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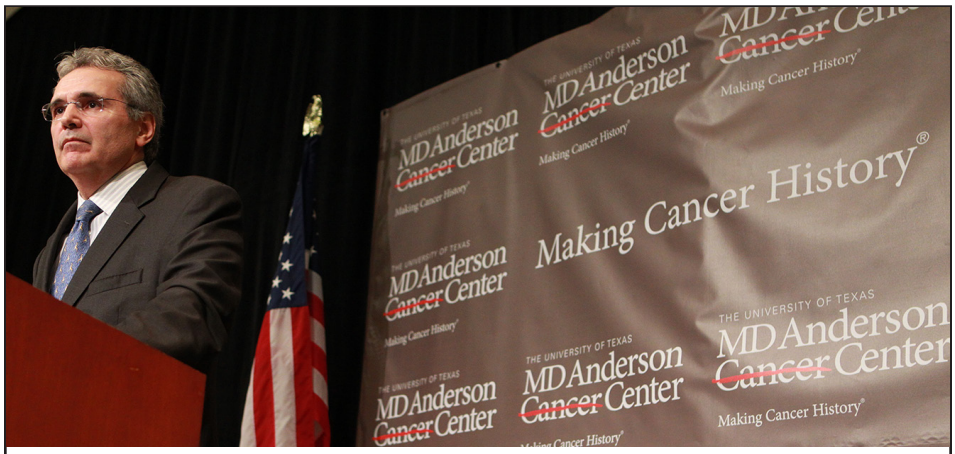

DePinho Explains Tenure Decision, Professors Dispute Key Details

By Matthew Bin Han Ong

Confronted with the prospect of censure by an academic freedom group, Ronald DePinho, president of MD Anderson Cancer Center, is defending his decision to deny tenure renewal to two faculty members.

Responding to an inquiry by the American Association of University Professors, DePinho said that his critics are incorrect in asserting that his administration gave no formal explanation for denying tenure renewal to two faculty members.

(Continued to page 2)

Moffitt, Ohio State Form Network, Invite Major Cancer Centers to Join

By Paul Goldberg

Moffitt Cancer Center and the Ohio State University Comprehensive Cancer Center—Arthur G. James Cancer Hospital and Richard J. Solove Research Institute earlier this week announced that they are constructing a bioinformatics framework that would enable a multi-center collaboration.

The network, called the Oncology Research Information Exchange Network, or ORIEN, is seeking to form partnerships with other leading cancer centers in North America.

(Continued to page 8)

ASCO 2014: Special Awards

The Special Awards honorees at the 2014 meeting of the **American Society of Clinical Oncology** are:

• **H.M. (Bob) Pinedo** was named the recipient of the **David A. Karnofsky Memorial Award and Lecture.**

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DePinho: We Gave Them Reasons

(Continued from page 1)

Kapil Mehta and Zhengxin Wang, the faculty members, were, in fact, given reasons for non-renewal, DePinho wrote in his letter to AAUP.

Following this publication's coverage of the tenure dispute, the AAUP had launched an inquiry into MD Anderson's treatment of Mehta and Wang, demanding their reinstatement (The Cancer Letter, May 16).

"Assuming the essential accuracy of the foregoing account, we would strongly urge you to rescind the notice of non-reappointment issued to both professors and immediately reinstate them to their full-time appointments," an AAUP official wrote in the May 13 letter to DePinho. "Our further course of action in these cases will depend upon how you will act now."

Mehta and Wang had received unanimous votes for renewal from the Promotions & Tenure Committee (The Cancer Letter, April 25).

If censured by the AAUP, MD Anderson would join a list of over 50 institutions.

In his letter to the AAUP, DePinho wrote:

• Mehta was informed that his tenure was not renewed because he had insufficient external funding, and because the administration had received a non-renewal recommendation from his former department chair, Garth Powis.

• Wang was not given a written explanation for the non-renewal of his tenure because he did not "fully exhaust" all appeal processes. The administration is unable to comment further because Wang filed an external legal discrimination complaint.

Others questioned the accuracy of DePinho's account. The letter can be found on page 5.

In a rebuttal letter submitted to the AAUP in response to DePinho's account, MD Anderson professor Douglas Boyd said, "there are several inaccuracies, and the administration skirts the important issues at hand." Boyd is chair of the Faculty Senate Promotion & Tenure Issues Committee.

Boyd said that:

• Mehta was well funded for most of his tenure—others who had similar or greater lapses in funding had their tenure renewed at the time when Mehta's was denied. Many faculty members do not fulfill the 40 percent salary requirement. Also, contrary to DePinho's version of events, Powis had submitted a written recommendation *in favor* of renewal.

• Wang had completed the appeals process, contrary to DePinho's account. The steps that Wang did not use are optional, and occur after the decision by the provost to deny the appeal. No reasons were provided to Wang when the appeal was denied, Boyd reaffirmed.

The faculty appeals process can be downloaded from The Cancer Letter website.

MD Anderson officials said they are standing by DePinho's letter to the AAUP.

"We believe our records support the information in our May 23, 2014, letter to Dr. Gregory Scholtz, with the American Association of University Professors," officials said in a statement to The Cancer Letter.

It is unclear whether the AAUP would continue to spar with the DePinho administration, or whether it would initiate a formal investigation.

Mehta: What Letter?

Mehta, a professor in the Department of Experimental Therapeutics, said he exhausted the appeals process, and obtained letters of support from superiors, including one written by Powis in 2011.

However, DePinho, in his letter to the AAUP, said that Powis had actually recommended against the renewal of Mehta tenure. Mehta said he wasn't aware of any written negative recommendation from Powis.

"I would be very surprised," Mehta said to The Cancer Letter. "I had requested to check my package in the office of Academic Affairs, and I did not see anything from [Powis] that was negative. All the tenure renewal documents should have been filed in this package. If it

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had existed, it should have been in there.

"I don't see any reason why Dr. Powis will write a strong recommendation and then change it six months later and not send me a copy, unless he was under some sort of pressure from the leadership.

"When he wrote the positive letter, I had the signed copy. The reasons for my dismissal never became clear to me, even now."

Powis's letter can be downloaded from The Cancer Letter website.

According to DePinho, Mehta had received an explanation for the non-renewal of his tenure in the form of a memo, dated Oct. 11, 2012, saying: "Your current lack of peer review funding makes the achievement of near-term scientific goals difficult."

DePinho's letter to AAUP continues:

"Thus, we do not agree with any allegation that no written reasons were given for the non-renewal of Dr. Mehta's term appointment or that his requests for a written explanation of the basis for the decision have been withheld.

"MD Anderson's policy on salary support requires 40 percent of salary support come from extramural grants for faculty members whose primary responsibility is scientific research. Determinations about a faculty member's compliance with policy are made by academic leadership in making final determinations concerning renewal of a term appointment.

"Compliance with policy requirements concerning adequate grant support of one's compensation is an important example of the additional factors the Provost and President must take into account when considering all of the available data in the renewal process. Therefore, when a faculty member fails to comply with this policy requirement, there should be, and was in this instance, written notification of that being a reason for non-renewal."

The 40 percent salary support requirement—up from 30 percent—was implemented in September 2011.

The requirement only applies to basic research faculty, whereas clinical faculty has full financial support from the institution, according to Mehta.

Mehta said he had managed to raise the required 30 percent of his salary in external funds for most of his tenure term.

"If you take a snapshot of any particular time at MD Anderson, I would guess that more than 50 percent of faculty is not able to meet the 40 percent salary requirement from grants, under the current funding environment," Mehta said.

The lapse in funding was only a transient situation, Mehta said. "For most of my tenure, I had good funding; I was paying that portion of my salary and met all the goals in all five categories," he said. "I was either on par, or exceeded other faculty members' performance.

"We are supposed to be evaluated for tenure-renewal based on overall performance in research (publications, funding, patents etc.), education, impact, and service. In my case, Dr. DePinho ignored the other areas of my performance, and focused on that current situation, which was transient, and which probably would have changed if they had given me at least two years to regain funding."

Mehta's department chair, division chair, and division vice chair for research—Varsha Gandhi, Waun Ki Hong, and Elizabeth Grimm, respectively—had signed a letter requesting the provost and executive vice president to extend Mehta's tenure by at least two years.

That request was turned down.

Contacted by The Cancer Letter, Powis declined to comment. He left MD Anderson over a year ago, and is now director of Sanford Burnham Medical Research Institute.

Finkin: "Horrendous" to Remove Tenured Faculty Based on Money

The act of removing a tenured faculty member because he or she is unable to raise adequate funds is a major distortion of the research mission, said Matthew Finkin, director of the Program in Comparative Labor and Employment Law & Policy, and Albert J. Harno and Edward W. Cleary Chair in Law at the University of Illinois.

"Number one, what [MD Anderson] insists on calling 'tenure' isn't tenure," Finkin said to The Cancer Letter. "And it really verges on being a trap for the unwary.

"First of all, you have to raise external funds, and if you don't raise external funds that are adequate by our measures, we're going to fire you," Finkin said. "I call it a hunting license. It's not tenure—the 1940 Statement of Principles on Academic Freedom and Tenure says that tenure exists for two reasons, one of which is economic security."

Finkin is the author of two definitive books on tenure in the U.S.—The Case for Tenure, and For the Common Good: Principles of American Academic Freedom. He is also an author of Labor Law, a leading casebook in American legal education.

"To say that we're going to fire you if you have not raised external funds adequate to pay 40 percent of your salary—I've never heard of a true tenure being termed with cause to dismiss because you've not been able to persuade granting authorities to give you money,"

Finkin said. "It also calls into question: Has this policy been consistently applied at MD Anderson, or is there an element of arbitrariness or discrimination?

"Yes, the capacity of an individual to persuade granting authorities to pay, that's part of the portfolio, but it's not to make it the dominant aspect, which apparently, this institution does.

"First of all, you're at the whim of, sometimes, literally, or certainly the exigencies of a granting system where money is increasingly short. So, even very worthwhile projects don't get funded. Secondly, what happens to fundamental research, or areas of research where those funds may not be available? Do we close that off because it's not currently popular?

"I understand the financial situation, but I think it's pretty horrendous, it's educationally unsound, and just as a matter of treatment of human beings, it's a terrible way to behave.

"I'm not surprised that in medicine as in any of the other sciences, the ability to raise external support is a feature of the scene. But I've never heard of a situation where a faculty member can be terminated—allegedly a faculty member who has claimed to be 'tenured' because he or she has not been able to raise sufficient grant money to pay their own way. I hope MD Anderson is not typical of medical education.

"It raises the question of, 'What do you have? Is this a relationship to an institution, or is it what I'd call a hunting license? You have an affiliation with us only insofar as you are able to persuade the external funding sources to give you money?'

"To make an entire faculty contingent on the popularity of the fields of research that are currently centered on works as a major distortion of the research mission, not just in medical education."

In his review of DePinho's letter, Finkin said that tenure issues larger than the fate of two faculty members are at stake.

"The University of Texas, Permian Basin, had the same policy, and later changed it to regular tenure policy. I wrote about that policy, and I think I said it verged on being a fraud on the faculty. To call something tenure when it isn't is misleading to the world as to what your policy really is.

"Secondly, [MD Anderson] wraps the need for that system in the fact that they are a medical center. The AAUP has a couple of reports on tenure in medical education. But the argument that somehow medical education is different than engineering or law or anybody else that has tenure—in the authentic sense—is a red herring. And I think it's slightly insulting."

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AAMC: Most Medical Institutions Offer Permanent Tenure

Nearly 90 percent of medical colleges and institutions offer permanent tenure, according to the American Association of Medical Colleges.

"In 2008, 111 medical schools out of 126 offered tenure," AAMC Chief Scientific Officer Ann Bonham said to The Cancer Letter. "I would say that the majority of medical schools who have tenure view it as something of permanence."

For instance, appointments with tenure at Memorial Sloan-Kettering Cancer Center, a private institution, are made without stated terms.

"Faculty appointments with tenure come with a commitment from MSKCC to support the continued employment of the individual; this commitment is made until the individual resigns or retires," officials said in a statement to The Cancer Letter.

The continued employment of tenured faculty at MSKCC is not contingent on their ability to raise external funds, although salary support is expected.

"MSKCC expects faculty members (tenured or otherwise) to be accountable for a portion of their salary through research, clinical, and/or educational activities," officials said.

Bonham said many medical colleges and institutions expect faculty to support their salaries with external funding.

"In 2008, for clinical faculty, even those that received tenure, only about 44 percent have some financial guarantee," Bonham said. "So it's really more tenure with title.

"And for the basic science faculty, the Ph.Ds that were largely engaged with research, while half of the tenured faculty had some financial guarantee, only less than 10 percent had full institutional salary. So it's very small. Even though there are tenure offerings, it does not necessarily guarantee a full institutional salary, but it may guarantee some aspect of it."

For the majority of medical institutions that offer permanent tenure, a number are having conversations about a post-tenure review, Bonham said.

"With tenure, there's an expectation of increasing productivity, however that's defined by the institution," she said. "So in a post-tenure review, institutions are beginning to look at the productivity after tenure.

"But off the top of my head, I can't think of institutions who are explicitly taking tenure away.

"I can't comment on MD Anderson's terminology, but I do know that institutions are really grappling with a terminology that's consistent and fair, and transparent to both the faculty and the institution."

Separately, Wang has filed a complaint with the U.S. Equal Employment Opportunity Commission claiming discrimination based on race and retaliation.

"In contrast to Dr. DePinho's statement in his letter that I either discontinued or abandoned my appeal before exhausting all steps of the faculty appeal process provided by policy, I finished all appeal processes and received a letter from the provost declining my appeal," Wang said to The Cancer Letter.

"I also filed a charge through the EEOC on Aug. 8, 2013, and asked them to investigate the potential discrimination issues."

Wang's complaint can be downloaded from The Cancer Letter website.

DePinho's Letter to the AAUP

Responding to an inquiry by the American Association of University Professors, MD Anderson Cancer Center President Ronald DePinho said his critics are incorrect in asserting that his administration gave no formal explanation for denying tenure renewal to two faculty members.

The full text of the letter, addressed to Gregory Scholtz, AAUP associate secretary and director of the Department of Academic Freedom, Tenure and Governance, follows:

Dear Dr. Scholtz:

This letter is in response to your May 13, 2014 correspondence concerning your interest in the non-renewal of appointments for Dr. Kapil Mehta and Dr. Zhengxin Wang, as well as the protection of academic freedom and due process for faculty at The University of Texas MD Anderson Cancer Center.

You wrote that the information provided to your organization regarding Drs. Mehta and Wang has come primarily from those individuals, and you also acknowledged that MD Anderson may have additional information that would contribute to your understanding of these matters. We very much appreciate your invitation to comment on this matter and value the opportunity to provide additional information on our processes.

Regrettably, we do not believe you have all of the relevant information pertaining to these matters.

While it is MD Anderson's practice to avoid communications with outside parties related to faculty personnel matters, we appreciate the opportunity to respond.

We are providing the information below so that the American Association of University Professors may better understand MD Anderson's policies and practices that honor, protect and enhance the professional careers of our esteemed faculty at our comprehensive cancer center.

The practice of awarding seven-year term appointments (sometimes referred to as term tenure) for MD Anderson faculty members has been in place for several decades. While each appointment is for seven years, the overwhelming number of term-appointed faculty have those appointments renewed for additional seven-year periods, often on multiple occasions.

In the last three fiscal years, in a total number of 181 cases considered, the average renewal rate has been 92%. The system we use is well known to our faculty and is specifically identified to candidates in their offer letters and in the annual memoranda confirming their appointments.

As an academic institution, we both vigorously support and champion academic freedom and due process. In fact, it is well known that some of the most vocal faculty critics of MD Anderson's administration have had their term appointments renewed many times, as it is our duty to encourage and defend academic freedom.

Likewise, as a publicly supported comprehensive cancer center, we have a responsibility to our patients and to the public that our faculty and staff maintain the highest level of excellence and accountability. This is why we strongly believe the longstanding term appointment system at MD Anderson serves to balance these two crucial needs while providing a high level of long-term career security to our term-appointed faculty, as evidenced by the average renewal rate stated above.

Additionally, for the small percentage of term appointments not renewed during the last three fiscal years, the faculty members of the promotion and tenure committee recommended non- renewal in 13 out of 15 cases. It may also be of interest that academic leadership has, on occasion, decided in favor of extending or promoting the service of faculty who have received an adverse recommendation by the committee.

Again, we must emphasize that when one considers the overall renewal rate, coupled with the overwhelming consistency between final non-renewal determinations and the committee's recommendations for non-renewal, any suggestion that our faculty are at risk of non-renewal of their appointment for capricious purposes is simply not supported by the facts.

As a leading cancer center, we are fully committed to the recruitment and retention of outstanding faculty

in all stages of their development. This includes, among others, recruited faculty recognized through additional financial support by both State of Texas granting authorities and The University of Texas System, as well as our recently established Clark Fellows program, which recognizes the achievements of junior faculty members.

Our support of our faculty is holistic and includes formal mentoring programs, wellness programs, and internal financial support of research projects that surpasses virtually all other academic medical centers. Our faculty is crucial to the success of this institution.

In the mid 1970's, with the active and full participation of our faculty members, MD Anderson adopted extensive, detailed policies and procedures governing both the initial award of seven- year term appointments, as well as the subsequent renewal of those appointments. These policies and practices provide significant safeguards of academic freedom and a commitment to a process that is fair and documented.

In fact, in the two instances about which you raised questions in your correspondence, we cannot find a single allegation by either of those individuals that either their academic freedom has been infringed upon, or, conversely, that renewal was denied as a result of their exercise of academic freedom.

You also have asserted that Drs. Mehta and Wang were not provided appropriate due process. As noted above, in respect for a person's privacy, we usually do not comment to external third parties on faculty personnel matters. However, in this instance, your organization has apparently been requested to represent the interests of these individuals and has taken responsibility for the consequences of doing so.

Our records indicate that Drs. Mehta and Wang were both notified, in accordance with established policy, more than one year before the anticipated conclusion of their seven-year term appointments that their appointments would end and that they would not be reappointed to another MD Anderson term appointment.

We believe this to be more than timely notice of non-reappointment.

In your letter, you allege that neither Dr. Mehta nor Dr. Wang was made aware of the reasons for the non-renewal of their term appointment, and as a result you voice concerns about a lack of due process in our reappointment process.

It appears that you may not have received all of the relevant information from Drs. Mehta or Wang related to the non-renewal of their term appointments. Both faculty members were fully and timely notified of their right and ability to appeal the non-renewal of appointment decisions. Both timely initiated the internal MD Anderson faculty appeal process.

In Dr. Wang's circumstances, however, he either discontinued or abandoned his appeal before exhausting all steps of the faculty appeal process provided by policy.

As we are sure you are aware, when an individual seeks to challenge whether or not a particular review process comports with due process, it is essential that the individual fully exhaust all internal procedural steps concerning his or her case. Unfortunately, that did not occur with Dr. Wang.

To the contrary, he initiated a separate complaint in an external legal forum. Had he completed the appeal process, he would have received a written explanation concerning any final determination. Because of Dr. Wang's instigation of an external legal process prior to exhausting the internal MD Anderson processes made available to him, we are now unable to comment further about his non-renewal.

However, we can state with confidence that written information available to Dr. Wang was more than adequate to apprise him of the basis of non-renewal, despite his failure to exhaust all internal due process steps available to him.

Dr. Mehta fully exhausted the MD Anderson appeal process, but has apparently advised you that he does not know why his appointment was not renewed. Again, the record indicates a different conclusion than the one you were provided.

In fact, Dr. Mehta's appeal reached beyond what is commonly provided for by policy. In addition to the due process appeal rights and steps provided in MD Anderson policies, Dr. Mehta's appeal process was extended because he requested additional reviews and because MD Anderson experienced changes to the Provost and Executive Vice President position during the course of Dr. Mehta's appeal process. The institution felt it was necessary to make accommodations in light of these special circumstances related to the leadership change.

Contrary to the assertion that no written explanation for non-renewal was provided to Dr. Mehta, the pertinent records demonstrate that Dr. Thomas Buchholz, Provost and Executive Vice President, *ad interim,* reviewed and considered Dr. Mehta's appeal and advised him of specific reasons for the non-renewal of his appointment in writing on two separate occasions.

Included in the record is a memorandum dated October 11, 2012 wherein Dr. Buchholz informed Dr. Mehta, "However, based upon my review of this matter, including your current lack of expected external funding and the recommendation for non-renewal of

your appointment by your department chair, Dr. Garth Powis, it is my decision that the non-renewal of your faculty appointment action should be upheld."

After subsequently meeting with Dr. Mehta in person to discuss the reasons for the non-renewal of his term tenure appointment, Dr. Buchholz again wrote Dr. Mehta on November 20, 2012. In that memorandum, Dr. Buchholz informed Dr. Mehta of his conclusion to uphold the decision to not renew Dr. Mehta's term appointment.

In addition to other information in that memorandum, Dr. Buchholz wrote, "Your current lack of peer review funding makes the achievement of near-term scientific goals difficult."

Thus, we do not agree with any allegation that no written reasons were given for the non-renewal of Dr. Mehta's term appointment or that his requests for a written explanation of the basis for the decision have been withheld.

MD Anderson's policy on salary support requires 40% of salary support come from extramural grants for faculty members whose primary responsibility is scientific research. Determinations about a faculty member's compliance with policy are made by academic leadership in making final determinations concerning renewal of a term appointment.

Compliance with policy requirements concerning adequate grant support of one's compensation is an important example of the additional factors the Provost and President must take into account when considering all of the available data in the renewal process. Therefore, when a faculty member fails to comply with this policy requirement, there should be, and was in this instance, written notification of that being a reason for non-renewal.

We hope this correspondence has provided both information and insight into our commitment to academic freedom, due process, and the recruitment, retention and support of our faculty, whom we consider to be second to none.

Our national leadership in conducting peer-reviewed, grant- supported research and recognized world-class patient care speaks to a long tradition that will continue into the future - a spectacular group of faculty passionately dedicated to, and personally rewarded by, the exceptional work they do at MD Anderson.

Thank you for the opportunity to respond to your concerns.

Sincerely,

Ronald DePinho

Boyd's Rebuttal to DePinho's Letter to the AAUP

Douglas Boyd, a professor at MD Anderson, sent his own letter to the American Association of University Professors, responding to DePinho's version of events.

Boyd is chair of MD Anderson's Faculty Senate Promotion & Tenure Issues Committee.

The full text of the letter, addressed to Gregory Scholtz, AAUP associate secretary and director of the Department of Academic Freedom, Tenure and Governance, follows:

Dear Dr. Scholtz,

I feel that I must respond to the letter from Dr. DePinho in response to yours of May 13, 2014 since there are several inaccuracies and the administration skirts the important issues at hand. Relevant sections are extracted verbatim and my response follows each.

1) Dr. Buchholz informed Dr. Mehta (Oct 11, 2012), "based on my review of this matter including your current lack of expected external funding…my decision that the non-renewal…should be upheld"

Response: The review by the *Faculty Senate Promotion Tenure Committee Issues* committee determined (a) Dr. Mehta was well funded by the NIH (i.e. external funding) over the six years (grants NIH CA135218 and CA092115 and bringing in over $770,000) through 2012 (i.e. at the time he was reviewed for tenure renewal) not to mention an additional $725,000 from other peer-reviewed (also external) grants.

Importantly, with the extremely competitive nature of national funding in the current era (-7% of applications are funded), many of our faculty do NOT fulfil the 40% salary requirement.

Indeed, the review by our *Faculty Senate Promotion Tenure Committee Issues committee* showed two faculty members who were **not** funded for one and two of the six years evaluated (and hence NOT meeting the 40% requirement)—nevertheless these individuals were renewed for tenure over the same period that Dr. Mehta was denied.

2) Dr. Buchholz informed Dr. Mehta (Oct 11, 2012), "based on my review of this matter including…the recommendation for non-renewal of your appointment by your department chair Dr. Garth Powis…my decision that the non-renewal…should be upheld."

Response: In its investigation, the *Faculty Senate Promotion Tenure Committee Issues* committee reviewed the letter of recommendation from the Chair-Or. Powis

and determined it to be favorable for renewal.

I attach a copy of the letter provided by Dr. Mehta. Clearly the letter by Dr. Garth Powis is supportive of Dr. Mehta's renewal.

3) "had he (Dr. Wang) completed the appeal process, he would have received a written explanation concerning any final determination."

Response: Indeed Dr. Wang had completed the appeals process—please see (attached) the memorandum from the Provost stating that he has "decided to uphold the decision to not renew (Dr. Wang's) appointment."

Note that steps 13 and 14 of the Appeals process document (ACA0041 -attached) are discretionary (the phrase **"may"** is employed for Step 13.0 of this document) and occur **after** the decision by the Provost to deny the appeal.

Thus as it stands and importantly, the administration has failed to provide a reason as to why Dr. Wang was overturned by the President after receiving a **unanimous** vote by the MDACC Promotions and Tenure committee.

Again it is important to stress that in our evaluation, *the Faculty Senate Promotion Tenure Committee Issues* committee determined that Dr. Wang was comparable to, or exceeded, at least one of his peer(s) in publications, funding and teaching—individuals who received tenure renewal in the corresponding period.

Sincerely,
Douglas Boyd

Moffitt, Ohio State Bioinformatics Collaboration Has Gathered Consent from 100,000 Patients

(Continued from page 1)

ORIEN has over 100,000 consented patients who have agreed to donate tissue and clinical data. The network will use a single protocol, Total Cancer Care, to create a collaborative, "rapid learning" environment that will share de-identified data to accelerate the development of targeted treatments.

The two founding centers said theirs is likely the largest collaboration of its kind to accelerate discoveries in cancer research. Financial details of the collaboration and the terms on which other centers can join were not disclosed.

"If we can bring on a couple of centers a year, that would be good," said Dan Sullivan, associate center director for clinical sciences at Moffitt, chief medical officer of M2Gen, a subsidiary of Moffitt that will serve as ORIEN's operational and commercial provider for data management and informatics. "We've had interest expressed by probably 10 to 15 different sites."

The network is one of the arrangements that has emerged recently, as institutions are vying to identify patients with mutations—frequently rare mutations—that are becoming increasingly important in determining cancer care and running clinical trials.

"With ORIEN, we are amassing a true national cancer database for the first time," Michael Caligiuri, director of The Ohio State University Comprehensive Cancer Center and CEO of the James Cancer Hospital. "The collaboration across academic centers and

with health care industry will not only help speed discovery, but will also provide patients with more personalized treatment options and ultimately, lead to better outcomes."

The network has a dual purpose. "One is for our own researchers to utilize the molecular and annotated clinical data in the discovery," Caligiuri said. "And second, to partner with pharma in development of therapeutics."

Potential breakthroughs in cancer have been stalled "because we've lacked an efficient way to share incremental insights," said Alan List, president and CEO of Moffitt. "Even more frustrating, until today we've had no system to quickly match cancer patients from anywhere in the country with ongoing clinical research with the most potential to help them," he said. "By partnering with The Ohio State University through ORIEN, we've built a cancer research expressway."

According to its founders, the new network builds upon the strengths of its founding centers: Moffitt's Total Cancer Care protocol, biorepository and data warehouse of patients' genotypic and phenotypic data, and OSUCCC-James's depth and breadth in translating molecular- and genetic-based discoveries into more effective ways to prevent, detect, treat and ultimately cure cancers.

Other players in the bioinformatics field see this collaboration and others as the next phase in cancer research.

"It is great to see multi-institution, standards-based information resources like this come together," said John McIlwain, president of Velos, a company that produces an internet-based platform for clinical research.

"A confluence of information technology advances has made such projects viable, particularly the widespread emergence of electronic medical records and low cost gene sequencing," said McIlwain, who isn't involved in the collaboration. "Matching patients with promising clinical research and mining this kind of data for drug discovery has great value. Velos and some of our customers have systems or initiatives along these lines in place that likely have complimentary elements. This is the right direction."

ORIEN is an outgrowth of Moffitt's collaboration with Merck Pharmaceuticals.

That collaboration continued for five years, between 2006 and 2011. During that time, Moffitt created a network of 17 regional hospitals in 10 states, enrolling close to 100,000 patients on its protocol.

Instead of sharing de-identified data, the Moffitt protocol prospectively consented patients up-front to allow life-long follow-up, as well as granting the researchers the right to use tissue and associated clinical data in any way that advances cancer treatment. Patients also consented to being contacted if any important developments occur in the treatment of their disease.

Two years ago, William Dalton, then-CEO of Moffitt, began conversations with Ohio State's Caligiuri.

"Many institutions have collaborated on sharing de-identified data," Caligiuri said to The Cancer Letter. "But to my knowledge there has not been a partnership where you prospectively consented patients to allow the use of their clinical data and their cellular and molecular data whenever you need to advance treatment strategies for cancer."

Ohio State adopted an enrollment protocol identical to Moffitt's. The two centers are also working on making data obtainable across their electronic medical record systems. Ohio State is developing an in-house system, called Nvision, to integrate its Epic HER system with Moffitt's Health Research Informatics system.

"When we first adopted that protocol here, we approached 2,000 patients to see whether they would allow us to track them for life, use their tissue for whatever we need it for, and re-contact them at any time," Caligiuri said.

"And over 85 percent of people immediately consented to the protocol. Patents and society are demanding a new treatment model, and they want to be involved, they want to be followed, they want to be able to track their own progress up against the progress of other patients."

ASCO 2014: Special Awards

(Continued from page 1)

Pinedo is professor emeritus of the VU University Medical Center and a consultant to the Board of the VUmc Cancer Center in Amsterdam.

In a four-decade-long career, Pinedo has focused on original, translational cancer research combining leading-edge basic science with clinical excellence. He has served as a founder of the Center for Translational Molecular Medicine in Eindhoven, The Netherlands, and as president of the European Society of Medical Oncology.

• **Harald zur Hausen** was named the recipient of the **Science of Oncology Award and Lecture.** He is a virologist and cancer researcher who discovered the important role that human papillomavirus plays in cervical cancer. His ground-breaking research in the 1970s and 1980s paved the way for the development of the HPV vaccine in 2006. He received a Nobel Prize in Medicine in 2008 for this achievement.

Throughout his career, Hausen has focused on furthering the understanding of cancer through his innovative research in the field of oncoviruses. He served as scientific director of the German Cancer Research Center from 1983-2003, and from 2000 to 2009 served as editor-in-chief of the International Journal of Cancer.

• **Graham Colditz** was named the recipient of the **ASCO-American Cancer Society Award and Lecture.** He is an internationally renowned epidemiologist and public health expert with a long-standing interest in the causes and prevention of chronic disease, particularly those affecting women.

He is the Niess-Gain Professor of Surgery; chief of the Division of Public Health Sciences; and deputy director of the Institute for Public Health at Washington University in St. Louis. Colditz pursues approaches to the translation of epidemiologic data to improve risk stratification and to tailor prevention messages and screening strategies.

He has published more than 900 peer-reviewed publications, six books and six reports for the Institute of Medicine.

• **Stuart Lichtman** was named recipient of the **B.J. Kennedy Award and Lecture for Scientific Excellence in Geriatric Oncology.** He is an attending physician at Memorial Hospital for Cancer and Allied Diseases, a member of Memorial Sloan-Kettering Cancer Center and their 65+ Clinical Geriatric Group (which he chaired from 2006 to 2009), and professor of medicine at Weill Cornell Medical College. He received his medical degree from Mount Sinai School of Medicine and has devoted his career to providing quality care to underserved and undertreated older populations with cancer.

Lichtman is also actively involved with the Cancer and Leukemia Group B and the Elderly Task Force of the Gynecologic Oncology Group, Cancer and Aging Research Group, and Editorial Board of the Journal of Geriatric Oncology.

• **Jaime de la Garza** was named recipient of the **Distinguished Achievement Award.** He is the executive secretary of the Science Advisory Council for the president of the Mexico, as well as a clinical research investigator at the Instituto Nacional de Cancerología in Tlalpan.

De la Garza is universally recognized as the pioneer of medical oncology in Mexico, authoring over 180 articles and a book, Relato Histórico de la Oncologia Medica en Mexico, and has lectured internationally at over 1,000 events.

• **Michael Levy** was named recipient of **the Excellence in Teaching Award.** He is professor and vice-chair of the Department of Medical Oncology at the Fox Chase Cancer Center, medical director of Payer Relations at Fox Chase, and a professor of medicine at Temple University School of Medicine.

He is a master trainer for ASCO's Education for End-of-Life Care–Oncology train-the-trainer program, and a member of ASCO's Supportive Care Guidelines Advisory Group. Levy served as director of the Lippincott Family Hospice Program and the Pain and Palliative Care Program, and served as chair of the Medical Ethics Committee at Fox Chase.

Levy is a past-president of the American Academy of Hospice and Palliative Medicine, and he has served on the Board of Directors of both AAHMP and the National Hospice and Palliative Care Organization. He has served as chairperson of NHPCO's Ethics Committee and the National Comprehensive Cancer Network's Palliative Care Guideline Panel.

• **Aron Goldhirsch** was named recipient of the **Gianni Bonadonna Breast Cancer Award and Lecture.** He is an international leader in the field of breast cancer. His areas of research include new adjuvant treatments for breast cancer, definition of biologic features that predict responsiveness or resistance to anticancer treatments, and quality-of-life-oriented approaches.

Goldhirsch serves as director of the Multidisciplinary Program of Senology and deputy

scientific director at the European Institute of Oncology, in Milan, Italy. He is also professor of medical oncology at the University of Bern, Switzerland.

• **Surendra Shastri** was named recipient of the **Humanitarian Award.** He has been dedicated to preventive oncology and public health initiatives for the past 20 years. Since 1997, he has served as professor and head of the Department of Preventive Oncology at Tata Memorial Centre in Mumbai, India.

Shastri also heads the World Health Organization's Collaborating Centre for Cancer Prevention, Screening and Early Detection, and often serves on their expert panels for cancer and non-communicable diseases. Devoting most of his career to public health, he works to improve preventative initiatives and screening for cancer in the developing world, including a low-cost cancer control program in rural districts.

• **Michael Katz** was named recipient of the **Partners in Progress Award.** He is vice president of the International Myeloma Foundation. Katz has served as chairman of the Patient Representatives Committee at the Eastern Cooperative Oncology Group, the NCI Director's Consumer Liaison Group, and the Association of Cancer Online Resources. In these positions, Katz has actively contributed to improved outcomes for patients with cancer through in-person, telephone, and online educational and support programs.

• **Leslie Robinson** was named recipient of the **Pediatric Oncology Award and Lecture.** She is the associate director for cancer prevention and control at St. Jude Comprehensive Cancer Center and chair of the Department of Epidemiology and Cancer Control at St. Jude Children's Research Hospital.

Robinson is the principal investigator of the groundbreaking Childhood Cancer Survivor Study, a multi-institutional study begun in 1994 that is evaluating a cohort of more than 35,000 five-year survivors of childhood cancer diagnosed between 1970 and 1999, yielding significant, practice-changing findings in every aspect of cancer survivorship.

More recently, Robison has had a leadership role in the establishment of the St. Jude Lifetime Cohort, providing lifelong comprehensive systematic medical assessments of long-term survivors of childhood cancer.

• **Congressman John Carney** was named recipient of the **Public Service Award.** Carney (D) serves as Delaware's lone representative in the House of Representatives and has a career in public service that spans more than 20 years.

During his time as lieutenant governor, he worked to pass the Delaware smoking ban and led the passage of the Cancer Right to Know law. He is a member of the Advisory Committee and the former chair of the Disparities Committee of the Delaware Cancer Consortium, a dedicated group of community leaders focused on reducing cancer incidence and mortality risk in Delaware.

Carney has also worked on the national level to address prescription drug shortages by proposing several reforms in the Prescription Drug User Fee Authorization designed to provide doctors and patients with more access to needed medications.

• **James Armitage** was named recipient of the **Special Recognition Award.** He is the Joe Shapiro Professor of Medicine at the University of Nebraska Medical Center and past president of both the American Society of Clinical Oncology and the American Society of Blood and Marrow Transplantation.

Armitage is globally recognized as a leading expert on non-Hodgkin lymphoma, and he has played a critical role in advancing bone marrow transplantation.

He developed and directed the bone marrow transplant programs at the University of Iowa and later at the University of Nebraska, where he also served as vice chair of Internal Medicine, chief of the Section of Oncology and Hematology, chair of the Department of Internal Medicine, and dean of the College of Medicine.

He has served on the U.S. National Cancer Advisory Board; the Scientific Committee of the International Congress on Anti-Cancer Treatment in Paris, France; the International Symposium on Hodgkin Lymphoma in Cologne, Germany; and the International Conference on Malignant Lymphoma in Lugano, Switzerland.

THE CONQUER CANCER FOUNDATION OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY announced the recipients of the 2014 Young Investigator Awards, Career Development Awards, and the Advanced Clinical Research Award in Breast Cancer.

The recipients will be recognized during the Grants and Awards Ceremony at the 2014 ASCO Annual Meeting.

The 2014 Recipient of the Advanced Clinical Research Award:

• **Vandana Abramson** was named recipient of the Advanced Clinical Research Award in Breast Cancer. Abramson, of Vanderbilt University Medical Center, will conduct two complementary clinical trials that use recent advances in the molecular understanding of triple negative breast cancer. The trials will highlight novel, molecularly-targeted treatments for recently defined subtypes of TNBC. This grant is supported by The Breast Cancer Research Foundation.

The 2014 Recipients of the Career Development Award:

• **Constantine Albany**, Indiana University, for "Hypomethylation Induced Resensitization to Platinum in Refractory Germ Cell Tumors (rGCT)"

• **Matthew Davids**, Dana-Farber Cancer Institute, for "A Phase 1b/2 Study of IPI-145 in Combination With Fludarabine, Cyclophosphamide, and Rituximab (iFCR) in Previously Untreated, Younger Patients Wth Chronic Lymphocytic Leukemia"

• **Alexander Drilon**, Memorial Sloan-Kettering Cancer Center, for "Identification of Mechanisms of Sensitivity and Resistance to RET Inhibition in RET Fusion-Positive Lung Cancers"

• **Rachel Grisham**, Memorial Sloan-Kettering Cancer Center, for "A Phase II Study of Enzalutamide for Treatment of Androgen Receptor Positive Ovarian, Primary Peritoneal, or Fallopian Tube Cancer"

• **Simon Kim**, Yale University, for "National Trends in Active Surveillance for Prostate Cancer and Barriers to its Use"

• **Erin Macrae**, The Ohio State University, for "Targeting Molecular Pathways in Metastatic Triple Negative Breast Cancer"

• **Jae Park**, Memorial Sloan-Kettering Cancer Center, for "Evaluating Clinical Efficacy and Molecular Mechanisms of BRAF Inhibition in Hairy Cell Leukemia"

• **Marcia Russell**, University of California, Los Angeles, for "The Impact of Surgical Technique on Quality of Life after Rectal Cancer Surgery: Patient-Reported Outcomes in National Surgical Adjuvant Breast and Bowel (NSABP) Protocol R-04"

• **Rona Yaeger**, Memorial Sloan-Kettering Cancer Center, for "Maximizing ERK Inhibition to Treat MAPK-Activated Colorectal Cancer"

The 2014 Recipients of the Young Investigator Award:

• **Wassim Abida**, Memorial Sloan-Kettering Cancer Center, for "The Androgen Receptor Protein Interactome in Prostate Cancer Drug Response"

• **Melissa Accordino**, Columbia University Medical Center, for "Electronic Educational Alert to Reduce Overuse of Granulocyte Colony Stimulating Factor in Patients Hospitalized for Febrile Neutropenia"

• **Andrew Aguirre**, Dana-Farber Cancer Institute, for "Validation of Novel KRAS Synthetic Lethal Candidate Genes as Therapeutic Targets in Pancreatic Ductal Adenocarcinoma"

• **Mekhail Anwar**, University of California, San Francisco, for "Development of a Real-Time Intraoperative Fluorescent Imager for Microscopic Residual Tumor"

• **Bradley Blaser**, Dana-Farber Cancer Institute, for "Regulation of Hematopoietic Stem Cell Engraftment by the Endothelial Cell Niche"

• **Jason Brayer**, H. Lee Moffitt Cancer Center and Research Institute at the University of South Florida, for "Targeting Histone Deacetylase 11 (HDAC11) to Selectively Promote T Memory Stem Cell Development and Improve T-Cell Antitumor Immunity"

• **David Cescon**, Princess Margaret Hospital, for "Co-Clinical Trial and Biomarker Evaluation of CFI-400945, a First-in-Class Inhibitor of PLK4, in Patient-Derived Breast Cancer Xenografts (PDX)"

• **Steven Corsello**, Dana-Farber Cancer Institute, for "Discovery of P53 therapeutics via the Connectivity Map"

• **Karen Effinger**, Stanford University, for "Longitudinal Evaluation of Health Status in Survivors of Pediatric Astrocytoma"

• **Anna Farago**, Massachusetts General Hospital, for "Assessing Response and Resistance to Combination BH3 Mimetic and TORC Inhibition Therapies in Small-Cell Lung Cancer Using Genetically Engineered Mice"

• **Surbhi Grover**, University of Pennsylvania, for "The Impact of HIV Infection and Antiretroviral Treatment on Cervical Cancer Therapy Outcomes"

• **Alex Herrera**, Dana-Farber Cancer Institute, for "Minimal Residual Disease and Relapse in Patients

with Lymphoid Malignancies Following Allogeneic Hematopoietic Stem Cell Transplantation"

• **Christine Heske**, National Cancer Institute, for "Identification of PDGFR-ß activation as a Bypass Resistance Pathway in a Model of Acquired Resistance to IGF-1 Receptor Blockade"

• **Franklin Wei Huang**, Dana-Farber Cancer Institute, for "Investigating the Genomics of African-American Prostate Cancer"

• **Siwen Hu-Lieskovan**, David Geffen School of Medicine at UCLA, for "Combined Targeted Therapy and Immunotherapy in Melanoma"

• **Andrew Intlekofer**, Memorial Sloan-Kettering Cancer Center, for "Investigating the Role of Oncometabolite D-2-Hydroxyglutarate in Normal Hematopoiesis and Leukemogenesis via Manipulation of D-2-Hydroxyglutarate Dehydrogenase"

• **Douglas Johnson**, Vanderbilt University Medical Center, for "Driver Mutations in Melanoma and their Impact on Immune Based Therapy Outcomes"

• **Rafi Kabarriti**, Montefiore Medical Center, for "Radiation Therapy in Combination with Listeria Monocytogenes-Based PSA Vaccine as a Therapeutic Approach in a Murine Model of Prostate Cancer"

• **Junne Kamihara**, Dana-Farber Cancer Institute, for "Determining the Prevalence of Germline Cancer Predisposition Mutations Among a High-risk Cohort of Pediatric Oncology Patients"

• **Meghan Karuturi**, MD Anderson Cancer Center, for "The role of Inappropriate Medication Use in Elderly Patients Receiving Adjuvant Chemotherapy for Breast and Colorectal Cancer"

• **Jaime Libes**, Vanderbilt University Medical Center, for "Standardization of Wilms Tumor Therapy to Increase Survival of Kenyan Patients"

• **Yanyan Lou**, MD Anderson Cancer Center, for "Investigating Tumor Microenvironment Immune Phenotypes in Epithelial-Mesenchymal Transition and EGFR Tyrosine Kinase Inhibitor-Resistant NSCLC: Implication for Immunotherapy"

• **Kathleen Mahoney**, Beth Israel Deaconess Medical Center, for "PD-L1 and a Secretory Variant in Renal Cell Carcinoma"

• **Stephanie Markovina**, Washington University, for "Squamous Cell Carcinoma Antigen as a Novel Therapeutic Target in Cervical Cancer"

• **Jane Meisel**, Memorial Sloan-Kettering Cancer Center, for "Using Circulating Tumor DNA (ctDNA) to Identify Secondary Somatic Mutations Restoring BRCA 1/2 in Hereditary Ovarian Cancer: A Potential Selection Biomarker for Treatment With Platinum and Inhibitors of Poly (ADP) Ribose Polymerase (PARP)"

• **Tamara Miller**, The Children's Hospital of Philadelphia, for "Determination of the Frequency and Diagnostic Yield of Invasive Diagnostic Procedures for Evaluation of Pulmonary Nodules Concerning for Invasive Fungal Infection in Pediatric Oncology Patients Using Administrative/Billing Data"

• **Parisa Momtaz**, Memorial Sloan-Kettering Cancer Center, for "Quantification of tumor-derived cell free DNA (cfDNA) using Digital-PCR (Dig-PCR) to assess tumor burden in patients with BRAFV600E mutated melanoma"

• **Kent Mouw**, Dana-Farber Cancer Institute, for "Characterization of Novel Nucleotide Excision Repair Pathway Mutations in Bladder Cancer"

• **Oreofe Odejide**, Dana-Farber Cancer Institute, for "Processes and Outcomes of End-of-Life Care for the Hematologic Malignancies"

• **Bilal Omer**, Baylor College of Medicine, for "Administration of Most Closely HLA-Matched Multivirus-Specific Cytotoxic T-Lymphocytes for the Treatment of EBV, CMV, Adenovirus, HHV6, and BK virus Infections post Allogeneic Stem Cell Transplant"

• **Phillip Palmbos**, Baylor College of Medicine, for "Administration of Most Closely HLA-Matched Multivirus-Specific Cytotoxic T-Lymphocytes for the Treatment of EBV, CMV, Adenovirus, HHV6, and BK virus Infections post Allogeneic Stem Cell Transplant"

• **Healther Parsons**, Johns Hopkins University, for "Can Less Be More? A novel approach to reducing overtreatment in adjuvant systemic therapies"

• **Mary-Elizabeth M. Percival**, Stanford University, for "Clinical and pharmacodynamics evaluation of MEK inhibition in combination with conventional chemotherapy in RAS-mutated AML"

• **Vassiliki Saloura**, The University of Chicago, for "The Histone Epigenome as a Novel Yherapeutic Avenue in Head and Neck Cancer"

• **Payal Deepak Shah**, Memorial Sloan-Kettering Cancer Center, for "Targeting PI3K-alpha in estrogen receptor-positive (ER+) metastatic breast cancer (MBC): Phase 1 trial expansion and correlative studies"

• **Stacey Shiovitz**, Fred Hutchinson Cancer Research Center, for "Identification of Host Genetic Markers and Environmental Exposures Conducive to the Development of Metastatic Colorectal Cancer"

• **Alexander Shoushtari**, Memorial Sloan-Kettering Cancer Center, for "Phase Ib Trial of AEB071, a PKC Inhibitor, in Combination with BYL719, a PI3K-alpha Inhibitor, in Patients with Metastatic Uveal Melanoma"

• **Dean Shumway**, University of Michigan, for "Physician Views on Adjuvant Radiotherapy for Elderly Women with Early Stage Breast Cancer: Evaluating the Factors that Influence Translation of Evidence into Practice"

• **Corey Speers**, University of Michigan, for "Identification and Valdiation of Novel Targets for the Management of Triple-Negative and Treatment-Refractory Breast Cancer"

• **Anna Speafico**, Princess Margaret Cancer Centre, for "Transcriptome Analysis of the mTOR pathway in Well-Differentiated Gastrointestinal and Pancreatic Neuroendocrine Tumors"

• **Erica Stringer**, The University of Chicago, for "The Role of the Glucocorticoid Receptor Signaling in High-Grade Serous Ovarian Carcinoma"

• **Daniel Suzman**, Johns Hopkins University, for "A pharmacodynamics study of vismodegib in men with metastatic castration-resistant prostate cancer (mCRPC) with accessible metastatic lesions for tumor biopsy"

• **Mala Talekar**, The Pennsylvania State University College of Medicine, for "Preclinical evaluation of ONC201 as a novel targeted therapy for pediatric lymphoma"

• **Noam VanderWalde**, University of North Carolina at Chapel Hill , for "A Randomized Phase II Study of a Walking Intervention for Radiation-Related Fatigue in Older Breast Cancer Patients Receiving Adjuvant Radiation"

• **Frederick Wilson**, Dana-Farber Cancer Institute, for "A Genomic Approach to Identify Drivers of Resistance to ALK Inhibition"

• **Melissa Wilson**, University of Pennsylvania, for "Combination of BRAF Inhibitor and MM-121, a Fully Human Monoclonal Antibody Targeting ERBB3, in Patients with Advanced Melanoma"

• **Kit Man Wong**, University of Toronto, for "Exploiting the Receptor Tyrosine Kinase MER for the Targeted Therapy of Colorectal Cancer"

In Brief

Big Ten Research Consortium Names Goodin Exec. Officer

SUSAN GOODIN was named executive officer of the **Big Ten Cancer Research Consortium**.

Goodin is executive director for statewide affairs at Rutgers Cancer Institute of New Jersey and professor of medicine at Rutgers Robert Wood Johnson Medical School. She possesses more than 20 years of clinical research leadership experience, including serving as the deputy director of operations, associate director of clinical trials and therapeutics, and director of the Division of Pharmaceutical Sciences at the Cancer Institute of New Jersey.

Goodin will work closely with the consortium's administrative headquarters, pharmaceutical partners, and other physicians and researchers as well as serve as the primary spokesperson and representative for the consortium at meetings and events.

She played a key role in the establishment of the cancer institute's clinical practice and designed its clinical research infrastructure, including the Center's research office, research pharmacy, and protocol review and monitoring system and is a founding co-leader of the Cancer Institute of New Jersey's statewide clinical trials network that includes 15 hospitals under the Center's clinical research infrastructure.

Goodin's research has focused predominantly on the development of both prevention and therapeutic pharmaceutical interventions. She has served as principal investigator on numerous clinical trials, has been published in prestigious journals, and has presented nationally on the topics of cancer treatment, chemoprevention, and supportive care.

Goodin is an active member or board member of the Board of Pharmacy Specialties, American Society of Health-System Pharmacists, American College of Clinical Pharmacy, American Society of Clinical Oncology, and the International Society of Oncology Pharmacy Practice.

Goodin's appointment comes at a time of growth as the Big Ten CRC is developing clinical trial concepts through various working groups, including physicians or researchers from each member institution with expertise in genitourinary, gastrointestinal, thoracic, and breast cancers.

THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY launched an online ACA Resource Center to help oncologists and patients understand the Patient Information and Affordable Care Act and the law's impact on oncology practices and patients.

The online resources provide details about the law, new requirements for practices, and changes to patient insurance coverage.

Most U.S. citizens and legal residents are now required to have health insurance or face a penalty. Exchanges have been set up in all 50 states to help the uninsured shop for coverage. Oncology practices are treating considerably more patients with these new exchange-based plans and adapting to changes in existing plans.

THE JAMES GRAHAM BROWN CANCER CENTER at the University of Louisville received a three-year, $5.5 million grant to develop new treatments and vaccines for various forms of cancer from the **Leona M. and Harry B. Helmsley Charitable Trust.**

The funding will help researchers move into clinical trials vaccines for cervical and colon cancer. Additionally, researchers will further develop plant-based drug delivery systems to allow for higher concentrations of anticancer drugs to be transported directly to human tumors, as well as to increase a tumor's sensitivity to anticancer treatment. The plants involved in the research range from tobacco to soybeans to colored berries.

The trust also has funded UofL research focused on spinal cord injuries. To date, the trust has provided UofL with nearly $15 million in research funding.

MD ANDERSON CANCER CENTER signed an agreement with **Concord Medical Services Holdings Limited** to serve as a consultant for its cancer hospital projects under planning in Shanghai and Beijing.

According to the agreement, MD Anderson will provide consulting services to Concord Medical with respect to the enhancement of its cancer care program for the company's two projects, Shanghai Concord Cancer Hospital and Beijing Concord Cancer Hospital, which will be located in Shanghai New Hongqiao International Medical Center and Beijing International Medical Center, respectively.

MD Anderson will also provide technical management and medical support to Concord Medical's cancer hospitals.

Concord Medical acquired 19.98 percent ownership of The MD Anderson Proton Therapy Center in Houston, Texas at the end of 2012.

Shanghai Concord Cancer Hospital plans to open 400 beds and install the most advanced cancer diagnostic and treatment equipment and multidiscipline system.

Beijing Concord Cancer Hospital will be wholly owned by Concord Medical and will provide comprehensive cancer therapies, including surgery, chemotherapy, radiotherapy, and gene therapy to cancer patients. The hospital will be part of Beijing International Medical Center, a joint project initiated by the Beijing municipal government, the Ministry of Health, and several other Chinese government agencies to introduce world-standard medical services to China.

THE MAYO CLINIC signed an agreement with **N-of-One** to provide access to clinical interpretation information to aid molecular diagnostics.

Under the agreement, in select cases, N-of-One will assist in therapeutic options and potential clinical trials for patients who undergo next generation cancer sequencing. Mayo Clinic will use the clinical interpretation services for Mayo Medical Laboratories, a global reference laboratory operating within Mayo Clinic's Department of Laboratory Medicine and Pathology, as well as in its Center for Individualized Medicine.

THE CENTERS FOR DISEASE CONTROL AND PREVENTION is recruiting for the position of **Director of the Division of Cancer Prevention and Control** in the National Center for Chronic Disease Prevention and Health Promotion.

Duties will include leading and managing approximately 145 medical, scientific and technical staff and a $323 million annual budget, supporting a broad portfolio of prevention programs, surveillance and applied research activities.

Interested candidates should send their CV to Dana Shelton at dzs8@cdc.gov no later than June 16.

Funding Opportunity

DoD Offering $10.5 Million For Lung Cancer Research

The Department of Defense Lung Cancer Research Program will provide $10.5 million to support innovative, high-impact lung cancer research during fiscal 2014.

The Lung Cancer Research Program is administered by the U.S. Army Medical Research and Materiel Command through the Office of Congressionally Directed Medical Research Programs. FY14 LCRP Program Announcements and General Application Instructions for the following award mechanisms are posted on the Grants.gov website.

Areas of Emphasis: The FY14 LCRP encourages research projects that specifically address the critical needs of the lung cancer community in the following Areas of Emphasis:

• Identification or development of noninvasive or minimally invasive tools to improve the detection of the initial stages of lung cancer.

• Identification, development, and/or building upon already existing tools for screening or early detection of lung cancer. Screening may include, but is not limited to, computed tomography scans, X-rays, other imaging biomarkers, genetics / genomics / proteomics / metabolomics / transcriptomics, and assessment of risk factors.

• Understanding the molecular mechanisms of progression to clinically significant lung cancer.

• Understanding the molecular mechanisms that lead to various subtypes of lung cancer.

• Identification of innovative strategies for prevention and treatment of early and/or localized lung cancer.

• Understanding predictive and prognostic markers to identify responders and nonresponders.

• Understanding susceptibility or resistance to treatment.

Military Relevance: The FY14 LCRP strongly encourages research projects that are relevant to the health care needs of military service members, veterans, their families, and other military beneficiaries.

Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate military relevance: use of military or veteran populations or data in the proposed research; collaboration with DoD or VA investigators; involvement of military consultants or specialty leaders to the Surgeons General in a relevant specialty area; explanation of how the project addresses an aspect of lung cancer that has direct relevance to military service members, veterans, their families, or other military health system beneficiaries

The Concept Award supports the exploration of a highly innovative new concept or untested theory that addresses an important problem relevant to lung cancer. The award is not intended to support an incremental progression of an already established research project but, instead, allows principal investigators the opportunity to pursue serendipitous observations. This award mechanism supports high-risk studies that have the potential to reveal entirely new avenues for investigation. Applications must describe how the new idea will enhance existing knowledge of lung cancer or create an entirely new avenue for investigation. Submissions from and partnerships with investigators at Military Treatment Facilities**,** military labs, the Department of Veterans Affairs Medical Centers and research laboratories are strongly encouraged.

For the Concept Award, a letter of intent is **due July 29, 2014.** The award is available to all investigators at or above the level of postdoctoral fellow, and supports highly innovative, untested, potentially groundbreaking concepts in lung cancer with an emphasis on innovation. Projects involving human subjects or human biological substances must be exempt under 32 CFR 219.101(b) or eligible for expedited review under 32 CFR 219.110 or 21 CFR 56.110. Clinical trials are not allowed and preliminary data is discouraged. The award offers a maximum of $100,000 in funding. Period of performance is not to exceed one year.

All applications must conform to the Program Announcement and General Application Instructions that are available for electronic downloading from the Grants.gov website. A listing of all USAMRMC funding opportunities can be obtained on the Grants.gov website by performing a basic search using CFDA Number 12.420.

A pre-application is required and must be submitted through the CDMRP electronic Biomedical Research Application Portal prior to the pre-application deadline. Applications must be submitted through the federal government's single-entry portal, Grants.gov. Requests for email notification of the Program Announcements release may be sent to help@eBRAP.org.

For more information about the LCRP or other CDMRP-administered programs, please visit the CDMRP website.

Drug Approvals

FDA Approves Vectibix in mCRC Along with KRAS Diagnostic

FDA approved the Amgen agent **Vectibix** (panitumumab) for use in combination with FOLFOX as first-line treatment in patients with wild-type KRAS (exon 2) metastatic colorectal cancer.

With this approval, Vectibix becomes the first and only biologic to offer a significant survival benefit as a first-line treatment with FOLFOX. In addition, this approval converts the accelerated monotherapy approval to a full approval for Vectibix.

FDA also approved the **therascreen KRAS RGQ PCR Kit** developed by Qiagen as a companion diagnostic for Vectibix.

The approval is based on results from Amgen's PRIME and ASPECCT trials. The PRIME phase III trial showed that patients with wild-type KRAS tumors in exon 2 achieved statistically significant improvement in progression-free survival with Vectibix and FOLFOX, compared to FOLFOX alone (9.6 vs. 8.0 months, p=0.02) and a significant 4.4 month improvement in overall survival versus FOLFOX alone (23.8 vs. 19.4 months).

The phase III ASPECCT study met its primary endpoint of non-inferiority for improving overall survival in patients taking Vectibix versus Erbitux (cetuximab) as a single agent for the treatment of mCRC in patients with wild-type KRAS tumors who have not responded to chemotherapy.

Vectibix is the first fully human anti-EGFR antibody approved by the FDA for the treatment of mCRC. Vectibix was approved in the U.S. in September 2006 as a monotherapy for the treatment of patients with EGFR-expressing mCRC after disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy.

THE EUROPEAN MEDICINES AGENCY'S Committee for Medicinal Products for Human Use issued a positive opinion for changing the marketing authorization for **Arzerra (ofatumumab)** to include a combination with chlorambucil or bendamustine for the treatment of chronic lymphocytic leukemia.

Developed by GlaxoSmithKline and Genmab A/S, Arzerra would be available for patients who have not received a prior therapy and are ineligible for fludarabine-based therapy.

The CHMP recommendation is based on results from two trials: the phase III COMPLEMENT 1 study, a randomized, open-label, parallel-arm study evaluating a combination of Arzerra and chlorambucil compared to chlorambucil alone; and a phase II single arm study evaluating the efficacy of ofatumumab in combination with bendamustine.

A final decision by the EC is anticipated during the third quarter of 2014, the sponsors said.

Arzerra is a monoclonal antibody that is designed to target the CD20 molecule found on the surface of CLL cells and normal B lymphocytes. In the U.S., Arzerra is approved for use in combination with chlorambucil for the treatment of previously untreated patients with CLL for whom fludarabine-based therapy is considered inappropriate.

The CHMP also issued a positive opinion for Halaven (eribulin) for the treatment of patients with locally advanced or metastatic breast cancer who have progressed after at least one chemotherapeutic regimen for advanced disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting, unless patients were not suitable for these treatments.

The opinion is based on clinical evidence from two, global, phase III trials: EMBRACE and study 301. These studies involved more than 1,800 women.

EMBRACE demonstrated eribulin can prolong median overall survival in heavily pre-treated women with MBC compared to women receiving an alternative treatment of physician's choice by 2.7 months (13.2 vs 10.5 months; HR 0.81 [95% CI 0.67, 0.96] p=0.014). EMBRACE is one of only 25 studies to demonstrate a significant extension in overall survival in MBC in the last 40 years.

Study 301, a head-to-head trial comparing eribulin and capecitabine, had a co-primary endpoint of overall survival and progression-free survival. The study demonstrated a trend favoring improved overall survival with eribulin compared to capecitabine in the intent-to-treat population, although the improvement was not statistically significant.

Women treated with eribulin had a median overall survival of 15.9 months compared to 14.5 months with capecitabine (HR 0.879; 95% CI: 0.770-1.003; p=0.056).

Based on today's ruling, approval of the new indication by the European Commission is anticipated within three months. The extension application was not submitted in the U.S. following discussions with FDA, according to the drug's sponsor, Eisai.