THE CANCER LETTER

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Government on Hold

No Site Visit For Georgetown Lombardi As Federal Government Shuts Down

By Paul Goldberg

On Oct. 2, Georgetown University's Lombardi Comprehensive Cancer Center was ready for a site visit.

"We were excited about the opportunity to do this, we were looking forward to it; we wanted to highlight the things we have accomplished," said Louis Weiner, director of the center.

The 21 cancer researchers who were scheduled to conduct the on-site examination had cleared their schedules and familiarized themselves with Georgetown's 1,600-page application.

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Cancer Programs Close Amid Gridlock

By Matthew Bin Han Ong

Less than a day before the federal government closed its doors, HHS Secretary Kathleen Sebelius reaffirmed the Obama administration's commitment to continue to invest in cancer research and end the sequester.

"I wish I had a crystal ball and can tell you when or if sequester would end," Sebelius said Sept. 30 at the annual meeting of the Association of American Cancer Institutes. "I could tell you it is one of the highest priorities of the administration.

"It is one of the worst economic policies that has been put in place in a long time, although we are about to see a few others unfold."

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In Brief

Curley Named Chief of Surgical Oncology At Baylor's Dan L. Duncan Cancer Center

STEVEN CURLEY was named chief of the division of surgical oncology and associate director for clinical affairs at the **Dan L. Duncan Cancer Center at Baylor College of Medicine**. Curley is also professor of mechanical engineering of materials science at Rice University.

Curley joins BCM from MD Anderson Cancer Center, where he was professor and Charles B. Barker Chair in surgery, chief of gastrointestinal tumor surgery, and medical director of the MD Anderson Gastrointestinal Cancer Multidisciplinary Care Center.

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When a Site Visit Is Called Off, No One Knows What Comes Next

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The site visit is an important part of the cancer center core grant application, because it allows the reviewers to see directly how the center in question functions.

Last Friday, NCI officials informed Weiner that in the event the government closed, the site visit likely would be canceled. And since efforts to avoid the shutdown failed Sept. 30, members of the review team received an email from an NCI official Tuesday morning, Oct. 1:

> **Importance:** High
>
> Dear Reviewers,
>
> Thank you for your contributions to the NIH peer review process. The site visit review scheduled between October 2 and 4, 2013, for the Lombardi Comprehensive Cancer Center is cancelled due to the absence of annual appropriations and the absence of a continuing resolution.
>
> During this time, NIH staff will not be able to send or receive email or other communications, and NIH computer systems that support review functions will not be operational. You will be contacted as soon as possible after operations resume.
>
> Your hotel reservation will be cancelled by the NIH, as will your travel arrangements (if you made arrangements through World Travel). You will need to cancel your travel arrangements, if you made reservations on your own.

What will this cancellation mean for Georgetown? What will it mean for members of the site visit team? And if the government stays closed, what will happen to other cancer centers awaiting similar site visits?

Mayo Clinic Cancer Center appears to be next, with a site visit scheduled for Oct. 17.

While questions proliferate, there is no place to take them, because, in a Catch-22-worthy snafu, the government shut down on Oct. 1. The website of the NIH Office of Extramural Research sports a big red-letter notice:

> **Due to the lapse in government funding, the system on this web site may not be up to date, transactions submitted via the web site may not be processed, and the agency may not be able to respond to inquiries until appropriations are enacted.**

In this situation, history is a lousy guide. No cancer center site visit seems to have been missed in decades, if ever.

"I assumed that there must have been a somewhat analogous event like this at some point in the history of cancer centers, which might have caused site visits to be canceled," Weiner said. "But we've done an informal polling of everybody we could find in the entire cancer center movement, and as far as we can determine, there is no precedent."

Weiner said he is as puzzled as he is disappointed. "It's not a show, it's not an entertainment activity, but it was as if you were scheduled to open a show, and somebody said it's canceled," he said to The Cancer Letter.

"It's a shame that it happened, and I wish our government was able to function more cohesively and effectively to prevent this kind of challenge."

What's the right way for NCI to fix this problem? Weiner says he doesn't presume to have the answers.

"In a perfect world, we would have our site visit next week or as soon as the government reopens, but I don't believe that's feasible, because the site visitors all have scheduled lives and getting everyone back together again is hard," he said.

"One of the challenges for us is that, as is

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customary, the site visitors had just recently read our application. It means that either they will have to re-review everything or rely upon their memories, or some combination of the two, whenever the re-review were to happen.

"There are lots of other approaches that one could imagine being taken, but all those other approaches carry with them complexities. Some of it may depend on how long the government stays out. If this is resolved tomorrow, it may be easier to have an expeditious rewiring of everything. But what if the government is out for two or three weeks? All the work will pile up—that's going to be a pretty big challenge for all involved."

Georgetown's NCI funding is scheduled to expire in about six months.

"The site visit was timed in such a fashion that there would be more than enough time for us to have the review, and have the final funding decisions made," Weiner said. "I don't even know what the implications are for that."

The reviewers are disappointed, too.

"The biggest losers in this are Georgetown, because they prepared, prepared, prepared—and now they don't know when this will be rescheduled for," said a member of the review team, who was independently identified by The Cancer Letter and who spoke on the condition that his name would not be used.

"On average, you have 20 to 30 people on a site visit—that's 20 to 30 busy, experienced people who get invited," the team member said. "When are you going to get the agendas of 20 to 30 people rescheduled for them to get a fair site visit?

"My next availability is probably not before mid-to-late November. Either I would have to call in—which is not as good—or they will have to replace me, which is not good either, because I have already done the work."

While this uncertainty persists, the member of the site visit team said he would refrain from speaking with any of his colleagues at Georgetown.

"Once I was named to the site visit team, I couldn't talk or collaborate or discuss anything with Georgetown faculty," the site visit team member said. "With this delay, I still can't."

The worst-case scenario is a backup in grant review, but that's unlikely, said Stanton Gerson, chair of Georgetown's external advisory board.

"The good news is that the center is ready for their presentations," Gerson said.

"The awards are so late in comparison with the review and the site visit that there is plenty of time to backfill," said Gerson, distinguished university professor at Case Western Reserve University and director of Case Comprehensive Cancer Center, Seidman Cancer Center and the National Center for Regenerative Medicine.

"If the government is closed, there are not going to be any new grants awarded, so nothing will change," he said.

"It will be suspended animation."

Weiner said he is keeping his problems in perspective.

"In our case, this is an inconvenience that we will get through, but there are children who were scheduled to be started on clinical trials at NIH who weren't able to enter those studies because of the shutdown," Weiner said. "So what's inconvenient for us is potentially disastrous for those children.

"We will carry on, but the broader implications are that much of what the government does—particularly at NIH—has a direct impact on human life," he said. "And I am not sure that any political parties' ideologies are worth a person's life."

NIH Furloughs 75% of Workers; Kids With Cancer Turned Away

(Continued from page 1)

The federal government shut down Oct. 1, after the Senate rejected a House spending bill that combined the funding of the government with a measure to defund the Affordable Care Act and delay its implementation (The Cancer Letter, Sept. 20).

"We will be continuing to move forward on the Affordable Care Act," Sebelius said.

Oct. 1 marks the beginning of the 2014 fiscal year, and with Congress deadlocked over the budget, both the implementation of the ACA and the federal shutdown occurred on the same day.

"The president and his Office of Management and Budget are committed to fighting to end this sequester, and I know that's important to all of you, but as long as we have members of Congress holding these investments hostage, we are going to pay in huge missed opportunities, lost potential, and discoveries," Sebelius said. "And we are going to take a huge toll on human life."

The text of Sebelius's speech begins on page 6.

Shutdown Strikes NIH

After the shutdown began, NIH furloughed 13,698 of its 18,646 employees, or nearly three-quarters of its workforce.

Moreover, about 200 new patients per week will be deferred admission to the NIH Clinical Center during the shutdown. "About 30 of these deferred patients will be children, and about one-third of these children have cancer," said an NIH statement.

Patient care for current NIH Clinical Center patients will continue, as will minimal support for ongoing protocols, animal care services to protect the health of NIH animals, and minimal staff to safeguard NIH facilities and infrastructure.

NIH has notified grantees that it will not take any actions on grant applications or awards during a government shutdown. However, HHS is continuing to operate the Payment Management System, enabling grantees with current grants to continue to draw down their grant funds.

NIH isn't enrolling new patients in any of the 1,437 studies now underway, though an exception is made for patients with life-threatening medical problems.

"Included in the 1,437 protocols are 497 clinical trials, which will study a new drug or device," the NIH statement said. "Of these, 255 are studying treatments for cancer. Fifty of those involve children with cancer."

Reacting to reports of patients being turned away from NIH, House Republicans drafted a joint resolution that would provide immediate funding for NIH through Dec. 15 "at the same rate and under the same conditions as in effect at the end of the just completed fiscal year."

Introduced Oct. 2 by Rep. Jack Kingston (R-Ga.), the Research for Lifesaving Cures Act was rejected when it reached the Senate.

Senate Democrats said House Republicans should restore funding for the entire government, and not pick and choose which federal agencies to reopen.

"We are also not going to choose between veterans and cancer research," said Senate Majority Leader Harry Reid (D-Nev.) Oct. 3.

The American Society for Biochemistry and Molecular Biology, which represents over 12,000 scientists, similarly opposed the House attempt to carve out NIH from the shutdown.

"We appreciate Congress' awareness of the importance of federal support for investments in the National Institutes of Health," ASBMB Director of Public Affairs Benjamin Corb said in a statement. "However, this approach does little to help the scientific community sustain American research.

"Although the NIH is the largest federal investor in biomedical research, other agencies including the National Science Foundation, Department of Veterans Affairs, Department of Defense, and the Department of Energy also make critical investments in research that lead to breakthroughs improving the quality of life and well-being of Americans."

At this writing, neither side is signaling willingness to compromise.

President Barack Obama reiterated his refusal to negotiate a change in his signature healthcare law at an Oct. 2 meeting with congressional leaders.

"I am exasperated with the idea that unless I say to 20 million people, 'You can't have health insurance,' they will not reopen the government. That is irresponsible," Obama said.

The White House has indicated its desire to link the fight over government funding to a separate battle over raising the $16.7 trillion debt ceiling, which must be raised within two weeks.

Reid said House Speaker John Boehner (R-Ohio) was unwilling to pass a short-term continuing resolution and a debt ceiling raise to negotiate on a broader budget deal.

Cancer Groups React

Professional societies are calling for the budget deadlock to be resolved as soon as possible.

"The current government shutdown is just the tip of the iceberg, in terms of the challenging fiscal environment for medical research that patients, scientists, clinicians, and trainees (post-docs) have had to confront during the past decade," said Jon Retzlaff, managing director of office of science policy and government affairs at the American Association for Cancer Research.

"While the current shutdown is halting NIH's ability today to conduct lifesaving research, as well as creating a lot of anxiety among AACR members and everyone else throughout our nation, it's important to remember that NIH's budget was also cut outright by $1.6 billion on March 1," Retzlaff said to The Cancer Letter. "In addition, and even before the $1.6 billion cut, NIH's budget has also declined by more than 20 percent since 2003, when factoring in inflation.

"It's really hard to believe that in this current time of unprecedented scientific opportunities (many of which were described and illustrated in the recently released AACR Cancer Progress Report 2013), our policymakers are reducing the number of promising new grant proposals that can be supported, diminishing

the funding available to cancer centers where critical bench-to bedside research and care is taking place, and slowing the progress of clinical trials.

"In terms of the House's recent efforts to fund the NIH until Dec. 15, we applaud them for wanting to focus attention on the importance of investing in the NIH, especially in light of the agency's current fiscal predicament.

"Additionally, the added emphasis on funding the NIH, which we believe is the crown jewel of the federal government, is going to be reassuring to the hundreds of people who participated in the Rally for Medical Research Hill Day on Sept. 18 in that their message about the importance of NIH to the health and economic security of our nation is clearly being heard in the more than 200 offices that were visited on Capitol Hill.

"However, we also are very aware that the government shutdown is only going to be resolved through a broader agreement between the House, Senate, and the president, as opposed to through a piecemeal attempt to fund the federal government."

Millions of lives and scientific progress depend on the nation's legislators, said Clifford Hudis, president of the American Society of Clinical Oncology.

"This is a sad state of affairs and we must insist that, moving forward, our elected leaders do better to ensure that millions of Americans with cancer can continue to rely on their government for essential cancer care, life-saving research, and the advancement of safe and effective drugs into practice," Hudis said.

"The short-term impact on clinical and laboratory research was felt first thing today when investigators were notified that the federal agencies that are critical to ongoing and planned clinical research would not be available until further notice.

"However, it's the long-term disruption to government services that could be even more devastating to research innovation and the overall health of the nation for decades to come," Hudis said.

"We call on Congress and the administration to work together to pass a budget that will continue our country's commitment to individuals with cancer."

Instructions to NCI Staff

NCI employees are prohibited from participating in any NIH-related activities while furloughed, according to an email from the NCI Office of Ethics.

The text of the email to the NCI staff follows:

In the event of a government shutdown, please refer to these FAQs for instructions regarding ethics matters. Note: the answers to these questions may differ from those posted on the shutdown sharepoint site. These answers reflect NIH's current policy.

Does an employee need permission to participate in an outside activity while furloughed?

An outside activity may be permissible without prior approval as long as the activity does not involve:

1) professional or consultative services;

2) teaching, speaking, or writing that relates to the employee's NIH duties;

3) service to an outside organization as an officer, director or board member, or as a member of a group which provides advice; or

4) employment with a prohibited source (generally, an entity connected to the NIH). For example, substituting at a high school, working at a retail store, or writing for a newspaper on a subject other than NIH programs or operations are permissible activities that do not require prior approval before an employee engages in them.

How does an employee receive permission if his or her IC DEC is non-exempt from furlough and is also out of the office?

As usual, the employee files the request through NIH,s electronic ethics system, NEES (https://nees.nih.gov). In addition, he or she must send an e-mail to his or her IC DEC (names of IC DECs can be found at: http://ethics.od.nih.gov/decs.pdf) and copy the NIH DEC, Dr. Lawrence Tabak, to inform them that the request has been filed in NEES. If the employee's IC DEC is a non-exempted employee, the NIH DEC will review and approve (or disapprove) the request.

Can an employee attend events approved under the WAG gift exception during the period of the shutdown?

Yes, he or she may attend the event in his or her personal capacity provided that permission to attend the event was received before the government shutdown and the event is local.

Impact on CMS and FDA

At the Centers for Medicare and Medicaid Services, Medicare claims will be processed and paid on time in the short term, according to an ASCO statement. If the shutdown continues for several weeks, however, payments to providers could be delayed.

FDA will be able to continue limited activities to its user fee funded programs, including the activities in the Center for Tobacco Products.

"FDA will also continue select vital activities including maintaining critical consumer protection to handle emergencies, high-risk recalls, civil and criminal investigations, import entry review, and other critical public health issues," according to the statement. "However, the FDA will be unable to support the majority of its food safety, nutrition, and cosmetics activities.

"FDA will also have to cease safety activities such as routine establishment inspections, some compliance and enforcement activities, monitoring of imports, notification programs (e.g., food contact substances, infant formula), and the majority of the laboratory research necessary to inform public health decision-making."

Sebelius: Congress Harming Nation's Investment in Science

NIH stands to lose $19 billion in research funds over the next decade if sequestration cuts aren't restored, said HHS Secretary Kathleen Sebelius at the Association of American Cancer Institutes' annual meeting in Washington, D.C.

"That's just the dollar amount," Sebelius said, addressing cancer center directors Sept. 30. "That doesn't take the tally of what we are missing out on—the discoveries, the cures, the advances that might never happen if we are not willing to find a way to pay for them."

However, NIH can't be spared the sequestration cuts that affect the rest of HHS.

"There is a lot of dispute about why don't you just spare NIH," Sebelius said. "When you have cuts that have to be made, NIH is 40 percent of our discretionary budget at the Department of Health and Human Services, and holding it harmless is a very difficult budget challenge, because it means that you must take cuts out of other agencies.

"And with that funding drying out, you don't have to be a high-level scientific researcher to find out why more than half of the nation's federally funded research science have either laid-off staff or say they intend to do that."

Sebelius's remarks follow:

It's a great way to begin a Monday morning to have a chance to be with one of our sunflower superstars, Roy Jensen [director of the University of Kansas Cancer Center].

He was born and raised in Kansas, but then went away to do big things, and one of the great opportunities I had as governor was to participate in the team to recruit Roy back to Kansas and ask him to lead, at that point, a project that resulted in the University of Kansas Cancer Center being designated an NCI cancer center.

Little did I know at that point that I would end up being the secretary at the time—I had to recuse myself from any sort of interference in the NCI process, but I did get to return to Kansas and make the official pronouncement, and that was a pretty nice full circle.

He and many, many of you in this room do incredible life-affirming work every day, and I know you've been here for a day or two, but I want to start by welcoming you to the nation's capital, and to suggest that you are here at a very interesting time, as the Chinese might say.

I do feel, on a regular basis, we sort of live in parallel universes because we have, on one hand, my weekend was spent with regular operational updates from our folks who are ready for tomorrow being the launch of the new marketplace, as in the Affordable Care Act, and on the other hand, dealing with our personnel—division and agency leaders—on what it is that we will tell our employees and what government shutdown will actually look like, and what kind of impact it will make on the work of some critical government agencies.

The question that all of us are asking today is, "Will the government shut down?" and frankly, I don't know. It looks more likely today than it did yesterday, but I don't know.

But I can tell you that on the operational front, we will be continuing to move forward on the Affordable Care Act. And we are less than 24 hours away from open enrollment in the new marketplace, and I want to share a few thoughts about that in a moment.

"Progress, Innovation and Discovery Are Not Free"

I wanted to come here today because of who you are and the work that you do each and every day. I was reminded, as the facts for this talk were put together, that we've got cancer expected this year to claim the lives of about 580,000 Americans—our mothers, our fathers, sisters, brothers, sons and daughters.

I was actually with a college friend over the weekend who has just joined that group being diagnosed with very serious cancer, and she is beginning in this journey, but all of us have friends and relatives and family members involved in that.

The progress, though, that you all are making, means everything to the patients and families afflicted with this disease. And the progress is significant, and it's tangible.

The past spring, the American Association of Cancer Research reported on just how significant the process is. When it comes to scientific discoveries fueled by federal investments, the discoveries have already led to decreases in the incidents of more than 200 types of cancer, and they are clearly helping patients every day live longer and better lives.

I think the shining example is the dramatic improvements achieved fighting childhood cancer. In the 1970s, fewer than 60 percent of children survived five years or more, today, 80 percent survive five years or more.

And there are now more than 300,000 long-term childhood cancer survivors living in the U.S., and those numbers are growing every day. But we wouldn't be achieving those kinds of results accidentally.

It really comes directly from investment and research, and particularly the kind of research collaboration involving the Children's Oncology Group, sponsored by the NCI.

Many of you are also involved in the advances being made in personalized or precision medicine. And I was just at NIH about a month ago, and had an opportunity, as I do each time I go there, to talk to a couple of researchers who were just doing amazing things with very particular kinds of tumor research that are now having not only incredible results, but incredibly fewer impact on the patients that they are targeted for.

Clearly, those therapies hold the promise of being more selective for cancer cells than normal cells, reducing the side effects. As one of the researchers told me, what we used to do is carpet bomb—we just put stuff out there and hope that enough good cells survive and you can make it through the chemo. We now have these therapies that can really target what's going on.

And we've got an FDA who is committed to continuing to exercise regulatory flexibility for those types of treatment. Let me just give you a recent example.

FDA has a new breakthrough therapy designation, and they are expediting development for new drugs and review of new drugs. And it can be a significant difference for patients to have currently unmet needs.

I want you to understand that President Obama does get this. He understands the critical nature of scientific investment, particularly in this day and age, and he understands the fact that, globally, lots of nations also understand this, and are beginning to put huge assets toward research investment.

The president believes that progress, innovation and discovery are not free. And they won't just happen on their own. They take federal investment.

With all the debate about possible government shutdown and with the debate about the debt ceiling just around the corner, there's lot of talk in Washington about spending and costs.

Now with all the talk about how much federal investment costs, we often lose sight of the coda that neglecting to invest has a huge cost.

It also costs, real time, when as a country, we neglect to invest in NIH, the gold standard for research in the world, we pay for that neglect. We had 640 fewer competitive research grants than we were able to issue last year, and hundreds more projects that will be unable to advance in the year ahead.

If the federal government does shut down, entrance to new clinical trials will stop right away at NIH. That's one of the results that will happen. We pay in terms of 750 fewer patients that were able to participate in clinical trials last year because of sequester-driven budget cuts.

NIH Cannot Be Spared

And what you have to understand the HHS budget, because there's a lot of dispute about why don't you just spare NIH. When you have cuts that have to be made, NIH is 40 percent of our discretionary budget at the Department of Health and Human Services. Forty percent.

We have 13 operating agencies, this is one, but they have 40 percent of the discretionary budget. And holding it harmless is a very difficult budget challenge because it means that you must take cuts out of other agencies.

For the sequester, we had no choice at all. A billion and a half dollars in 7 months of a fiscal year had to come off the top of NIH. That's what the sequester looks like for the National Institutes of Health.

But even in budgets that have an overall cut in

discretionary budgets going forward, which we have done the last couple of years, to just hold harmless; which means that that 40 percent of discretionary cuts get shifted to all of the other agencies and the departments—so it has a real impact.

If we neglect to restore those investments, we'll lose $19 billion in NIH research over the next decade, just through sequester—$19 billion. That's just the dollar amount. That doesn't take the tally of what we are missing out on—the discoveries, the cures, the advances that might never happen if we are not willing to find a way to pay for them.

And with that funding drying out, you don't have to be a high-level scientific researcher to find out why more than half of the nation's federally funded research science have either laid-off staff or say they intend to do that.

Now, last week, the Washington Post ran a pretty compelling article about a George Mason University researcher who has already published and is doing groundbreaking work on HIV and AIDS. He's had to cut his staff of 14 paid employees to one post-doc candidate. And he's not even sure that that candidate will stay in the field.

According to a recent study by the American Society for Biochemistry and Molecular Biology, nearly one-in-five scientists say they thought about picking up and moving overseas so they can have a better chance of getting funding.

So this doesn't only have a repercussion for individual health and family health and public health, it actually has a significant repercussion on our global competitiveness.

What we know is this: even before sequester, countries like India, China, South Korea, Brazil, and Japan were increasing their investments in research at the very time when, in America, we were slashing ours.

Now, I wish I had a crystal ball and can tell you when or if sequester would end. I could tell you it is one of the highest priorities of the administration. It is one of the worst economic policies that has been put in place in a long time, although we are about to see a few others unfold.

What I can tell you is that the president and his Office of Management and Budget are committed to fighting to end this sequester, and I know that's important to all of you.

But as long as we have members of Congress holding these investments hostage, we are going to pay in huge missed opportunities, lost potential, and discoveries. And we are going to take a huge toll on human life.

Implementing the Affordable Care Act

Now, at the same time, I just want to say a few words about the Affordable Care Act, because tomorrow is a big kickoff day, and it's a very important part of the new implementation timeline.

But I want you—I know you've heard from my friend Zeke Emanuel [vice provost for global initiatives and chair of the Department of Medical Ethics and Health Policy at the University of Pennsylvania] yesterday, and he was certainly very engaged and involved in this process—and you just heard a statistic from Roy that I'm frankly going to use regularly, but I hadn't heard before, about the impact on cancer patients if you have insurance versus those who aren't covered.

But here's basically what the Affordable Care Act is about. Eighty-five percent on the market side—I should say, that piece of the puzzle—85 percent of the people in this country already have health insurance, and health insurance has worked pretty well for them and their families.

So they work for a big company, they have a military benefit, they are in Medicare, they are in Medicaid, they are a government employee—that's about 85 percent of folks.

And for them, the Affordable Care Act has already provided additional benefits in the 3.5 years since the president signed it. So we have three million young adults who now have coverage under their parents' plan, who, in 2010, are totally uninsured. But that's part of the Affordable Care Act.

We've got about $71 million adults who now have preventive care—as part of their old insurance policies, if you will, their ongoing insurance policies—they have to cover prevention, mammograms, cervical cancer screenings, other screenings, without copays or coinsurance, as an attempt to take down some financial barriers to get preventive care.

It's against the law, currently, to rescind somebody's policy because they get a diagnosis—that's a practice that frankly, have been done on a pretty regular basis in the individual market, dumping people out because they got sick. That can no longer happen.

It's against the law to deny coverage to a cancer patient because they make a mistake on their application. If you paid your premiums and had a policy, you cannot be forced out of the market once you get sick.

It's now against the law for an insurance company to deny chemotherapy, radiation, or other treatment because they've reached a lifetime limit on their

benefits. That no longer is in place. So families won't run out of money in the middle of treatment. That's all for people who currently have insurance.

Now, starting next year, it will illegal, ever again in this country, to deny anyone coverage because they have cancer or any other diagnosis, or because there is survival.

If you have a pre-existing condition, you can no longer be locked out of the health insurance market—already in place for kids, about to be in place for everybody. Starting Jan. 1, the days of not being able to get insurance because of pre-existing condition will be over.

So the new markets are really for that other 15 percent, and these are people who either have no coverage at all, currently, they are in the workforce typically but their employer doesn't offer coverage, they can't afford it in the market, they don't have it. Or they are in and out of the so-called individual market.

In one of my former lives, I was an insurance commissioner. I am a recovering commissioner; I know this market pretty well. I did it for 8 years, and I what I can tell you is that the individual market—so if you are an entrepreneur, or if you are a self-startup, if you are a farm family and purchasing coverage for yourself and your family, the individual market really didn't have many rules.

It didn't have consumer protections, it didn't have many rating rules, it didn't have a lot of oversight. It was basically companies who can cherry-pick who they wanted, they can pretty much charge what they wanted, and they can dump people out, lock people out, price people out of the market, and that happened on a regular basis.

So there are lots of people who have been sort of in and out of the individual market without the protection that you have in a large group. These are the folks that suddenly will have an option for the new market.

And the theory is, if you don't have an employer paying a share of your coverage, you don't have affordable insurance through your workplace, you will now have the federal government helping to pay a share of your coverage, because we feel it's better for everyone to have primary coverage. It's better for everyone to be in the market.

There will be a simple, one-stop shop, easy to use in every state of the country, where people can, online, for the first time, look at plans side-by-side, figure out what's available, figure out what the premiums are, and actually shop online the same way you could buy a TV or a pair of shoes.

You have never ever been able to do that in the insurance market. You've never been able to do much price comparison, you've never been able to see, transparently, what the policies offer, what the fine print says. This will finally be a brand new day.

So those are the markets that open tomorrow. And the key date really is Dec. 15 because if you purchase a policy by Dec. 15, coverage starts on Jan. 1. That's when all the coverage starts. And for many states, also, Medicaid expansion coverage will be enrolling tomorrow.

So for millions of Americans, new options will include benefits like mammograms and cancer screenings, hospital stays, prescription drugs—all the things that you would need if you get, God-forbid, a diagnosis, and then need to follow through on a treatment. You will have a way to pay for that, you will have a way to complete that treatment.

And for millions of Americans, the new options are going to be affordable, within their own budgets. So Jan. 1 can be a new day. It can begin to change these statistics that Dr. Jensen just gave you, where we will no longer have a large population in this country who doesn't have access to the best medical care that the world offers, which is what you all provide, doesn't have access to the best treatment that is available.

In fact, I talked to people all the time, who frankly, have been terrified to even get a diagnosis because they say, "There's nothing I could do about following through with the treatment, I can't figure out what's going on because all it will do is add an additional burden to my life."

Those days are hopefully coming to an end.

So I want to thank you for what you are doing every day—saving lives, changing the world, a person at a time. I want to thank you for the kinds of incredibly innovative research that's going on and treatment and cures that you are working on day in and day out.

I want to tell that we are going to do everything that we can to make sure that NIH continues to have the resources and support that we need to help fuel the pipeline of change that you all are making, and that we will continue to work on this at the same time that we will work on expanding the market of Americans who have available affordable insurance company coverage, and finally join the rest of the world in being able to say, "We believe that all of our citizens should have a right to healthcare."

In Brief

Curley Named Surgical Oncology Chief at Baylor Cancer Center

(Continued from page 1)

At BCM, Curley will lead efforts to build a multidisciplinary surgical oncology program at the McNair Campus as well as a new collaborative GI and metabolic surgery group from the divisions of surgical oncology and general surgery.

Curley has 22 years of experience working in basic science laboratories and has helped develop two FDA-approved devices for invasive radiofrequency ablation needles used to treat unresectable liver cancers.

Curley's research is focused on design, bench testing, and clinical study of novel noninvasive radiofrequency field treatment devices. He is also working on targeted delivery of metallic or semiconducting nanoparticles that release heat under RF field induction to cause thermal cytotoxicity in cancer cells. His group has also performed complex physicochemical measurements of nanoparticles, conjugating them to antibodies, peptides, and pharmacologic agents to target them on cancer cells.

In other appointments at Baylor:

William Fisher was named chief of the division of general surgery, joining Curley in leading the GI and metabolic surgery group.

Fisher, a professor of surgery and director of the Elkins Pancreas Center, has been a member of the BCM faculty since 1998. He has collaborated with and led a team of surgeons and scientists, including researchers with the Human Genome Sequencing Center at BCM, in examining the genetic basis of pancreatic center. He has also established a pancreatic cancer tissue resource and extensive clinical database.

Fisher also coordinates the general surgery programs at the Harris Health System's Ben Taub Hospital, the Michael E. DeBakey VA Medical Center, and the new BCM Medical Center. He is also a member of the Duncan Cancer Center at BCM.

Daniel Albo takes on the new role of vice-chair for network development, and as director for surgical network development at BCM, as the department seeks to expand its clinical program. He is currently professor of surgery and Dan L. Duncan professor in the Duncan Cancer Center at BCM.

Albo will identify, analyze, and help establish new surgical practice opportunities beyond the Texas Medical Center for the department of surgery and for BCM. Albo, whose clinical expertise is minimally invasive gastrointestinal surgical oncology with a special emphasis on colorectal malignancies, will continue to serve as director of the gastrointestinal oncology program in the Duncan Cancer Center.

Albo's research is focused on translational and health services research in colorectal cancer. He has developed a unique retraining program that has led to the conversion of open colorectal surgical units into minimally invasive ones.

Christine Ann O'Mahony was appointed section chief of renal transplantation.

She is also surgical director of kidney transplantation at Texas Children's Hospital, surgical director of kidney transplant at St. Luke's Medical

Center and surgical director of Kidney Transplantation at the Michael E. DeBakey VA Medical Center.

O'Mahony has been a member of the BCM faculty since 2004 and specializes in adult and pediatric liver transplantation, hepatobiliary, and the surgical management of liver tumors.

ANA MARIA GONZALEZ-ANGULO, a breast cancer expert at MD Anderson Cancer Center, was indicted by a **Harris County grand jury** on the felony charge of aggravated assault against a family member.

Gonzalez-Angulo is alleged to have poisoned a colleague, George Blumenschein, with ethylene glycol. Court documents state that Gonzalez-Angulo and Blumenschein were in a "dating relationship."

According to the filing, the incident occurred on Jan. 27. Earlier filings state that the poison was placed in Blumenschein's coffee. The indictment was dated Sept. 26. Charges against Gonzalez-Angulo were filed in May.

"We are sorry to see this indictment, but we know our client is innocent and we trust that a Harris County jury will ultimately agree," Gonzalez-Angulo's attorney Derek Hollingsworth said in a statement. "Dr. Gonzalez-Angulo is a world renowned breast cancer doctor, and these allegations are inconsistent with her lifetime of work dedicated to treating patients with breast cancer.

"This ordeal has been devastating to her career and her practice," Hollingsworth said.

Gonzalez-Angulo is on administrative leave, and Blumenschein, a head-and-neck cancer expert, is back at work.

YALE CANCER CENTER's designation as a comprehensive cancer center was renewed by NCI, and extended for an additional five years.

The grant award includes $12.2 million in funding over five years to support the center's seven research programs and eight shared resources, along with the continuation of the center's comprehensive status.

Yale Cancer Center is one of 41 comprehensive cancer centers in the nation and the only one in Connecticut. Yale was one of the first 11 cancer centers to be designated comprehensive under the National Cancer Centers plan in 1974. The NCI designation is given to centers who meet strict criteria for patient care, cancer research, clinical trials, and community outreach and education.

THE KNIGHT CANCER INSTITUTE at Oregon Health & Science University announced a collaboration with **The Leukemia & Lymphoma Society** to bring together researchers from multiple disciplines to better understand acute myeloid leukemia.

The multi-institution Beat AML cancer research initiative acknowledges that AML is a diverse collection of poorly understood rare diseases that share some common traits. Because of its complexity, improving prospects for AML patients requires an approach that acknowledges the biological diversity across AML cases.

"This innovative collaboration—involving the world's largest nongovernment funder of blood cancer research, a group of leading academic research institutions, two advanced technology companies and potentially multiple pharmaceutical and biotechnology companies—is among the first of its kind in the cancer space and unprecedented in terms of the range of expertise involved," said Brian Druker, director of the Knight Cancer Institute.

The project will be led by Druker and includes researchers at Stanford University, UT Southwestern Medical Center and Huntsman Cancer Institute at the University of Utah. Intel Corporation is providing computational analysis and Illumina is providing the genetic sequencing expertise.

The three-year project also seeks to add more collaborators, including additional pharmaceutical and biotech companies to test a comprehensive offering of novel drugs that will address the underlying molecular complexity of AML. As part of this effort, Array BioPharma will be the first biopharmaceutical company to evaluate its therapeutics with this project.

The initiative will create a profile of the possible genetic drivers of AML by conducting a deep genomic sequencing analysis of patients' samples. As information is gathered on potentially relevant mutations, researchers will simultaneously test the response of leukemia cells to different drugs and combinations of drugs.

LLS has committed to investing more than $8.2 million in the initial three-year project which will analyze samples of cancerous cells from 900 patients with AML. Researchers involved hope this data set will lead to identification of potential new drug targets as well as novel combinations of drugs.

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THE WINTHROP P. ROCKEFELLER CANCER INSTITUTE at the University of Arkansas for Medical Sciences has begun a collaboration with **Highlands Oncology Group**.

The collaboration will allow the institute and Highlands, located in Northwest Arkansas, to enroll patients in clinical trials being offered at UAMS. Highlands physicians will consult with their counterparts at UAMS through video conferencing.

"This affiliation is vitally important for the future of cancer research and treatment in Arkansas," said Peter Emanuel, director of the cancer institute and a professor in the UAMS College of Medicine.

NAPOLEONE FERRARA was appointed editor-in-chief of **Molecular Cancer Therapeutics**, one of the eight peer reviewed journals published by the **American Association for Cancer Research**.

Ferrara is a professor of pathology and senior deputy director for basic sciences at Moores Cancer Center at the University of California San Diego Medical Center, and his team focuses on investigating mechanisms of tumor angiogenesis.

His research in 1989 led to the identification of the vascular endothelial growth factor gene and the development of two FDA-approved drugs: anti-VEGF monoclonal antibody bevacizumab (Avastin) as a cancer therapy, and anti-VEGF monoclonal antibody fragment ranibizumab (Lucentis) for the treatment of age-related macular degeneration.

Ferrara held various scientific positions at Genentech between 1988 and 2012, prior to which he served as a postdoctoral research fellow at the Cancer Research Institute at the University of California, San Francisco.

He has received the Pezcoller Foundation-AACR International Award in 2009, the Lasker-DeBakey Clinical Medical Research Award in 2010, and most recently, the Breakthrough Prize in Life Sciences in 2013.

PAUL ENGSTROM was named the recipient of the Outstanding Achievement in Clinical Research Award by the **Association of Community Cancer Centers**. The association will present Engstrom with the award on at the 30th National Oncology Conference in Boston.

Engstrom is acting chairman of medical oncology and senior vice president of extramural research programs at Fox Chase Cancer Center. In 1979, he established the first Cancer Prevention and Control Program at Fox Chase. Twelve years later, he established an ongoing training and career development program in cancer prevention and control research.

Engstrom is a founding member of the American Russian Cancer Alliance, which helped lead the Russian Duma and the Blokhin Russian National Cancer Center to pass legislation controlling cigarette sales, smoking restrictions and smoking cessation programs in Russia.

UNIVERSITY HOSPITALS SEIDMAN CANCER CENTER broke ground on a $30 million proton therapy center. There are only 11 operational proton therapy centers in the country. This site will be the first in Ohio.

Scheduled to open to patients in 2015, the center will be an 11,000-square-foot facility on the UH Case Medical Center campus. The technology will be used primarily for pediatric cancer patients as well as patients with certain brain and spine malignancies.

THE AMERICAN SOCIETY FOR RADIATION ONCOLOGY elected four officers to serve on its board of directors. The new officers' terms began at the society's annual meeting in Atlanta.

The new officers are:

• President-elect **Bruce Minsky**, of MD Anderson Cancer Center.

• Secretary/Treasurer-elect **Jeff Michalski**, of the Washington University School of Medicine and Siteman Cancer Center.

• Health Policy Council Vice-chairman **Thomas Eichler**, of the Thomas Johns Cancer Hospital.

• Science Council Vice-chairman **Theodore DeWeese**, of the Johns Hopkins University School of Medicine.

Minsky is the deputy division head and professor of the Division of Radiation Oncology at MD Anderson. He is an active clinician and clinical research investigator on MD Anderson Cancer Center's gastrointestinal cancer multidisciplinary team. He served as a member of the ASTRO board of directors from 2003 to 2006, as the chairman of the Education Council.

Michalski is the Carlos Perez Distinguished Professor and vice-chairman of the Department of Radiation Oncology at Washington University School of Medicine in St. Louis. He is the medical director of Siteman Cancer Center's Clinical Trials Core, which provides support for the center's clinical research activities including protocol development,

regulatory submissions, study coordination and data management. His research interests include radiation dose escalation in the management of prostate cancer; conformal therapy to reduce toxicity in late neurocognitive effects in children with medulloblastoma; and assessment of quality of life in survivors of adult and childhood malignancies.

Michalski is the vice-chairman of the Radiation Therapy Oncology Group, and leads the group's Advanced Technology Integration Committee. He is also a member of the National Comprehensive Cancer Network's bladder cancer panel.

Eichler is the medical director of radiation oncology at Thomas Johns Cancer Hospital in the CJW Medical Center in Richmond, Va., a position he has held since 2002. He is a founding member of Thomas Johns Cancer Hospital's Oncology Executive Committee and served as chairman of the hospital's Multidisciplinary Cancer Committee from 2003 to 2009.

He has been senior editor of ASTROnews since 2010, ASTRO's quarterly member magazine; a member of the Health Policy Committee since 2006; and a member of the Corporate Relations Committee since 2007.

Eichler has served as a presenter on ASTRO's behalf at the AMA CPT Editorial Panel and the AMA Relative Value Update Committee.

DeWeese is professor and chairman of the Department of Radiation Oncology and Molecular Radiation Sciences at Johns Hopkins University School of Medicine. Since 2011, he has held the positions of vice-chairman of the medical board and chairman of the administrative committee of the medical board at Johns Hopkins Hospital. He has been at Johns Hopkins University since beginning his residency in 1991, with roles including associate professor of oncology and urology and the director of the radiation biology research program.

His work with ASTRO includes immediate past chairman of the Annual Meeting Scientific Committee, chairman of the Annual Meeting Scientific Program, and associate chairman of the Scientific Program Subcommittee. He is also a member of the Biology Resource Panel of the Clinical Affairs and Quality Committee, a member of the Task Force on Proton Beam Therapy under the Research Council and a member of the NIH Subcommittee of the Government Relations Council.

FDA News

Accelerated Approval Granted To Perjeta Neoadjuvant Therapy

FDA granted accelerated approval to the Perjeta regimen for neoadjuvant treatment in patients with high-risk, HER2-positive early-stage breast cancer.

The approval is based primarily on data from a phase II study showing that nearly 40 percent of people receiving a combination of Perjeta (pertuzumab), Herceptin (trastuzumab) and docetaxel chemotherapy had no evidence of tumor tissue detectable at the time of surgery, known as a pathological complete response.

The Perjeta regimen is the first neoadjuvant breast cancer treatment approved by FDA and is also the first to be approved based on pCR data.

The approval follows the overwhelming recommendation by the FDA's Oncologic Drugs Advisory Committee, which in its Sept. 12 meeting voted 13 to 0, with one abstention, to recommend approval (The Cancer Letter, Sept. 20).

At the ODAC meeting, FDA officials and the agency's clinical advisors said that they were willing to approve Perjeta based on the totality of evidence.

Indeed, the extent of evidence supporting the Perjeta application is unusual for a new drug:

• The sponsor provided data from a trial in a metastatic disease setting, which showed a statistically significant and robust clinical effect on overall survival.

• A fully-accrued adjuvant therapy trial.

• A well-studied mechanism of action of Perjeta in the HER2 pathway, with evidence that a sister drug, Herceptin, can improve disease-free survival.

• Also, the sponsor had submitted a database reflecting extensive exposure of thousands of patients to the drug in a variety of breast cancer settings.

Realistically, can this amount of evidence be expected to accompany future applications for neoadjuvant indications?

The answers will have to wait, as it is not publicly known whether there are any other applications for neoadjuvant indications before the agency.

"A new approval pathway has made Perjeta available to people with HER2-positive early breast cancer several years earlier than previously possible," said Hal Barron, chief medical officer and head of global product development at Genentech, a unit of Roche and Perjeta's sponsor. "Together with the FDA, we've charted new territory. We look forward to working with health authorities around the world to explore additional ways to bring promising medicines

to patients more quickly."

The new neoadjuvant indication for Perjeta is for use prior to surgery in combination with Herceptin and docetaxel chemotherapy in people with HER2-positive, locally advanced, inflammatory, or early stage (tumor is greater than two centimeters in diameter or node positive) breast cancer. This use of Perjeta is based on an improvement in the percentage of people who had no evidence of cancer in the breast or lymph nodes at the time of surgery.

The safety of Perjeta as part of a doxorubicin-containing regimen has not been established. The safety of Perjeta administered for greater than six cycles for early stage breast cancer has also not been established.

The Perjeta neoadjuvant indication is based primarily on results from the NEOSPHERE study, a phase II study of Perjeta in high-risk, HER2-positive early stage breast cancer. Additional data from the TRYPHAENA study, as well as longer-term safety data from the phase III CLEOPATRA study of Perjeta in HER2-positive metastatic breast cancer were also submitted in support of the approval. TRYPHAENA is a phase II study of Perjeta in HER2-positive early stage breast cancer designed primarily to assess cardiac safety.

A full review of data from the ongoing phase III APHINITY study will be required for the accelerated approval to be converted to a full approval.

APHINITY compares Perjeta, Herceptin and chemotherapy with Herceptin and chemotherapy for adjuvant treatment of people with HER2-positive early stage breast cancer. Data from APHINITY are expected in 2016.

Roche said it's discussing the option of submitting Perjeta in the neoadjuvant setting to regulatory authorities in other countries. Perjeta is approved in a number of countries, including the U.S., for people with HER2-positive metastatic breast cancer or locally recurrent, unresectable breast cancer who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

The NEOSPHERE study (Neoadjuvant Study of Pertuzumab and Herceptin in an Early Regimen Evaluation) was a randomized, multicenter, international phase II study that was conducted in 417 people with newly diagnosed HER2-positive, locally advanced, inflammatory, or early-stage breast cancer. Participants were randomized to four study arms and received four cycles (12 weeks) of neoadjuvant treatment. The primary endpoint was pCR. Secondary endpoints included clinical response, time to clinical response, safety profile, disease-free survival, breast-conserving surgery rate and biomarker assessment.

Study data showed the following:

• Treatment with Perjeta, Herceptin and docetaxel chemotherapy significantly improved the rate of total pCR by 17.8 percentage points compared to Herceptin and docetaxel alone (39.3 vs. 21.5 percent, respectively; p=0.0063).

• pCR of 21.5 percent for Herceptin and docetaxel.

• pCR of 39.3 percent for Perjeta, Herceptin and docetaxel.

• pCR of 11.2 percent for Perjeta and Herceptin.

• pCR of 17.7 percent for Perjeta and docetaxel.

The TRYPHAENA study (ToleRabilitY of Pertuzumab, Herceptin and AnthracyclinEs in NeoAdjuvant breast cancer) is a randomized, multicenter phase II study that was conducted in 225 people with HER2-positive, locally advanced, inflammatory, or early stage breast cancer with tumors greater than two centimeters.

Participants were randomized to one of three neoadjuvant Perjeta regimens. The primary endpoint was cardiac safety. Secondary endpoints included pCR, clinical response, breast-conserving surgery rate, disease-free survival, progression-free survival, overall survival, and biomarker assessment.

The study was not powered to compare the three study arms. The rates of total pCR in the three arms were as follows:

• pCR of 56.2 percent for Perjeta, Herceptin and anthracycline-based chemotherapy, followed by Perjeta, Herceptin and docetaxel.

• pCR of 54.7 percent for anthracycline-based chemotherapy, followed by Perjeta, Herceptin and docetaxel.

• pCR of 63.6 percent for the anthracycline-free arm (Perjeta, Herceptin, docetaxel and carboplatin chemotherapy).

No new or unexpected cardiac adverse events were observed in any of the study arms; those observed were consistent with those seen in previous studies of Perjeta, Herceptin and chemotherapy, either in combination or alone.