THE CANCER LETTER

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No Justification Provided

DePinho's Nixing of Tenure Renewals May Bring Censure to MD Anderson

By Matthew Bin Han Ong

A year before Kapil Mehta's tenure term expired last August, the 11-member Promotions and Tenure Committee at MD Anderson Cancer Center had unanimously recommended renewal.

"I've done everything I'm supposed to do during my tenure," Mehta said to The Cancer Letter. "I've done publications, organized international meetings, service, teaching—everything."

Mehta's application was personally rejected by MD Anderson President Ronald DePinho, who overruled the PTC recommendation in May 2012.

Mehta appealed, and a second committee—the Faculty Appeals Panel—endorsed the PTC's recommendation to renew Mehta's tenure. However, the administration wasn't swayed. DePinho's decision stood.

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Itri Pays Fine, Agrees Not to Serve As Company Officer for Five Years

By Paul Goldberg

The Securities and Exchange Commission earlier this week said it has settled insider-trading charges against a prominent cancer researcher who was also an executive of a now-defunct company.

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In Brief

Morgan to Lead UAMS Myeloma Institute

GARETH MORGAN was named director of the **University of Arkansas for Medical Sciences Myeloma Institute for Research and Therapy**.

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All Documents Referenced In This Issue Are Available On The Cancer Letter Website

Experts: Refusal to Explain Arbitrary Behavior "Despicable"

(Continued from page 1)

Mehta, 63, a professor in the Department of Experimental Therapeutics and an MD Anderson employee for 30 years, said he was never given reasons for the rejection.

The vetoes of tenure renewals unanimously recommended by PTC aren't limited to Mehta: DePinho's presidential pen struck twice more over the following year, denying tenure to Zhengxin Wang, an associate professor in the Department of Cancer Biology, and another faculty member, whose name hasn't been publicly revealed.

All three received unanimous votes in 2012 and 2013.

MD Anderson offers seven-year "termed tenures," which differ from indefinite tenures at other institutions. However, the initial requirements and review process for tenure applications are the same.

Cover Photo: Zhengxin Wang and Kapil Mehta, two faculty members that were denied tenure renewal by MD Anderson President Ronald DePinho despite unanimous recommendation by the MD Anderson Promotions and Tenure Committee

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"At MD Anderson, the president and the provost receive recommendations from the faculty's Promotion and Tenure Committee," MD Anderson Provost Ethan Dmitrovsky said in a statement to The Cancer Letter. "We then make decisions based on that information, along with additional factors. Our decisions take into account performance measures that can be tracked and counted.

"However, those are not the only factors considered. We also discuss non-statistical information, such as the opinions and observations from those who work closely with the faculty member."

"Non-Statistical Information"

In most universities, candidates are entitled to see what the administration puts into a case file, said Hank Reichman, first vice president and chair of Committee A on Academic Freedom & Tenure at the American Association of University Professors.

"'Non-statistical information' opens the door to a real follow-up question—what sort of non-statistical information is it?" Reichman said to The Cancer Letter. "Using non-statistical information still does not change the simple fact that they haven't given any specific reasons to the candidates who were turned down. They've gone against the unanimous faculty recommendations, and whatever kind of information it is, it can be abused.

"In most universities, when you come up for a promotion, tenure—or, in this case, it's really a term contract renewal—you submit information and the administration has the right to add to it."

Mehta and Wang had each received multiple letters of support from their colleagues, superiors and external referees, requesting that they be granted renewal or, failing that, an extension to their existing term.

"So, when the administration says they use 'non-statistical information,' that should be in the file," Reichman said. "It could be anything from a wonderful letter that they conjured themselves to an anonymous allegation from a neighbor."

Providing reasons for denying tenure is standard practice in academia, 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.

"Actually, MD Anderson doesn't have tenure," Finkin said to The Cancer Letter. "It has term appointments, which it calls tenure. That's inherently deceptive, and they should do away with that."

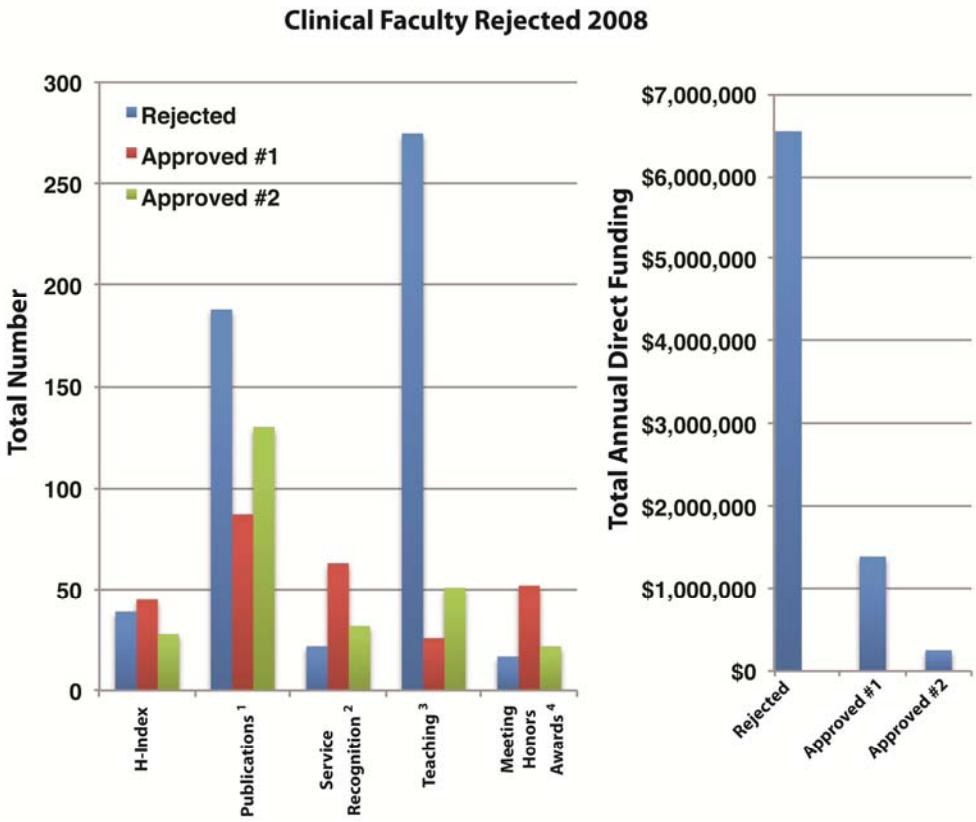
Finkin authored two definitive books on tenure in the U.S.: The Case for Tenure and For the Common Good:

Principles of American Academic Freedom. He is also an author of Labor Law, a leading casebook in American legal education.

"The standards I'm referring to certainly apply not just to denials of real tenure, but non-renewals of appointment," Finkin said. "If a faculty member is voted on by the levels of review and found to be worthy of renewal, and the president says no, the president has to explain.

"He can't just say, 'No, and trust me, I know what I'm doing.' That harkens back to a different and more autocratic era in American higher education. It was questionable then, it's disreputable now.

"The administration's refusal to explain itself is essentially arbitrary—it should have no place in a properly run institution of higher education," Finkin said. "It's outrageous. My heart goes out to those people. I wouldn't want to work in that place."



The MD Anderson Faculty Senate's comparison of performance metrics between members rejected and approved for tenure renewal. *Source: MD Anderson Faculty Senate PTC*

The Presidential Veto

Within two years, DePinho had vetoed more tenure renewals than the previous president, John Mendelsohn, had in seven.

Recent denials of tenure in cases where applicants received unanimous recommendations from the PTC prompted the Executive Committee of the Faculty Senate to investigate the renewal process.

"There has been some concern that the presidents (past and present) have invoked their veto pen, without justification, to override a unanimous recommendation for renewal by the PTC," wrote Douglas Boyd, chair of the Faculty Senate PTC Issues Committee in his final report. "Of 260 faculty going up for tenure renewal between 2005 and 2011, only two were rejected by the past president (i.e. 0.77 percent).

"However, fast-forward to 2012-2013, under new governance, and the rate shot up threefold (3 of 130 tenure renewal applicants) to 2.31 percent," wrote Boyd, a professor in the MD Anderson Department of Cancer Biology. "Of course, with our institution having received much (unwanted) scrutiny by the media over the last 12 months, one wonders if the latter rate may have been even higher in the absence of the public microscope."

Boyd's report can be downloaded from The Cancer Letter website.

The DePinho administration did not provide reasons for the vetoes when challenged by the Faculty Senate.

In a Feb. 19, 2014, email to Oliver Bogler, MD Anderson senior vice president of academic affairs, Boyd wrote:

"The practice of not capturing in writing the decisions or reasons for the denial by the President and not making such deliberations available to the faculty run in flagrant disregard to statements adopted by the Association of American Colleges and Universities (of which MDACC is signatory)—which states that an

Table 2. Comparison of Academic Achievements for Faculty Denied or Approved for Tenure Renewal by the President

Year	Faculty Basic Science	Publications [1]	H-Index	Total Funding	Years Funded (out of 6)	Service Recognition [2]	Teaching [3]	Meeting Honors Awards [4]	Recommendation Letter Score
2005	Rejected	99	23	$1,563,879	6	18	29	11	Nnauthorized
	Approved	54	29	$1,312,698	6	7	9	1	N/A
	Approved	90	34	$50,000	6	35	233	10	N/A
2012	Rejected	87	37	$1,507,774	6	25	28	31	2
	Approved	76	32	$3,019,950	6	19	12	11	N/A
	Approved	83	23	$1,887,500	4	8	20	12	N/A
2013	Rejected	53	28	$763,000	6	8	19	14	30
	Approved	55	23	$787,000	6	14	13	33	N/A
	Approved	35	19	$1,163,470	5	19	46	18	N/A

[1] Sum (impact factor for each first/senior author publication) + sum (journal impact factor /total # authors) for each co-author paper. [2] Sum MDACC committees/study sections/editorial board/presentations at academic institutions/patents. [3]Sum trainees/student committees, didactic lectures. [4]Meeting organization & invited conference presentations/honors/awards. Highlighted values indicate that the faculty member denied for tenure renewal by the President equaled or exceeded the measure for at least one faculty at the same rank in the same discipline approved in the corresponding year.

administrative reversal of faculty judgment on faculty status should occur only 'in rare instances and for compelling reasons which should be stated in detail."

Bogler replied:

"As explained in MD Anderson policies, the actions of the PTC are advisory to the president. The president, along with the Board of Regents, is responsible for making the final decisions on appointments, promotions and term tenure awards and renewals.

"Although I will not comment or express opinions on particular personnel matters or specific faculty members who may not have been promoted or received renewals of term tenure appointments, I am confident that the presidents' decisions in the rare instances where they did not agree with PTC recommendations were not arbitrary. I am also confident that our faculty members are evaluated and treated fairly in these processes."

Administrators of institutions of higher learning are expected to concur in the faculty judgment except in extraordinary cases, where reasons for disagreement ought to be stated to the faculty in detail, said Finkin, the law professor at the University of Illinois.

"The MD Anderson administration has given no reason why it hasn't given an explanation except to say, in essence, 'We've done our job. Trust us,'" Finkin said. "The standards of the academic community for just about 50 years have recognized that in furtherance of the shared mission of the institution, the basis of disagreement should be explained in reasonable detail, and should be sufficiently compelling to override the primacy effect of the judgment. So there is a fundamental breach of the principles of good institutional governance that is involved in this system.

"The institution is obligated to explain itself. The claim to reserve power to behave arbitrarily is despicable."

That said, faculty members who are denied tenure have limited options for challenging such decisions.

"The courts don't want to get these cases," Finkin said. "They defer to the judgment of the institution, and the courts are not going to be tenure committees.

"If those affected or the Faculty Senate itself chooses to complain to the accrediting agencies, there may be a basis for their intervention—both the regional accreditors and medical accreditors.

"They can complain to the AAUP, which could conduct its own investigation and then, potentially, post the institution prominently as one where governance principles are not observed.

"It pays a reputational cost, in other words," Finkin said. "Whether it pays a legal cost, I don't know, but what is certain is there is potential for reputational harm."

AAUP List of Censured Administrations

MD Anderson appears to be at risk of ending up on the AAUP list of censured university administrations, tenure experts said.

"As a general principle, Professor Boyd is absolutely correct that our policies are that tenure decisions should be in the realm of the faculty, and that faculty recommendations should usually be accepted," said AAUP's Reichman. "It is normal for the president or board of trustees or regent to have a final say—what is a problem, I think, is when they don't provide any reasons.

"It appears they are doing that at MD Anderson," Reichman said. "And that would be a violation of AAUP principles.

"This is a tenure violation issue. Our position would hold either way, regardless of whether it is termed tenure, or tenure in the usual sense, where there is a lifetime presumption without cause that you should be rehired.

"Anyone who is entitled to employment review for reappointment, promotion, tenure, or for termed appointment, whatever it is, is entitled to due process, to an appeals process, and to getting the real reason if they are turned down."

Contacted by The Cancer Letter, Boyd indicated that, in his capacity as an AAUP member, he would be "submitting a formal request for a full investigation of the University of Texas MDACC by that association regarding the denial of tenure for the faculty who received a unanimous vote by the PTC."

The censure of a university administration is not a boycott, according to the AAUP.

"Our policy in such cases is for the reasons to be provided in detail," Reichman said. "One caveat is that they have told the reasons to the candidate themselves, and the candidate is satisfied."

Experts in academic freedom say a case at Northeastern Illinois University appears to be reminiscent of recent events at MD Anderson.

"Our investigating team found a decision by NIU's president—overruling a recommendation without providing reasons—to be a violation of our principles," Reichman said. "NIU's administration then claimed that we were interfering in a personnel matter, that we were demanding that they tell us information that should be confidential.

"We said, 'No, we're demanding you to tell the candidate why. You don't have to tell us.' All we needed to know was that the candidate had been told the reasons."

The AAUP list of censured administrations is closely observed by other organizations.

"Our power is only really that of shame and suasion," Reichman said. "When other professional organizations publish advertisements for jobs, if it comes from an institution that's on the list, there'll be an asterisk that says, 'The administration of this institution is on the AAUP censure list.'

"I will confess to you that there are administrations out there that think, 'Oh good, it is good to get on this AAUP list, because it shows that we're not bossed around. We're tough with faculty.'

"But I think most people in higher education believe that this is an embarrassment for the institution. Most institutions end up wanting to get off the list."

Experts: Chilling Effect on Academic Freedom

An administrator who makes ultimate decisions and provides no reasons undermines faculty governance and shared governance, said Karen Miksch, associate professor of postsecondary teaching and learning at the University of Minnesota.

An expert on higher education law, Miksch is chair of the university's Faculty Senate Academic Freedom and Tenure Committee.

"This is a group of people in the largest cancer center in the world, so we certainly want them to be innovative and not to worry that, in some arbitrary way, they are going to lose their jobs," Miksch said to The Cancer Letter. "Which is why we have tenure—you don't want faculty to be careful when they're trying to seek truths.

"The University of Minnesota's processes and tenure code are very consistent and mirror the AAUP's statements on tenure and also some other procedural documents, sometimes word for word," Miksch said. "Frankly, those are a touchstone for us across the country.

"[MD Anderson] has a promotions and tenure committee that reviewed everything, and they had to give a report, so if the president says no, at that point, there needs to be some explanation."

The implications are obvious, Finkin said.

"When you live in an institution which retains the right to make arbitrary judgments, without justifying the fact that it retains the power to make arbitrary judgments, without dispelling the cloud of arbitrariness that hangs over the exercise of that power—who would want to work in an environment like that?"

It is problematic for administrators who may not have expertise in a particular field to impose their decisions on people who do have the expertise, Miksch said.

"It can have a potential chilling effect on academic freedom," she said. "When you start seeing, 'Oh, I have this colleague, and for no reason at all that was given anyway, got unanimous votes all the way along, and now all of a sudden is being removed,' it could potentially concern other members of the faculty.

"Again, that's why the AAUP applies the same procedures to termed tenure and tenure appointments—if a large section of your faculty doesn't have academic freedom, then, is anyone really able to exercise it?

"That's very concerning to me, and I'm sure, to other faculty there, because it's going to make them think, 'Oh my goodness, this seems so arbitrary, it's coming down to this one person deciding whether I keep my job or not, I'd better be careful about what I say and what I do.'"

When an administration acts imperiously, without consultation or in direct disregard of the faculty, it is bound to have a negative effect on their morale, AAUP's Reichman said.

"I think there would be people who would say, 'Well, if this is where this place is going, I don't want to work here,'" Reichman said. "I thought the recommendations in Boyd's letter from the Senate committee on how to deal with this were reasonable.

"I would say that MD Anderson does have a process that does involve faculty participation. It does sound that in the majority of cases, the process works, and faculty recommendations are heeded.

"It is, however, getting to a point where members of the faculty there have growing concern that there appears to be a growth in the number of seemingly arbitrary decisions to reject their recommendations. If the faculty is concerned, then it's enough of a problem within reason."

The Case of Kapil Mehta

Before his tenure ran out, Mehta sought to change DePinho's mind. He appealed the decision, and a second independent committee, the Faculty Appeals Panel, supported the PTC recommendation.

"Dr. Raymond DuBois, the provost at the time, was very surprised—he's the guy who told me to go to the FAP," Mehta said. "In the meantime, [DuBois] stepped down, and the new guy took over—Tom Buchholz—I asked him for the FAP recommendation in order to arrange a meeting with Dr. DePinho.

"[Buchholz] said they can't share the recommendation with me," Mehta said. "I was very surprised—that is my future. I have emails from him asserting that these recommendations were forwarded to the executive vice president, and that they are not supposed to share it with faculty.

"And then I met with Dr. Louise Strong, a senior faculty member and ex-chair of the Faculty Senate, who wrote a very strong letter that the FAP recommendation belongs to me, and that I have all the right to know what the recommendation is. Then they immediately released the letter and I was really surprised—there was nothing negative."

Mehta had higher scores for six of seven measures, compared with at least one of his peers successful in their bid for tenure renewal, according to Boyd's report.

Mehta arranged a meeting with DePinho in December 2012 to discuss his accomplishments and plans.

"I took along with me another senior faculty member—an advocate—and I shared with Dr. DePinho the exciting progress in my lab," Mehta said. "I told [DePinho], 'If you don't want to give me seven years of tenure, it's fine, but give me at least three years so that I can take these lab findings to the clinic.'

"I had a year-by-year plan for how I would move it to the clinic, and I told [DePinho], 'If, by the end of that third or fourth year, I don't deliver a drug to you, I will voluntarily retire from MD Anderson.'"

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

"He refused, despite all that," Mehta said. "I don't know what he has in mind; it doesn't make any sense. All the faculty I talked to, they are very surprised with his arrogance and adamant behavior.

"Even at the end of that meeting, Dr. Randy Legerski [professor and deputy chair in the Department of Genetics, and a professor in the UT Graduate School of Biomedical Sciences] asked Dr. DePinho, and Dr. DePinho said, 'Everything looks good.'

"So what is he seeing that is different from everyone else? But once again, he went around the issue and said, 'No, there are several factors which we are looking at.'"

Mehta has continued to work part time for 20 percent of his former salary. He has two active grants, and says his lab is close to advancing promising strategies for reversing drug resistance in cancer patients.

"I hope nobody in the future really has to go through what I went through for the last one-and-a-half years," Mehta said. "I hope this will shake them up and make them understand that they cannot destroy people's careers.

"It's kind of a dictatorship," he said. "You just can't fire anybody without any reasons. After working for 30 years for an institution with full dedication, I deserve to know why I'm being denied the renewal."

The Case of Zhengxin Wang

Zhengxin Wang, an associate professor in the Department of Cancer Biology, said he received similar treatment.

DePinho's refusal to renew his tenure appears to be related to a new department chair, Raghu Kalluri, who, according to Wang, wanted him out of the department.

Kalluri didn't respond to a request for an interview.

"Dr. Kalluri told me that the standards for tenure renewal are higher now, because the leadership of the institute has changed, and based on his judgment, I was not qualified for tenure renewal," Wang, 52, said to The Cancer Letter. "Dr. Kalluri asked me to seek a position outside, because I have served MD Anderson Cancer Center for a long time—12 years.

"Dr. Boyd, who investigated this issue, compared in his report my qualifications with people in the same rank, and I'm qualified. It's clear."

In his PTC report, Boyd wrote that Wang's scores were higher in both publication and teaching measures relative to at least one of his peers approved in the corresponding cycle.

"His funding was just shy ($763,000 versus $787,000) of that garnered by a comparison faculty member deemed worthy of tenure renewal by the president," Boyd wrote. "Also and importantly, whereas [Wang] was funded for all six years of the evaluation period, one of the comparison faculty members showed a lapse for one of the six years.

"What was different for this applicant was a letter opposing tenure renewal written by his departmental chair, a recruit of the president, brought in without input by an MD Anderson search committee.

"However, in this case, the applicant had secured several outside letters of support. Indeed, the letters of support by outside referees were all strongly in favor of renewal. How much? Using the metrics described for letter evaluation, the overall sum in this category was +30 inclusive of the negative values."

Wang said he had to compel Kalluri to submit his application.

"I told him I met all the requirements, but he refused to submit my application," Wang said. "I called Faculty Academic Affairs and they said he should submit it regardless of support from the department chair, in accordance with policy."

After Wang announced that he had applied to move to the Department of Urology, Kalluri changed his mind and stated that Wang has met all his goals, Wang said.

Five days later, Kalluri reverted to his initial decision, and announced in a later meeting that Wang's application to the other department had been turned down.

"Why did you change it to 'did not meet goals' again?" Wang said he asked Kalluri. "[Kalluri] told me, 'Now I know that your application to the Department of Urology was declined, you cannot go anywhere inside the cancer department. That's why I marked you as not meeting your goals.'

"I didn't even know that my application to the other department was declined," Wang said. "He used this to force me out of the department."

Wang filed a complaint to the Department of Faculty Academic Affairs, but was routed through two more departments before coming full circle to the FAA.

"I also filed the complaint with human resources—there was no response for several months, and finally someone called me and he said he doesn't believe this is disruptive behavior," Wang said. "Then I filed the complaint to the Institutional Compliance Office, which determines whether this behavior is against the policy or not, and they said I should talk to Faculty Academic Affairs. Then I gave up after that.

"I don't know Dr. Kalluri before, I don't have any problems with him, and I don't know why he is treating me this way. I know he wants to get rid of me, and the president is his friend. The president is willing to do what [Kalluri] wants."

Wang received his rejection letter via FedEx on May 31, 2013.

"The reasons for non-renewal are that your renewal of term tenure was not approved," the letter said.

"This is trouble for my research, for my life. In this economic situation, it's very hard to find a tenure job," Wang said. "My appeal to the provost was trumped—I don't have any chance to appeal. I don't know whether I will file an appeal to the chancellor.

"They gave me no reason, they won't tell me why they rejected my application," Wang said. "This is completely unacceptable."

SEC Complaint: Genta Executive Tipped Off Friend About Results

(Continued from page 1)

Loretta Itri was charged with passing information about negative results of a cancer clinical trial to a long-time friend, who then passed the tip on to his friend. Both men executed trades within minutes of getting the information, the complaint states.

Itri, former president of pharmaceutical development and chief medical officer of Genta Inc., was not accused of executing trades.

SEC officials say she and the other two co-defendants have agreed to pay fines to settle the charges. Itri would also be barred from serving as an officer or director of a public company for five years.

"Dr. Itri is pleased to have been able to resolve this personal matter," said Itri's attorney Barry Bohrer. "She has dedicated her life to bringing innovative, life-saving, clinical products to market and will continue to devote herself to these endeavors."

Itri and the others admitting no wrongdoing as they settled the claims.

According to court papers, Itri disclosed negative results of the phase III trial of a melanoma drug to a friend before these results were made public.

The friend, Neil Moskowitz, whom Itri met at medical school and had known for about 40 years, was an emergency room physician in Syosset, N.Y. Moskowitz then tipped off his acquaintance Matthew Cashin, whom he had met several months earlier, when Cashin was treated in the ER.

Cashin invested in Genta as a result of his conversations with Moskowitz, the SEC complaint states.

On Oct. 28, 2009, within minutes of hearing bad news about the trial, Moskowitz and Cashin sold their shares. The next day, Genta shares fell by about 70 percent, from $0.66 to $0.20 per share. As a result of trading based on nonpublic information, Moskowitz and Cashin made about $139,000 in illegal gains.

The settlement, which is subject to court approval, requires Itri to pay civil penalty of approximately $64,000. The settlement requires Moskowitz to return $64,300 of gains, plus prejudgment interest of $9,556, and pay a civil penalty of $64,300. Cashin, is to return $75,140 of gains, plus prejudgment interest of $10,955, and pay a civil penalty of $37,570, which reflects the cooperation he provided to the SEC's investigation, officials said.

Genta was aggressive in its dealings with FDA. After the agency's Oncologic Drugs Advisory Committee nixed the Genasense application for relapsed and refractory chronic lymphocytic leukemia, the company appealed the decision (The Cancer Letter, Sept. 8, 2006). The challenge was unsuccessful.

When the application for the melanoma indication went to the Oncologic Drugs Advisory Committee in 2004, the presentation began with an appearance by then Rep. Peter Deutsch (D-Fla.) and the reading of a letter from then Rep. Mike Ferguson (R-N.J.).

At the time, both served on the House Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations (The Cancer Letter, May 7, 2004). With Congressmen included, 15 supporters came to an open mic to offer testimonials for Genasense, matching the record of the number of people who came to convince ODAC to approve the drug Iressa (gefitinib) for lung cancer (The Cancer Letter, Sept. 27, 2002).

Genta submitted an unblinded phase III study of 771 patients randomized to receive Genasense plus dacarbazine or dacarbazine alone as first line therapy for metastatic melanoma. The primary endpoint was survival. The study showed no survival improvement for the Genasense and dacarbazine arm, and the advantage in progression-free survival was less than a month, FDA said. Also, the agency was concerned about response assessment and bias that can occur in an unblinded study.

The committee voted 13 to 3 against approval at the time.

The company continued to develop Genasense, and, according to the SEC complaint, no later than on Oct. 27, 2009, the company received the top-line results of its phase III trial, which revealed that Genasense "did not show a statistically significant benefit for its co-primary endpoint of progression-free survival" and stated that "[s]econdary endpoints of overall response rate and disease control rate…also did not show a statistically significant benefit."

Genta declared bankruptcy in August 2012.

Before Genta, Itri was a senior vice president for worldwide clinical affairs, chief medical officer and member of the board of directors at Ortho Biotech Inc. In this role, she was responsible for phase III and phase IV clinical development for oncology, hematology, and immunology product lines, including Procrit.

She has served on FDA Advisory Collaboration on Drug Development Improvement (1997), the NCI Boards of Scientific Counselors for the Division of Cancer Treatment (1990-1994) and the Division of Cancer Prevention and Control (1982-1985), as well as the NCI Director's Cancer Clinical Trials Advisory Board (1986-1994).

ASCO Releases Three Guidelines For Cancer Survivorship Care

The American Society of Clinical Oncology published three clinical practice guidelines for the prevention and management of neuropathy, fatigue, depression, and anxiety.

They are the first in a series of evidence-based guidelines on survivorship care. ASCO has also updated information for survivors on its Cancer.Net website based on the recommendations. The guidelines were published April 14 in the Journal of Clinical Oncology.

Managing Peripheral Neuropathy

ASCO's Prevention and Management of Chemotherapy-induced Peripheral Neuropathy in Survivors of Adult Cancers guideline offers recommendations for prevention and treatment of the debilitating side effect of certain chemotherapy regimens, particularly those containing platinum drugs, vinca alkaloids, bortezomib, and/or taxanes. For a minority of patients, severe symptoms can last for years.

The guideline identifies a handful of drugs that may be helpful in diminishing the symptoms of CIPN, but it does not recommend any agents for prevention of CIPN. Specifically, the recommendation says, the following agents should not be taken for prevention of CIPN: acetyl-L-carnitine, amifostine, amitriptyline, CaMg, dietyldithio-carbamate, glutathione, nimodipine, Org 2766, all-trans retinoic acid, rhuLIF, and vitamin E.

While there is no strong evidence of benefit from for use of tricyclic antidepressants, gabapentin, and a topical gel containing baclofen, amitriptyline, and ketamine, it may be reasonable to try those agents in select patients, according to the guideline. Clinicians may also offer duloxetine.

Screening and Management of Fatigue

ASCO's fatigue guideline adaptation provides recommendations on screening, assessment, and treatment approaches for adult cancer survivors. It is recommended that all survivors be evaluated for symptoms of fatigue upon completion of primary treatment and be offered strategies for fatigue management, and healthcare providers should assess fatigue history, disease status, and treatable contributing factors.

All patients should be educated about differences between normal and cancer-related fatigue, causes of fatigue, and contributing factors, according to the guideline. Patients should be offered strategies to manage fatigue, including physical activity, psychosocial interventions—e.g., cognitive and behavioral therapies, psycho-educational therapies—and mind-body interventions, such as yoga or acupuncture.

The guideline adaptation is based on a pan-Canadian guideline on fatigue and two National Comprehensive Cancer Network guidelines on cancer-related fatigue and survivorship.

Managing Anxiety and Depression

In its third guideline, ASCO emphasized that healthcare providers have a vital role to play in mitigating the negative emotional and behavioral side effects of cancer, recommending that supportive care services should be offered to all, and that those who display moderate or severe symptoms of anxiety and depression be referred for appropriate interventions.

The guideline also recommended that providers periodically evaluate all survivors for symptoms of depression and anxiety, using validated, published measures and procedures. Supportive care services, such as education about normalcy of stress in the context of cancer, signs and symptoms of distress, stress reduction strategies, and fatigue management, should be offered to all survivors.

Psychological, psychosocial, and psychiatric interventions should be offered to survivors with moderate or severe symptoms of depression or anxiety.

In Brief

Morgan Named Director Of UAMS Myeloma Institute

(Continued from page 1)

Morgan, currently a clinician and researcher with the Myeloma UK Research Centre at the Institute of Cancer Research in London, will begin at UAMS in July. He is a director of Myeloma UK as well as a member of the Scientific Board of the International Myeloma Foundation, scientific secretary for the UK Myeloma Forum and founding director of the European Myeloma Network.

Morgan will succeed Bart Barlogie, the institute's founder and director since 1989, who has chosen to step down, but will remain to focus on clinical care and research.

MICHAEL GORDON was named medical director for the **Virginia G. Piper Cancer Center Clinical Trials**, a partnership of Scottsdale Healthcare and the Translational Genomics Research Institute. He will oversee the center's phase I program.

Gordon is CEO of Pinnacle Oncology Hematology, a division of Arizona Center for Cancer Care, focusing on translational research and the care and management of cancer patients seeking phase I and phase II clinical trials. He is a clinical professor of internal medicine at the University of Arizona College of Medicine and is co-director of the Oncology Block.

His principal research interests are in development of cancer therapies with a focus on targeted and immunologic therapies as well as drugs that affect angiogenesis. His disease focuses include kidney cancer, melanoma, prostate cancer, lung cancer, gastrointestinal stromal tumors and ovarian cancer.

THE CLINICAL RESEARCH FORUM presented its 2014 Top Ten Clinical Research Achievement Awards during its annual meeting April 10.

The top prize was awarded to a project that discovered a potential treatment for pediatric leukemia. Two other cancer-related studies were honored. All the studies were published in The New England Journal of Medicine and Lancet. Summaries of all ten studies are available from the forum's website.

• **Stephan Grupp**, professor of pediatrics at Perelman School of Medicine at the University of Pennsylvania, and director of translational research of the Center for Childhood Cancer Research at The Children's Hospital of Philadelphia, received the Herbert Pardes Clinical Research Excellence Award for his study, "Chimeric antigen receptor-modified T cells for acute lymphoid leukemia."

• **Daniel Rader**, the Edward S. Cooper, MD/ Norman Roosevelt and Elizabeth Meriwether McLure Professor of Medicine and Pharmacology at the University of Pennsylvania Perelman School of Medicine, received a Distinguished Clinical Research Award for the study "The MTP inhibitor lomitapide as a first-in-class new mechanism of therapy for homozygous familial hypercholesterolemia."

• **Susan Huang**, associate professor of infectious disease at the University of California, Irvine School of Medicine, and medical director of Epidemiology and Infection Prevention, received a Distinguished Clinical Research Award for the study "Targeted vs. Universal Decolonization to Prevent ICU Infection."

• **Denise Aberle**, professor of radiology at UCLA David Geffen School of Medicine and professor of bioengineering at UCLA Henry Samueli School of Engineering and Applied Sciences, was honored for "Results of the Two Incidence Screenings in the National Lung Screening Trial."

• **John Byrd**, D. Warren Brown Chair of Leukemia Research and professor of medicine and medicinal chemistry at The Ohio State University, was honored for "Targeting BTK with Ibrutinib in Relapsed Chronic Lymphocytic Leukemia."

• **Anna Greka**, assistant professor of medicine at Massachusetts General Hospital, was honored for "Abatacept in B7-1–positive proteinuric kidney disease."

• **W. H. Linda Kao**, professor in the Johns Hopkins Bloomberg School of Public Health, was honored for "APOL1 risk variants, race, and progression of chronic kidney disease."

• **Stephen Kimmel**, professor of medicine, in the University of Pennsylvania Cardiovascular Medicine Division, was honored for "A pharmacogenetic versus a clinical algorithm for warfarin dosing."

• **David Nelson**, professor of medicine, molecular genetics and microbiology, director of the University of Florida Clinical and Translational Science Institute, and associate dean for clinical research of the Division of Gastroenterology, Hepatology, and Nutrition, was honored for "Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options."

• **Manikkam Suthanthiran**, Stanton Griffis Distinguished Professor of Medicine,and professor of medicine in surgery and biochemistry at Weill Cornell Medical College, was honored for "Urinary–cell mRNA profile and acute cellular rejection in kidney allografts."

THE CONQUER CANCER FOUNDATION of the American Society of Clinical Oncology announced the recipients of the **2014 Merit Awards, Oncology Travel Trainee Awards, Medical Student Rotation Awards and Resident Travel Awards**.

This year the foundation is honoring 99 young oncologists for the research they will present at the 2014 ASCO Annual Meeting. The full list of 2014 Merit Award Recipients is available at www.conquercancerfoundation.org.

The foundation is also granting 36 Oncology Trainee Travel Awards. These awards foster the continuing education and professional development of trainee oncologists by defraying travel expenses and providing complimentary annual meeting registration to young investigators attending the 2014 Annual Meeting.

Four recipients will be presented with Special Merit Awards for receiving the highest ranking scores in their respective abstract categories as determined by the ASCO Scientific Program Committee:

• **Joshua Zeidner**, of The Johns Hopkins University, received the Bradley Stuart Beller Special Merit Award for the highest ranked abstract overall: "Randomized multicenter phase II trial of timed-sequential therapy with flavopiridol (alvocidib), cytarabine, and mitoxantrone (FLAM) versus "7+3" for adults with newly diagnosed acute myeloid leukemia (AML)"

• **Renata Amorim**, of Faculdade de Ciências Médicas da Santa Casa de São Paulo, received the Brigid Leventhal Merit Award for the top-ranking abstract in Pediatric Oncology: "Increased risk of second malignant neoplasms (SMN) in young children with embryonal rhabdomyosarcoma (ERMS): Evidence for a cancer predisposition syndrome"

• **Cesar Santa-Maria**, of The Johns Hopkins University, received the Pain and Symptom Management Award for the highest-ranked abstract in pain management research: "A phase II study evaluating efficacy of zoledronic acid in prevention of aromatase inhibitor (AI)-associated musculoskeletal symptoms: The ZAP trial"

• **Andrew Place**, of Dana Farber Cancer Institute, received the James B. Nachman ASCO Junior Faculty Award in Pediatric Oncology for the top-ranking abstract submitted by a junior faculty member in pediatric oncology: "Outcome of childhood T-cell acute lymphoblastic leukemia (T-ALL): Results from DFCI protocol 05-001"

The Medical Student Rotation Award for Underrepresented Populations and the Resident Travel Award for Underrepresented Populations provide opportunities for young researchers of diverse backgrounds.

The Medical Student Rotation Award for Underrepresented Populations provides 8- to 10-week clinical or clinical research oncology rotations for U.S. medical students and pairs students with oncologists for academic and career mentorship. The 2014 Medical Student Rotation Awards for Underrepresented Populations are supported by Amgen; Conquer Cancer Foundation Mission Endowment; and the Doris Duke Charitable Foundation.

The recipients are:

• **Nancy Anoruo**, George Washington University

• **Omatola Ashorobi**, The University of Illinois

• **Peter Cruz-Gordillo**, University of Massachusetts Medical School

• **Shekinah Elmore**, Harvard Medical School

• **Dembi Huya-Kouadio**, Meharry Medical College

The Resident Travel Award for Underrepresented Populations provides financial support for residents who are undecided on their specialty to attend ASCO's Annual Meeting to further explore career possibilities in oncology. The 2014 Resident Travel Awards for Underrepresented Populations are supported by Amgen; Conquer Cancer Foundation Mission Endowment; and Janssen Biotech, Inc.

The recipients are:

• **Brandon Blue**, Washington University in Saint Louis

• **Chukwuemeka Ezeoke**, Saint Louis University

- **Catherine Handy**, The Johns Hopkins University
- **Abiola Ibraheem**, Morehouse School of Medicine
- **Deniece Johnson**, Morehouse School of Medicine
- **Vivian Jolley Bea**, Medical University of S.C.
- **Cheryl Mensah**, North Shore Long Island Jewish
- **Sonya Reid-Lawrence**, Meharry Medical College
- **Fatima Wilder**, Robert Wood Jonson Medical School

FDA Approvals

Cobas HPV Test Approved For Primary Cervical Screening

FDA approved the cobas HPV test for women 25 and older that can be used alone to help a health care professional assess the need for a woman to undergo additional diagnostic testing for cervical cancer. The test also can provide information about the patient's risk for developing cervical cancer in the future.

Using a sample of cervical cells, the test detects DNA from 14 high-risk HPV types. The test specifically identifies HPV 16 and HPV 18, while concurrently detecting 12 other types of high-risk HPVs.

Based on results of the cobas HPV Test, women who test positive for HPV 16 or HPV 18 should have a colposcopy. Women testing positive for one or more of the 12 other high-risk HPV types should have a Pap test to determine the need for a colposcopy. Health care professionals should use the cobas HPV Test results together with other information, such as the patient screening history and risk factors, and current professional guidelines.

The FDA first approved the test in 2011 for use in conjunction with or as a follow-up to a Pap test (cell cytology), which examines cervical cells for changes that might become cervical cancer. This approval expands the use of the test to include use as either a co-test or as a primary cervical cancer screening test, however; it does not change current medical practice guidelines for cervical cancer screening.

Data supporting the use of the cobas HPV Test as a primary screening test for cervical cancer included a study of more than 40,000 women 25 years and older undergoing routine cervical exams. Women who had a positive Pap test or whose cervical cells screened positive for HPV, as well as a subset of women whose Pap and HPV tests were both negative, underwent a colposcopy and cervical tissue biopsy. All biopsy results were compared to the Pap and cobas HPV Test results. The cobas HPV Test is manufactured by Roche Molecular Systems Inc.

FDA approved a supplemental biologic license application for the use of Arzerra (ofatumumab), a CD20-directed cytolytic monoclonal antibody, in combination with chlorambucil for the treatment of previously untreated patients with chronic lymphocytic leukemia for whom fludarabine-based therapy is considered inappropriate.

The approval of the first-line indication is based on results from a phase III study, COMPLEMENT 1, which demonstrated statistically significant improvement in median progression-free survival in patients who received the combination of Arzerra and chlorambucil compared to patients who received chlorambucil alone.

The results from COMPLEMENT 1, the randomized, open-label, parallel-arm, pivotal Phase III study evaluating the combination of Arzerra and chlorambucil (n=221) versus chlorambucil alone (n=226) demonstrated statistically significant improvement in median PFS in patients randomized to Arzerra and chlorambucil compared to patients randomized to chlorambucil alone (22.4 months versus 13.1 months, respectively) (HR=0.57 [95% CI, 0.45, 0.72] $p < 0.001$). Arzerra is sponsored by GlaxoSmithKline and Genmab A/S.

FDA approved Cyramza (ramucirumab) to treat patients with advanced stomach cancer or gastroesophageal junction adenocarcinoma.

Cyramza is an angiogenesis inhibitor that blocks the blood supply to tumors. It is intended for unresectable or metastatic cancers that have been treated with a fluoropyrimidine- or platinum-containing therapy.

Cyramza's safety and effectiveness were evaluated in a clinical trial of 355 participants with unresectable or metastatic stomach or gastroesophageal junction cancer. Two-thirds of trial participants received Cyramza while the remaining participants received a placebo.

Results showed participants treated with Cyramza experienced a median overall survival of 5.2 months compared to 3.8 months in participants receiving placebo. Additionally, participants who took Cyramza experienced a delay in tumor growth compared to participants who were given placebo. Results from a second clinical trial that evaluated the efficacy of Cyramza plus paclitaxel versus paclitaxel alone also showed an improvement in overall survival.

The FDA reviewed Cyramza, marketed by Eli Lilly, under its priority review program and was also granted orphan product designation.