept. 5.

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High-Profile Case Ends in Silence; Settlement Details Confidential

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To end the fight, a company co-founded by Thompson, Agios Pharmaceuticals Inc., licensed some undisclosed intellectual property from the University of Pennsylvania, the parties said in press statements.

One of the few morsels of substantive information was to be found in a press release quote attributed to Chi Van Dang, director of the Abramson Cancer Center at Penn:

"We are pleased to be moving forward in a collaborative manner around newly identified intellectual property. We look forward to working with Agios on this project and potentially other unrelated projects in the future."

This statement, contained in the Aug. 31 announcement of the settlement agreement, suggests that this "newly identified" intellectual property—presumably the intellectual property that was at the center of litigation—has now been licensed from Penn.

Motions that had been previously filed by the Thompson side had asserted that his role in the disputed discoveries didn't rise to the level of "inventorship," as defined by U.S. patent law.

It's not known whether any money has changed hands in the licensing deal, but Penn now apparently stands to earn royalties if the findings covered by these patents result in development of commercial products.

No publicly available documents have been filed in the case at the U.S. District Court for the Southern District of New York at this writing.

"You can't tell from that press statement what's going on," said Robert Cook-Deegan, director of the Center for Genome Ethics, Law & Policy at the Institute for Genome Sciences & Policy and Sanford School of Public Policy at Duke University.

"Since this is not going to be litigated, we are not going to have the public record that would allow us to learn what actually happened."

While the facts of this high-profile case are singular and driven by outsized personalities, observers say that the dispute is likely to make institutions more mindful of asserting their intellectual property claims. The dispute was all the more unusual, because it was driven not by an institution, but by its major donor, the entrepreneur Leonard Abramson.

Thompson made no separate statement, and while some observers interpret the settlement as an implicit recognition that the discoveries should have been Penn's to begin with, it's equally plausible that he agreed to a deal to terminate a legal dispute that continued to cast a dark shadow on his reputation.

The deal also made it possible Memorial Sloan-Kettering to maintain the posture of non-involvement, clearly a plus for Thompson's career at Memorial. Calls to Thompson's attorney were not returned.

"From the outset, the suit looked to me like a corporate negotiation strategy," Cook-Deegan said. "It looked like it was filed by somebody who is used to running a business, somebody who is used to filing law suits to get someone's attention, not because anyone expects to actually go to court. This lawsuit no doubt became a major impediment to Thompson's daily life. This is a way to get somebody to the negotiating table."

For a biotech firm, ongoing litigation with a major academic institution was also a negative.

From the point of view of the law, the case was shaky, Cook-Deegan said.

"With Thompson not listed as an inventor on any of the patents listed in the dispute, if it had actually gone to court, it would have been hard for them to claim intellectual property," he said. "I suspect that going to trial would have been a throw of the dice for both sides."

Thompson left Penn in October 2011, accepting the top job at Memorial Sloan-Kettering. The parting seemed amicable at first.

However, on Dec. 13, 2011, the Abramson Institute, a separate non-profit affiliated with the University of Pennsylvania Abramson Cancer Center, filed a suit alleging that Thompson had "absconded"

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with intellectual property he had developed while at the university and the institute (The Cancer Letter, March 16).

The suit claimed the rights to intellectual property Thompson may have produced between 1999 and 2010, the years he worked at Penn.

The filing came as a surprise to officials at both Penn and Memorial, sources said.

Similarly, officials at Agios Pharmaceuticals, the company Thompson co-founded while at Penn, apparently had no warning. Celgene Corp., a firm that invested in Agios, is said to have been similarly surprised.

The action was initiated by Abramson, the philanthropist who started U.S. Healthcare and took home an estimated $1 billion after selling the company to Aetna.

Abramson's action ultimately prompted the University of Pennsylvania to file a separate complaint against Thompson. That action was filed on Feb. 22 (The Cancer Letter, March 9).

The Abramson suit sought over $1 billion in each of three counts. The University of Pennsylvania sought at least $100 million in each of six counts. The two complaints can be found at: http://www.cancerletter.com/categories/documents.

Some observers say that it's likely that the university filed its suit in order to appease the donor who had given the institution over $100 million. Penn filed a separate complaint for procedural reasons, attorneys in the case said at the time. It was easier to do so than to intervene as a party to the Abramson litigation.

The Penn suit focused on two papers published in major scientific journals, which list Thompson as an author. However, authorship doesn't always equal a patent claim, and Thompson isn't listed as an inventor on the patents and patent applications held by Agios.

The first paper is "Cancer-associated IDH1 mutations produce 2-hydroxygluterade," Nature, Dec. 10, 2009.

Thompson is listed as one of the authors, along with scientists from Agios, Princeton University, University of California Los Angeles, Beth Israel Deaconess Medical Center, and the Massachusetts Institute of Technology.

Thompson is neither a senior author nor a corresponding author on this paper.

The second paper is "The Common Feature of Leukemia-Associated IDH1 and IDH2 Mutations Is a Neomorphic Enzyme Activity Converting alpha-Ketoglutarate to 2-Hydroxyglutarate," Cancer Cell, March 16, 2010.

Thompson is the senior author and the corresponding author of this paper. The paper includes the disclosure that Thompson has financial interest in Agios.

According to the Penn lawsuit, the findings described in the Cancer Cell paper build on the data in the Nature paper. Thompson "failed to disclose the subject matter of the publication to [the Penn Center for Technology Transfer] and the University, as required by the patent policy."

However, the university's public affairs office apparently knew about the publication. In fact, the university issued a press release, which is posted at: http://www.cancerletter.com/categories/documents.

"A press release would not satisfy most university policies on invention disclosure, which is a formal process of reporting to the tech licensing office," Cook-Deegan said. "So it may seem odd to the outside world, but if the tech transfer folks don't know about it, they can't report to NIH or Abramson Institute, which they probably have a contractual obligation and have as a statutory requirement to NIH if there was NIH money involved."

According to the Penn complaint, Agios had filed at least 20 provisional patent applications "for the same subject matter disclosed in the Nature and Cancer Cell articles."

Presumably these are the inventions which Agios has now agreed to license.

The two press releases announcing the conclusion of the case follow:

• New York, NY, Aug. 31—The parties to the lawsuits captioned, The Leonard and Madlyn Abramson Family Cancer Research Institute at the Abramson Cancer Center of the University of Pennsylvania v. Craig Thompson, M.D., Agios Pharmaceuticals, Inc., and Celgene Corporation and Trustees of the University of Pennsylvania v. Craig Thompson, M.D., and Agios Pharmaceuticals, Inc., are pleased to announce that they have entered into an agreement that will result in the dismissal of both cases in their entirety. The terms of the parties' agreement are confidential.

• Cambridge, Mass. and Philadelphia, Penn., Aug. 31—Agios Pharmaceuticals, Inc. ("Agios") and The University of Pennsylvania ("Penn") today announced that, in connection with the resolution of litigation announced earlier today, Agios and Penn have entered into a licensing agreement involving new intellectual property focused on the development of diagnostic products to detect the metabolism of certain cancers.

The collaboration could result in significant benefits to cancer patients, as well as financial benefits to Agios, Penn and the Abramson Family Cancer Research Institute.

"We are pleased to be collaborating with Penn and value the contributions of their scientists to this exciting field," stated David Schenkein M.D., Chief Executive Officer of Agios. "We are excited to now focus on the most important task of all – transforming the lives of cancer patients."

"We are pleased to be moving forward in a collaborative manner around newly identified intellectual property," commented Chi Van Dang, M.D., Ph.D., Professor of Medicine and Director of the Abramson Cancer Center at Penn. "We look forward to working with Agios on this project and potentially other unrelated projects in the future."

Earmarks for Research

House Committee Rewrites Pancreatic Cancer Research Bill

(Continued from page 1)

Even the bill's title, Pancreatic Cancer Research and Education Act of 2012, is gone.

Instead, the Subcommittee on Health of the House Committee on Energy and Commerce has moved far away from staging a "disease Olympics"—it has delivered a bill that does not mention any specific cancer.

Though the bill's number hasn't changed, its language has. The title has changed, too.

The measure is now called the Recalcitrant Cancer Research Act. Recalcitrant cancers are defined as diseases that have a "five-year relative survival rate of less than 10 percent" and the "cause the death of at least 30,000 individuals in the U.S. per year."

"We do have some concerns with the proposed [amendment] to H.R.733 which we believe lessen the impact that this legislation will have on advancing research and increasing survival rates of individuals diagnosed with pancreatic cancer," PanCAN CEO Julie Fleshman wrote in a letter to the bill's primary sponsors, Reps. Anna Eshoo (D-Calif.) and Leonard Lance (R-N.J.).

Fleshman's organization launched the aggressive drive that produced the original bill. PanCAN's lobbying tactics included visiting Congressional offices to hand out morgue toe tags bearing the names of constituents who died of pancreatic cancer.

The group's campaign materials also slammed NCI for failing to devote sufficient resources to pancreatic cancer (The Cancer Letter, Aug. 3, Aug. 10).

Though cancer researchers who objected to the first version of the bill were glad to see it go, some of them may be less than pleased with the definition of recalcitrant, which lies at the heart of the latest version. Survival, for example, isn't the most useful metric, because it can be compromised by the lead time bias.

The old version of the bill mentioned a five-year relative survival rate of less than 10 percent and the incidence of 30,000 in the U.S. per year. In the new version, the metric has shifted to mortality. Only lung and pancreatic cancers would likely meet that bar.

There will be additional opportunities to fix the language. The bill is scheduled for Senate committee markup Sept. 19.

Then, if the Senate passes a bill that differs from the House version, the two chambers will have to hammer out a new common bill. This may be difficult to accomplish before the election.

The New Recalcitrant Cancer Legislation

The new version instructs NCI to choose one or more deadly cancers to research and keep everyone posted on the progress.

Instead of being downgraded to a minority player, as it was in the first iteration of the bill, NCI would be given almost complete control over the creation of "scientific frameworks"—research guidelines on cancers with low survival rates.

With no clauses earmarking institute funds for specific research activities, the director would be able to independently manage NCI's budget.

Furthermore, the institute would no longer need to consult with the secretary of health and human services on awarding research grant applications. Nor would there be an external peer review advisory panel to reckon with.

To direct the development of the scientific framework, the House bill now requires the director of the institute to identify one or more recalcitrant cancers within six months after the bill becomes law. A literature review regarding the "prevention, diagnosis and treatment of such cancer[s]" would follow, and NCI is tasked with identifying promising scientific advances and qualified researchers.

The director would also have to explore possible initiatives and research partnerships with relevant national research institutes, federal agencies, and non-federal public and private entities.

The scientific frameworks would have to be developed within 18 months after the bill is signed into

law. Progress and information on awarded grants would be documented in biennial reports.

If the bill passes, the director of the institute would have the authority to review and update each scientific framework as necessary and, may, at any time, identify other recalcitrant cancers for research.

The measure also instructs the director to convene for each recalcitrant cancer "a working group comprised of representatives of appropriate federal agencies and other non-federal entities to provide expertise on, and assist in developing a scientific framework."

A Wave of Letters

The mechanism of the bill's metamorphosis is not publicly known.

What is known is that an unusually large number of cancer scientists and organizations involved in research wrote letters objecting to the old version of the bill.

The most recent letters were submitted by American Association for Cancer Research, the Coalition for Life Sciences, Association of American Medical Colleges, and MD Anderson Cancer Center President Ronald DePinho.

"The AACR Board of Directors has enormous empathy for patients and their families who have been affected by pancreatic cancer," wrote AACR President Frank McCormick and CEO Margaret Foti in an Aug. 20 letter to the bill's co-sponsor Sen. Sheldon Whitehouse (D-R.I.). "That said, we are not in agreement that there is a 'legislative fix' to improve the mortality and morbidity rates for pancreatic cancer patients.

"This legislation would undermine the National Institutes of Health (NIH) peer review process and may have the unfortunate effect of slowing advances in the diagnosis, treatment, and cure of this devastating disease…especially at this unprecedented moment in time when we are increasing our understanding of how different cancers share molecular features and applying the knowledge learned across many different types of cancers."

The Coalition of Life Sciences, an advocacy group representing over 60,000 researchers, sent a similar letter to the House Committee on Energy and Commerce to address a provision in the original bill that would establish a 13-member panel to allocate funds under the supervision of the HHS secretary.

NCI had only one vote on the committee in the original measure.

"This separate authority to prioritize and award grants would bypass and disrupt the NIH-wide merit review system, which has, for over 65 years, identified and selected for support the most important biomedical discoveries in the world," said CLS Chair Keith Yamamoto. "H.R.733/S.362 would also limit the perspective of the NCI Director, Nobel Laureate Harold Varmus, in defining the overall research priorities of his institute and coordinating his efforts with those of the other NIH Institute Directors.

"I, or any of my colleagues on the CLS, would be happy to discuss the recent advances in pancreatic cancer research and to discuss ways we can mutually advance a strategic plan that helps win the fight against this deadly cancer," Yamamoto wrote.

MD Anderson Cancer Center President Ronald DePinho also warned the House against passing the original bill, which would set a precedent "certain to be pursued" by other disease-focused organizations.

"As a cancer scientist with specific experience in PDAC (pancreatic ductal adenocarcinoma), I respectfully submit that prescribed allocations would harm progress in pancreas cancer research, near- and long-term," DePinho said. "Although there is little doubt that progress would result from additional funding in PDAC, this investment would be at the expense of funding across the entire NCI portfolio, taking a significant toll on other critical programs."

The Association of American Medical Colleges, which represents nearly 400 hospitals and health systems, wrote that the legislation would isolate pancreatic cancer research from advances made with other cancers and across the spectrum of medical research.

"The research agenda of the NCI has been developed within an overall research context based on a broad perspective that will remain essential to the understanding, treatment, and cure of pancreatic cancer," said AAMC President and CEO Darrell Kirch. "A legislative mandate, such as H.R.733/S.362, that constrains that perspective will not serve patients or their families."

The letters from scientists prompted PanCAN CEO Fleshman to acknowledge the concern that the legislation would bypass or otherwise disrupt the NIH peer review system.

"We propose eliminating those sections of the bill that reference the peer review process and clarifying the language to reflect the intended advisory role of the Pancreatic Cancer Coordinating Committee," wrote Fleshman in an August 15 letter to Reps. Eshoo and Lance. "Along the same lines, we would revise the coordinating committee's make up and placement within NCI's current organization structure."

However, the changes went far beyond Fleshman's

suggestions.

The Text of the House Bill

Amendment in the Nature of a Substitute to H.R. 733

SCIENTIFIC FRAMEWORK FOR RECALCITRANT CANCERS

(a) DEVELOPMENT OF SCIENTIFIC FRAMEWORK—

(1) IN GENERAL— For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall develop a scientific framework for the conduct or support of research on such cancer.

(2) CONTENTS— The scientific framework with respect to a recalcitrant cancer shall include the following:

(A) CURRENT STATUS—

(i) REVIEW OF LITERATURE—A summary of findings from the current literature in the areas of—

(I) the prevention, diagnosis, and treatment of such cancer;

(II) the fundamental biologic processes that regulate such cancer (including similarities and differences of such processes from the biological processes that regulate other cancers); and

(III) the epidemiology of such cancer.

(ii) SCIENTIFIC ADVANCES—The identification of relevant emerging scientific areas and promising scientific advances in basic, translational, and clinical science relating to the areas described in subclauses (I) and (II) of clause (i).

(iii) RESEARCHERS— A description of the availability of qualified individuals to conduct scientific research in the areas described in clause (i).

(iv) COORDINATED RESEARCH INITIATIVES— The identification of the types of initiatives and partnerships for the coordination of intramural and extramural research of the Institute in the areas described in clause (i) with research of the relevant national research institutes, Federal agencies, and non-Federal public and private entities in such areas.

(v) RESEARCH RESOURCES— The identification of public and private resources, such as patient registries and tissue banks, that are available to facilitate research relating to each of the areas described in clause (i).

(B) IDENTIFICATION OF RESEARCH QUESTIONS— The identification of research questions relating to basic, translational, and clinical science in the areas described in subclauses (I) and (II) of subparagraph (A)(i) that have not been adequately addressed with respect to such recalcitrant cancer.

(C) RECOMMENDATIONS—Recommendations for appropriate actions that should be taken to advance research in the areas described in subparagraph (A)(i) and to address the research questions identified in subparagraph (B), including the following:

(i) RESEARCHERS— Ensuring adequate availability of qualified individuals described in subparagraph (A)(iii).

(ii) COORDINATED RESEARCH INITIATIVES— Promoting and developing initiatives and partnerships described in subparagraph (A)(iv).

(iii) RESEARCH RESOURCES— Developing additional public and private resources described in subparagraph (A)(v) and strengthening existing resources.

(3) TIMING—

(A) INITIAL DEVELOPMENT AND SUBSEQUENT UPDATE— For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall—

(i) develop a scientific framework under this subsection not later than 18 months after the date of the enactment of this section; and

(ii) review and update the scientific framework not later than 5 years after its initial development.

(B) OTHER UPDATES— The Director of the Institute may review and update each scientific framework developed under this subsection as necessary.

(b) IDENTIFICATION OF RECALCITRANT CANCER—

(1) IN GENERAL— Not later than 6 months after the date of the enactment of this section, the Director of the Institute shall identify one or more recalcitrant cancers that each—

(A) have a 5-year relative survival rate of less than 10 percent; and

(B) are estimated to cause the death of at least 30,000 individuals in the United States per year.

(2) ADDITIONAL CANCERS— The Director of the Institute may, at any time, identify other recalcitrant cancers for purposes of this section.

(c) WORKING GROUPS—For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall convene a working group comprised of representatives of appropriate Federal agencies and other non-Federal entities to provide expertise on, and assist in developing, a scientific framework under subsection (a). The Director of the Institute (or the Director's designee) shall participate in the meetings

of each such working group.

(d) REPORTING—

(1) BIENNIAL REPORTS— The Director of NIH shall ensure that each biennial report under section 403 includes information on actions undertaken to carry out each scientific framework developed under subsection (a) with respect to a recalcitrant cancer, including the following:

(A) Information on research grants awarded by the National Institutes of Health for research relating to such cancer.

(B) An assessment of the progress made in improving outcomes (including relative survival rates) for individuals diagnosed with such cancer.

(C) An update on activities pertaining to such cancer under the authority of section 413(b)(7).

(2) ADDITIONAL ONE-TIME REPORT FOR CERTAIN FRAMEWORKS— For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall, not later than 6 years after the initial development of a scientific framework under subsection (a), submit a report to the Congress on the effectiveness of the framework (including the update required by subsection (a)(3)(A)(ii)) in improving the prevention, diagnosis, and treatment of such cancer.

(e) RECOMMENDATIONS FOR EXCEPTION FUNDING— The Director of the Institute shall consider each relevant scientific framework developed under subsection (a) when making recommendations for exception funding for grant applications.

(f) DEFINITION— In this section, the term 'recalcitrant cancer' means a cancer for which the five-year relative survival rate is below 50 percent.".

Amend the title to read as follows: "A bill to provide for scientific frameworks with respect to recalcitrant cancers."

PanCAN Objects to the Changes

After seeing the new House bill, PanCAN CEO Fleshman voiced her concerns.

The text of her letter to the House cosponsors follows:

Dear Representatives Lance and Eshoo:

We write to thank you for your leadership in combating pancreatic cancer by introducing H.R. 733, the Pancreatic Cancer Research and Education Act.

We are encouraged the bill has moved forward through mark up in the Health Subcommittee because we believe it will set in place a process to better focus research on and create accountability for pancreatic cancer and other recalcitrant cancers at the National Cancer Institute.

We do have some concerns with the Amendment in the Nature of a Substitute (AINS) and the recalcitrant cancer initiative and we look forward to working with you to address these concerns as the bill moves forward.

H.R. 733 as introduced has broad bipartisan support, including a majority of the Energy & Commerce Committee and a super majority of the House. We know you are aware that pancreatic cancer is a deadly disease that requires Congressional attention.

The 5-year survival rate for pancreatic cancer is only 6 percent, making pancreatic cancer the only major cancer that continues to have a 5-year relative survival rate in the single digits. By comparison, the 5-year survival rate for all cancers is 67 percent, including 100 percent for prostate cancer and 90 percent for breast cancer.

While overall cancer incidence and death rates are declining, the number of new pancreatic cancer cases is projected to increase by 55 percent between 2010 and 2030, and it is projected to become the second leading cause of cancer death by 2020, possibly as early as 2015. There are currently no early detection tools or effective treatments for pancreatic cancer.

The National Cancer Institute (NCI) currently does not have a long-term and comprehensive plan to address this disease.

The Pancreatic Cancer Action Network has been working in good faith to address issues raised by Members of Congress, third parties and the National Cancer Institute regarding the bill as introduced. However, we do have some concerns with the proposed AINS to H.R. 733 which we believe lessen the impact that this legislation will have on advancing research and increasing survival rates of individuals diagnosed with pancreatic cancer.

Chief among our concerns:

1. Clarify the types of non-Federal entities to be represented in the working group.

• Insert the wording in bold in (c):

"WORKING GROUPS— For each recalcitrant cancer identified under subjection (b), the Director of the Institute shall convene a working group comprised of representatives of appropriate Federal agencies and other non-Federal entities, including investigators whose expertise includes basic, translational, and clinical science focused on the recalcitrant cancer

involved, individuals affiliated with a leading research or advocacy organization focused on the recalcitrant cancer involved, and individuals in fields relevant to the involved recalcitrant cancer, to provide expertise on, and assist in developing, a scientific framework under subsection (a).

2. Include benchmarks in the scientific framework by which NCI can measure its progress advancing research in the ways described in the framework.

• Insert the wording in bold in (a)(2)(C):

"Sec. 2(a)(2)(C) RECOMMENDATIONS—Recommendations for appropriate actions that should be taken to advance research in the areas described in (A)(i) and to address the research questions identified in subparagraph (B) and for appropriate benchmarks to measure progress on achieving those actions, including the following:"

3. Require that the scientific framework be made public and reported to Congress.

• After Sec. 2 (a)(3)(B) "OTHER UPDATES" include the following:

"(4) PUBLIC NOTICE.—With respect to each scientific framework developed under subsection (a), the Director of the National Cancer Institute shall—(A) submit such framework to the Committee on Energy and Commerce and Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and Committee on Appropriations of the Senate within 30 days of completion of the framework; and (B) publish and maintain each framework on the Website of the Department of Health and Human Services within 30 days after the completion of the framework.

4. Change the timeline by which the scientific framework is reviewed and updated based on TA from NIH. It is important to have regular updates to capture the changing dynamics of the since and to incorporate what is being learned through the scientific framework progress.

• TA from NIH suggest that a periodic review of the scientific framework should occur, "not later than 2 years after the publication of a scientific framework described in subsection (b)(1) for a specific recalcitrant cancer, and periodically but not later than every three years thereafter…"

In (a)(3)(A)(ii), change "not later than 5 years after its initial development" to "not later than 3 years after its initial development and every 3 years thereafter."

The modifications outlined above would improve the process outlined by the AINS, while better providing for accountability of taxpayer funds.

It is absolutely critical to expand research and education to improve survival rates for recalcitrant cancers, and pancreatic cancer in particular because it has the lowest survival rate of any major cancer.

We look forward to working with you and your colleagues to make the changes requested above and ensure the bill is passed this Congress.

In Brief

SU2C Raises $81 Million In Pledges In Cancer Telethon

(Continued from page 1)

Fine comes to NYU Langone from the NCI Center for Cancer Research, where he served as the chief of the Neuro-Oncology Branch and held a joint appointment with the National Institute of Neurological Disorders and Stroke as an adjunct investigator. In his new role, he has a wide range of responsibilities including directing clinical programs in solid tumor oncology, developmental therapeutics, malignant hematology and experimental hematology.

Before joining NCI in 2000, Fine was both director of the Neuro-Oncology Disease Center at Dana-Farber Cancer Institute and of the Neuro-Oncology Program at the Dana-Farber/Harvard Cancer Center.

STAND UP TO CANCER announced that more than $81 million has been pledged in connection with its Sept. 7 telecast. The initiative plans to fund a new pediatric cancer research "dream team."

SU2C is still accepting donations at www.su2c.org and at 1-888-90-STAND. The telecast is available at: www.hulu.com/stand-up-to-cancer.

ABC, CBS, FOX and NBC donated one hour of simultaneous, commercial-free primetime for the fundraising special.

The program included a tribute to film producer Laura Ziskin, who was an SU2C co-founder and executive producer of the telecasts in 2008 and 2010. Ziskin died of breast cancer in June 2011.

SU2C and the St. Baldrick's Foundation will issue a "call for ideas" to the scientific community for a collaborative pediatric cancer dream team within the next two weeks.

The American Association for Cancer Research is responsible for the scientific review, grants administration, and scientific oversight of SU2C research projects in conjunction with the SU2C

Scientific Advisory Committee, led by Phillip Sharp, institute professor at the David H. Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology.

The following seven Dream Teams have been supported by SU2C: the SU2C Epigenetics Dream Team, the SU2C Pancreatic Cancer Dream Team, the SU2C PI3K Pathway Dream Team, the SU2C Breast Cancer Dream Team, the SU2C Circulating Tumor Cell Chip Dream Team, the SU2C-MRA Melanoma Dream Team and the SU2C-PCF Prostate Dream Team. SU2C and the Cancer Research Institute will announce the selection of an SU2C-CRI Dream Team focused on cancer immunology in the near future.

ANDREW KUNG was named director of the Division of Pediatric Hematology Oncology and Stem Cell Transplantation in the Department of Pediatrics at **New York-Presbyterian Morgan Stanley Children's Hospital/Columbia University Medical Center**.

He is the recipient of the NCI's Howard Temin Award and the Sidney Kimmel Translational Science Award, and was also a fellow of the St. Baldrick's Foundation. He is also an elected member of the Society for Pediatric Research and the American Society for Clinical Investigation.

Kung has been on the faculty at Harvard Medical School since 1999, and the Harvard Stem Cell Institute since 2011.

Kung's translational oncology research integrates molecular biology, genomics, proteomics, bioinformatics, cell biology, preclinical models, drug development and molecular imaging.

THE CONQUER CANCER FOUNDATION of the **American Society of Clinical Oncology** announced the first-ever recipients of its **Quality Care Symposium Merit Awards**. The recipients will be recognized at ASCO's inaugural Quality Care Symposium, November 30 and December 1 in San Diego.

The Conquer Cancer Foundation of ASCO Merit Awards are designed to promote clinical cancer research by young investigators and provide them with the opportunity to present their research. The symposium brings together researchers, patient advocates, health system administrators, and practicing physicians to share results in measuring and improving the quality of cancer care.

This year's awardees include:

• **Jeffrey Cao**, London Health Sciences Centre; for "Categorization of measures of quality in radiation treatment."

• **Laura Chin-Lenn**, University of Calgary; for "Using quality indicators to monitor changes in adherence to clinical practice guidelines for treatment of ductal carcinoma in situ (DCIS) of the breast."

• **Nathan Connell**, Brown University Oncology Group; for "Assessment of the effectiveness of a pre-chemotherapy teaching session: A Brown University Oncology Group study."

• **Sinead Cuffe,** Princess Margaret Hospital, University of Toronto; for "Cancer patients' and physicians' preferences for decision making regarding pharmacogenomic testing (PGT)."

• **Brendan Curley**, Mary Babb Randolph Cancer Center at West Virginia University; for "Patient understanding and impression of hematology/oncology fellows."

• **Isabella Glitza,** MD Anderson Cancer Center; for "Attrition rates, reasons and predictive factors in supportive/palliative oncology clinical trials at a comprehensive cancer center."

• **Alex Haynes,** MD Anderson Cancer Center; for "Socioeconomic and clinical factors associated with delayed initiation of adjuvant chemotherapy for stage III colon cancer."

• **Maria Ho**, BC Cancer Agency – Vancouver Centre; for "Improving the quality of abstract reporting for economic analyses in oncology."

• **Joseph Klink,** Glickman Urological and Kidney Institute, Cleveland Clinic; for "Nomogram predicting treatment-related urinary incontinence for men with localized prostate cancer treated by radical prostatectomy (RP), external-beam radiotherapy (EBRT), or brachytherapy (PI)."

• **Naomi Ko,** Boston University Medical Center; for "The impact of patient navigation on receipt of quality breast cancer treatment in the national patient navigation research program."

• **Aaron Mansfield,** Mayo Clinic; for "Skin cancer surveillance and malignancies in patients with chronic lymphocytic leukemia (CLL)."

• **Petra Martin**, St. Vincent's University Hospital; for "Use of iPad technology to determine cancer patient- reported preferences for and understanding of pharmacogenetic testing (PGT)."

• **Mark Mishra**, Kimmel Cancer Center, Thomas Jefferson University; for "Natural language processing (NLP) of Internet conversations to evaluate prostate cancer (PC) patients' perceptions of active surveillance (AS)."

• **Andrew Moore,** Vanderbilt University Medical Center; for "Morbidity, mortality, and improvement (MM&I) conference leading to change."

• **Sarah Mougalian,** The University of Texas MD Anderson Cancer Center; for "Feasibility and savings of a suspicion of cancer clinic at a large county hospital."

• **Manali Patel,** Stanford University Medical Center; "Can equitable care eliminate colon cancer disparities?"

• **Anjana Ranganathan,** University of Pennsylvania; for "Documentation of code status at an outpatient academic cancer center: A marker of discussing end-of-life preferences."

• **Sonia Reichert,** Mount Sinai School of Medicine; for "Compliance to select quality measures in a non-QOPI subspecialty academic practice: A pilot quality improvement initiative."

• **Rakesh Roy,** Dip Pall Med (UK); for "Information technology transforming quality of cancer care in developing nation."

• **Yvonne Sada,** Michael E. DeBakey Veterans Affairs Medical Center; for "The effect of gaps in chemotherapy on survival in patients with high-risk stage II and stage III colon cancer."

FDA News

FDA Approves Imaging Agent For Recurrent Prostate Cancer

FDA approved Choline C 11 Injection, a Positron Emission Tomography imaging agent used to help detect recurrent prostate cancer. The injection is used to help locate body sites for follow-up tissue sampling and testing.

PET imaging with Choline C 11 Injection is performed in patients whose blood prostate specific antigen levels are increasing after earlier treatment for prostate cancer.

Choline C 11 Injection must be produced in a specialized facility and administered to patients shortly after its production. While PET imaging with Choline C 11 Injection has been performed at a few facilities over the past several years, none of these facilities were approved to manufacture the agent.

The FDA Modernization Act directed the agency to establish appropriate approval procedures and current good manufacturing practice requirements for all PET products marketed and used in the U.S. The Mayo Clinic is the first FDA-approved facility to produce Choline C 11 Injection.

The safety and effectiveness of Choline C 11 Injection were verified by a systematic review of published study reports. Four independent studies examined a total of 98 patients with elevated blood PSA levels but no sign of recurrent prostate cancer on conventional imaging. After PET imaging with Choline C 11, the patients underwent tissue sampling of the abnormalities detected on the PET scans.

In each of the four studies, at least half the patients who had abnormalities detected on PET scans also had recurrent prostate cancer confirmed by tissue sampling of the abnormal areas. PET scan errors also were reported.

Depending on the study, falsely positive PET scans were observed in 15 percent to 47 percent of the patients. These findings underscore the need for confirmatory tissue sampling of abnormalities detected with Choline C 11 Injection PET scans.

Letter to the Editor

To The Editor:

I commend you on your recent issue exploring developments here at MD Anderson. I enjoyed reading every word.

I also want to correct one error and one possible misperception. The error: I am not a clinical psychologist but rather a marriage and family therapist. The misperception: Because I was the only faculty member identified by name as critical of an administration policy, readers might assume that I am one of your "inside sources" at MD Anderson, which is not the case. (The Cancer Letter, Sept. 7.)

In writing for MD Anderson's Faculty Voice blog I've tried to be as open and transparent as possible so as to enhance communication and build trust within our organization—even when discussing contentious issues. I don't want the leadership of MD Anderson to think that I have broken that trust. I'm not criticizing The Cancer Letter for doing its important job of investigative reporting, only saying that I am in a different role as moderator of an internal, institutional blog. I don't want to compromise our effectiveness here at MD Anderson by being perceived as working covertly with external media.

Warren Holleman is a professor of behavioral science and director of faculty health & well-being at MD Anderson Cancer Center.