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DePinho Accepts Responsibility As MD Anderson's Losses Grow

By Paul Goldberg

Operating losses at MD Anderson Cancer Center ballooned again in October—swelling to \$60.9 million on top of September's \$41.5 million.

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Senate Approves 21st Century Cures; CR Slates \$300M for NCI and Moonshot

By Matthew Bin Han Ong

The Senate approved the 21st Century Cures Act, a wide-ranging bill that authorizes \$1.8 billion over seven years for cancer research as well as \$500 million over the next decade for FDA to streamline drug and device approval processes.

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Being an Acting Director, NCI's Lowy Isn't Required to Submit Resignation

By Matthew Bin Han Ong

Doug Lowy will continue to lead NCI in his role as acting director in 2017 unless president-elect Donald Trump decides to appoint a different, new director.

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DePinho Accepts Responsibility As MD Anderson's Losses Grow

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Losses for the first two months of fiscal year 2017 add up to \$102.4 million, and the institution's executives are scrambling to cut costs, boost revenues, and shore up faculty morale.

"Who is accountable for the financial performance? I take full responsibility for the challenges," MD Anderson President Ronald DePinho said Nov. 15, addressing a faculty forum convened to discuss the institution's finances.

The task of finding the solution to this problem lies squarely on the shoulders of everyone at MD Anderson, DePinho said.

"I also have learned that in this room, our collective wisdom, capability our knowledge, our efforts are the solution, and all of us coming together is going to be important, so the solution really lies with all of us, so our responsibilities are adjoined in that regard," DePinho said.

The forum was open to MD Anderson faculty only, and a recording is posted on an internal website.

MD Anderson executives are urging faculty members to add clinical days and make efforts to convince out-of-town patients to remain at the Houston-based cancer center for the duration of their treatments. Also discussed are frugality measures, including eliminating overtime, instituting a hiring

freeze, curbing catering, and turning holiday parties into potluck events.

MD Anderson officials often repeat that the center's long-term financial outlook is strong.

"Like other major health care institutions locally and nationwide, we are facing decreasing clinical reimbursement from government and insurance companies, a shrinking pool of potential patients as insurance providers restrict coverage, and record rates of automatic denials by insurance companies contributing to bad debt," MD Anderson's four top executives wrote in a recent email.

Other large freestanding cancer centers aren't reporting operating losses:

- Memorial Sloan Kettering Cancer Center, an institution similar in size and stature to MD Anderson, reported \$164 million in operating income through the first nine months this year, a 14.6% increase from the same period last year. Growth in the volume of outpatient visits and overall surgical visits resulted in an 8.9% growth in operating revenue to \$2.9 billion. Operating expenses grew 8.6% to \$2.8 billion.
- Fred Hutchinson Cancer Research Center reported total revenues of \$126.4 million and operating expenses of \$117.1 million, giving it a \$9.3 million operating surplus for the first quarter, which ended Sept. 30, 2016. For the fiscal year ended June 30, Fred Hutchinson reported total revenues of \$615.5 million and expenses of \$484.6 million, creating a \$130.9 million surplus.

DePinho has triggered several controversies over his five years at MD Anderson, but past controversies—such as famously appearing on a Wall Street television show and touting the stock of a company he cofounded and in which he held stock—occurred when MD Anderson was in the black.

"MD Anderson has reserves and non-operating revenues that give us the opportunity to adjust our operating revenue and expense structure without making overly drastic changes," Dan Fontaine, MD Anderson executive vice president for administration said to The Cancer Letter. "We are implementing action plans now to ensure we can address short-term losses and maintain our focus on our mission."

Fontaine said that, these two months notwithstanding, the institution is projecting a positive

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City of Hope

has formed an alliance with

Translational Genomics Research Institute (TGen).

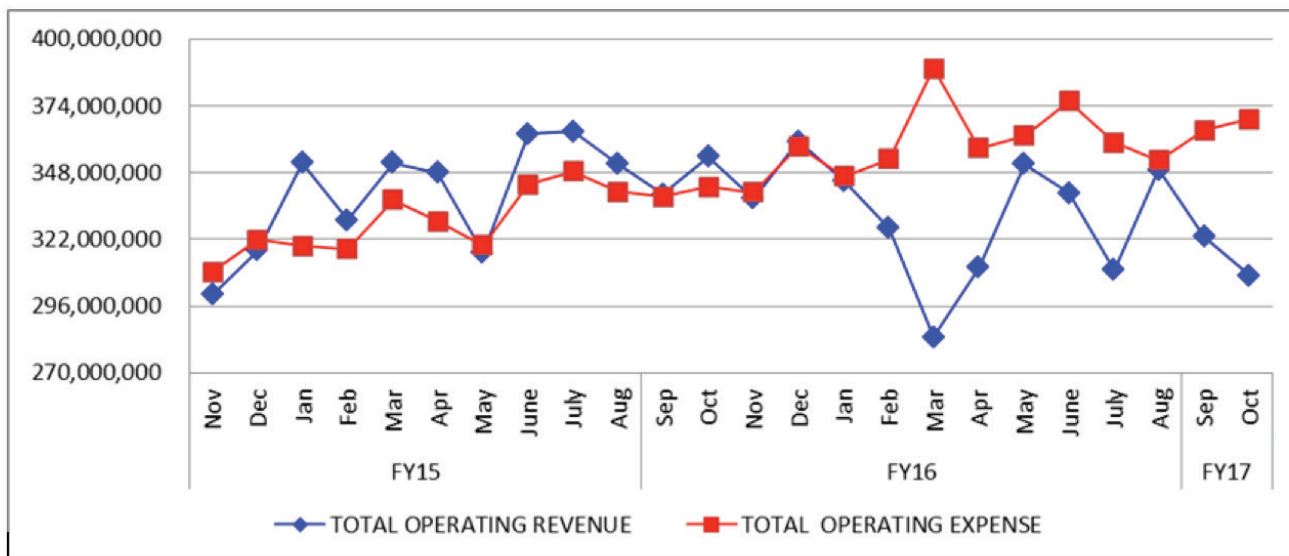
On November 16, 2016, City of Hope formed an alliance with TGen to create the future of precision medicine for patients.



1500 East Duarte Road
Duarte, CA 91010
CityofHope.org



445 N. Fifth St.
Phoenix, AZ 85004
tgen.org



Source: "Our Finances: October 2016," an overview document sent to MD Anderson executives, department chairs, administrators and clinical and research faculty.

operating margin in fiscal 2017.

Stamped "CONFIDENTIAL" and "For Management Use Only," MD Anderson's financial report for October indicates that gross operating revenues—\$307.9 million—were \$70.2 million below budget. Expenses—\$368.8 million—were \$15.9 million lower than the budgeted level.

Total operating revenues for September and October were at \$630.8 million—\$109.7 million below budget.

Average daily census was budgeted at 629 beds in October. The actual census was 8.8 percent lower—574 beds.

If high census alerts are an indication, even with these lower than projected occupancy levels, the hospital slips into overcrowding. For example, on Nov. 16, the morning after DePinho addressed the faculty, MD Anderson issued a census alert, declaring that it was more than 90 percent full.

Clinicians were urged to:

- Please prepare patients being admitted for extended wait times
- Please prepare for possible delays in the OR
- Please prepare for the possible need to reschedule patients
- Please assess patients in the MICU for readiness to transfer to primary units.

The October financial report is posted [here](#). MD Anderson lost \$267.1 million on its operations

during the fiscal year 2016, which ended Aug. 31.

In September, the first month of the current fiscal year, the institute's officials projected that unless costs are slashed and revenues boosted, losses would reach \$400 million to \$450 million (The Cancer Letter, [Dec. 2](#)).

"We have taken significant efforts to proactively and transparently communicate with our faculty and staff regarding our finances," Stephen Hahn, Division Head, Radiation Oncology, said in a letter to the editor published in The Cancer Letter last week. "Through a series of meetings, forums and communications, we are openly facing our concerns as a community and empowering all faculty and staff to be part of the solution in reducing expenses and increasing revenues. Due to our early and swift actions, we continue to project a positive margin for Fiscal Year 2017."

"Nothing is off the table"

At the Nov. 15 faculty forum, DePinho said all programs, including his signature Moon Shots program, could end up getting trimmed.

This is noteworthy, because MD Anderson recently filed a suit as well as opposition motions with the Patent and Trademark Office, alleging that the entrepreneur Patrick Soon-Shiong has infringed MD Anderson's Moon Shots trademark (The Cancer Letter, [Nov. 18](#)).

"Nothing is off the table, and I am committed to reviewing and reprioritizing all our operational investments and looking for expense reductions in

programs including the Moon Shots,” DePinho said at the faculty meeting. “It’s important that we have to address the short term needs, but at other times in the history of the institution—even in 2008 and 2009—we continue make really important strategic investments that will continue to allow the institution to maintain its preeminent status, and we are going to continue to do so.”

Responding to questions from The Cancer Letter, Fontaine confirmed that the Moon Shots aren’t immune from trims.

“We are reviewing and reprioritizing our operational investments and looking for expense reductions in all programs, including the Moon Shots Program,” Fontaine said.

Fontaine acknowledged that plans for staff reductions are being considered.

“We are working collaboratively to increase revenues and decrease expenses to avoid the difficult decision of reducing our dedicated workforce. Personnel costs continue to be our largest expense,” Fontaine said. “While every measure is being taken to avoid reducing positions, we must have plans in place in case that option becomes necessary.

“It is an action none of us wants, but it has to be considered to preserve the long-term financial health of the institution. All personnel decisions will be guided by compassion and thoughtfulness.”

In September, a group of MD Anderson officials attributed the institution’s sagging financials to four factors (The Cancer Letter, [Nov. 4](#)):

- Epic system (tools, reports, technology fixes);
- Providers – Capacity (Mondays & Fridays; weekends for select services; services at right location);
- Demand (wait times, rate of incoming calls/ requests to set up appointments);
- Insurance coverage.

At other institutions, moving to Epic and other electronic medical record systems enabled physicians to capture more charges, but, with each encounter requiring capturing data, doctors report seeing fewer patients.

At the faculty forum Nov. 15, DePinho characterized the institution’s problems as short-term.

“We are all concerned about the financial situation, but I am very confident we will be able to get our finances back on track,” he said. “A couple of

key points that I want to emphasize:

“No. 1: The situation requires serious attention, but it is not out of control, our long term balance sheet is strong.

“No. 2: In order to remain on solid footing, we have to take actions now, and we are doing just that. We budgeted for a loss for the first few months, but the numbers are larger than anticipated.

“No. 3: Everybody is part of the solution. That is why I was very grateful of having this forum and many other interactions across the institution and it’s been really heartening to see everybody work together toward common goals.”

A \$52 Million Contract with PricewaterhouseCoopers

At the Nov. 15 faculty forum there appeared to be no discussion of cutting the Institute for Applied Cancer Science, an in-house hybrid of an academic cancer center and a drug company, one of DePinho’s signature programs.

In a recent editorial in ASCO Post, DePinho wrote that IACS employs about 100 “industry-seasoned professionals,” who “interact with MD Anderson’s critical mass of 1,700 accomplished faculty, which is supported by an approximately \$800 million annual research budget focused on cancer.”

Actual expenditures on IACS and the manner in which they are offset by industry royalties and contracts aren’t publicly known.

At the faculty forum, DePinho was asked about MD Anderson’s plan to spend up to \$52 million over three years to build a hardware and software system that would integrate longitudinal, patient-level clinical and research data.

The system would be financed through hospital revenues and built by PricewaterhouseCoopers Services LLC. The proposal was approved by the UT System Board of Regents at its meeting Nov. 9-10.

A faculty member asked DePinho to pinpoint the long-term initiative to which the project is tied. “With the financial downturn and the possibility of reduction in workforce, FTEs, these funds will undoubtedly come from clinical revenue, how are you going to address this with the employees of our institution?” the faculty member asked.

DePinho’s comments appear to signal that there would be some leeway on the project and that the need to balance the institution’s long-term investments would need to be balanced against its shortfalls.

“That’s an approval [of the \$52 million contract],

October Key Drivers

Gross Patient Revenue	Red Status	Our total gross patient revenue was 11.1% under budget for October. Many factors are contributing to this decline but clinical activity is a priority. Read the latest update on plans to increase clinical activity .
Personnel Expense	Green Status	Caution: Thanks to your efforts, we've made progress in reducing this expense. But, it still remains our largest expense and we're still spending more than we're making. We must rethink the way we work and staff to our current workload.
Managing Overtime	Yellow Status	Thanks to your efforts, we saw a decline in overtime costs. More information will be shared by email and on the Our Finances blog on steps to take to further reduce these expenses.
Purchased Services	Red Status	We exceeded the budget by 5.3%. We must do everything necessary to eliminate or significantly reduce costs so that we stay under budget.

■ > 5% loss to budget
 ■ +/- 5% to budget
 ■ > 5% to budget

Source:

"Our Finances: October 2016," an overview document sent to MD Anderson executives, department chairs, administrators and clinical and research faculty.

but not a commitment, and in the contract we have the right to terminate, so we can move forward with that or not, depending on what the financial situation is, and that's, quite frankly, true for everything," DePinho said.

"The reality is, with respect to our data infrastructure for research, there are 50 different research databases throughout our departments, and its incredibly expensive to maintain.

"This is an attempt to integrate, so everyone in this room here could take advantage of the data that's being generated across the entire institution, which would be a game changer, so we are actually the leading institution in the nation right now that are integrating clinical and research data, thanks to the efforts of a lot of folks on the faculty, and so the idea is to create that infrastructure that allows us to do things efficiently, which all institutions are trying to move towards. We just happen to be in the leadership role.

"Having said that, we have to look at all the investments we are making, even though that might be a cost-saving in the longer term, we've got to be very careful in what investments we make."

Responding to questions from The Cancer Letter, Fontaine confirmed that the \$52 million may or may not change hands.

"MD Anderson received approval from the Board of Regents to enter into a contract for services to assist in the building of such a system," Fontaine said. "That contract does not obligate MD Anderson to expend the funds and may be terminated on short notice at any time. Currently, all programs involving capital investment, including this one, are being reviewed for appropriate adjustments to assist in returning the institution to consistent monthly operating margins."

A Global Problem?

In an email to the faculty and staff, MD Anderson's top executive—DePinho, Fontaine, Executive Vice President and Physician-in-Chief Tom Buchholz, and Provost and Executive Vice President Ethan Dmitrovsky—described their institution's problem as analogous to those affecting other cancer centers:

The long-term financials of the institution are strong, yet our current revenue and expense numbers require urgent action to maintain our mission.

Like other major health care institutions locally and nationwide, we are facing decreasing clinical reimbursement from government and insurance companies, a shrinking pool of potential patients as insurance providers restrict coverage, and record rates of automatic denials by insurance companies contributing to bad debt.

We have many long-term solutions for this evolving health care revolution. In the near term, leaders across the institution have been implementing robust changes to control or eliminate expenses, increase productivity and better use our people in critical positions or shared services.

We must be as efficient as possible while improving quality and patient satisfaction, and continuing to invest in our mission. Many of you have been involved in these efforts, and we thank you for your contributions. The financials from October, however, show we must do more as teams and individuals.

Now is the time for our core values to guide our hard work and decisions. Personnel costs continue to be our largest expense. While every measure is being taken to avoid reducing positions, we must have plans in place in case that option becomes necessary. It is an action none of us wants, but it has to be considered to preserve the health of the institution. We can assure you that any personnel decisions will be guided by compassion and thoughtfulness.

We're more committed than ever to frequent communication. We're posting questions and answers, along with other communications, on the [MD Anderson – Our](#)

[Finances site](#). [The site cannot be accessed outside MD Anderson]. Expect to see updates often.

We are the most impactful cancer center in the world. We thank you for your commitment to doing everything you can to help us navigate the opportunities and challenges of an evolving health care system. Our patients are counting on us to cure their disease and to push the frontiers of knowledge for future generations. Together, we can continue fulfilling our shared mission to end cancer.

In another email, dated Nov. 12, Buchholz set forth the new guidelines for increasing clinical activity:

As you are aware, we have been acutely monitoring our financial performance since last March. Our Shared Governance Committee, ECOT and administrative leadership team is committed fully to reducing expenses across our entire organization and rectifying any identified loss in revenue capture. We will share details on these efforts soon.

While there are many factors that contributed to this situation, our revenue shortfall is directly tied to the decrease in our upstream clinical activity and downstream volumes. In July, we requested that each faculty member increase activity. We were able to realize some gains in the month of August, but the activity for September and October left a sobering shortfall in operating revenue.

At the end of last week, I chaired a meeting with Clinical Department Chairs and Center Medical Directors to discuss immediate actions, because our current path is unsustainable. The methodology we have used to increase clinical activity has not worked thus far. We agreed we need a new strategy to increase our activity numbers and afford patients access to our outstanding clinical care.

Starting in the month of November, all **clinical care faculty should add one day in clinic per month to see new patients**. The implementation of this must be done in coordination with the CMD and CAD of the center. Currently, we have a large percentage of blocked clinic days due to faculty travel or PTO. These days will now be used to schedule new patients for faculty who are present. We also will use times, such as Fridays, when many clinics historically have lighter schedules.

To fill these slots, we will reduce and, in some cases, eliminate medical acceptance criteria. We will commit to see **local patients within 48 hours and consultations from our colleagues within 48 hours**.

During our meeting, we recognized that some services already have open templates and no demand to fill current capacity. In these cases, if the Chair and CMD confirm with their access team that there is no delay in accepting any new patient, then the templates will not be changed. If increasing template availability will result in any increase in activity, then we all commit to make the necessary changes. For those areas with low demand, we encourage the providers to work closely with Physician Relations to build referral relationships in the community.

In addition to increasing new patients, it is critical that we provide all patients the opportunity to receive their imaging, laboratory studies, chemotherapy and radiation

within our institution. We have seen a significant decrease in the utilization of these services and this has had a major impact on our financial performance.

At all times, the patient and their family must be our primary focus. Quality and safety can never be compromised. We must continue to strive toward high reliability and patient-centered, value driven care.

We recognize that we are potentially less efficient than in the past. Many of you asked for additional training so you can document patient care in the EHR with ease. A resource that helped me—and one that I hope will help you, too—is OneConnect's personalization training ([Register now](#) - search for "OneConnect and Dragon Personalization" to find dates and times). Departments also are able to schedule a OneConnect Tips & Tricks session at a provider meeting. Please invest your time in participating in these opportunities.

To achieve a rapid acceleration in activity, we ask that you communicate openly and respectfully across teams. We are MD Anderson, and we must demonstrate our core value of caring with patients and with each other. We share this situation and have the opportunity to share solutions, too.

Thank you for all you do to end cancer.

Separately, Buchholz urged MD Anderson physicians to convince their patients to stay at MD Anderson for the duration of their care instead of going home after initial treatment:

"Can't I just get treatment at home? They built a new cancer center in our city that has state-of-the-art equipment."

I've heard this hundreds of times during my career as a radiation oncologist at MD Anderson. I am sympathetic to those who ask the question. After all, radiation treatments for breast cancer typically take 4-6 weeks of daily outpatient treatments. To be displaced from your home, support system and family for that long is tough. In addition, the expenses to stay in Houston for that long are also quite burdensome.

Despite these difficulties, the majority of patients with whom I engage in this conversation elect to stay, because I tell them what makes MD Anderson special. It's not just experienced and thoughtful decision-making by outstanding subspecialty-trained oncologists, or even our state-of-the-art equipment (although that certainly helps). Rather, it's the implementation and execution of what we do that leads to superior outcomes.

I may have mentioned before that I know Phil Mickelson. He told me exactly what I need to do to hit a drive 300+ yards down the middle of the fairway. He's also let me test the high-tech driver he uses. Despite having the same knowledge and technology, my drives still mostly end up in the woods and barely reach 200 yards. See—implementation and execution are the key!

This year, we've seen a lower percentage of new patients stay for diagnostic studies and chemotherapy treatment. Patients may assume that if they are on a specific systemic therapy protocol, they can get the same quality of care at home. As they are considering this, we should inform them of the specific expertise here in our institution that may increase their chances for a positive outcome. For example, we perform over 11 million lab studies each year, almost exclusively in cancer patients. We perform over

500,000 diagnostic imaging studies for these same patients! Our technical staff and faculty in Pathology and Laboratory Medicine and in Diagnostic Imaging are the world's leaders in what they do. No wonder we so commonly change the diagnosis and/or stage of disease during review of outside studies. As an insider in the oncology industry, I know how important it is for patients to have this expertise on their side!

When it comes to treatment, our therapeutic delivery expertise isn't limited to radiation and surgery. Our chemotherapy nurses, advanced practice providers, clinical oncology pharmacists and technical support are industry-leading experts in systemic treatment delivery. We prepare medication on-site and have multiple safety checks in place to ensure the right patient receives the right treatment and has the right information to manage the side effects of these dangerous substances. While it might be impractical to fly in and out for every chemotherapy cycle, it's worthwhile to receive initial cycles here and return for restaging and additional treatments, when indicated.

I guess what they say in real estate is true in cancer care, too—LOCATION MATTERS! I want to encourage you to learn more about our excellent services by reaching out to some of the people who know just how special we are:

Path/Lab:

Stan Hamilton, M.D.; Liz Wagar, M.D.; Victor Prieto, M.D., Ph.D; Jeff Medeiros M.D.; Ignacio Wastuba, M.D.

Diagnostic Imaging:

Marshall Hicks M.D.; Joey Steele, M.D.

Chemotherapy delivery and support services:

Patrick Hwu, M.D. (Cancer Medicine); Joel Lajeunesse (Pharmacy); Carol Porter DNP (Nursing); Brenda Brown (Ambulatory Treatment Center)

Then share what you learn with our patients, so they too can be insiders in the oncology world and make informed decisions about their care.

Senate Approves 21st Century Cures; CR Slates \$300M for NCI and Moonshot

(Continued from page 1)

The bill, which passed by a vote of 94-5 on Dec. 7, authorizes \$4.976 billion for the NIH Innovation Account over 10 years. This money would fund Vice President Joe Biden's National Cancer Moonshot Initiative, the Precision Medicine and BRAIN Initiatives, and regenerative stem cell research.

In a direct endorsement of Biden's moonshot efforts, the first item in the nearly 1,000-page bill is named "Beau Biden Cancer Moonshot and NIH Innovation Projects," an indication that the funds for cancer research are to be used for moonshot priorities.

NIH and NCI are "extremely fortunate" that support for research in Congress is bipartisan, said NCI Acting Director Doug Lowy at a joint meeting of the National Cancer Advisory Board and the Board of Scientific Advisors.

"I want to point out that [the Cures Act] includes Blue Ribbon Panel recommendations, but it says specifically, 'Research that has the potential to transform the scientific field that has inherently higher risk and that seeks to address major challenges associated with cancer.' This actually is quite broad," Lowy said at the meeting Dec. 6.

The House version of the bill didn't mention the moonshot (The Cancer Letter, [Dec. 2](#)).

"We want to recognize and thank Majority Leader Mitch McConnell (R-Ky.) and Minority Leader Harry Reid (D-Nev.) for co-sponsoring an amendment that renamed the cancer portion of the bill after Vice President Joe Biden's son, Beau Biden, who passed away from brain cancer in May 2015," Nancy Davidson, president of the American Association for Cancer Research and director of the University of Pittsburgh Cancer Institute and AACR CEO Margaret Foti said in a joint statement.

The Beau Biden amendment appeared to be a surprise to Joe Biden, said M.K. Holohan Quattrocchi, director of the NCI Office of Government and Congressional Relations.

"The vice president was a very well-liked senator," Quattrocchi said at the advisory board meeting Dec. 6. "When the procedure vote was over and he was leaving the chamber, he told reporters that he was going to run for president in 2020. One reporter said, 'You know, we're going to run with that.'

"He said, 'Go ahead.' I don't know if that was just the emotion of the moment or if he's serious. He [had] a tissue in his hand, one of the clerks had snuck up some tissues to him."

President Barack Obama is expected to sign the legislation, despite opposition from consumer advocacy groups and a number of lawmakers, who said the bill fails to protect patients from harmful medical devices and will weaken FDA regulations in order to accelerate approval for drugs and devices (The Cancer Letter, [Dec. 2](#)).

Immediate Funding for NCI, FDA in CR

The Senate approval comes two days before the current continuing resolution expires Dec. 9. The House passed a second CR on Thursday that would keep the federal government funded through

April 28, 2017.

The GOP leadership decided to extend the CR into April—instead of March—after dropping the initial fiscal 2017 appropriations bills to tailor spending to Trump and Republican priorities (The Cancer Letter, [Nov. 18](#)).

The CR would also accommodate what lawmakers anticipate to be a packed legislative schedule in the first 100 days of president-elect Donald Trump's administration. This includes confirmation of presidential appointees and Supreme Court nominees.

The CR would extend funding for most federal agencies at a rate of operations that is 0.1901 percent below FY 2016 levels. According to a summary by the House Committee on Appropriations, the CR “maintains the current budget cap level of \$1.07 trillion put into place under the Budget Control Act of 2011.” The stopgap measure would allow appropriators to complete work on the FY 2017 spending bills in the 115th Congress.

In a move lauded by cancer groups, the CR provides the full \$352 million made available to NIH in FY 2017 through the Innovation Account established in the Cures Act. Under the Cures Act, the funding will be transferred to the NIH director for the following initiatives in FY 2017:

- \$300 million for cancer research;
- \$40 million for the Precision Medicine Initiative;
- \$10 million for the BRAIN Initiative; and
- \$2 million for clinical research in regenerative medicine.

The CR also allocates \$20 million from the FDA Innovation Account in FY 2017.

At the joint NCAB-BSA meeting Dec. 6, Lowy thanked board members for urging Congress to direct moonshot funds to the institute (The Cancer Letter, [Dec. 2](#)).

“I can't thank you enough. The BSA has been instrumental in giving us advice, especially about RFAs—for example, today you'll be hearing about the results with the SPORE program—and the NCAB has been really instrumental in at least two different ways in very recent past,” Lowy said at the meeting. “One is with the Blue Ribbon Panel report, when we presented it initially, there were a number of important comments that were made by the NCAB and the report was modified in accordance with those comments.

“A second very important part is that, at the

initiative of the board, the board talked about the 21st Century Cures and the cancer research part of that, and advocating for that funding, if it is made, for it to go to the NCI.”

Capitol Hill insiders say they expect the \$300 million in cancer research funds to be fully channeled to NCI through the NIH director.

Of that amount, \$15 million may be allocated to the FDA Oncology Center of Excellence, a moonshot initiative led by Richard Pazdur, director of the agency's Office of Hematology and Oncology Products (The Cancer Letter, [July 1](#)).

“The NCI, under [Acting] Director Doug Lowy's clear leadership, has laid out a well-defined path for making the Vice President's Moonshot vision a reality,” said Chris Hansen, president of the American Cancer Society Cancer Action Network. “With the legislation and the funding now in place Moonshot can move forward and accelerate the pace of progress against this disease.

“The Senate's passage of Cures represents a significant victory for cancer patients and their families nationwide. The additional funding set aside in this bill would enable NIH and NCI to begin implementing many of the National Cancer Moonshot Initiative's recommendations for accelerating cancer research,” Hansen said in a statement Dec. 7. “These expert recommendations range from improved data sharing—so researchers can see patterns and possibilities across studies and cancers more quickly—to increased focus on emerging and promising treatments, like immunotherapy where the body's own immune system is harnessed against cancer. Now is the time to re-invest in cancer research and capitalize on so many new and potentially life-saving developments in diagnostic tests and treatments for this disease.”

Cures Bill Had Bipartisan Support

The Cures Act is a bipartisan achievement that focuses on helping patients, said Ellen Sigal, chair and founder of Friends of Cancer Research.

“This monumental victory for patients could not have been done without the collaborative efforts of so many in the science and advocacy community over the past couple of years, and especially not without Vice President Biden's fortitude and determination,” Sigal said to The Cancer Letter. “We are thrilled that the act includes many provisions Friends of Cancer Research has been instrumental in developing, including the establishment of the FDA Oncology Center of Excellence.”

The bill will spur development and delivery of promising new treatments for patients, said Daniel Hayes, president of the American Society of Clinical Oncology.

“The remarkable bipartisan, bicameral support for the 21st Century Cures Act proves that congressional lawmakers are serious about the need for scientific research, effective care-delivery, and the removal of barriers to scientific progress,” Hayes said in a statement. “We thank Chairman Lamar Alexander (R-Tenn.) and Ranking Member Patty Murray (D-Wash.) for their persistent effort and leadership in advancing this legislation in the Senate.”

The Cures Act invests in precision medicine and builds toward a future where patients are treated with precise, individualized care, said Jonathan Hirsch, president of Syapse, a company that licenses informatics software for integration of oncology data from electronic health records with genomic data.

“The continued funding of the Cancer Moonshot and Precision Medicine Initiative illustrates our government’s commitment to fight cancer and support medical innovation,” said Hirsch, whose company was highlighted by Biden and the moonshot (The Cancer Letter, [July 1](#)). “Most importantly, it ensures timely access to lifesaving therapies by encouraging the use of real-world evidence for drug approvals. The Cures Act leaves us optimistic about the future of medicine in America, where patients are treated with precise, individualized care. Syapse is dedicated to the goals embodied in the Cures Act through developing and delivering software to improve care, reduce costs and improve the patient experience through precision medicine.”

The approval of the Cures Act represents more than two years of information gathering, collaboration and a commitment from stakeholders across the research enterprise to accelerating medical progress, said Mary Woolley, president and CEO of Research!America.

“The bill is a crucial step towards removing barriers to innovation, securing funding for major initiatives like the cancer moonshot and streamlining drug development to ensure more patients benefit more quickly from lifesaving therapies and devices,” Woolley said in a statement. “Regretfully, the Prevention and Public Health Fund will be reduced to offset the costs of the Cures Act which will inevitably impact efforts to address health threats.

“But we should be reminded that the Cures Act will incorporate the patient voice in the regulatory

decision-making process, among other important provisions, and provide resources to help those impacted by mental illness and the opioid epidemic.”

Being an Acting Director, NCI's Lowy Isn't Required to Submit Resignation

(Continued from page 1)



As acting director, Lowy is not required to submit a resignation—or at least, that is the presumption, because the permanent position of director is subject to presidential appointment.

Presidential appointees are required to submit their resignations by Dec. 7.

“I am in the situation that I am acting director, and therefore, I am not a presidential appointee,” Lowy said at a joint meeting of the National Cancer Advisory Board and the Board of Scientific Advisors Dec. 6. “It has really been exhilarating for me to be leading the NCI for the last year-and-a-half, and I look forward to continuing to do so as long as the administration allows me to.”

If Trump chooses to appoint a different director in 2017, the process could take between one to two years—or more—to complete. The presidential cabinet positions are always filled first.

For instance, Harold Varmus, the immediate past NCI director, took office 16 months after President Barack Obama was inaugurated. NIH Director Francis Collins was took office after six months.

These positions take a long time to fill, said M.K. Holohan Quattrocchi, director of the NCI Office of Government and Congressional Relations.

“If you look at the past couple of administrations, and just starting with the furthest one back, it took 27 months for Dr. [Bernadine] Healy to take office as the NIH director from the time the president was inaugurated,” Quattrocchi said at the Dec. 6 meeting.

“Under President [Bill] Clinton, it took six months for Dr. Varmus to take office as director of NIH, and it took 31 months for Dr. [Richard] Klausner to take over as NCI director. Under George W. Bush, for Dr. [Elias] Zerhouni, [15th NIH director] 14 months.

“The presumption is that, when you have a person in place as an acting, they’re not a political appointee. They do not need to, nor would they ever submit a resignation as an acting [director]. We are very fortunate in that regard that we do not have to face that. It tends to take a very long time for these procedural things to play out. They tend to play out top-down. I think we know it’s going to be rocky, and that’s all we know at this point.”

At the meeting, Lowy summarized NCI’s achievements during his tenure as acting director, citing progress on the Precision Medicine Initiative, health disparities research, an increase in funding for NCI-designated cancer centers, and the institute’s efforts for Vice President Joe Biden’s National Cancer Moonshot Initiative.

An excerpt of Lowy’s remarks at the Dec. 6 meeting follows:

I want to spend a few minutes talking about what’s been going on, as I see it, with some highlights from the last year-and-a-half.

But before I start, you may be aware that presidential appointees—today is Dec. 6—and presidential appointees are supposed to submit their resignations as of Jan. 20, and I guess all of you know that the permanent NCI director is a presidential appointee.

I am in the situation that I am acting director, and therefore, I am not a presidential appointee. It has really been exhilarating for me to be leading the NCI for the last year and a half, and I look forward to continuing to do so as long as the administration allows me to.

So, a few words about the accomplishments. When I started as acting director, I gave a talk a few weeks after that at [the American Association for Cancer Research], and three of the areas that I wanted to emphasize were, first, cancer health disparities, second, Precision Medicine Initiative in oncology, and third, investigator-initiated research.

We have had a number of conferences on cancer health disparities and have started the early onset of cancer—this is a cohort looking particularly at underrepresented minorities where there are cancer disparities, and to try to and essentially do as detailed molecular analysis as possible on these cases to try to get biological insight into similarities and differences with different racial populations. We are thinking about this, as I’ve mentioned previously, in terms of biology, health care access and utilization, and lifestyle factors and with different conditions, there are different factors that play a larger or smaller role.

You’ll be hearing from [Director of the NCI Division of Cancer Treatment and Diagnosis] Jim [Doroshov] about the Precision Medicine Initiative in oncology. It was fully funded

exactly a year ago in December of last year, and because of that funding, it has been possible for us to go forward with PMI Oncology, and this is really one aspect of another light motif that has been especially enjoyable for me, which is the strong bipartisan support that NIH has had for biomedical research and, equally important, the strong support for cancer research at the level of the White House last year with PMI Oncology, and this year with the Cancer Moonshot.

I’ll be talking about investigator-initiated research and showing you the latest data from 2016 from the RPG pool in a few minutes. But I now want to turn to the area of the NCI-designated cancer centers. We’ve always recognized how important the cancer centers are, but we have been trying to emphasize their importance in a number of new ways, and also to have them—where it is appropriate—to work more closely together between different cancer centers.

So we increased the funding for the Cancer Center Support Grants; we also have given a number of administrative supplements and really making more use of this than we have in the past.

I have, in the last year and a half, visited 15 different NCI-designated cancer centers, and each time I visit one, I learned something new and important. It’s really been an exhilarating experience for me to see the high quality activity, commitment, and dedication of the people at the different cancer centers.

In 2014, we gave some supplements for promoting HPV vaccination, and at the beginning of this year, all 69 cancer centers banded together to make an announcement, essentially, about the importance of HPV vaccination. This also is in the Blue Ribbon Panel report.

There have already been several meetings between the cancer centers, also involving representatives from the Centers for Disease Control at these meetings. The most recent one, Electra [Paskett, director of the Division of Cancer Prevention and Control in the College of Medicine], was one of the hosts at Ohio State University, and it’s already planned to have another meeting at the [Medical] University of South Carolina.

Another aspect in line with the Blue Ribbon Panel recommendations is for smoking cessation. We are planning to give more emphasis to smoking cessation, especially starting with the cancer centers so that we make smoking cessation much more incorporated, not just that it is standard of cancer, but that it is disseminated. Bob Croyle and his colleagues organized a meeting last month with a number of different people who came together and have made some recommendations. We’re really looking forward to that kind of being the next joint effort for the cancer centers.

The Cancer Moonshot and the Blue Ribbon Panel have really occupied us. I can’t thank all of you enough for your input. Everybody who was involved had a day job that they were supposed to doing something else. They added the Blue Ribbon Panel and the Cancer Moonshot to what they were doing.

I’m especially grateful to Dinah [Singer, acting deputy director of NCI and director of the Division of Cancer Biology], Liz [Jaffee, professor and deputy director for translational research at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University], and to Tyler [Jacks, director of the Koch Institute for Integrative Cancer Research at MIT], for co-chairing the Blue Ribbon Panel.

In Brief
**Drebin Appointed Chair of
Surgery at MSKCC**



JEFFREY DREBIN was named chair of surgery at **Memorial Sloan Kettering Cancer Center**, a position he will assume early next year. He is the chair of the Department of Surgery at Penn Medicine and the 14th John Rhea Barton Professor of Surgery at the Perelman School of Medicine.

At MSKCC, Drebin will replace **Peter Scardino**, who is stepping down after ten years as chair of the Department of Surgery.

In an email to *The Cancer Letter*, Scardino said he plans to “continue to practice and conduct research in prostate cancer as a member of the Urology Service in the Department here at MSK for many years, and, I hope, continue to participate in the development of new diagnostic and treatment approaches for the disease and help explain why PSA is still an invaluable marker that, used correctly, will continue to help reduce the mortality rate from prostate cancer.”

In an email to the faculty, Penn officials wrote:

While we are extremely proud of Dr. Drebin being selected for this prestigious position at MSKCC, there is no question that his presence here will be sorely missed. Jeff has conveyed to each of us the difficulty he had in making this decision, but ultimately the opportunity to focus his career on cancer became the right choice for him.

Dr. Drebin has been an outstanding leader and mentor at Penn Medicine. He came to Penn in 2004 as Chief of the Division of Gastrointestinal Surgery and was named Chair

of the Department in 2009. Since that time, Jeff has built a nationally leading department with responsibility for a diverse range of programs and services spanning 11 divisions, including advanced patient care, basic and clinical research and the surgical education program. The Department is consistently recognized for its outstanding performance led by excellent faculty, and to Jeff’s personal credit – for its strong group of residents and junior faculty who will become tomorrow’s leaders in academic medicine.

Dr. Drebin’s research has put him in the vanguard of the latest therapies for cancer with innovative research projects investigating new ways to treat pancreatic cancer. Further, his research has contributed significantly to the understanding of the genetic origins of cancer. He is currently the co-Principal Investigator on a clinical and translational “dream team” award from the Stand Up to Cancer Foundation for innovative studies in pancreatic cancer which joins Penn faculty with investigators at MSKCC to advance knowledge and improve patient care.

We will, of course, begin a national search for a new chair of surgery shortly with the knowledge that Jeff has set a very high bar indeed for his successor. Jeff is an outstanding leader, clinician, scientist and a valued colleague, and we will plan appropriate celebrations of his many accomplishments at Penn Medicine. Please join us in offering him heartiest congratulations on his new position.

MILTON BROWN was named director of the new **Inova Center for Drug Discovery and Development** and as deputy director for drug discovery for the Inova Schar Cancer Institute.

Brown is one of a handful of physician scientists in the United States who hold a Ph.D. in synthetic chemistry and an M.D.

He will bring his team of more than 20 scientists including research instructors, post-docs, technicians, graduate students, and research assistant professors to Inova. The disciplines covered by these individuals include synthetic chemistry, medicinal chemistry, pharmacology, cancer biology, ADME toxicity specialization, animal pathology, and spectroscopy.

“Having Milt and his team at the Inova Schar Cancer Institute will further differentiate cancer care at Inova,” said Skip Trump, executive director and CEO, ISCI. “Cancer is not one disease and we are discovering, through genomics, proteomics and other sophisticated approaches, new and important targets in cancer cells that drive the growth and spread of cancer. Dr. Brown’s life’s work is about finding and developing new drugs to block those drivers – the right drug for the right patient at the right time. It’s about saving lives and improving the quality of life of our patients.”

Brown was on the faculty at the University of Virginia from 2000 through 2006, when he accepted the position as the founding Director of the Drug Discovery

Program at the Georgetown Medical Center. He was appointed as the Edwin H. Richard and Elisabeth Richard von Matsch Endowed Chair in Experimental Therapeutics, tenured associate professor in the Department of Oncology, and associate director for the experimental therapeutics program at the Lombardi Comprehensive Cancer Center.

Brown serves as a scientific counselor on the National Toxicology Program Board.

THE ROYAL NETHERLANDS Academy of Arts and Sciences named cancer researcher **Bert Vogelstein** as the very first recipient of the KNAW Bob Pinedo Cancer Care Award.

In the 1980s, Vogelstein demonstrated the genetic mechanism that leads to cancer. He is now working on cancer therapies that utilize the patient's immune system. He is also developing genetic tests for early cancer detection.

Vogelstein is director of the Ludwig Center for Cancer Genetics and Therapeutics at Johns Hopkins Kimmel Cancer Center and Clayton Professor of Oncology and Pathology at Johns Hopkins University.

Vogelstein has co-authored more than five hundred academic publications and more than one hundred patents. He is one of the most cited researchers in the world and has received dozens of distinctions, including the Breakthrough Prize in Life Sciences in 2013. Vogelstein is a member of the National Academy of Sciences and the European Molecular Biology Organization, among others.

The KNAW Bob Pinedo Cancer Care Award is a new biennial award for internationally acclaimed researchers in cancer care. It is named after the renowned Dutch oncologist and researcher Bob Pinedo (born in Curaçao in 1943). The award is intended for researchers currently active in pioneering cancer research or compassionate cancer patient care. The award winner receives 100,000 euros to use for research. He or she also receives a bronze sculpture in the form of Professor Pinedo's right hand, symbolising strength and hope of healing. The sculpture is designed by Floris Tilanus. Nominations may be submitted by research institutes and researchers around the world. A jury headed by an Academy member assesses the nominations.

THE U.S. SURGEON GENERAL VIVEK MURTHY today released a new report, [E-Cigarette Use Among Youth and Young Adults.](#)

"We applaud the Surgeon General for bringing attention to the serious public health problem of youth

use of e-cigarettes and the resulting adverse health effects," said Chris Hansen, president of the American Cancer Society Cancer Action Network. "The report issues a call to action for parents, teachers, scientists, the public health community, policymakers and the tobacco industry to take precautionary measures now to prevent e-cigarette use and future impact from these products among youth and young adults."

The report was reviewed by 150 experts, highlights some of the risks associated with using electronic cigarettes, including nicotine addiction, behavior risks—including the use of other drugs and other tobacco products - as well as the potential harm from ingesting the aerosol from electronic cigarettes, which is not merely water vapor and contains potentially harmful chemicals.

"While alternative nicotine delivery devices may have a role in cessation, this role needs to be supported by science," said Laurent Huber, executive director of Action on Smoking and Health. "In addition, there is a worrying trend that major tobacco companies such as Philip Morris (Altria), British American Tobacco, Japan Tobacco International, RJ Reynolds and others are aggressively expanding into the electronic cigarette markets, in part due to the less strenuous regulatory environment.

"Given that their aim is not to help smokers quit but rather to increase the demand for their nicotine products, the recommendations from the Surgeon General's report, particularly the suggestions for regulating marketing and sales, will aid in ensuring that electronic cigarettes do not become a new public health threat in years to come."

MICHAEL ZINNER was elected chair of the **Board of Regents of the American College of Surgeons.**

Zinner is a general surgeon with expertise in pancreatic-hepatobiliary diseases. Since 2016, he has been the founding chief executive officer and executive medical director of the Miami Cancer Institute--Baptist Health South Florida.

Prior to that time, he served as surgeon-in-chief and Moseley Professor of Surgery at the Brigham and Women's Hospital and Harvard Medical School. During this time, Zinner also served as clinical director and chief of surgical services at the Dana-Farber/Brigham and Women's Cancer Center.

A fellow of the American College of Surgeons (FACS) since 1983, Zinner has previously served as vice-chair of the ACS Board of Regents (2010-2015)

and chair of the ACS Board of Governors (2008-2010).

JOHN JENKINS will retire from his job as director of the **FDA Office of New Drugs** on Jan. 6, 2017.

FDA will conduct a national search to fill his position. Janet Woodcock, director of the Center for Drug Evaluation and Research will serve as acting director of OND.

Announcing Jenkins's retirement, Woodcock wrote:

For the past 15 years, [Jenkins] has led OND in its difficult tasks of setting the U.S. standards for new drugs' safety and efficacy, overseeing the clinical testing of investigational drugs, and reviewing marketing applications under PDUFA timelines. He and his staff, which has grown to more than 1,000, have successfully navigated many high-profile controversies related to new drugs—while at the same time having thousands of interactions with industry and other stakeholders, and making timely decisions about INDs and NDAs.

John joined FDA in 1992 as a medical officer in CDER's former Division of Oncology and Pulmonary Drug Products. He later served as pulmonary medical group leader and acting division director before being appointed director of the newly created Division of Pulmonary Drug Products in 1995. In 1999, John was named director of the Office of Drug Evaluation II and served in that position until he was appointed OND director in January 2002.

John is credited for his pivotal role in designing and overseeing our current managed new drug review process, an initiative known as 21st Century Review.

He has also successfully implemented multiple process changes mandated by legislation or initiated through user fee agreements. John has championed the new biosimilars review program, which has been set up within the Office of New Drugs. Additionally, he has created many processes to help ensure consistency of policies and procedures in new drug review, including labeling, pediatrics, and safety requirements. John has set guidance and policy guiding OND staff in meeting FDA's public health mission in a complex and changing environment. He has been at the forefront of communications with regulated industry during drug development concerning a wide variety of clinical, scientific, and regulatory matters.

John has led OND in approving a notable number of novel drug therapies each year. These include drugs for rare diseases and drugs to treat life-threatening diseases, many of which were approved first in the United States. OND has also approved many new drugs that are additions to an existing class, or offer some symptomatic improvement to a non-serious illness.

Such drugs require careful scrutiny for safety. Other drugs have been successfully switched over-the-counter, improving people's access to self-care. With John at the helm, OND has effectively used various regulatory and scientific tools to ensure safe and efficient development, review, and approval of new therapies—all while maintaining high standards for safety, effectiveness, and quality.

As a trusted colleague, John is known and respected

for his contributions both inside and outside FDA. He is both brilliant (for example, read his prescient review of NSAID safety, done during the height of that controversy), and steady—a rare combination.

He is known for his fair-minded approach to differences, and he has served as a role model for a new generation of reviewers. I have benefitted from his insight and guidance over our many years of working together.

TEMPUS, a technology company focused on supporting physicians delivering customized cancer care, and the **University of Pennsylvania Abramson Cancer Center** partnered to better determine which patients will have a positive response to immunotherapy treatment based on next generation genomic and transcriptomic sequencing.

As part of a research collaboration, Tempus will provide sequencing and analysis of de-identified pancreatic and melanoma cancer patient data to Penn. Utilizing next-generation sequencing, machine learning and bioinformatics, Tempus will help physicians analyze these data sets for relevant patterns that can help inform which immunotherapies are most likely to be effective in a given cohort of patients.

"Tempus is committed to bringing relevant information and technology to healthcare providers battling cancer," said Eric Lefkofsky, co-founder and CEO of Tempus.

"Putting cutting-edge technology into the hands of our physicians enhances the resources they need to best serve their patients," Chi Van Dang, professor & director, Abramson Cancer Center.

Tempus enables physicians to deliver personalized cancer care through its interactive analytical and machine learning platform. The company provides genomic sequencing services and analyzes molecular and therapeutic data to empower physicians to make real-time, data-driven decisions.

THE PARKER INSTITUTE for Cancer Immunotherapy and the **Cancer Research Institute** announced a Collaboration focused on neoantigens. The search for these unique cancer markers has become a robust area of research as scientists believe they may hold the key to developing a new generation of personalized, targeted cancer immunotherapies.

The collaboration, the Tumor neoantigen SeLECTION Alliance (TESLA), includes 30 of the world's leading cancer neoantigen research groups from both academia and industry. Because these tumor markers are both specific to each individual and unlikely to be present on normal healthy cells,

neoantigens represent an optimal target for the immune system and make possible a new class of highly personalized vaccines with the potential for significant efficacy with reduced side effects.

Participating research groups will receive genetic sequences from both normal and cancerous tissues. Using each laboratory's own algorithms, each group will output a set of predicted neoantigens that are anticipated to be present on the tumor cells and recognizable by the immune system. The predictions will then be validated through a series of tests to assess which predictions are most likely to be correct and recognizable by T-cells. Through this effort, each participant will be provided with data to inform and to further improve their algorithms and therefore the potential effectiveness of personalized neoantigen vaccines for cancer.

"Bringing together the world's best neoantigen research organizations to accelerate the discovery of personalized cancer immunotherapies is exactly the type of bold research collaboration that I envisioned when launching the Parker Institute," said Sean Parker, founder of the Parker Institute for Cancer Immunotherapy. "This alliance will not only leverage the immense talents of each of the researchers but will also harness the power of bioinformatics, which I believe will be critical to driving breakthroughs."

The goal of the initiative is to help participating groups test and continually improve the mathematical algorithms they use to analyze tumor DNA and RNA sequences in order to predict the neoantigens that are likely to be present on each patient's cancer and most visible to the immune system. In support of this, Parker Institute and CRI have partnered with the open science nonprofit, Sage Bionetworks, to manage the bioinformatics and data analysis.

Initially, the project is expected to focus on cancers such as advanced melanoma, colorectal cancer and non-small cell lung cancer that tend to have larger numbers of mutations and thus more neoantigens. Over time, the initiative will seek to broaden the relevance of neoantigen vaccines to a wide range of cancers.

Participants come from universities, biotech, the pharmaceutical industry and scientific nonprofits. The researchers represent a wide swath of scientific fields, including immunology, data science, genomics, molecular biology, and physics and engineering.

Neoantigens are markers present on the surface of cancer cells but absent on normal tissue, making them attractive drug target candidates. They commonly arise from mutations that occur as tumor cells rapidly

divide and multiply. The immune system can recognize these markers as "foreign," and as a result, target the cancer cell for destruction. In order to predict which neoantigens will be present on a patient's tumor, researchers have developed software programs to analyze tumor DNA and output the unique set of markers that the immune system is most likely to recognize.

ABBVIE signed separate five-year collaboration agreements with two cancer centers: the **Robert H. Lurie Comprehensive Cancer Center of Northwestern University** and the **Johns Hopkins University School of Medicine**.

The agreements are intended to advancing research and discovery in oncology.

AbbVie and Northwestern will work in several areas of oncology research, which could include, lung, colorectal, breast, prostate and hematological cancer.

"One of the best steps AbbVie can take to deliver new therapies in oncology is to combine our research and discovery expertise with the talents and insight of our colleagues in academic medicine," said Gary Gordon, vice president, oncology clinical development, AbbVie. "The opportunity to work with leading researchers and clinicians from the Lurie Cancer Center enhances AbbVie's ability to help oncology patients even more in the future."

The collaboration provides Lurie Cancer Center scientists with the opportunity to access new therapies developed by AbbVie for preclinical research funded under the agreement. Lurie Cancer Center scientists will also work closely with AbbVie's research teams to support scientific knowledge exchange. In addition, the agreement provides AbbVie with the option to obtain an exclusive license of certain Lurie Cancer Center discoveries made as a result of the five-year collaboration.

"The ability to investigate new therapeutic agents with AbbVie provides us with a great opportunity to expand our translational oncology efforts," said Leonidas Plataniias, director of the Lurie Cancer Center. "Our partnership with AbbVie will facilitate and accelerate the development of innovative new therapies against a wide variety of different cancers."

The agreement with Johns Hopkins will focus on several areas of oncology research, which could include lung, colorectal, breast, prostate and hematological cancer.

"As an alumnus and a former faculty member of the Johns Hopkins University School of Medicine, I

know from my own experience that we will be able to combine AbbVie's expertise in oncology with some of the most talented academic researchers in the field of medicine today," Gordon said in a statement. "This collaboration will combine our resources and talent with Johns Hopkins Medicine to help further advance our ability to develop new therapies available for cancer patients in need."

The agreement allows Johns Hopkins Medicine physicians and scientists access to explore new therapies developed by AbbVie for use in preclinical research funded by the collaboration. In addition, the relationship includes opportunities for research and development teams from both organizations to work closely to promote scientific knowledge exchange. AbbVie also gains an option for an exclusive license to certain Johns Hopkins Medicine discoveries made under the agreement.

"The importance of cancer research is critical to developing new therapies that could have life-changing implications," said William Nelson, director, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. "Opportunities to advance science and further research help move us in a direction to yield positive outcomes."

In these collaborations, joint steering committees consisting of representatives from each organization will determine the research projects that the collaboration will undertake. Researchers will also participate in annual symposia to discuss their joint research and evaluate potential new projects.

GEORGE WASHINGTON UNIVERSITY has formally launched the **GW Cancer Center**.

The GW Cancer Center is a collaboration between GW Hospital, The GW Medical Faculty Associates, the GW School of Medicine and Health Sciences, and the Milken Institute School of Public Health at GW, to expand GW's efforts in the fight against cancer.

The GW Cancer Center incorporates all existing cancer-related activities at GW, serving as a platform for future cancer services and research.

ST. JUDE MEMPHIS MARATHON WEEKEND Dec. 3 raised \$10 million for **St. Jude Children's Research Hospital**.

Over the past 15 years, participants running as St. Jude Heroes have joined the fight against childhood cancer and raised more than \$60 million to support St. Jude.

About 23,000 people took part in the race that

drew 40,000 spectators.

Unique to this event is the race route through the St. Jude campus where patient families cheer from the sidelines to remind walkers and runners they are running for a greater purpose—to help ensure families never receive a bill from St. Jude for treatment, travel, housing or food.

The marathon weekend is a collaborative effort between ALSAC/St. Jude Children's Research Hospital and the Memphis Runners Track Club.

JOSHUA COLEMAN was named vice president of medical affairs at **GenomOncology**.

He will oversee clinical content development and curation of scientific evidence, enhancing the company's proprietary knowledge-enabled platform. The GenomOncology software suite empowers molecular pathologists with a seamless workflow for the interpretation of genetic sequencing data and clinical decision support, from quality control through reporting.

Prior to joining GenomOncology, Coleman held an appointment of assistant professor at The Ohio State University College of Medicine and practiced molecular genetic pathology in the James Cancer Hospital Molecular Laboratory. He is board-certified in hematopathology and molecular genetic pathology.

NANCY HESSE was named president and CEO of the **Cancer Treatment Centers of America Eastern Regional Medical Center (Eastern) in Philadelphia**.

Hesse has served as interim president and CEO since February 2016, and before that as chief nursing executive for CTCA and chief nursing officer at Eastern.

Hesse joined CTCA in 2014 after a long tenure at Abington Memorial Hospital. She began her career as a staff nurse in the Emergency Trauma Center and advanced to become the Director of Emergency Trauma and then Chief Nursing Officer for Abington – Lansdale Hospital.

CTCA is a national network of five cancer hospitals.

Advertise your meetings and recruitments

In The Cancer Letter and The Clinical Cancer Letter
Find more information at: www.cancerletter.com

THE AMERICAN COLLEGE OF RADIOLOGY board of selected three innovators as **2017 Gold Medalists** for their extraordinary service to the college or radiology. Honors will be presented bestowed during [ACR 2017 - The Crossroads of Radiology](#) meeting in Washington May 21-25, 2017.

The following individuals will receive the ACR Gold Medal:

- **Bruce Hillman**, of Wake Forest, NC, professor of radiology and medical imaging and health evaluation sciences and former chair of radiology, University of Virginia, and founding and current editor-in-chief of the Journal of the American College of Radiology,
- **John Patti**, of Lynnfield, MA, senior lecturer in radiology at Harvard Medical School and thoracic radiologist at Massachusetts General Hospital and Harvard Medical School, and past chair of the board and president of ACR,
- **Jeffrey C. Weinreb**, of New Haven, CT, professor of radiology and biomedical imaging and vice chair for strategic planning and innovation at Yale-New Haven Hospital/Yale School of Medicine, and past BOC member and vice-president of ACR

The following candidates were approved to receive [Honorary Fellowships](#) in recognition of their contributions to the science or practice of radiology:

- **Berend J. Slotman**, of Amsterdam, professor and chair of radiation oncology, VU University Medical Center Amsterdam,
- **Jacob Sosna**, of Jerusalem, chair, division of imaging, Hadassah Hebrew University Medical Center, and president of the Israel Radiological Association.

In addition, **Pamela Wilcox**, of Ridge, MD, will receive the [Distinguished Achievement Award](#) for notable service to the college and the profession. Wilcox served as ACR executive vice president of quality and safety, retiring in 2015 after 28 years of service.

UT HEALTH NORTHEAST in Tyler, TX, and **MD Anderson Cancer Center** announced a partnership to provide greater access to the most advanced cancer care available for adult patients in

northeast Texas and the surrounding region.

Through the partnership, UT Health Northeast's Cancer Treatment and Prevention Center joins MD Anderson Cancer Network, an international collaboration of hospitals and health systems that share and contribute to MD Anderson's mission to end cancer. The center in Tyler will be known as UT Health Northeast MD Anderson Cancer Center when it officially launches in 2017.

UT Health Northeast's cancer program will be clinically and operationally integrated with MD Anderson Cancer Center, joining only six other healthcare institutions across the U.S. and three facilities in Brazil, Spain and Turkey. Enhanced local access to MD Anderson's multidisciplinary care, treatment innovations, standards of care and clinical trials will be hallmarks of the partnership.

The two organizations will join forces in the recruitment of all future program physicians and allied health staff. A national search to hire a medical director to lead the new program is planned.

Drugs and Targets

Avastin Plus Chemo Gets FDA Approval for a Type of Ovarian Cancer

AVASTIN (bevacizumab) received **FDA approval** to be used either in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine chemotherapy, followed by Avastin alone, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer.

Women are said to have a 'platinum-sensitive' form of the disease if a relapse occurs six months or longer following the last treatment with a platinum-based chemotherapy.

"With today's approval of Avastin plus chemotherapy, women in the U.S. with recurrent, platinum-sensitive ovarian cancer now have a treatment option that showed a survival difference of more than five months compared to chemotherapy alone in a clinical trial," said Sandra Horning, chief medical officer and head of Global Product Development. "This approval was based in part on a Gynecologic Oncology Group cooperative clinical trial and reinforces the importance of partnerships with study groups to identify new treatment options for people in need."

Avastin in combination with chemotherapy for platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer was granted priority review, and today's approval is based on results from two randomized, controlled phase III studies, GOG-0213 and OCEANS.

The GOG-0213 study demonstrated that adding Avastin to chemotherapy showed an overall survival difference of five months compared to chemotherapy alone (median OS: 42.6 months vs. 37.3 months; Hazard Ratio (HR)=0.84, 95% CI: 0.69-1.01 and HR=0.82, 95% CI: 0.68-0.996, depending on stratification factor). Both the GOG-0213 and OCEANS studies demonstrated a significant improvement in the time women lived without their disease getting worse (progression-free survival, PFS).

The GOG-0213 study showed that women lived a median of 3.4 months longer without disease progression with the addition of Avastin to chemotherapy compared to chemotherapy alone (median PFS: 13.8 months vs. 10.4 months; HR=0.61, 95% CI: 0.51-0.72). The OCEANS study showed that Avastin in combination with chemotherapy significantly improved PFS compared to placebo plus chemotherapy (median PFS: 12.4 months vs. 8.4 months; HR=0.46, 95% CI: 0.37-0.58; $p<0.0001$).

Overall survival, one of the secondary endpoints in the OCEANS study, was not significantly improved with the addition of Avastin to chemotherapy (HR=0.95, 95% CI: 0.77-1.17). Adverse events in both studies were consistent with those seen in previous trials of Avastin across tumor types for approved indications, but also included fatigue, low white blood cell count with fever, low sodium level in the blood, pain in extremity, low platelet count, too much protein in the urine, high blood pressure and headache.

In November 2014, Avastin received an FDA approval for the treatment of women with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan chemotherapy. Women are considered to have a 'platinum-resistant' form of the disease if a relapse occurs less than six months after the last treatment with a platinum-based chemotherapy.

ABBVIE said the European Commission granted conditional marketing authorization for **Venclyxto** (venetoclax) monotherapy for the treatment of chronic lymphocytic leukaemia in the presence of 17p deletion or TP53 mutation in adult patients who are unsuitable

for or have failed a B-cell receptor pathway inhibitor; and for the treatment of CLL in the absence of 17p deletion or TP53 mutation in adult patients who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor.

The EC approved Venclyxto as a first-in-class, oral, once-daily medicine that selectively inhibits the function of the BCL-2 protein. BCL-2 prevents the natural death of cells, including CLL cells.

Venclyxto is being developed by AbbVie and Genentech, a member of the Roche Group. It is jointly commercialized by the companies in the U.S. and by AbbVie outside of the U.S.

The 17p deletion, a genomic alteration in which a part of chromosome 17 is absent, is found in 3 to 10 percent of previously untreated CLL cases and up to 30 to 50 percent of relapsed or refractory CLL cases. A TP53 mutation occurs in 8 to 15 percent of patients at first-line treatment and up to 35 to 50 percent of cases in refractory CLL. Those with the 17p deletion or TP53 mutations often have a particularly poor prognosis and a median life expectancy of less than two to three years with current standard-of-care regimens.

Conditional marketing authorization is granted to medicines that address an unmet medical need, where the benefit of its immediate availability to patients outweighs the risk of limited data availability, and where comprehensive data will be provided.

In April 2016, FDA granted accelerated approval of Venclexta (venetoclax) tablets for the treatment of patients with CLL with 17p deletion, as detected by an FDA-approved test, who have received at least one prior therapy.

The FDA approved this indication under accelerated approval based on overall response rate, and continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial.

AMGEN and **Allergan plc** submitted a Marketing Authorization Application to the European Medicines Agency for ABP 215, a biosimilar candidate to Avastin (bevacizumab).

The companies said they this submission is the first bevacizumab biosimilar application submitted to the EMA.

ABP215 is a biosimilar candidate to bevacizumab, a recombinant immunoglobulin G1 monoclonal antibody that binds to vascular endothelial growth factor and inhibits the interaction of VEGF with its receptors, VEGF receptor-1 and VEGF receptor-2,

thus inhibiting establishment of new blood vessels necessary for the maintenance and growth of solid tumors.

The MAA submission includes analytical, pharmacokinetic and clinical data, as well as pharmacology and toxicology data. The phase III comparative efficacy, safety and immunogenicity study was conducted in adult patients with non-squamous non-small cell lung cancer. The phase III study confirmed no clinically meaningful difference to bevacizumab in terms of efficacy, safety and immunogenicity.

In December 2011, Amgen and Allergan plc. (then Watson Pharmaceuticals, Inc.) formed a collaboration to develop and commercialize, on a worldwide basis, four oncology antibody biosimilar medicines. Under the terms of the agreement, Amgen will assume primary responsibility for developing, manufacturing and initially commercializing the oncology antibody products.

NOVOGENE, a commercial provider of genomic services, **AITbiotech Pte Ltd**, a Singapore biotechnology company, and the **Genome Institute of Singapore** announced that NovogeneAIT Genomics Singapore--a new joint venture between Novogene and AITbiotech--will establish a joint whole genome sequencing center at Biopolis, Singapore.

The new center will provide Illumina HiSeq X based whole genome sequencing and bioinformatics analysis of human, plant and animal samples for biomedical and agricultural researchers. The center will devote a major portion of its sequencing capability to support public research projects and empower super scale sequencing initiatives in Singapore and the region.

In addition, NovogeneAIT will collaborate with GIS to develop new applications of next-generation sequencing, such as WGS solutions for cancer diagnosis and stratified cancer treatment.

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