# THE CANCER LETTER

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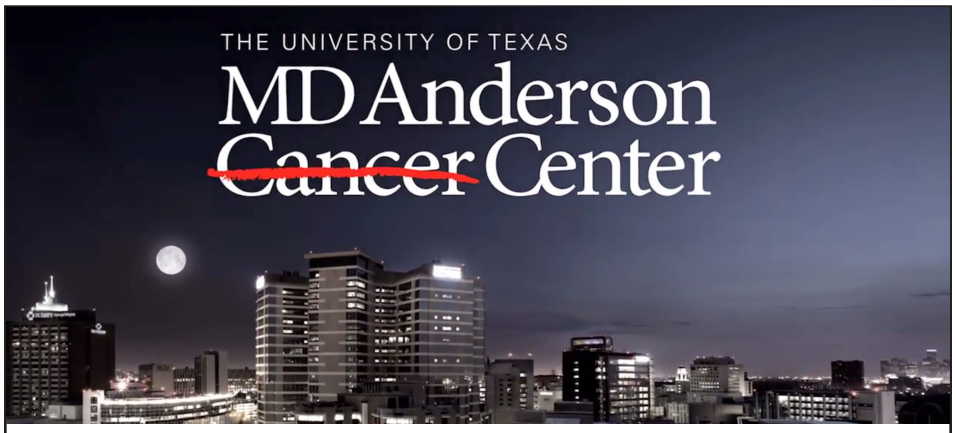


## DePinho Will Not Meet With AAUP In Probe of Tenure Denial Dispute

*By Matthew Bin Han Ong*

MD Anderson Cancer Center President Ronald DePinho and his executive team declined to meet with the investigation committee dispatched by the American Association of University Professors to his institution.

"We will not personally meet with representatives of a non-governing entity conducting an unauthorized investigation with a pre-determined outcome." they wrote in a Sept. 17 email to MD Anderson faculty and staff.

(Continued to page 2)

## Officials: Poisoning Unrelated to MD Anderson; Critics Allege Dysfunction in Handling of Affair

*By Paul Goldberg*

Images of the gleaming buildings and distinctive logo of MD Anderson Cancer Center have been flashing on television screens and appearing on pages of respectable newspapers and scandal sheets alike.

The reason has nothing to do with the Moon Shots aimed at curing cancers. Rather, the name of the venerable cancer center is being dragged through the mud because one of its doctors stands accused of trying to poison another.

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*In Brief*

## Tweardy named Head of Internal Medicine At MD Anderson Cancer Center

**DAVID TWEARDY** was named division head of internal medicine of **MD Anderson Cancer Center** effective Dec. 1.

Tweardy comes from Baylor College of Medicine, where he is professor of medicine and section chief of infectious diseases.

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# AAUP Team Holds Interviews With Faculty, UT Leadership

(Continued from page 1)

The AAUP group is investigating a tenure dispute at MD Anderson. If they find MD Anderson at fault, the institution could face censure by the association, which promotes academic freedom and shared governance.

While DePinho and his team refused to meet with the investigators, their UT System superiors, Raymond Greenberg, executive vice chancellor for health affairs, and Daniel Sharphorn, general counsel and vice chancellor, agreed to be interviewed in a Sept. 19 teleconference.

"It does seem a little bit discrepant; doesn't it?" Gregory Scholtz, associate secretary and director of the AAUP Department of Academic Freedom, Tenure and Governance, said to The Cancer Letter. "When we initially contacted both the MD Anderson administration and the UT System administration, we got a note back from Greenberg saying they would be happy to meet with the committee in person, or telephonically.

"He was gratifyingly friendly."

The AAUP investigation was triggered by refusal on the part of the MD Anderson administration to provide justification for denying tenure renewals to two faculty members.

The faculty members in question—Kapil Mehta and Zhengxin Wang—received unanimous votes in favor of renewal from the Faculty Senate Promotions & Tenure Committee, but DePinho ultimately decided not to extend their tenure (The Cancer Letter, April 25).

After an exchange of acrimonious letters with MD Anderson that ended on Sept. 16, AAUP sent four volunteer investigators to the Houston cancer hospital. They planned to conduct two days of fact-finding meetings with the faculty and the executive leadership.

"[The] executive leadership has corresponded with the AAUP representatives and informed them that we're happy to answer any written questions they may have that have not been previously answered and are a matter of public record," DePinho wrote in the Sept. 17 email to the faculty and staff. Those letters are available on The Cancer Letter website.

The two-day visit by the committee—the first phase of AAUP's formal investigation of the MD Anderson executive leadership—concluded Sept. 19.

Internal sources said that MD Anderson employees who have agreed to speak with the investigators included basic and clinical faculty members who either have been impacted by, or who are concerned about, DePinho's decisions on tenure renewal.

Among those interviewed were senior faculty members who have served on the institution's Promotions and Tenure Committee, and past Faculty Senate members. The current Executive Committee of the Faculty Senate has also agreed to meet with the investigators.

"I think it's safe to say that the investigating committee members are meeting several dozen faculty members," AAUP's Scholtz said.

Scholtz said AAUP considers MD Anderson's willingness to cooperate in writing as a positive development.

"Initially, we weren't sure if they were going to cooperate at all," he said. "We are pleased that they are willing to receive questions in writing."

AAUP does not pay the investigators. "It's completely voluntary; there is no remuneration involved," Scholtz said. "The association pays their traveling expenses, and that's it."

Three of the four investigators are employed by medical institutions. They are:

• Gloria Giarratano, a professor of nursing at Louisiana State University Health Sciences Center.

• David Gregorio, a professor of community medicine and health care at University of Connecticut Health Center,

• Marie Monaco, an associate professor in the Department of Neuroscience and Physiology at New York University Langone Medical Center, and

• Debra Nails, the committee chair, and a professor

**Cover Photo:** A still from an MD Anderson video promoting its Moon Shots Program.

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of philosophy at Michigan State University.

Giarratano was involved in a previous AAUP investigation of the UT Medical Branch at Galveston, which resulted in imposition of censure in 2010 (The Cancer Letter, July 18).

"We try to select people who we think are best qualified for the investigating committee," Scholtz said. "It is important for us to have people who know something about, first and foremost, AAUP recommended standards and principles, and also about institutions of higher educations."

**"No Intention of Changing" Appointment System**

In his Sept. 17 email to faculty and staff, DePinho and his team called AAUP a "relatively small special interest group" whose main operation "appears to be to unionize college and university professors and other select groups of faculty at universities where such activity is not prohibited by law."

According to its website, AAUP was founded in 1915, and represents 47,000 faculty members, with more than 300 chapters and 33 state organizations throughout the U.S.

"[AAUP's] self-generated tenure standards and authority to investigate have never been endorsed by a single university or college," they wrote.

Over 200 educational organizations and disciplinary societies endorse AAUP-supported principles on academic freedom and tenure, and will not accept job postings from or allow chapters to be opened at censured institutions (The Cancer Letter, July 18).

Higher education law experts from the University of Minnesota and the University of Illinois College of Law say that the AAUP statements on tenure and procedural documents are a "touchstone," and that the majority of institutions of higher learning have tenure codes and processes that mirror, or are consistent with those statements (The Cancer Letter, April 25).

Nearly 90 percent of medical colleges and institutions—including Memorial Sloan Kettering Cancer Center, MD Anderson's rival for top ranking by U.S. News & World Report—offer permanent tenure, according to the American Association of Medical Colleges (The Cancer Letter, May 30).

"We have no intention of changing our seven-year renewable term appointment system that has served us well for decades with an appropriate balance of academic freedom, employment security and accountability," they wrote. "And we cannot predict with certainty what would be affected by changing our system to lifetime appointment.

"However, changing to a lifetime appointment system could require new standards for granting tenure. Those new standards might have to be applied to both faculty that have a current seven-year appointment, as well as for any faculty seeking tenure for the first time. Since the institution would be taking on a greater obligation for those with lifetime tenure, faculty compensation and faculty benefits such as professional development funds and extramural leave might also be affected."

Scholtz, who had served on five investigating committees, declined to comment on whether the refusal to adopt a permanent tenure system would have an impact on AAUP's decision.

"Most institutions we investigate are not interested in changing their appointment systems at all," he said. "There's nothing unusual about that. The investigation is not an AAUP staff matter; it is now in the hands of the investigating committee.

"Their charge is to conduct a fair, impartial investigation of the [Mehta and Wang] cases, as well as conditions for academic freedom and governance at the institution, including institutional regulations in those two areas."

**"Never Seen a Reaction Anywhere Close"**

On July 15, AAUP announced its intention to launch a formal investigation.

DePinho's administration responded two weeks later with a five-page letter—four of which contained a long list of questions—quizzing the AAUP on issues ranging from its authority to investigate, to its organizational structure and tax status.

AAUP replied Aug. 25, and the DePinho leadership declared that the organization's answers were dissatisfactory.

"The AAUP's incomplete answers to our questions, as well as its numerous admissions in the answers provided, have raised additional concerns from our institution about the validity of the proposed process," wrote Dan Fontaine, MD Anderson executive chief of staff, in an Aug. 29 letter to the AAUP.

MD Anderson's response to the AAUP investigation is one-of-a-kind, an education and employment law expert said.

"I've never seen a reaction anywhere close to this set of [the MD Anderson] lawyer's interrogatories for an AAUP investigation," said Matthew Finkin, director of the Program in Comparative Labor and Employment Law & Policy and the Albert J. Harno and Edward W. Cleary Chair in Law at the University of Illinois, in an email to The Cancer Letter.

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.

"I think the Association should be flattered that it is being taken so very seriously," said Finkin, who has participated in four AAUP investigations and chaired two.

However, the most "vehement" response from administrations typically come after the investigating committee has completed its report, according to Scholtz, who has served on the AAUP staff for six years.

"MD Anderson's was a very serious and thorough response, but I think it's not atypical in my experience dealing with administrations," he said. "There tend to be fewer who cooperate very willingly, it seems, there are some who cooperate with certain restrictions, and invariably there are many who refuse to cooperate at all. Some refuse to cooperate with extreme prejudice—to quote Apocalypse Now—and there are some who do not.

"Most of the conflicted discourse, as I said, occurs when they respond to the draft report—it is given to them for their comments.

"We're just pleased that the MD Anderson administration is willing to receive questions from the investigating committee in writing, and we expect to have a very solid report from this very strong investigating committee."

*The text of the Sept. 17 email to faculty and staff, signed by DePinho and his executive team, follows:*

Last May, our institution was informed by an outside organization, the American Association of University Professors, that it disapproved of, and intended to conduct an investigation of, MD Anderson's long-standing system of renewable seven-year faculty term appointments and, out of the many renewals that did occur, the decision to not renew the appointments of two of our faculty members.

Although we had no obligation to do so, we carefully explained to the AAUP the multiple reviews and steps that formed the basis for the two non-renewal determinations. We also provided a detailed history of the seven-year term appointment system, as well as the involvement of The University of Texas Board of Regents in the establishment of that system.

Additionally, we provided information about the numerous ways this system provides stable employment for many of our hard-working faculty members while still maintaining accountability for our patient care and cancer research. Read the AAUP's original letter and our reply.

Despite our detailed response, the AAUP insisted it would investigate MD Anderson. When that communication was received, and in consultation with officers of The University of Texas System and Board of Regents members, we responded with additional questions.

Our intention was to better understand why the AAUP believed it had the authority to investigate our institution, and how such an investigation would be conducted.

The responses to our questions were quite surprising. Essentially, the AAUP admitted it had no authority to conduct an investigation of MD Anderson and that it did not intend to conduct its investigation in accordance with well-recognized standards of a fair investigation. On the same day, the AAUP sent a second letter to inform us of their on-site interviews, which are taking place on Sept. 18 and 19, 2014.

Because we know the AAUP has directly contacted some of you, we thought it best to provide some detailed answers to questions that we've heard about this process.

**Q: What is the AAUP?**

A: The AAUP is a relatively small special interest group. Its main operational objective appears to be to unionize college and university professors and other select groups of faculty at universities where such activity is not prohibited by law. The membership of the AAUP represents about 3% of all faculty members working at U.S. universities and colleges.

**Q: What authority does the AAUP have to investigate decisions by our institutional leadership?**

A: None. By the AAUP's own admission, its authority is self-appointed, as it is neither an accrediting agency nor a governing body. The organization further admitted that its authority rests in part on the fact that it has never been challenged by a university threatened with an AAUP investigation. Its self-generated tenure standards and authority to investigate have never been endorsed by a single university or college.

**Q: If the AAUP has no authority, why are we allowing them to come to our campus?**

A: As a public institution that strongly believes in open expression of ideas and academic freedom, we have no reason to prohibit visits from anyone that respects the obligations we have to care for our patients.

**Q: Are our institutional leaders concerned about anything the AAUP might investigate?**

A: Absolutely not. While it is our policy to respect our employees' privacy and not discuss employment matters publicly, because the two faculty members in question authorized the AAUP to ask questions, we provided detailed information concerning both matters and a complete explanation of our seven-year term

appointment system.

**Q: Who asked the AAUP to investigate the institution?**

The two faculty members whose tenure was not renewed and another faculty member who is an AAUP member apparently asked for the investigation. Our Executive Committee of the Faculty Senate (ECFS) denies it took any official action to invite the investigation. At the same time, the ECFS has accepted an invitation to meet with the AAUP committee this week.

**Q: Haven't we had a seven-year term appointment system for a long time, and if so, why is the AAUP just now investigating us?**

A: Our seven-year term appointment system is the only tenure system we've ever had at MD Anderson. It was established under Dr. Lee Clark, our founding president. Many of our faculty members are appointed with renewable seven-year term appointments. In the overwhelming number of instances, these appointments are renewed for successive terms, often on multiple occasions.

All three presidents since Dr. Clark, (Drs. LeMaistre, Mendelsohn and DePinho) have served as president of our institution when seven-year term appointments were not renewed for a very few faculty members. In all cases, the faculty members had an extensive appeal process available to them and multiple reviews of the decision to not renew their appointment.

The overwhelming majority of the time (92% in the past three fiscal years) seven-year term appointments are renewed. Accordingly, we believe the current action by the AAUP is not so much about our system not working, but instead is an attempt to generate adverse publicity about MD Anderson simply because we've insisted on accountability in our system. The AAUP has specifically rejected the concept of faculty job performance accountability in any review after an initial grant of tenure.

**Q: Does the AAUP believe everyone who holds a faculty position for a certain period of time is entitled to a lifetime appointment?**

That appears to be the case. The AAUP has stated publicly that (1) It does not believe in post-tenure reviews; (2) It does not believe universities should be able to conduct criminal background checks before hiring faculty (apparently that would even include doctors who treat patients); and (3) It has even tried to impose a standard that would require a university to keep a faculty member on the payroll when the faculty member had been indicted for serious criminal behavior, maintaining that position even when the faculty member was later convicted of the crime.

**Q: What is the worst thing that the AAUP can impose on us?**

A: In the past when the AAUP disagreed with a university's decision concerning a faculty member, it has placed the institution on its censure list. By the AAUP's own admission, being placed on the censure list has never been shown to affect a university's ability to obtain grants or recruit outstanding faculty.

**Q: What would happen if we decided to change our seven-year appointment system to lifetime appointment?**

A: We have no intention of changing our seven-year renewable term appointment system that has served us well for decades with an appropriate balance of academic freedom, employment security and accountability. And we cannot predict with certainty what would be affected by changing our system to lifetime appointment.

However, changing to a lifetime appointment system could require new standards for granting tenure. Those new standards might have to be applied to both faculty that have a current seven-year appointment, as well as for any faculty seeking tenure for the first time. Since the institution would be taking on a greater obligation for those with lifetime tenure, faculty compensation and faculty benefits such as professional development funds and extramural leave might also be affected.

**Q: Do I have to talk to the AAUP representatives if anyone asks me to do so?**

A: While any employee of MD Anderson is free to talk to AAUP representatives, there's no requirement to do so. As noted above, we asked the organization if it intended to abide by basic, well-recognized standards for conducting its investigation, and it denied that it would follow those standards.

We further asked if the AAUP would assure us that if we disagreed with its findings we could submit a written dissent that would be published with any report it issued. The organization admitted that in the past it had refused to publish a university's dissent in its entirety and further indicated that it felt no obligation to do so in this instance.

Accordingly, we can offer no reassurance to any employee that communicates with the AAUP that you will be quoted accurately or that it will correct any misstatements in its report to its membership that may become public. The organization already has admitted that it made allegations in its correspondence to us that were demonstrably untrue, but offered no explanation as to why it had done so.

We hope that we have answered some of your

concerns in advance of the AAUP's visit and what you may read in the media. We're very proud of everyone who works at MD Anderson who is committed to our mission of reducing the human burden of cancer, including our faculty members with seven-year and year-to-year appointments, as well as our classified and administrative staff employees.

Because of that commitment, and because of the facts we have gathered since May, executive leadership has corresponded with the AAUP representatives and informed them that we're happy to answer any written questions they may have that have not been previously answered and are a matter of public record, but that we will not personally meet with representatives of a non-governing entity conducting an unauthorized investigation with a pre-determined outcome.

Ron DePinho, President

Ethan Dmitrovsky, Provost and Executive Vice President

Tom Buchholz, Executive Vice President and Physician-in-Chief

Tom Burke, Executive Vice President for MD Anderson Cancer Network

Leon Leach, Executive Vice President and Chief Business Officer

Dan Fontaine, Executive Chief of Staff

## MD Anderson Poisoning Trial Triggers Global Media Circus

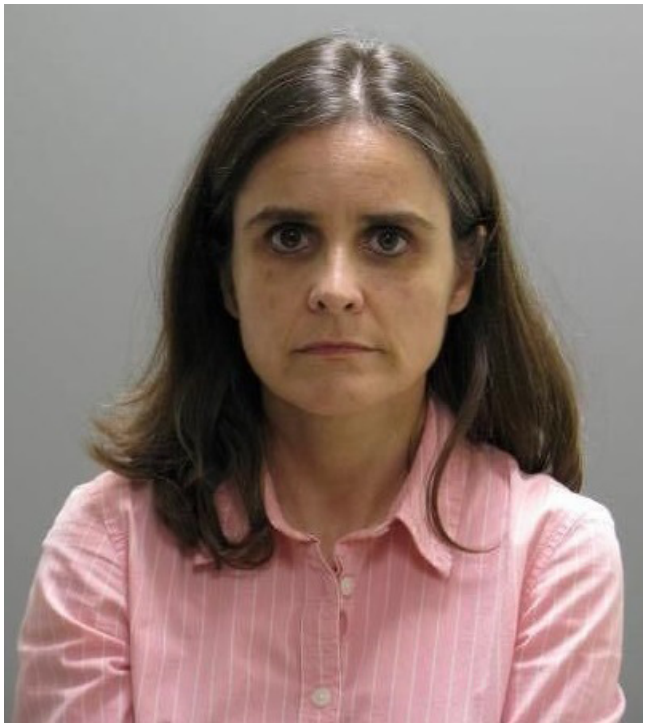
(Continued from page 1)

As the world watched bizarre events unfold in a courtroom at the Harris County 248th District Criminal Court, officials at MD Anderson said that the trial is not about the cancer center.

"This trial is not about MD Anderson," the institution said in a statement emailed to The Cancer Letter. "It is a trial related to personal matters between two people who happen to be employees of MD Anderson. Because it is a personal matter, we will not comment."

Ana Maria Gonzalez-Angulo, the 43-year-old oncologist accused of aggravated assault in connection with poisoning her lover with ethylene glycol, remains on paid administrative leave from the cancer center.

"Until these legal issues are resolved, we do not intend to take any action that might potentially influence the outcome of these proceedings," MD Anderson officials said in a statement.



The booking photo of MD Anderson physician **Ana Maria Gonzalez-Angulo.**

That said, the media in Texas and worldwide as seen a parade of top MD Anderson doctors testifying in a trial that has already lasted a week and is expected to go on for two. Gonzalez-Angulo's colleague, collaborator, former lover, and alleged victim, George Blumenschein, is expected to take the stand. Blumenschein is currently back at work at MD Anderson.

If Gonzalez-Angulo takes the stand, she may have to answer questions about statements she made in telephone conversations in which she said she has had people killed in the past.

Perhaps the most shocking tidbit was testimony—by at least two physicians—that Blumenschein's colleagues were accessing his medical record at the cancer center when he was receiving treatment there after the alleged poisoning. According to testimony, one of the physicians was reprimanded for accessing Blumenschein's records.

Some aspects of the story—as reported in the press—were unabashedly salacious. Chief among them was an account of Blumenschein's and Gonzalez-Angulo's final rendezvous, Jan. 27, 2013, which included oral sex and shots of vodka before work, the Houston Chronicle reported.

The MD Anderson story also caused considerable mirth on CBS This Morning.

It's difficult to see precisely how the proceedings reflect what insiders at MD Anderson have known for years, schadenfreude aside.

One insider, who spoke on condition of not being identified by name, said to The Cancer Letter that the affair—which seemed to be obvious to Gonzales-Angulo and Blumenschein's colleagues—was negatively impacting the work environment.

In the case of the phase I program, in which the couple was involved, it was well known that Blumenschein and Gonzales-Angulo were trying to create an alternate in-house program based on the "biologic relationship between breast and lung cancer."

When these plans were brought to the attention of the administration, concerns were brushed off, a knowledgeable source said to The Cancer Letter. Skeptics cited the reason for their opposition: there is no known significant biologic relationship between lung and breast cancer.

"This was more about the biologic relationship between the two investigators," the skeptical colleague said to The Cancer Letter.

Blumenschein was identified as the principal investigator on a phase I trial of a compound under development by AVEO Pharmaceuticals, a company co-founded by MD Anderson President Ronald DePinho and his wife Lynda Chin, a senior scientist at the institution.

In June 2012, this publication reported:

"Questions arising from such a close relationship between a cancer center and a company can reach deep. For example, MD Anderson recently took part in a multi-institutional phase I study of an AVEO compound and exploratory biomarkers in patients with advanced solid tumors: http://www.aveooncology.com/wp-content/uploads/2012/05/AVEO-AV-203-Ph1-Initiation-PR-Final-52312.pdf.

"Can conflicts of interest at the top of the institution creep into this and other studies involving AVEO compounds? This could be particularly sensitive in a phase I study, which is conducted with no therapeutic intent, ethics experts say.

"DePinho said he didn't have first-hand knowledge of how the phase I study of an AVEO compound was scrutinized. 'This is something that is very heavily managed in academic institutions,' he said. 'These are things that are very stringently examined at the level of systems and at the level of compliance, and these are things that have been examined in great detail with tremendous transparency (The Cancer Letter, June 1, 2012).'"

Six weeks later, in July 2012, when the story of Blumenschein's involvement in the clinical trial was reported by the Houston Chronicle, MD Anderson officials denied that their institution was leading the phase I study of the compound. In the course of the newspaper's reporting, AVEO changed its statement, saying that no lead investigator was chosen.

After following the first two days of coverage of the Gonzalez-Angulo trial in the media, Leonard Zwelling, a former MD Anderson official who became an internal critic of the institution's leadership, decided to cover the remainder of the trial on his blog.

"I am not attending this trial to find out whodunit," Zwelling wrote Sept. 18 after covering the fourth day of the trial. "That will be in the Chronicle soon enough and I can read it. I am desperately searching for a clue as to how the greatest force for good in the fight against cancer has become such a den of iniquity."

Zwelling is unwilling to accept MD Anderson's view that this is a "personal matter between two people" that doesn't involve the institution.

Zwelling writes:

"1. This highly visible couple was carrying on an affair about which 'everyone knew' and yet also were working colleagues trying to start a drug development program to compete with the established MD Anderson Phase I program already in existence at Anderson.

"2. Dr. Blumenschein was clearly behaving like a 16 year-old despite having major patient care responsibilities. A friend has said that if I am looking for an absence of promiscuity, the Texas Medical Center is no place to look. Perhaps, but when I was at Anderson, we were expected to set the standards, not sink to those of others with whom we shared a parking lot.

"3. Were any of the leaders even aware of the possible downside of these relationships? At least two people I know tried to make this right but were unable to do so. I suspect there is much more to that than I know now or may ever know.

"4. But when the typical 'back-biting of academia, because there is so little at stake,' morphs into questionable financial matters, nepotism, conflicts of interest and self-dealing, not to mention taking large sums of money from less than admirable foreign governments to support building projects on a state university campus, perhaps we shouldn't be surprised what will be on the docket next."

*Sept. 9 NCAB Meeting*

# Varmus: Expect Another CR For Funding Through December

NCI Director Harold Varmus said Congress is moving slowly on appropriations bills, and a continuing resolution lasting until December is the best that can be expected in the short term.

"Depending on the outcome of the election in November, there may be an interest among the Republicans that if they regain the Senate that this should be postponed until after they're back in charge in both sides of the bicameral legislature," Varmus said at the Sept. 9 meeting of the National Cancer Advisory Board.

*An edited transcript of Varmus's remarks follows:*

It would be inappropriate for me to speak to you without talking about appropriations, but I don't have much to say, because not much has happened since we last met.

And I just remind you that despite all the rosy predictions that were made by the House and Senate appropriation chairs our friend Barbara Mikulski [D-Md.] on the Senate side and also Hal Rogers [R-Ky.] on the House side that we would have appropriation bills before the fiscal year 2015 began.

We're back in our usual circumstance, last month of the fiscal year, we don't have a bill, we don't know what the hell has been happening. Elections are coming.

We're now expecting the so-called clean CR, that is a continuing resolution at FY 14 levels without a lot of bells and whistles—although there is interest in some supplemental appropriation, for example for Ebola response and other things. Not clear whether that will happen, but people who think they know something tell me that there will be a CR that lasts until about mid-December, Dec. 11 or 12.

But, of course depending on the outcome of the election in November, there may be an interest among the Republicans that if they regain the Senate that this should be postponed until after they're back in charge in both sides of the bicameral legislature.

Everyone is a pundit in the game, and by the time it happens, people will forget whether you are right or wrong. Obviously, our overall goal here is to have further recovery from the sequestration that was imposed in FY 13. We got halfway back from the 6 percent reduction in FY14. That was good. It felt like an increase even though we were 3 percent below previous levels.

The president proposed for FY 15, a one percent increase over the 2014 levels. The Senate markup was up yet another percent, but never got passed by the full Senate.

Nevertheless, they were still under the usual schedules, preparing for FY 16, and many people seem to have forgotten that FY 16 could be a terrible year because sequestration rules could bring us back to another severe reduction.

So advocacy for the NIH should be at a high level at this point. As the planning of the president's budget moves forward and we begin to wonder who will be running the committees and what are their dispositions toward NIH, toward research, toward health.

We mentioned last time that Chairman [Jack] Kingston [R-Ga.] on the House side was in a difficult primary, and headed for a runoff, which he lost. He will not be in the next Congress. And we are at a loss to know who will be the chairs, the all-important seats in our appropriation subcommittees.

The House is very unclear. It will be almost certainly be a Republican house, but who will be chairing the committee will not be known. On the Senate side, we're losing Sen. [Tom] Harkin [D-Iowa], I will say a bit more on that in a moment. But the rumors have it that Sen. [Patty] Murray [D] from Washington State is likely to be the chair.

That would be good for us. She's a friend of the NIH for sure—and very close to the leaders of our cancer center in Seattle, Hutchinson Cancer Center. That would be a good thing. But the Senate could easily become Republican, and we don't know who the leader would be.

Congress is not going to solve too many problems before the election. They have been out on August recess. They returned Sept. 8, yesterday, and they will spend 10 working days in September in business. And then they'll be out until after the election. And so there is an imperative to get some kind of CR passed. Nobody wants a shutdown; that's one piece of good news I have in this domain. But don't expect a whole lot of activity, other than this expected CR, along the lines that I described.

Despite the relative level of inaction, I did have my second opportunity to make a presentation before the Congress with a hearing held by the science subcommittee of the House Science Committee, that the chairman, Dr. Larry Bucshon [R-IN], is a physician, a very well intentioned guy with a genuine interest in science.

In July, his staff pulled together an eclectic panel including Jay Keasling, from the Lawrence Berkeley

labs; Marc Tessier-Lavigne, head of Rockefeller University and J. Craig Venter from, what else, the J. Craig Venter Institute.

My own testimony, which is available in the board book, didn't break great new ground conceptually, but did allow me to restate some important themes, the importance of interdisciplinary research, the importance of sustaining basic research efforts if we will make medical advances in the future. I pointed out that the number of funders of medical research has increased and diversified and it is important that the funders work in a way that is mutually informed and synergistic.

I described some examples of ways that NCI, in particular, and the NIH in general, have been working together in support of what we call team science.

It was extremely friendly. A lot of questions, for the record. Quite well attended, not a lot else going on. If you want to read about other legislative activities there is a lengthy report, that I encourage you to look at.

I want to mention both in admiration for Tom Harkin, who is leaving the Senate this year, and because it is nice to know somebody is thinking about us, Harkin proposed a bill for which he never found a Republican cosponsor to try to restore the losses we've sustained over the last decade due to a range of misfortunes that include budgets below inflation and frank budget cuts and sequestration.

His goal has been to drive the budget up fairly rapidly for a few years and sustain it at 5 percent increases so we would reach a $46 billion budget by 2021.

Those numbers look good to me, absorbable over that period of time, but the bill's not going to go anywhere, especially without Republican co-sponsorship.

The last thing I will mention that is congressionally related has to do with an unusual activity being led by the House Energy and Commerce Committee by Fred Upton [R] from Michigan, as the chair and is clearly someone with our interest at heart.

And his partner [Rep. Diana] DeGette [D-Colo.], who many of you may know because of her extreme interest in diabetes and other medical conditions. So this group put together what they call the 21st Century Cures Initiative.

I'm told by my colleagues that are advisors on the Hill that you can't have an initiative for the NIH that doesn't have the word "cures" in it. That is bizarre, but that is the state of the conversation at the moment.

This group, I commend them for doing this, is putting together white papers on a variety of topics relevant in the NIH. Holding hearings, gatherings around the country to tell whoever comes to their things, probably mainly state executives of various kinds and members of state legislatures and various groups.

On the Hill another event will go on tomorrow talking about various aspects of medical research that make it hard for us to get as much work done as we would like and link the products of that work to clinical advances.

**Administrative Burden**

There is a special focus on various kinds of administrative and regulatory burdens and in my conversations with people from the university it is clear there is a rapid increase in the amount the universities are spending, especially on compliance with the regulatory initiatives. So this could be quite worthwhile.

I don't hear a lot from these groups yet about trying to increase the budget or make other radical changes in the way in which we're governed by Congress, but the administrative and regulatory burden part of this could be important and especially the time when a lot of other groups are actively engaged in these issues, including the Office of Science and Technology Policy, the National Research Council, the AAU, all running studies.

They're not the first studies we've had of these matters but maybe enough consensus on something to get some relief from what is proving to be a major cause of expense at universities and I heard from the AAU that the calculated administrative cap for 26 percent for indirect cost that was laid down for some years ago is becoming increasingly inadequate that the average cost—the percentage of administrative cost is now between 22 and 34 percent.

And, increasingly, the government is not fully supporting the cost of the administrative expense associated with the research that we're asking people to do.

**FY 2014 Grant Levels to be Similar to FY 2013**

Couple of words about grant-related issues. We will provide, as we have in the past, an account of the awards we made at the NCI over past year. But you may have noticed FY 14 is still open.

We have some cash at the end of the year, we're giving out more grants this month. Increases are still continuing. It looks as though the results for FY 14 will be extremely similar to those of FY 13, which we discussed here before and are available on our website.

And our next meeting, the joint meeting, I will give a full report.

I just remind you of some changes in policies and

mechanisms that we have announced publicly. Our Outstanding Investigator Award: I won't go through the specifications, we did that last time, but this has been warmly applauded by those who are concerned about getting adequate support to our best investigators and providing them with stable support, a seven-year award up to $600,000, with some institutional support.

And those who are thinking about the instability of the scientific community are pleased by this.

I know from talking to my fellow institute directors there will be more such awards made by other institutes. Certainly [National Institute of General Medical Sciences] will be one of the first out of the box on this.

We also are trying to strengthen our expectations of grantee behavior, asking that they report on all initiated trials of whatever kind of results. That we can do on our own.

There is a general NIH commitment to asking that all grantees commit to service on review panels if asked to serve. And I've been pressing NIH leadership, Dr. [Francis] Collins [NIH director], to get that actually in print as soon as possible.

**Frederick National Lab**

Ok, perhaps one quick word about the Fredrick National Lab, which was already discussed here.

Joe Gray [chair of the Department of Biomedical Engineering at Oregon Health and Science University] has agreed to take on the chairmanship of the Frederick National Advisory Committee.

We will have the next meeting at the end of September, at which we will hear from folks who are interested in starting important initiatives, like the RAS initiative, and we'll be hearing from a couple of folk who have plans hopefully get another initiative going soon.

And in addition, we established a separate oversight committee chaired by Levi Garraway at Brigham and the Broad [Institute] to oversee that activity.

They held the first meeting, which was highly successful. Minutes are available for those who would like them. I think that has been a good way to ensure that in addition to having the central Frederick committee looking at the projects, we have some group that is highly specialized providing advice to Frank McCormick head of the scientific efforts of the RAS program and the *David A. Wood Distinguished Professorship of Tumor Biology and Cancer Research* at UCSF] and others leading the charge out there.

We are also introducing the Frederick National Lab to leaders of major universities in the area, just to explore the idea that when we recompete the contract, might be industrial partners and commercial partners involved in the maintenance of the organization….

The other big NIH topic in general that the steering committee and institute directors are dealing with is the evaluation of the intramural program. You will hear about it from our three leaders, Drs. [Stephen] Chanock, [director of the NCI Division of Cancer Epidemiology & Genetics], [Robert] Wiltrout, [director of Center for Cancer Research], and [Lee] Helman, [scientific director for clinical research at the Center for Cancer Research].

And you will see that, in my view, NCI has done a good job trying to analyze what we do with the intramural program, which is the largest, and consumes the largest fraction of clinical trial activities, and it has the most complex set of interactions—with on one hand the contract program in Frederick and extramural and patient population.

I think it is very much worth the attention of the NCAB to hear about the complexities of the relationships, think about what this review, which is of course being just started by us, but will be judged and extended by a subcommittee of the advisory committee to the director.

You may ask some questions about the speed and even the alacrity of how this is proceeding, and you may ask some questions about what is the intended consequence of this evaluation. I will leave it at that until you hear further from them….

I would take a moment for a callout to Karen Maurey, [director of the NCI Technology Transfer Center], the one leading the charge among the technology transfer offices in developing the new plan which decentralizes the program and takes more of the authorities which were originally in Building One and disseminates them among the institute.

The NCI, with many customers for our centralized service facility, is where most of that happens. NCI being the biggest user of technology transfer to begin with, but now increasingly carrying burden for lots of other institute, in part for the excellent service she provides. We're trying to make this as close to cost neutral as we can for the NCI.

We are insisting that there be a program manager be brought in to help with the transition and that the transition occur at a moderate pace without causing undue stress.

It is not easy to change an activity as large as this, immediately…

Before I take questions, I will ask [NCI Deputy Director] Doug [Lowy] to make comments about

technology transfer, and other things on his mind, and Jim to make comments about the clinical trial discussion we will have today.

**LOWY:** Thank you.

The area of tech transfer is one that really was started about 20 years ago when the Office of Technology Transfer was created at the NIH level. The rationale for it at that time was really quite persuasive, to try to develop one office where you could have a coherent and cohesive kind of situation for licensing of technology.

**VARMUS:** I like that because 20 years ago they made a distinguished director of the NIH–[Laughter].

**LOWY:** I won't correct you on that one. I agree.

But over the ensuing 20 years, the office has evolved to some degree as well as tech transfer in the institutes has evolved. As Harold mentioned, one of the situations is that actually the NCI accounts for a high proportion of the tech transfer activity at the NIH. About 40 percent of the tech transfer activity; although we represent about 20 percent in the intramural program.

And it was decided by the NIH a few months ago to try to essentially decentralize some of the operations of the office of technology transfer, specifically the areas of licensing and patenting, which has been under their purview. And so those responsibilities then devolved to the institutes.

And it happens that the NCI is a service center for a number of other institutes, because they have chosen to use our tech transfer center for their tech transfer activities.

And 11 of those institutes have said that they wish to continue to work within the tech transfer center of NCI. So that we would be responsible for the vast majority of tech transfer activities in this domain within the NIH. And Karen Maurey, the head of the tech transfer center, has really has been the point person for the NIH in trying to help to coordinate that transfer.

And we think that this is going to actually make it easier, from the point of view of the biotech and pharmaceutical industries in dealing, by and large, with one office, rather than with two offices. Because often the biotech and pharmaceutical industries need to interact with OTT as well as with the tech transfer center.

The transfers, however, involve some financial aspects and I think we're very fortunate and NIH is fortunate that Karen is at the center of this to try to help to make sure that this is revenue-neutral.

At the moment all of the institutes are tapped to help support the office of technology transfer and we would like to have at the end to be able to be doing this without it incurring additional costs by anyone, or by any one institute. From our perspective, especially by NCI.

We see this as really a positive outcome, because to be able to be involved in doing this for various institutes, we think would really rationalize and make a very consistent type of situation. This is a work in progress, but over the next year we hope the transition will be as seamless as possible and that the tech transfer activities then will continue to work.

I should point out that the NCI receives more than three-quarters of royalties from all of NIH. We're one of the few institutes that has a positive cash flow. But while I say that, I want everyone to understand that public health is the principal purpose at the NIH for the licensing and patenting of our inventions.

## AACR 2014 Cancer Report: More Federal Funds Needed

The American Association for Cancer Research published its 2014 Cancer Progress Report Sept. 16, highlighting the need for greater federal investments in biomedical research.

The report is a "comprehensive educational tool that chronicles the progress that has been made against cancer…and calls on the administration and Congress to prioritize the growth of the NIH and NCI budgets," according to AACR.

AACR estimates that cancer incidence in the U.S. will grow over the next two decades to 2.4 million, up from 1.6 million this year.

"While we are continuing to make impressive progress against cancer, the pace of that progress is being slowed due to years of declining budgets at the NIH and NCI," said Carlos Arteaga, AACR president and professor of medicine and cancer biology at Vanderbilt-Ingram Cancer Center.

"If we are to fully realize the promise of science to transform cancer care, it will require leadership in Congress and within the administration to ensure that biomedical research in cancer becomes a major priority for our nation."

The NIH budget, while basically remaining a flat number, has effectively shrunk by $3.5 billion over the last five years because it has not been kept pace with biomedical inflation.

According to the report:

• There are estimated to be nearly 14.5 million cancer survivors alive today in the U.S., and almost 380,000 of these individuals received their cancer diagnoses as children or adolescents.

• Between Aug. 1, 2013, and July 31, 2014, FDA approved six new anticancer therapeutics and new uses for five previously approved drugs.

• During the same period, two imaging agents received new cancer-related approvals, as did a previously approved screening test.

• Research discoveries continue to advance precision medicine: five of the six new approved drugs are molecularly targeted agents.

• Patients with some types of cancer have three or more molecularly targeted treatment options, should their cancer recur or become resistant to the primary therapy.

• Cancer immunotherapeutics are continuing to yield long-lasting patient responses in several types of cancer.

*Funding Opportunities*

## AACR Accepting Submissions To Two Dream Team Grants

**THE AMERICAN ASSOCIATION FOR CANCER RESEARCH** is accepting submissions of ideas to two dream team grants: one offering $20 million for lung cancer research, and one for $6 million for ovarian cancer research.

Funding for the lung cancer research grant will be provided by Stand Up To Cancer, the American Cancer Society and Bristol-Myers Squibb.

The research will be expected to involve new immunological approaches. Proposals for the grant must describe plans indicating how the group will use a transformative and synergistic approach, and how the work will be translated into the clinic. To maximize creativity, innovation, and collaboration, the projects should span multiple disciplines and use modern scientific tools to attack research questions in a coordinated effort.

A joint scientific advisory committee will evaluate applications in a multistep scientific review process. The committee is chaired by Nobel Laureate Phillip Sharp, institute professor at the David H. Koch Institute for Integrative Cancer Research at MIT. Arnold Levine, professor at the Institute for Advanced Study in Princeton, and at the Cancer Institute of New Jersey; and William Chambers, national vice president of extramural research at the American Cancer Society, will serve as vice-chairs.

Letters of Intent are due Nov. 5 via proposalCENTRAL.

The ovarian cancer research grant provides funding over three years, and is sponsored by Stand Up To Cancer, the Ovarian Cancer Research Fund, the Ovarian Cancer National Alliance, and the National Ovarian Cancer Coalition.

Proposals for the grant must describe plans indicating how the group will use a transformative and synergistic approach, and how the work will be translated into the clinic.

The grant's joint committee is chaired by Levine. William Nelson, director of the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, and Jeff Boyd, senior vice president at the Fox Chase Cancer Center and chair of OCRF's Scientific Advisory Committee, will serve as vice-chairs.

Letters of Intent for ovarian cancer research grant are due Nov. 7. Recipients of both grants are scheduled to be announced in spring 2015.

**THE FOUNDATION FOR THE NIH** is accepting nominations for the **2015 Lurie Prize in Biomedical Sciences**, recognizing outstanding achievement by a young scientist in biomedical research. The deadline for nominations is Oct. 14.

The $100,000 prize is made possible by a gift from Ann Lurie, FNIH board member and president of the Ann & Robert H. Lurie Foundation. The nominator must be a member of an accredited educational and/or scientific institution, and the candidate must be 52 or younger on January 1, 2015. No self-nominations are allowed.

The jury is chaired by Solomon Snyder, FNIH board member and distinguished service professor of neuroscience, pharmacology & psychiatry at the Johns Hopkins University School of Medicine. More information can be found on the FNIH website.

*In Brief*

## Tweardy Named Division Head Of Int. Medicine at MD Anderson

He also has joint appointments as professor in molecular and cellular biology, and biochemistry and molecular biology. He recognized for his work in inflammation and apoptosis, particularly cytokine signaling and STAT protein structure and function.

Following three years at The Wistar Institute, he joined the faculty of the University of Pittsburgh in 1987 as assistant professor of medicine with a joint appointment in Molecular Genetics and Biochemistry. He was promoted to associate professor in 1993. From 1997 to 1999, he served as interim chief of the Division of Infectious Diseases. From 2006 to 2007, Tweardy served as Deputy Chair of Medicine at Baylor, and In 2007 he was named medicine chair ad interim, a role he performed until 2008.

Tweardy is also a fellow of the Infectious Diseases Society of America and the American College of Physicians. He was elected to membership in the Association of American Physicians and the American Clinical and Climatological Association.

**DAN GLICKMAN** was named to the board of directors of the **American Cancer Society Cancer Action Network**.

Glickman is a former secretary of agriculture and a nine-term congressman, and is the current executive director of the Aspen Institute Congressional Program. Glickman's term on the board extends through December 2015.

The board's vote Sept. 14 took place during the network's Leadership Summit and Lobby Day, where advocates urged Congress to protect federal funding for cancer research and prevention programs.

Glickman represented the Kansas 4th Congressional District in the House from 1977 to 1995, and served as a member of the House Agriculture Committee. He served as Secretary of Agriculture from 1995 to 2001. In 2012, Glickman chaired the Institute of Medicine panel "Accelerating Progress in Obesity Prevention."

He is also a Senior Fellow at the Bipartisan Policy Center, which was formed in 2007 by former Senate Majority Leaders Howard Baker, Tom Daschle, Bob Dole and George Mitchell.

Glickman served as Chairman of the Motion Picture Association of America, Inc. from 2004 until 2010. Prior to joining the MPAA, he was the director of the Institute of Politics at Harvard University's John F. Kennedy School of Government.

**MEMORIAL SLOAN KETTERING CANCER CENTER** began construction on a 285,000-square-foot outpatient **cancer treatment facility** in Middletown, N.J., with plans to open in late 2016.

The center will offer chemotherapy, radiation therapy, diagnostic and interventional radiology, outpatient surgery, clinical research trials, oncology rehabilitation, social work services, nutritional counseling, and support programs.

Currently, more than 6 percent of MSK patients live in the area that will be served by the facility, and the center plans to offer 160 salaried positions.

**BOEHRINGER INGELHEIM** and **CureVac** announced an exclusive global license and development collaboration focused on **CureVac's CV9202**, a novel investigational therapeutic mRNA vaccine in early clinical development for the treatment of lung cancer.

Boehringer Ingelheim will begin clinical investigation of CV9202 in at least two different lung cancer settings, in combination with afatinib (Gilotrif) in patients with advanced or metastatic epidermal growth factor receptor mutated non-small cell lung cancer; and in combination with chemo-radiation therapy in patients with unresectable stage III NSCLC.

CV9202 is a combination of mRNA molecules coding for six antigens overexpressed in lung cancer, designed to induce an immune response against the tumor. CV9202 and the preceding RNActive cancer vaccine CV9201 tested in initial clinical trials by

CureVac demonstrated activity in generating immune responses against all anti-tumor antigens.

**SOLIGENIX INC.** reached an agreement with **FDA** on the design of a phase III clinical trial evaluating SGX301 (synthetic hypericin) for the treatment of cutaneous T-cell lymphoma.

The trial is anticipated to begin in the first half of 2015 with primary data available in the second half of 2016. SGX301 is a novel, first-in-class, photodynamic therapy that is topically applied to skin lesions and activated by visible fluorescent light.

The upcoming protocol will be a double-blind, randomized, placebo-controlled, multicenter trial that seeks to enroll approximately 120 patients. Treatments will be administered twice weekly for the first 6 weeks and treatment response will be determined at the end of Week 8.

In the first treatment cycle, approximately 80 patients will receive SGX301 and 40 will receive placebo treatment of their index lesions. In the second cycle, all patients will receive SGX301 treatment of their index lesions and in the third (open-label) cycle all patients will receive SGX301 treatment of all their lesions. Subjects will be followed for an additional 6 months after the completion of treatment.

**SUTRO BIOPHARMA** and the biopharmaceutical division of **Merck KGaA** in Darmstadt, Germany, which operates as **EMD Serono** in the U.S. and Canada, announced a collaboration and license agreement to develop antibody drug conjugates.

Sutro and Merck KGaA will use Sutro's cell-free protein synthesis platforms, Xpress CF and Xpress CF+, to develop multiple ADCs for undisclosed targets. Sutro will be responsible for delivering ADCs for phase I clinical trials. Merck KGaA will be responsible for clinical development and commercialization of any resulting products.

**DENOVO BIOPHARMA** acquired enzastaurin from **Eli Lilly and Co**. Denovo gains all rights to develop, manufacture and commercialize enzastaurin globally, including transfer of all intellectual property and other rights, data, and information.

Lilly developed enzastaurin in a variety of indications, including in phase II and III clinical trials for diffuse large B-cell lymphoma. Enzastaurin achieved promising clinical results in the DLBCL induction setting in phase II trials, but did not meet the primary endpoint in the DLBCL maintenance setting in the phase III trial.

A subset of patients showed significantly improved progression-free survival and Denovo Biopharma intends to conduct genetic analysis to identify biomarkers that are related to this outcome.

Enzastaurin is an oral small molecule, serine/threonine kinase inhibitor of the PKC beta and AKT pathways and has been studied in more than 3,000 patients across a range of solid and hematological tumor types. Enzastaurin has received orphan drug designation from the FDA and EMA.

**THE LEUKEMIA AND LYMPHOMA SOCIETY** and **OncoPep** entered a partnership to advance an experimental cancer vaccine to treat patients with smoldering multiple myeloma, an asymptomatic stage of myeloma. The partnership is through the society's Therapy Acceleration Program.

OncoPep is developing a vaccine, PVX-410, designed to target tumor antigens associated with myeloma, a cancer of the plasma cells. The therapy was granted orphan drug designation from FDA last year. LLS has committed to an equity investment of $690,000 to help support the clinical development of the vaccine, the first half of which has been paid, and the second half to be paid upon the completion of patient enrollment.

To date, 12 patients have been treated with vaccine alone in the ongoing phase I/IIa clinical trial, and the trial has been expanded to include a second treatment arm adding concurrent courses of lenalidomide.

If the therapy moves forward, it would become the only clinical stage immunotherapy for SMM patients.

As part of the partnership, Lee Greenberger, LLS chief scientific officer, will have an observer seat on OncoPep's board, and Keting Chu, LLS vice president of research and head of its TAP program, will be a member of OncoPep's scientific advisory board.