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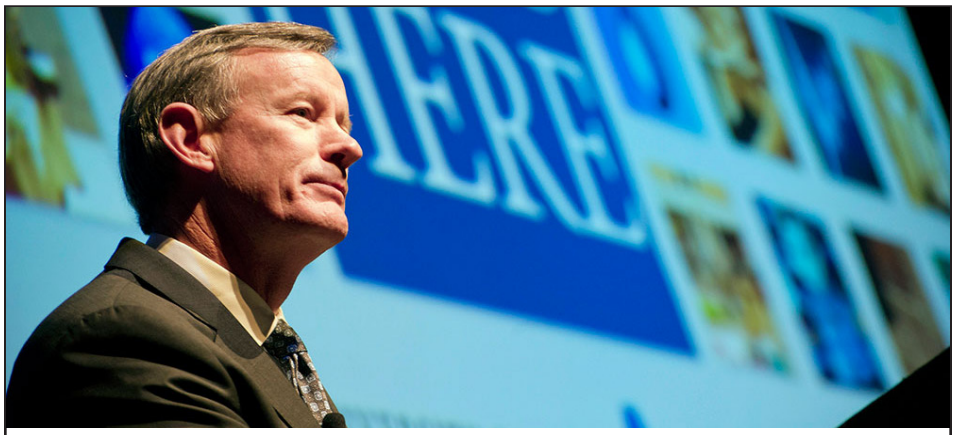

"Trust Has Been Broken" at MD Anderson; UT Chancellor Calls for Shared Governance

By Paul Goldberg

There will be no more faculty surveys at MD Anderson, UT System Chancellor William McRaven pledged to the institution's faculty in a closed-door meeting March 18.

"I don't intend to have any more surveys," McRaven said in a meeting where he acknowledged the concerns of the faculty, but also expressed support for the administration of the Houston-based cancer hospital.

"I think your surveys—at least the ones I've seen—give me a clear indication of where the faculty is," McRaven said at the meeting that lasted for about an hour-and-a-half. "And maybe it's not unanimous, but I've got to tell you that the numbers in the surveys are pretty damning, for the lack of a better term."

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Varmus Recommends Funding Boost For NCI Cancer Centers Program

By Conor Hale

NCI Director Harold Varmus announced plans to gradually increase in the institute's cancer centers budget over the next four to five years.

"It seems to me, we get more bang for our buck from the centers—many of which have many direct-cost budgets of no more than a million dollars, a lot less than the grants we give out," Varmus said at the March 11 meeting of the NCI Board of Scientific Advisors.

(Continued to page 6)

In Brief

Fadlo Khuri to lead American Univ. of Beirut

FADLO KHURI was named president of the **American University of Beirut**. He will begin his tenure there Sept. 1.

Khuri is the deputy director of the Winship Cancer Institute of Emory University, chair of the Department of Hematology and Medical Oncology,

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"Trust Has Been Broken," says UT Chancellor William McRaven

(Continued from page 1)

McRaven, the former admiral who, as head of the U.S. Special Operations Command, oversaw the covert operation responsible for killing Osama bin Laden, expressed support for the institution's Faculty Senate, thereby establishing it as the negotiating partner for the administration headed by President Ronald DePinho.

"Faculty Senate is where I am going to get my input," McRaven said.

Opening another channel of communication, McRaven gave out his personal email address and cell phone number, urging the faculty members to contact him directly should they become aware of any acts of retaliation from the DePinho leadership team.

Affirmation of the Faculty Senate as DePinho's negotiating partner was McRaven's principal message.

Drawing on his military experience, McRaven sees morale as a pivotal issue. "You don't move forward unless the folks that support you day in and day out are with you," he said.

DePinho doesn't have this support, McRaven declared. "I recognize that that trust has been broken," he said. "I think one of my first jobs is to bring us back together and rebuild that trust."

The task before DePinho fits under the rubric of you know it when you see it.

"Trust, communications and transparency. To me these are the three things that I have to solve to make sure that you understand what's going on, and that I understand what's going on, and that if anybody wants to look at how we are doing business they are in a position to do that."

McRaven urged the faculty and the administration to work out their differences.

"You need to know right now that I intend to stand by the leadership just as strongly as I stand by the faculty," McRaven said. "My job is to bring the faculty and the leadership and everybody in-between together, for the good of MD Anderson. So I need solutions. I don't need name-calling. I don't need retaliation. I need solutions."

Making a word choice that signals a new day, McRaven attributed MD Anderson's problems to the lack of "shared governance." The words shared governance conduct high voltage at MD Anderson, an institution where the office of the president has unimpeded power.

"I have talked to Ron about how we improve the shared governance," McRaven said. "Your voice should be not only heard, but it should be understood. It should be looked at in the context of what's going on here at MD Anderson every single step of the way.

"And I believe that firmly."

McRaven suggested a white paper with solutions be created and charged Gary Whitman, chair of the Faculty Senate with heading that task.

"Clear Guidance" for DePinho

The chancellor said he would be personally, directly involved.

"The issue for me really is how do I maintain daily contact with the faculty, with the leadership team," McRaven said. "This is not about me coming down here once and saying, 'Okay, I think I've got that done, now step back.' I can't do that. This is too important.

"This is the crown jewel in the UT System. I am going to stay constantly engaged. I have laid out some clear guidance for Dr. DePinho. I think he is moving in the good direction, and I am pleased with that.

"But if you think I am going to put some mark on the wall and step back, it's not going to happen. If I am not satisfied with how well he or his team have gotten at that point, then we will have another discussion. I like some of the innovative things that Dr. DePinho is doing."

McRaven said some of the problems could be traced to communications styles.

"Some of this, frankly, is interpersonal communications between Dr. DePinho and the faculty members and not talking all the time, but listening," McRaven said.

"It isn't about Ron DePinho. It's about MD Anderson. It's about making sure we are doing what's right by MD Anderson," McRaven said. "My concern

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is about some of the issues that have been raised. And frankly if only one member had raised the issue of retaliation, if only a couple had raised the issue of morale, if only a couple had raised the issue of transparency, they would still be equally important to me as if it were a unanimous decision on the part of the faculty."

MD Anderson Pre-empts AAUP Report by Releasing Draft to The Press—with a Foreword

By Matthew Bin Han Ong

MD Anderson's message to the American Association of University Professors boils down to this: A pox on your house.

For starters, President Ronald DePinho and his administration declined to meet with an AAUP committee when it came to campus to investigate a tenure dispute. (The Cancer Letter, Sept. 19, 2014).

This snub notwithstanding, AAUP provided MD Anderson with a draft report marked CONFIDENTIAL: NOT FOR RELEASE. The association's objective was to give MD Anderson the opportunity to comment—and a comment is exactly what they got.

In the afternoon of March 13, the cancer center's executive team threw the thing to the press.

Journalists received the confidential document, paired with a preface of sorts: a blistering letter calling it a "thirty-seven page biased editorial by misinformed individuals seeking to paint MD Anderson in the most negative light, possibly in hopes of recruiting additional membership to their labor union for certain university employees."

The draft report and the MD Anderson letter are posted here.

"MD Anderson does not typically release drafts of reports," officials said in an email explaining the contemptuous move to the press. "However, given the surprising focus of this document and the significant errors throughout, we feel that we need to be fully transparent about what the AAUP considers an honest and fair assessment of a public institution operating under both state and federal law.

"In addition to several significant fact errors, the majority of the 40-page report are devoted to unfair and inaccurate personal attacks on MD Anderson's president and his wife," MD Anderson officials said in the email. "These attacks are also unrelated to the AAUP's focus: faculty employment measures. We remain confused as to why the document includes these assaults.

"Our term appointment measures were created by The University of Texas System and have been in place for several decades. Our current president—who did not create these procedures nor has he altered them—has only been in office for three years."

The AAUP investigation was triggered by refusal on the part of DePinho and his administration to provide justification for denying tenure renewals to two faculty members (The Cancer Letter, April 25, 2014).

Debra Nails, a professor of philosophy at Michigan State University, chaired the AAUP investigation. The other three investigators are employed by medical institutions (The Cancer Letter, Sept. 19, 2014).

If the association finds MD Anderson at fault based on the investigating committee's final report, the cancer hospital could join over 50 institutions on the association's censure list. Founded in 1915, AAUP has 47,000 faculty members and 300 chapters.

MD Anderson's administration took exception to the broad scope of the AAUP report, which notes allegations of conflicts of interest on the part of DePinho and his wife Lynda Chin, a senior scientist at the cancer center.

The report also focuses on the controversy over plummeting faculty morale at the cancer center. The faculty's angst—namely, overwork and dissatisfaction with top leadership—has been shown in nearly identical results from four surveys over two years.

Now, DePinho is under a directive from the UT System Chancellor William McRaven to improve morale. McRaven is expected to meet with MD Anderson faculty in a closed-door meeting later today.

"A Tactical Cheap Shot"

According to AAUP, the final published report differs in most instances—at times, significantly—from the draft.

"Our investigating committee interviewed by telephone the chief medical officer for the six University of Texas medical schools, but the MD Anderson administration declined to meet with the committee when it visited Houston in September," the association said in a statement March 16. "Last Friday afternoon,

the administration submitted comments to us in response to the draft report. The same afternoon, it released those comments, along with our confidential draft report, to the media.

"It is hardly unusual for an administration to take issue with material in a draft report, but it is rare indeed for an administration to violate the confidentiality of the draft, which is maintained primarily to protect the institution and its administrators and faculty members."

Major research institutions generally do not resort to taking a "tactical cheap shot," said Matthew Finkin, director of the Program in Comparative Labor and Employment Law & Policy at the University of Illinois.

"I can't recall any major research institutions being in this position," said Finkin, who is also the university's Albert J. Harno and Edward W. Cleary Chair in Law. Finkin has participated in four AAUP investigations, chairing two of them.

"As I understand it, in this case, the administration refused to meet with them, although the central administration did, which I find very strange," Finkin said to The Cancer Letter. "The University of Texas System people were quite willing to meet with the committee. It's the MD Anderson people who were not."

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.

"For an institution to release the report when they know it's sent to them in confidence for the purpose of fact-checking, and then to publicly criticize the report for inaccuracies—most of which are terribly minor, if indeed they were inaccurate—is a tactical decision to attempt to discredit a process for doing what it should do to ensure the very end that the administration is criticizing in force."

AAUP abides by an open, scholarly process, Finkin said.

"That series of interrogatories that the MD Anderson leadership put to the association? I must say, it was responded to in a genial manner. If I were still general counsel, I would have said, 'Go to hell. Go back to the Utah report in 1915, it's been 100 years, we've been doing this ever since,'" Finkin said (The Cancer Letter, Sept. 19, 2014).

"MD Anderson criticizing AAUP for doing what they're supposed to be doing, as I said, is a tactical cheap shot to try to undermine the credibility of the report," Finkin said.

"I think this is in keeping with their whole approach to this problem—denial and attack. I find it rather tawdry."

MD Anderson Threatens to Sue AAUP

In a letter dated March 13, DePinho's administration threatened "likely" legal action for statements made in the draft report regarding Chin, who is married to DePinho.

AAUP officials declined to comment on the content of the draft report.

"As is our practice, the AAUP distributed the draft investigating committee report to interested parties at the MD Anderson Cancer Center on a confidential basis," said Gregory Scholtz, AAUP associate secretary and director of the Department of Academic Freedom, Tenure and Governance. "These included both the center and system administration, the subject faculty members, and others. Our purpose in doing so was to solicit their comments and corrections of fact so that the final report would be as fair and accurate as possible."

DePinho's administration demurred, saying that it is not their job to ensure accuracy.

"At the outset, we believe it is important to note that it is not our responsibility to correct factual misstatements in the document, nor do we purport to do so in every instance we have found," the executive leadership wrote in their letter to AAUP. "Reading the document, however, leaves the clear impression there was little or no effort by the AAUP to validate any factual statements, particularly given some of the more glaring errors. That being the case, we find the document to lack credibility in most respects."

AAUP appreciates MD Anderson's comments, Scholtz said to The Cancer Letter.

"Though the MD Anderson administration declined to meet with the investigating committee when it visited Houston, we are appreciative that they are now willing to provide us with their comments on the draft text," Scholtz said. "We will certainly take their comments into account as we prepare the report for publication, and we expect that, as a result, we will produce an even better final version.

"We have also received the comments of other interested parties, all of whom had a much different opinion of the quality of the report than that of the MD Anderson administration."

According to Finkin, there is nothing AAUP can do about a leaked draft report.

"If MD Anderson has released it, then it is now out in the ether," Finkin said. "It is what it is."

"Reinstatement Will Not Occur"

In the draft report's conclusions, the AAUP committee stated that DePinho's administration acted in disregard of its own policies, as well as tenure principles and procedures widely practiced by institutions of higher education.

"The administration of the University of Texas MD Anderson Cancer Center acted in disregard of the 1940 Statement of Principles on Academic Freedom and Tenure, which affords the protections of tenure to full-time faculty members after seven years of service, when it failed to retain Professors Kapil Mehta and Zhengxin Wang following thirty and twelve years of service, respectively, without having afforded them the protections of academic due process," the committee members wrote in the draft report.

The decision to censure an institution rests with the AAUP's annual meeting of members and delegates, which is usually convened in May or June.

"The investigating committee had neither the authority nor the desire to censure," the committee wrote. "The committee was committed to working with the faculty, the administration, and the University of Texas System generally to prevent the possibility of censure."

In its response to AAUP, DePinho's administration appears to have drawn the line:

"Despite the AAUP's repeated position that the only acceptable outcome concerning the two individuals in question is reinstatement, given that one is employed elsewhere and the other is retired and working at MD Anderson in a part-time capacity, reinstatement will not occur.

"We are left with the AAUP's conclusions in the document that are either demonstrably inaccurate or find fault with the administration of MD Anderson for not abiding by the non-authoritative AAUP's principles, by which MD Anderson has never been governed. Moreover, the rules that govern MD Anderson's handling of these matters, those promulgated by the Board of Regents of The University of Texas System, have been explicitly followed."

Finkin: Lawyers "Obviously" Did Not Read Report

The MD Anderson executive leadership—in a lengthy footnote in their March 13 letter to AAUP—cites previous AAUP investigations, implying that in certain cases, AAUP defended faculty members against dismissal even after they had been convicted for criminal activity:

"One would think such a high correlation between the Promotion and Tenure Committee recommendations and the actions of MD Anderson administration would demonstrate continued employment for term tenured faculty at the institution is indeed a matter of rebuttable presumption.

"However, our own investigation of AAUP decisions in other instances would make one believe that in the AAUP's opinion the presumption can never be rebutted since even criminal activity by a faculty member is still not reason for dismissal by their employer.

"See AAUP investigative reports concerning The University of South Florida (2003) (Faculty member pled guilty to and was convicted of, 'conspiring to make or receive contributions of funds, goods, or services to or for the benefit of the PIJ, a specially designated terrorist organization,');

"City University of New York (2004) (Faculty member convicted of providing material support to terrorist activity.)

"University of Virginia (2001) (Faculty member pled guilty to criminal financial misconduct, yet the AAUP stated, 'An arrest (and even a subsequent guilty plea) do not retroactively justify an administration's unilateral action to dismiss a member of the faculty.')"

MD Anderson's assertions are wrong, said Finkin.

"MD Anderson's footnote on presumptions is obviously drafted by a lawyer," Finkin said. "They cite the case of The University of South Florida. The faculty member was not convicted at the time. Ultimately, he was prosecuted, and found not guilty of the major charges. The jury hung on one minor charge and he later pled guilty to that to make the case go away. But he was actually acquitted of the major charges, which was supporting terrorist organizations."

As for the City University of New York faculty member, Finkin said the issue was whether he was convicted at the time of the AAUP investigation.

"I chaired that committee, and Debra Nails was on it. The faculty member in question wasn't convicted, he was indicted at the time of the case," Finkin said. "Two years later, there was a trial and he was convicted.

"However, the whole issue in the case was, 'Is an indictment enough merit for an administration to summarily suspend the faculty member?'

"That committee also consisted of the late Richard Uviller, a well-known professor of criminal law at Columbia University, a former city and federal prosecutor, and a very tough guy. The report goes on at length about what an indictment means.

"MD Anderson's assertion about the conviction was simply wrong. The faculty member was not convicted at the time of the investigation.

"If MD Anderson's lawyers had actually read the

report, they would see that was a critical distinction."

MD Anderson's executive leadership also took the University of Virginia case out of context, said Jordan Kurland, AAUP's associate general secretary.

"The case involved embezzlement. This was a faculty member who was using government funds for personal use," said Kurland, who has staffed AAUP investigations for 50 years. "The University of Virginia's procedures for dismissal were, on the face, exactly what AAUP recommends.

"The administration that was in authority at that time said, 'Well, that obviously means anything related to academic performance, either incompetence or neglect of work, or personal conduct i.e. making a pass at a student.'

"This is a question of stealing money from the state. The auditor's office of the Commonwealth of Virginia, not a faculty hearing, is the appropriate venue—they do this all the time," Kurland said to The Cancer Letter. "It was through the auditors of Virginia that the finding was reached, to which the professor pled guilty.

"We took the position in the case that no matter what the nature of the charges against the individual might be, in terminating a tenure case, a faculty body needs to pass on it. What we said to UVA at the time was they erred in not having a faculty body do this.

"We did not impose censure, we called for corrective action vis-à-vis policy by the administration, and in the months following, the UVA did adjust its rules as we recommended, and closed that loophole so that in the future, all cases would have been run by the faculty.

"So what I'm saying is, MD Anderson grabbed onto this one sentence without going into the reasons for it."

Attacking the credibility of AAUP, as opposed to disputing the facts and conclusions of its draft report, is not standard behavior, Finkin said.

"The snide insinuation that the AAUP will defend convicted criminals willy-nilly is simply not tied to the facts of those cases—certainly not South Florida, and not City University of New York," Finkin said.

"And here, MD Anderson's executive leadership had obviously not read the reports, and they're accusing AAUP."

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Varmus Recommends Increasing NCI Cancer Centers Funding

(Continued from page 1)

He suggested boosting the centers budget by $10-15 million per year, increasing the total cancer centers budget from $260 million to about $310 million. This plan follows a proposal to reconfigure the formula for awarding cancer center grants.

"It's been hard to get that proposal instantiated, in part because you don't want to see some centers take big losses, and it's hard to get the formula right," Varmus said in his opening remarks. "And so we've been playing with this, and have realized that one way to make this go in a way that's more acceptable to everybody is to provide the cancer centers program with more money, despite the fact that we're under fiscal constraint."

The plan for the budget increase still needs to be vetted by a working group, Varmus said, but is planned to be formally introduced to a joint meeting of the BSA and the National Cancer Advisory Board in June.

Varmus plans to resign as director of the NCI by the end of March. "At least that's the plan," he said. "I won't be here to execute it, but I hope others will carry these things out."

Douglas Lowy was named acting director for the NCI, effective April 1. Lowy also serves as the chief of the NCI Laboratory of Cellular Oncology. Varmus began the day's meeting with words of praise for his imminent successor.

"He and I have worked very closely together over the last five years, with great pleasure," Varmus said.

"I've known Doug for a long time, as a fellow student at Amherst College, among other things, and also as a colleague since Doug has distinguished himself in virology and in the study cancer genes, two areas where I had particular scientific interest," he said. "His performance has been extraordinary, and you all know him as not only a leading scientist, a member of the National Academy, but also as an extraordinarily insightful leader."

"My own personal bias is that—an action over which I have no authority—is that he should be made the actual director, very, very quickly, and serving at the president's disposal of course."

However, Varmus said, with the next presidential election just over a year-and-a-half away, "this would be as permanent as anything might be."

"One of the things I would be unhappy about is the prospect of having less than permanent or official leadership at the NCI for as long as a-year-and-a-half."

Additionally, Varmus discussed the FY16 federal budget, the NCI's work in global health, the use and funding of the NIH Clinical Center and the Frederick National Lab, and how the NCI can support the investigator community during times of tight budgets.

A transcript of Varmus's remarks to the BSA follows:

Welcome to all of you. Glad you could make this meeting. I usually begin with some discussion about NCI personnel.

Last time I complained it was hard to fill six of our empty spots on the National Cancer Advisory Board, and I'm glad to say that thanks to the energetic workings of the president's personnel office, we now have a fully approved slate, and when you have your joint meeting in June with the NCAB, you'll find at least 18 people invited to that meeting.

I think I mentioned last time that Linda Weiss was leaving as head of the Office of Cancer Centers, and she in fact is now departed after multiple recognitions and celebrations. Henry Ciolino is acting as the head, and we have a search in process, and Jim Doroshow is chairing the search committee.

By now you should have received my letter sent to all grantees and members of advisory boards as well as NCI employees.

That letter announcing my departure at the end of this month, exactly the end of this month, on March 31. I tried to summarize the number of the things we've done in the last five years, despite our penury, and some of the good things that have happened—largely due to prior investments, but nevertheless happened on this watch—and therefore exciting to consider and build on and report about. I'm not going to recite those things now. If you want to read about them again, go back and reread the letter or contest them or read about them somewhere else.

Instead I want to spend most of my allocated time today talking about some of the things that remain to be done, especially some of the items that need help from the advisory boards, you and the NCAB in particular, but several other subsidiary working groups and other advisory committees as well.

Before I get into those topics, of which there are seven, I wanted to say a couple of words about the context of which the NCI will operate in the future, that has to do with leadership and money as usual.

As you all have heard, Doug Lowy, the gentleman to my right—not politically—is going to be taking over as acting director. This is really good. He and I have worked very closely together over the last five years, with great pleasure.

I've known Doug for a long time, as a fellow student at Amherst College, among other things, and also as a colleague since Doug has distinguished himself in virology and in the study cancer genes, two areas where I had particular scientific interest. His performance has been extraordinary, and you all know him as not only a leading scientist, a member of the National Academy, but also as an extraordinarily insightful leader.

Very pleased that Jim is staying on as well to give Doug the help he needs, and Jim, too, of course, has distinguished himself and made my life tolerable. The troika, as we call ourselves, have been enjoying our interactions over the last four or five years with a lot of enthusiasm.

One very nice thing is that Doug could be appointed as acting director, or at least named as the acting director, on April 1, thanks to the fact that [NIH Director] Francis Collins and [HHS Secretary] Sylvia Burwell pitched in enthusiastically to get this through the White House, and it didn't hurt that he had recently had all of his credentials—scientific, political, and everything else—vetted for his National Medal of Technology and Innovation, as you'll recall, because we had quite a ceremony in December to talk about that.

My own personal bias is that—an action over which I have no authority—is that he should be made the actual director, very, very quickly, and serving at the president's disposal of course. But there will be very, very likely, unless we change the Constitution, a new president in a-year-and-a-half, so this would be as permanent as anything might be.

But subject to reconsideration by him or by the new government in a-year-and-a-half—I think that would be a way to solidify the leadership. One of the things I would be unhappy about is the prospect of having less than permanent or official leadership at the NCI for as long as a-year-and-a-half.

The Budget and the Precision Medicine Initiative

Budget. Well, as usual, not too much change and considerable uncertainty. I think many of you know what happened with the fiscal year 2015 budget, namely after a little bit of delay, but not much, the good news was we got our appropriations through the "CRomnibus" in the first quarter of the year. The NCI didn't have a decline in the budget, but the increase was less than 1 percent. And that was true across the board for the NIH. So our actions are more or less going to be like last year, with roughly the same number of dollars.

We have an interesting phenomenon; there's been a significant uptick in the number of R01 applications

this year, roughly 18 percent or so. We don't fully understand it. That reflects a change in policy about resubmission of grant applications, but we are trying to understand it, but it will affect the success rate a little bit, but it will not affect the number of grants that are issued.

What we all now care about now that we're in FY15 is what happens in FY16. And the outcome there is still uncertain. The president proposed a $1 billion increase for the NIH.

That seems like a substantial amount of money until you realize that with a budget of over $30 billion, that's a 3 percent increase, and when you further consider that this would get us back to where we were before sequestration, when we lost almost 6 percent. So if Congress gives us what the president asks for, we will be back to 2012, without consideration of inflationary loss.

This budget has a number of highlighted items—some may call them investments, some might call them earmarks, some might call them new adventures to draw attention to what science has to offer—but there's money in the president's request for the BRAIN initiative, for microbial resistance, for an influenza vaccine, and importantly for the NCI, for the presidential precision medicine initiative, about which I'll say more in a couple of minutes.

How are we doing with Congress? Well, we have new leadership on the appropriation committees; I won't go into that right now. We had a House hearing on March 3, that some of you may be aware of. I was not there, because I had a prior commitment to give a talk about cancer in global health to leadership in Norway, so I was in Norway on that day.

But there was a presentation by Francis Collins, accompanied by several of my fellow institute directors, and Francis talked about the role of oncology in the precision medicine initiative, and received a number of questions about brain tumors and pulmonary tumors, and a few other things.

There will be a Senate hearing some time at the end of April, and the nature of that hearing is still uncertain. So that's where we are. I think there's a reasonable chance that we will get some of the 3 percent that the president asked for, I doubt it will be like the old days where the Congress could up the ante beyond what the president asks for, but hope springs eternal. And it's not entirely clear about what Congress will say on how we should spend that money. It will affect behaviors here.

So I want to say a few things about seven issues, and let me start by talking about something I've already mentioned, namely the precision medicine initiative. I think most of you had a chance to learn a little bit about this, Francis Collins and I published an article a few weeks ago in the New England Journal of Medicine that summarizes what is intended. There are two parts of this for NIH. There are also roles for other agencies, including the FDA.

But in the NIH segment, in which the request from the president is $200 million, $70 million is to be devoted to oncological precision medicine carried out entirely by the NCI, and the rest of the $130 million goes across the NIH for a cohort study. I'll say more about that in a moment, and that effort will be led by the directors of the [National Human Genome Research Institute] and the National Heart Lung and Blood Institute.

Within the NCI proposal there are a series of efforts that will be building on existing programs within the NCI, and I will give you some brief outline of what we expect to have happen. It's designed by my co-architects in this, Dr. Doroshow, Lou Staudt, Warren Kibbe, and Jeff Abrams all to be overseen in FY16 by Doug Lowy. The three areas are genomics and attached parts of cancer biology.

So there will be more exploration of the genetic lesions that lead to cancer along with efforts to understand the nature of those lesions to build better models for preclinical testing and experiments to try to better design the use of combination therapy, especially targeted therapies, to understand the nature of drug resistance, and other things that have been part of the early days of precision medicine.

The second aspect will be clinical trials such as MATCH trial we discussed here before, a MATCH trial in the pediatric domain will be one of the first things that's designed and launched and those trials will be accompanied by better ways to analyze the tumor that's being treated and to capture both clinical and genomic data in a way that's useful.

The third component is in the informatics domain. You've heard here before the cloud computing pilots that we have underway and the launching of cancer genome data commons. There will be expansions of those efforts as well. So we are aiming to enhance our efforts in all three of these areas to a total of about $70 million. The plan as laid out in summary in the president's announcement and as described in detail in the New England Journal paper.

There will be an internal group that accounts for these expenditures so we can report to the

administration about how we spent the money; and to Congress if they have an interest, as I hope. And we will obviously be reporting to the BSA and the NCAB about the progress we make on this effort.

The NCI will also have a role in the much larger and still incompletely defined cohort study.

The intention that Francis Collins, as chief architect, has laid out is to assemble a cohort of a million people, not entirely clear who or what age, and to follow them over the course of many years with the tools for observing genetic variation, behaviors, environmental exposures and so forth. There was a workshop held here on the 11th and 12th of March to discuss how this might be done.

NCI has a deep interest in this whole effort. We have, ourselves, literally millions of people in various kinds of cohorts for various kinds of studies—especially behavioral studies and longtime observational studies—some of which you will hear about today. And so we have a lot of talent in that area, and of course a deep interest in this effort.

After all if we're going to study health in general as monitored by the tools of precision medicine, cancer, which is a leading cause of morbidity and mortality, will be a large part of the effort. And we will be taxed for it as money is gathered up to pay for the study and will be playing a role in it.

Increasing the Cancer Centers Program Budget

Second topic: cancer centers. I am aware of the importance of cancer centers, I ran one for 10-and-a-half years, and become even more aware of their significance as a structural element in the whole NCI enterprise. It is a place where most of our work is done and incredibly powerful tool for trying to get things moving quickly.

The center directors are a loyal lot; they come together once a year for discussion. They are all deeply committed to the various tasks we have in front of us, and I found that keeping the cancer centers in a healthy state is important.

One of the first things I learned when I got here, not that I didn't know something about this before, was that the size of the budgets could be viewed as inequitable and based too heavily on the history of center rather than its current quality. And thanks to the actions of a number of cancer center directors, we have come up with formulas to try to adjust the budgets to make them more reasonable and more consistent with the tasks at hand and the quality available of these centers at the current time.

It's been hard to get that proposal instantiated, in part because you don't want to see some centers take big losses, and it's hard to get the formula right. And so we've been playing with this, and have realized that one way to make this go in a way that's more acceptable to everybody is to provide the cancer centers program with more money, despite the fact that we're under fiscal constraint.

So we've had some general discussion this here and elsewhere, and we have agreed that we are going to increase the size of the overall budget for the cancer centers and compare them to other centers around the NIH campus, it seems to me, we get more bang for our buck from the centers—many of which have many direct-cost budgets of no more than a million dollars, a lot less than the grants we give out.

So we are now planning to put together a formula which we have internally agreed on, but need some vetting on the outside that will be formula-based, based on the size and intellectual activity at the center, plus its score and plus some supplementary money, with capped losses and capped gains and with a gradual increase of about $10-15 million a year for the cancer center program overall, bringing the current budget of $260 million to something in the order of $310 million over four or five years.

And as this plan will be vetted by a new working group that I'll mention in just a moment, and then brought to the joint session of this group with NCAB in June. At least that's the plan. I won't be here to execute it, but I hope others will carry these things out.

So to do the first round of vetting, we're putting together a small subgroup of the BSA which will be headed by two of our members who are distinguished heads of cancer centers. Chi Dang and Stan Gerson have volunteered, even enthusiastically, despite other chores they have.

They will not only vet these budget numbers, but do other things that I think will be useful for the cancer centers enterprise over the long haul. Namely, facilitate something the cancer centers are keen on: sharing reagents and equipment and methods, identify more the topics that are presented at the retreats, and also to propose some topics for supplementary activities—filling out the last 5 percent budget, which is intended to be used for supplements for various things, one of which you'll hear about later today, which is to encourage centers to establish relationships with cancer centers in poor and middle-income countries.

So number three, I will talk about the Frederick National Lab. As you know I've put a lot of effort

into making what the lab does a little more obvious to everybody and a little more exciting scientifically.

The keystone in that effort has been the RAS project, which is intended to develop new therapeutic strategies for dealing with cancers that have RAS mutations. There many such tumors and many of them are among the most deadly of cancers, and we've also asked the national lab and the Leidos company which has been managing it, to undertake more initiatives and pilot projects that could lead to projects on the scale of the RAS initiative.

I think we mentioned here last time that we recently had a workshop on cryo-electron microscopy, which could become an effort at the Frederick National Lab, but one of the consequences of the workshop that we held and the discussion that took place there is that the cryo-EM is going to be discussed by all the institute directors on the NIH campus. So this may be a more widespread effort to accelerate the application of cryo-EM to problems that affect all diseases and our understanding of basic biology.

One of my interests having viewed the activities of many national labs that are supported by the Department of Energy is to involve neighboring academic institutions, most obviously the university of Maryland or Johns Hopkins in the workings of the Frederick National Lab. And with the help of Joe Gray, who chairs the advisory group, we've been considering various ways in which to engage those institutions.

The contract for Frederick is competed on a regular basis and we're imagining the recompetition will occur late in 2016 or 2017. That will be an important moment to see how the conduct of research there is going to be managed, and whether we will have some academic institutions involved, not just companies that traditionally do management.

NCI and Global Health

The fourth topic I want to say something about is global health.

In my time here we created a Center for Global Health, bringing together a number of strains of work that had been conducted over many years by the NCI to study cancer abroad. [Center director] Ted Trimble has done a great job in using very limited resources through partnerships with a variety of other agencies and cancer centers and folks in other countries.

I'd like this group and the NCAB to be paying attention to how we do this, because I think we are having a major effect on one of the most acute problems that are facing world health over the next several decades. There's no doubt that unless we do something, the toll that cancer will take in poor countries will be truly astounding.

So Ted has been particularly effective at building relationships with cancer centers, mainly through awards of supplements of a couple hundred-thousand dollars and promoting technologies that might be useful in poor countries. He will tell but some of these at the end of the day today, but this of course leads to partnering not just with another institution, but with another country because countries are very interested when the NCI comes to say we would like to do more.

We built quite good relationships through either visits that I and Ted and others have made, or through actually stationing some of our personnel in countries. And we've been particularly interested in countries that have an eagerness to do something about their cancer burden and have some resources for doing that. I would single out India, China, Turkey, Indonesia, and Mexico among those that are developing new cancer plans, trying to start new cancer centers, building registries, and trying to train more people. I think there's a lot of excitement in the way we can deal with cancer as a threat to a very substantial portion of the world's population.

We've been talking with the other institutes at the NIH that have aspirations in global health, especially the Fogarty [International] Center and the [National Institute of Allergy and Infectious Diseases] and the Heart, Lung and Blood Institute, and one of the things that's particularly useful in thinking about those relationships is that as we consider the rise of noncommunicable diseases as major threats to world health, replacing to a certain extent, the threats infectious disease, which are traditionally associated with global health—we're recognizing that not only are the noncommunicable diseases themselves big threats to health, but many of the risk factors are held are in common, most obviously tobacco, but also obesity and other things, drug use and so forth.

We have tried to build investigator networks to help support these things. For example, Ted has been setting up a lymphoma network, we have an initiative on tobacco control and we will try to encourage development of better practices for restricting the use of tobacco, and a lot of that work has gone on in conjunction with cancer research agencies in other countries.

You may recall my reporting on a series of three annual meetings that we've had through the leadership of the NCI, the Cancer Research U.K., and the International Agency for Research on Cancer, IARC. And with some help from the French Cancer

Institute as well. Those meetings are far from being regular events.

We don't have a good governance body yet, and one of the things I hope this group may pay attention to is how we make more permanent a coalition of cancer research funding agencies that can promote better research and better care in the cancer domain.

Next topic is the intramural research program. We're proud of our program, it's a large one. It's got a lot of great young investigators, mostly laboratory based. The leadership of the IRB has done a great job.

We have three major domains: basic research, clinical research, population-based research. I have been very proud of how well those programs have worked over the last few years, but I do have a source of concern that is a general one about the NIH, not applying specifically or only to the NCI, and that is clinical research at the Clinical Research Center.

Now, I admit to a certain bias here. I learned to be a scientist as a clinical associate at the NIH in the late 60s as a member of the Public Health Service. I came here as a physician, became a scientist. It's a great place that brings patient care and research together, when I was the director of the NIH and we had a crisis about the decaying resource of the clinical center and apprehension and about how well the intramural program was doing, I had a very large role in building the new building, the Hatfield Clinical Research Center, so I have a loyalty to it.

But I am concerned about several things that imperil, in my view, the future of the clinical center—and in imperiling that, also imperiling the future of the intramural program and the NIH as a whole, because for many people in government, the centerpiece of the NIH is the clinical center. That's where congressmen come to have a visit and see what we do. It's the largest research hospital, purely research hospital, in the world. It's a place where a lot of people live and train and a lot of people have come from everywhere around the world to receive diagnoses for undiagnosed conditions to be involved in experiments that have been pace-setting in many fields of research.

First problem is funding. The clinical center—like every other clinical center in the world; every other academic health center—has rising costs in this hospital, but we have a fixed budget, a declining budget, and that is imperiling the way in which the clinical center operates.

Secondly, and more importantly, the number of new investigators, clinical investigators, working together has not increased. We've always had trouble recruiting very senior clinicians because of the pay differential between the outside world and the government. But at the junior level, where salary equity is possible, we have not had the recruitments of new investigators, despite the fact that just as I came in with negotiations with the Lasker Foundation, we have a new Lasker scholars program and I'm alarmed when I ask friends about the Lasker scholars program, they don't know what it is.

It's a program that supports young investigators who've already been tested and are known to be of high caliber to work in the intramural program for at least six years, a tenure track, and then have an option to go back to academia for a couple more years, doing clinical research without the routine clinical responsibilities that are usually imposed with academic health centers. What's wrong with that?

But we've had very few recruits for this program and that troubles me greatly because the vitality of the clinical centers depend to a very large extent on how well we do in bringing new people in to establish new clinical programs.

Now the NCI has outstanding programs that are well known in immunotherapy and lymphoma and renal carcinoma and other areas, but we as an institution need to find what the objectives will be in clinical research over the next 10-20 years. And I've asked my intramural team to come up with those and I hope they have a chance to vet those in front of you sometime in the near future, because I think our ability to recruit will depend not only on making programs like the Lasker program better known, but also by advertising the kinds of ambitions we have to do things with the tools available at the clinical center. Those tools are powerful and really very impressive once you get to see them up close.

So, we need to remember over the next several years, that the clinical research center is central to our mission and we at the NCI are already working closely with several other institutes that have similar high levels of involvement.

The NCI utilizes about 35-37 percent of the beds in the clinical center and there are five other institutes that have significant investments there out of the 20-something that have intramural programs. And we need to work closely with those with those fellow institutes to insure that sets of clinical research center remains vital, not just on this campus but as a national institution.

Some of you may know that we now have a cooperative agreement program that allows extramural

clinical investigators to work with people at the clinical center and make use of resources there and there have been successes but we don't have hundreds of applications by any means. And I think the opportunity for the clinical center to act as the centerpiece of the nation's clinical research efforts has been under-realized and more attention needs to be given to that.

Graduate Training

The last of these seven topics is my concern about providing from the NCI, a special kind of support for the investigator community at this difficult time.

Some of you are probably aware of the fact that I've been actively trying to—with three colleagues, Bruce Alberts, Marc Kirschner and Shirley Tilghman—to point out the plight that we've created as a part of our Malthusian dilemma: too many people pursuing expensive research with too little money. That has created an atmosphere of hyper-competition and frustration that I think is detrimental to the field which I entered at a time when I didn't worry about getting money, I worried about having a good idea.

And people should spend most of their time, more than they do now, thinking broadly about what the big unsolved problems are in cancer research. So I think those needs continued attention. I'm glad that the article we wrote is getting more attention; that there have been discussions on many major campuses.

I went to Duke recently, some my colleagues are going to the University of Wisconsin in a couple of weeks, and there's another one in the University of Michigan—groups of post-docs and students are having meetings to discuss some of the issues we raised in that article.

A number of major groups, FASEB, AAMC, the American Association of Universities, have had serious conversations. The four of us recently attended a group discussion at the AAU that was very, very productive.

They're thinking about experiments they can undertake, with the recognition that while, at times it seems as though university administrators and lab-bound scientists are at odds over certain issues about who gets carpet in their offices—in general we share the same general goals: to bring the highest level of research to American universities. And that the future of our country depends very heavily on research, and basic research is done almost entirely at universities, and increasingly when you go to university campuses, you recognize that medical research is one of the biggest things any university does.

And it's very striking whether you're at Hopkins, or Stanford, or the University of California system, or Harvard; that these institutions are now—I won't say dominated, but they have as very central feature, medical research. And if we don't have a productive and adventure-seeking community at those sites, we're in trouble.

So, there are places where the NIH generally, and the NCI, have a distinct role in trying to make corrections in a system that's gone a bit off the rails because of this Malthusian dilemma. It's hard to fix things because everything you do effects something else, but there are a number of points of attack—other than simply doing what we always are trying to do, which is to increase our budgets—that can provide help.

For example, supporting our outstanding people, focusing not just on projects but on past productivity and trying to stabilize the funding world for people who are among our best investigators, is critically important. We discussed here our new outstanding investigator award. The reviews and application of that award happening this week and so that's one of our efforts to try to bring some stability at least to the laboratories of some of our very best people.

There's general agreement that training takes too long, graduate school takes too long, it tends to be designed for one kind of career, namely a career that resembles the career of the graduate student mentor. Post-doc training is too long; people are starting independent careers too late.

So we're making efforts to try to accelerate training of the very best students, and you'll hear from [Jonathan] Wiest [director of the NCI Center for Cancer Training] in a moment about how we would like to do that.

It's important that graduate training be changed, and we should do some experiments. We re-established the credibility and importance of master's degrees in specialized areas. Perhaps have a different kind of Ph.D., not just one that's intended for someone who wants to be an academic investigator, but a Ph.D. for somebody who will do science policy or teaching of science in high school.

I think there are lots of ways we can manipulate graduate school curricula to cope with the new dilemma we're facing. Raising post-doctoral salaries will help. Acknowledging from the start of training that biology is an entry point to lots of kinds of careers—there's essentially no unemployment among Ph.D.'s in the biological sciences, but I don't think we're using the talents and the acquired skills in this cohort in the best possible way.

We will hear about a proposal that we're making for a new award that will be for a research specialist or staff scientist that addresses that problem to a certain degree, so people don't feel they're going through graduate school only to end up with the tough life that people face when they're lives depend on acquiring NIH grants to keep their careers afloat.

There are ways in which we can try to relieve the universities and, to a certain extent, scientists, of administrative burden. The American Association of Universities and National Academies of Science and others are paying attention to this.

We need to recognize that our country is becoming more diverse from a cultural and ethnic point of view and we need to find ways to appreciate that more profoundly. Last night I was over at the Howard Hughes Medical Institute and I heard them talk yet again about incredibly successful Meyerhoff program and we need to emulate that in ways to alleviate the particular level of difficulty faced by Hispanic and African-American folks that have aspirations to work in our world.

Team science has become the order of the day on many campuses even though everybody talks about independence. So finding some happy medium that allows people to work in teams which are often effective, and I'll just cite what happened in The Cancer Genome Atlas project, all team science, all happy to do it, but what kind of credit do you get for it? You need to do things that help accord proper credit.

One of the things I've tried to do is getting the NIH biosketch changed to allow people to present themselves as scientists, not simply by being one of 50 co-authors of a paper that happens to be in a good journal, but being able to describe what they've contributed to team science as well as science carried out in a small laboratory.

I think there are many ways in which we can reduce the cost of research and help alleviate the difficulty we're in financially. More shared facilities, and more staff scientists working between labs and other things that I think can approve the efficiency of the way we spend our money.

And we need to pay attention to the atmospherics; that is how people are evaluated and peer-reviewed. The NIH is now, after a bit more time that I would have liked, declared that it is expectation that every grant holder at the NIH that is asked to serve on a study section will serve.

Now, in fact, I think many do, we just have a lot of applications to review, and the study sections are not always ideally equipped to evaluate the work of so many applicants, but I think urging and making clear our expectation that everybody will serve when they're asked is an important step.

The more attention we pay to the way we evaluate publications is just wrong in this day and age when we have the tools, we have promulgating our work, and people need to have the recognition for work done, that paper is going back and forth between investigators and journal editors for a year or two years while people are struggling to get jobs. This is insane. This group could play a role in doing things about that.

A penultimate word about what this group does. We are here to review what we do. The review of existing programs is critical, especially in days of financial distress.

We cannot grow, make new programs, or enlarge new successful programs, unless we have some way to curtail the things we're doing, especially if the budget remains flat. It's easy to expand our world as was true in the 90's when a five percent increase in our budget was only mediocre, and that's an ironic thought—but it's a real one.

So as far as I can see, the budget's going to be pretty flat for the next five years or so, and that means that reviewing programs with the intent to award and expand those that are doing well, or curtailing those that aren't doing well, or have done well and served their purpose, is critical.

I would cite the review of this SPORE program which is now ongoing, which this group asked for. I would cite the changes we've made in other programs, deep structural changes in the way we conduct our clinical trials and the way we work with community cancer centers. Not reduce their budgets, but change the way they operate, because reviews have been useful. And same as been true with fiscal constraints as well, in incorporating physical sciences, for example, into NCI activities.

I've been extremely interested and proud of the Provocative Questions effort, but that too will need review sometime in the next few years to see if this little adventure, which has intellectual appeal, has been useful in producing good results.

Finally I want to thank my pal Dr. [Todd] Golub for taking on the chairmanship of this group and all of you for serving enthusiastically, and I delivered my commendations to my colleagues, Drs. Lowy and Doroshow before, but I want to thank them again for making my time here fun.

Lowy Discusses Reducing Cuts To Modular R01 Grants

Following Harold Varmus's remarks to the Board of Scientific Advisors, Douglas Lowy, soon-to-be acting director of the NCI, focused on reducing the amount of the planned cuts for modular R01 grants.

The plan is cut the reductions in half starting in this fiscal year, from the automatic 17 percent reduction to 8.5 percent, or cutting a 10 percent reduction to 5 percent.

"Our long-term goal is to try to eliminate those cuts completely, but this we estimate will cost about $10 million from the RPG pool, and we would like to see what the is impact on that," Lowy said.

A transcript of Lowy's remarks follows:

Thanks, good morning everyone, although I have not yet become acting director, I have already resisted the temptation to have slides.

I'm going to focus on the subject that I discussed with everyone at the joint BSA-NCAB meeting in December, which is the modular R01 grants.

And I asked during that presentation for input from you all, and largely there was enthusiasm for trying to increase the size of modular awards. Just to remind you, there are two components to that: one is the cuts we have for most of the award system; automatic 17 percent reductions. And then the second, which can only be done by the NIH, is to try to increase the ultimate size.

So after our discussion, it seemed that trying to increase the size of the awards was probably not something to be done in the very short term. On the other hand, there seemed to be enthusiasm for trying to reduce the amount of the cuts.

So, at the NCI leadership retreat, which [BSA Member] Curt [Civin, associate dean of research at the University of Maryland School of Medicine] participated in and was active and constructive in his comments, we refined this a little bit more and then, at a recent SPO meeting we discussed it as well, and what the policy that we are going to be putting forth in the next few days is to cut in half the automatic reductions for the modular R01 grants.

This does not apply to the non-modular grants and it does not apply to the R21 awards although they also are modular. So, the majority of those awards have carried up to now an automatic 17 percent reduction. A minority of them have had an automatic 10 percent reduction. Starting in this fiscal year, we will reduce the cuts from 17 to 8.5 percent, or from 10 to 5.

Our long-term goal is to try to eliminate those cuts completely, but this we estimate will cost about $10 million from the RPG pool, and we would like to see what the is impact on that. Plus, as you're aware, there are other changes with the RPG pool that will be going on. For example, the outstanding investigator award, and we just want to see where we stand. And importantly, in FY16, what will the budget be?

So, that is really the follow up that I have to discuss with you about the modular awards. I hope, maybe sometime later this year, we will tackle the more complicated problem of trying to ultimately raise the maximum size of the modular grants.

ASCO Announces Winners Of 2015 Special Awards

The American Society of Clinical Oncology announced the winners of its Special Awards Program.

The Special Awards recognize the dedication and significant contributions of researchers, patient advocates, and leaders of the global oncology community to enhancing cancer prevention, treatment, and patient care.

ASCO also named seven recipients of the Fellows of the American Society of Clinical Oncology distinction.

All of the awards and fellowships will be presented at the 2015 ASCO Annual Meeting, taking place in Chicago, May 29-June 2, with the exception of the Gianni Bonadonna Breast Cancer Award and Lecture, which will be presented at the 2015 Breast Cancer Symposium, Sept. 25-27 in San Francisco.

The 2015 Special Awards Honorees are:

• **Suzanne Topalian**, winner of the David A. Karnofsky Memorial Award and Lecture, is professor of surgery and oncology and director of the Melanoma Program in the Sidney Kimmel Comprehensive Cancer Center at the Johns Hopkins University School of Medicine.

Topalian's studies of human antitumor immunity have provided a foundation for the translational development of cancer vaccines, adoptive T-cell transfer, and immunomodulatory monoclonal antibodies. Her current research focuses on manipulating immune checkpoints such as programmed cell death-1 in cancer therapy and the discovery of biomarkers to aid in the development of these therapies.

• **James Allison**, winner of the Science of Oncology Award and Lecture, is professor and chair of the MD Anderson Cancer Center Department of Immunology.

Allison directs the Immunotherapy Platform and is deputy director of the David H. Koch Center for Applied Research in Genitourinary Cancers. He also is a Howard Hughes Medical Institute Investigator. His research focuses on T cell response mechanisms and applying that basic understanding to overcome cancer's evasion of attack by the immune system. These discoveries led to the clinical development of ipilimumab to block CTLA-4.

• **Ernest Hawk**, winner of the ASCO-American Cancer Society Award and Lecture, is vice president and head of the Division of Cancer Prevention and Population Sciences at MD Anderson Cancer Center, co-leader of the institution's Cancer Control Platform, executive director of the Duncan Family Institute for Cancer Prevention and Risk Assessment, and the Boone Pickens Distinguished Chair for Early Prevention of Cancer.

Hawk's research interests include preclinical and clinical chemoprevention; integrating risk assessment and preventive interventions in clinical trials; and increasing the participation of minority and underserved populations in translational and clinical research.

• **Silvio Monfardini**, winner of the B.J. Kennedy Award and Lecture for Scientific Excellence in Geriatric Oncology, is director of the Geriatric Oncology Program at Istituto Palazzolo, Fondazione Don Gnocchi, in Milan, Italy.

Monfardini has served as past president of the European Society for Medical Oncology (1984-1987), the Associazione Italiana di Oncologia Medica (1986-1988), and the International Society of Geriatric Oncology (2003-2004). Monfardini has also served as chief of the Division of Medical Oncology of the Istituto Oncologico Veneto of Padua, scientific director of the Istituto Nazionale per lo Studio e la Cura dei Tumori di Napoli, and scientific director of the Centro di Riferimento Oncologico of Aviano. He has authored more than 340 indexed publications in oncology, more than 95 of which are dedicated to geriatric oncology.

• **George Bosl**, winner of the Distinguished Achievement Award, is the Patrick M. Byrne Chair in Clinical Oncology at Memorial Sloan Kettering Cancer Center and is a professor of medicine at the Weill Cornell Medical College. Bosl is also chair of the MSKCC Department of Medicine. He served on the ASCO Board of Directors and was editor-in-chief of the Journal of Clinical Oncology.

Known for his work in the management of testicular cancer, Bosl also cared for patients with other genitourinary cancers and head and neck malignancies and was an early investigator in the application of larynx preservation techniques.

• **Dean Bajorin**, winner of the Excellence in Teaching Award, is an attending physician and member at Memorial Hospital at Memorial Sloan Kettering Cancer Center and is a professor of medicine at Weill Medical College of Cornell University in New York, serving as a member of the MSKCC Genitourinary Oncology faculty.

Bajorin is the director of MSKCC's Medical Oncology/Hematology Fellowship Program and the Advanced Oncology Fellowship Program. Bajorin's research focus is on the development of novel treatments for patients with genitourinary cancers, and he has published extensively in this area. He also has served as a reviewer for genitourinary cancer research in the Journal of Clinical Oncology and the New England Journal of Medicine.

• **Matthew Ellis**, winner of the Gianni Bonadonna Breast Cancer Award and Lecture, is co-leader for The Cancer Genome Atlas Breast Project and co-PI for the Clinical Proteomic Tumor Analysis Consortium that works to translate TCGA genomic discoveries into protein-based biomarkers with clinical utility. Ellis is director of the Lester and Sue Smith Breast Center and professor of Medicine and Cellular and Molecular Biology at Baylor College of Medicine.

Ellis has been instrumental in developing a Genome Atlas and Therapeutic Road Map for estrogen receptor-positive breast cancer. He also pioneered research into the clinical relevance of activating mutations in HER2 and in the deployment of patient-derived xenografts for the pharmacological annotation of breast cancer genomes.

• **Jose Angel Sanchez**, winner of the Humanitarian Award, is a hematologic oncologist at Hospital Escuela at the University of Honduras. He volunteers for the International Cancer Corps/Health Volunteer Overseas, which partners with oncologists and oncology nurses to discuss the needs of patients and health care providers in Honduras.

• **Mary Lou Smith**, winner of the Partners in Progress Award, co-founded the Research Advocacy Network.

Using focus groups and surveys, RAN has gathered information about patients' preferences for

various treatments to better understand the trade-offs they make between benefits and side effects. Smith is also co-chair of the Eastern Cooperative Oncology Group-American College of Radiology Imaging Network Cancer Research Advocate Committee and a member of the NCI Board of Scientific Advisors.

• **Stephen Sallan**, winner of the Pediatric Oncology Award and Lecture, is professor of Pediatrics at Harvard Medical School, and a pediatric oncologist at Dana-Farber Cancer Institute and Boston Children's Hospital. His research has focused on better understanding acute lymphoblastic leukemia.

• **Archie Bleyer**, winner of the Special Recognition Award, is a clinical research professor at the Knight Cancer Institute of the Oregon Health & Science University. He also served as chair of the Children's Cancer Group, the world's largest pediatric cancer research organization, and as the American Cancer Society professor at the University of Washington and head of the Division of Pediatrics at MD Anderson Cancer Center. He was a founding member of Critical Mass, an advocacy organization focused the treatment of young adults with cancer.

The Fellow of the American Society of Clinical Oncology distinction recognizes ASCO members for their extraordinary volunteer service, dedication, and commitment to ASCO.

The 2015 recipients of this distinction are:

• **Kathy Albain**, of Loyola University
• **Craig Earle**, of the Ontario Institute for Cancer Research
• **Roscoe Morton**, of the Cancer Center of Iowa
• **Lori Pierce**, of the University of Michigan
• **Lillian Siu**, of the University of Toronto
• **Eric Small**, of the University of California, San Francisco
• **Sandra Swain,** of the Washington Cancer Institute

In Brief

Khuri Named President of American Univ. of Beirut

(Continued from page 1)

and executive associate dean for research at Emory University School of Medicine.

Khuri, who grew up in Beirut, is also the Roberto C. Goizueta Distinguished Chair for Cancer Research. He previously served on the faculty of the MD Anderson Cancer Center.

His maternal great grandfathers, paternal grandfather, father and mother were all graduates of AUB. His father served as chair of the school's Department of Physiology and dean of the AUB Medical School.

"My 13 years at Emory have been professionally the happiest and most productive years of my life," Khuri said. "Emory has afforded me the opportunity to grow personally and professionally thanks to the collaborative and creative environment that is fostered here. I am grateful to have had the opportunity to work with, learn from and mentor some of the finest scholars and individuals in the world. I am especially grateful to all of my patients for everything they have taught me."

PHILIP LOW was awarded the ninth annual Award for Outstanding Achievement in Chemistry in Cancer Research by the **American Association for Cancer Research**.

Low is the Ralph C. Corley distinguished professor of chemistry and director of the Center for Drug Discovery at Purdue University. He is also a founder and chief science officer of two biopharmaceutical companies, Endocyte Inc. and On Target Laboratories LLC.

He will receive the award at the AACR 2015 annual meeting, to be held in Philadelphia, April 18-22. He will also present the award lecture, "Ligand-targeted Imaging and Therapeutic Agents for Cancer."

Low is being recognized for his pioneering development of low molecular weight ligands to deliver attached therapeutic and imaging agents selectively into pathologic cells such as cancer cells.

This targeted therapeutic approach improves potency and reduces toxicity. Currently, there are nine low molecular weight ligand-targeted drugs being tested in cancer clinical trials. One of these drugs uses folic acid to target the highly toxic chemotherapeutic agent desacetylvinblastine hydrazide to cancer cells bearing the folate receptor.

In 2011, the first fluorescence-guided surgery was performed on an ovarian cancer patient using the technology invented by Low: Surgeons were able to see clusters of cancer cells as small as one-tenth of a millimeter, as opposed to the average minimal cluster size of 2 millimeters in diameter using the current visual and tactile detection.

Low's research on low molecular weight ligand-targeted therapeutic and imaging agents has yielded more than 40 U.S. patents or patents pending.

His achievements have been recognized by numerous awards throughout his career, including the Morrill Award, the American Chemical Society's Award for Cancer Research (George and Christine Sosnovsky Award), the Watanabe Life Sciences Champion of the Year Award, and Brigham Young University's Distinguished Alumnus Award. He has also been elected to the National Academy of Inventors.

JULIE JOHNSON was awarded the 2015 Distinguished Scientist Award from the **Southeastern Universities Research Association**. Johnson is the dean of the University of Florida's College of Pharmacy.

As the head of UF's Personalized Medicine Program, Johnson's work has led to the use of genetic information to guide drug therapy decisions for patients at UF Health Shands Hospital.

In 2013, she was a member of the collaborative team that found a way to make a blood thinner safer by linking a gene variation to the dosage for some 40 percent of African-Americans who are prescribed the drug. In addition, her research has led to substantial advances in the understanding of antihypertensive and other cardiovascular drugs.

Johnson joined the UF faculty as an associate professor in 1998 after nine years with the University of Tennessee Health Science Center. She went on to become a distinguished professor in pharmacy and medicine, and in August 2013 was named the seventh dean of UF's College of Pharmacy. She is a member of the Institute of Medicine of the National Academies.

The award and its $10,000 honorarium are presented annually to a research scientist whose work fulfills SURA's mission to strengthen the scientific capabilities of its members and the nation. SURA is a nonprofit consortium of over 60 research institutions in the southern United States and the District of Columbia.

THOMAS MERCHANT was named chair of the Department of Radiation Oncology at **St. Jude Children's Research Hospital**. Merchant will also hold the Baddia J. Rashid Endowed Chair in Radiation Oncology.

Merchant joined St. Jude in 1996. His work with conformal radiation therapy for central nervous system tumors is the basis for guidelines used in most of the national cooperative group pediatric brain tumor trials, and he has led the development of treatment guidelines for intensity-modulated radiation therapy and proton therapy in all types of pediatric brain and solid tumors, according to St. Jude.

Merchant becomes chair of a department that was previously a division of St. Jude Radiological Sciences. St. Jude divided its radiological sciences area into two departments—Radiation Oncology and Diagnostic Imaging. **Larry Kun**, St. Jude clinical director and executive vice president, will head Diagnostic Imaging until a chair is appointed.

THE COMMUNITY ONCOLOGY ALLIANCE formed the **Community Oncology Pharmacy Association**.

COPA is a non-profit, non-commercial organization, under the direction of the COA Board of Directors, dedicated to addressing a variety of pharmacy issues.

COPA will establish standards, provide education and resources, work to enhance the exchange of information, and advocate for a model of integrated cancer care, with a special focus on oral cancer drugs, according to the association.

"Due to the increasing costs of cancer drugs, there are commercial interests, such as specialty pharmacies, attempting to separate oral cancer therapy from the point of care and oncologist control, thus interfering with the physician-patient relationship," said Ted Okon, COA executive director. "COPA was created to provide support to practice-based pharmacies while preserving the physician-patient relationship."

"The mission of COPA is to foster oral cancer therapy that is tightly integrated into cancer patient treatment at the site of care," said Ricky Newton, COA director of financial services and operations and a former oncology practice administrator. "Over two-thirds of all cancer patients receive their care from community oncologists, and oral cancer drugs are playing an increasing role in cancer treatment."

Drugs and Targets

EU Approves Jakavi in Polycythemia Vera

The European Commission approved Jakavi (ruxolitinib) for the treatment of adult patients with polycythemia vera who are resistant to or intolerant of hydroxyurea. Jakavi is the first targeted treatment approved by the European Commission for these patients.

The approval is based on data from the phase III RESPONSE clinical trial demonstrating that a significantly greater proportion of patients achieved the composite primary endpoint of hematocrit control without use of phlebotomy and spleen size reduction when treated with Jakavi compared to best available therapy (21 percent compared to 1 percent, respectively; $p<0.0001$).

In the study, a 50 percent or more improvement in PV-related symptoms was seen in 49 percent of Jakavi-treated patients compared to 5 percent of patients treated with best available therapy.

RESPONSE is a global, randomized, open-label trial conducted at more than 90 trial sites. 222 patients with PV resistant to or intolerant of hydroxyurea were randomized 1:1 to receive either Jakavi or best available therapy, which was defined as investigator-selected monotherapy or observation only.

The Jakavi dose was adjusted as needed throughout the trial. In the Jakavi arm, patients had a PV diagnosis for a median of 8.2 years and had previously received hydroxyurea for a median of approximately three years. Most patients had received at least two phlebotomies in the last 24 weeks prior to screening.

Novartis licensed ruxolitinib from Incyte Corporation for development and commercialization outside the U.S. Jakavi is marketed in the U.S. by Incyte Corporation as Jakafi for the treatment of patients with PV who have had an inadequate response to or are intolerant of hydroxyurea and for the treatment of patients with intermediate or high-risk myelofibrosis.

The European Medicines Agency granted an orphan drug designation to ImMucin for the treatment of multiple myeloma. ImMucin targets the less studied signal peptide domain of the MUC1 tumor antigen.

Orphan designation provides significant benefits, including ten years of market exclusivity following marketing approval, reductions in the fees and costs of the regulatory process and scientific assistance from the EMA in clinical development.

ImMucin, teaches the patient's immune system to identify and destroy cells which display a short specific 21-mer portion from the cancer target MUC1, which appears on 90 percent of all cancers cells but not in patients' blood.

In 2013, Vaxil, the drug's sponsor, completed a phase I/II clinical study with ImMucin on multiple myeloma patients which showed high safety profile, strong diversified T/B-cell immunity in all 15 patients across MHC repertoire and initial indications for clinical efficacy; 11 out of the 15 patients demonstrating stable disease or clinical improvement which did not require any further treatment.

The Hong Kong Department of Health approved Abraxane (albumin-bound paclitaxel) for use in combination with gemcitabine as first-line treatment for patients with late-stage pancreatic cancer.

The approval was based on the results of an open-label, randomized, international phase III clinical trial, one of the largest ever conducted in metastatic pancreatic cancer. The study included 861 participants and compared treatment with Abraxane plus gemcitabine with gemcitabine alone. Participants treated with Abraxane demonstrated a statistically significant improvement in overall survival with a 28 percent reduction in risk of death (8.7 vs 6.6 months; HR=0.72; $p<0.001$).

Abraxane, marketed by Celgene Corporation, was first approved in January 2005 by FDA for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy.

In October 2012, Abraxane was approved by the FDA for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy. In September 2013, the FDA approved Abraxane as first-line treatment of patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.