THE CANCER LETTER

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Congress Plans to Accelerate Development of Drugs, Devices

By Matthew Bin Han Ong

The House Committee on Energy and Commerce is spearheading legislation aimed streamlining development of drugs and medical devices.

The bipartisan initiative, called "21st Century Cures," was launched April 30, and is led by Rep. Fred Upton (R-Mich.), chairman of the committee, and Rep. Diana DeGette (D-Colo.), chief deputy whip.

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ACS President & COO Resigns Unexpectedly; Was Seen as Contender for CEO Position

By Paul Goldberg

Gregory Bontrager resigned from his position as chief operating officer and president of the American Cancer Society.

His resignation was announced in an email from ACS Chief Executive Officer John Seffrin Dec. 18. No reason for the departure was cited.

Bontrager, who became the COO in 2007 and president in 2013, was, in effect, the society's second-most-powerful official, and one of the engineers of its current move to a centralized structure.

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Editorial

A Record-Breaking Year for The Cancer Letter

By Paul Goldberg

2014 was a transformative year for The Cancer Letter.

• We launched a new website that makes our content possible to read online without downloading PDF files.

• We made the website "responsive," enabling it to adapt to all screen sizes, including smartphones and tablets. Now, about a third of our readers use these devices. An app will be available shortly.

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Bipartisan 21st Century Cures Report Expected in January

(Continued from page 1)

"We're taking the first comprehensive look—by the Congress—at the full arc of accelerating the cures from the discovery of clues and basic science to streamlining the drug development process, to unleashing the power of digital medicine and social media at the treatment delivery phase," Upton said at the 2014 Friends-Brookings Conference on Clinical Cancer Research, an annual meeting co-hosted by Friends of Cancer Research and the Engelberg Center for Health Care Reform at the Brookings Institution.

"We've got, I want to say, four or five pretty extensive white papers, generating ideas and thoughts. We want input on how we can better utilize digital medicine, asking patients about their diseases so that we know how we can help."

Upton said the committee has been working with advocacy organizations and other stakeholders, including NIH Director Francis Collins, FDA Commissioner Margaret Hamburg, and HHS Secretary Sylvia Burwell.

"Our goal is, again, to have a discussion draft by mid-January or so, not too late after that," Upton said. "Then, after we sit down with Ellen [Sigal, chairperson and founder of FOCR], introduce the bill. Our idea is to move it through the committee before the end of March and have it on the floor before Memorial Day. We're reaching out to the Senate.

"We want to get this bill enacted next year. That is our goal. And that means we need a big vote in the House to help with the Senate—there are different rules over there—be able to work out the differences; hopefully there's not going to be all that many. I don't expect real problems to get to the president's desk by the end of next year."

The following is a selection of Upton's remarks made at the 2014 Friends-Brookings Conference on Clinical Cancer Research. A video of Upton's speech is available on the FOCR website.

We have spent a year listening to folks around the country about what we can do to expedite the approval of drugs and devices. And we're getting close to coming up with legislation.

[Friends of Cancer Research Chair and Founder] Ellen [Sigal], in fact, was one of our first participants in our formal process in a roundtable that we had back in May—not a normal committee hearing, but literally a table we're all sitting at—it was a very positive experience as we listen to a dialogue between different parties on what we can do to work together.

Our plan, now, is to release a discussion draft early next, probably the second or third week of January. We're going to have a meeting with a number of you all—Ellen's going to get some of the important groups, and we can really sit down, and you can look at what our discussion draft does, because we want to continue to get that input.

We're looking for ideas. Maybe we missed something, maybe we went too—but really sit down and have a constructive discussion for a considerable amount of time before we actually move that bill into the next stage, which is to introduce it.

We have an ambitious goal, but there is no more issue to me in our committee than moving quickly and to expedite the approval of these drugs and devices. Seven thousand diseases—we have cures for only 500.

It's not a Republican or Democratic idea. I look at my family: my wife has lupus; my uncle had Parkinson's disease; my mom's a survivor of cancer. No different from any other family that's out there.

And I know that we can really make a difference for every family as we move on this legislation. I personally have been so impressed with the advances in technology. Molecular medicine has achieved, over the last couple of decades—in fact, I took my health team, I call them my "Dream Team" to go to different places around the country to actually kick the tires and see what they're doing, to listen and figure out what we can do to help in an even better way.

Cover Photo: Rep. Fred Upton. Source: C-SPAN.

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But if we want to save more lives and keep the U.S. the leader in medical innovation, we have to make sure there is not a major gap between the science of cures in the way that we regulate those therapies. That is our goal.

So we're taking the first comprehensive look—by the Congress—at the full arc of accelerating the cures from the discovery of clues and basic science to streamlining the drug development process, to unleashing the power of digital medicine and social media at the treatment delivery phase.

[The initiative is] bipartisan. One of the things we did with then-Majority Leader Eric Cantor (R-Va.), who tragically lost his election, but I've got to tell you, Kevin McCarthy (R-Calif.), who is taking his place as Republican majority leader now, has filled those shoes, and is fully supportive of what we're trying to do.

Steny Hoyer (D-Md.), former majority leader, and now the Democratic whip, number two in the Democratic leadership, also very involved. He testified with Ellen that first day at that first roundtable—very interested in making sure that the Democratic support is there, too because our goal is to absolutely keep this bipartisan.

We know that the cycle of discovery, development and delivery is what saves lives, and we want to work it faster, and more efficiently so that patients have better access to treatments. It needs to collaborative, which is why our first step has been listening to experts like you, so that together, we can achieve the common goal of accelerating the pace of cures, and keeping America at the forefront of medicine and discovery.

We learned that half of the venture capitalists have left the U.S. They're investing now overseas—we want to bring them back, we want their investment to be here. We've got to maintain that leadership role in research and health care that not only produces jobs, but also saves lives, which is why it was so important back in the 90s when Henry Waxman (D-Mass.) and I teamed up as the lead Republican and Democratic authors, along with John McCain (R-Ariz.) and Paul Wellstone (D-Minn.), to double the money for the NIH, that President Clinton signed into law.

We've been working very closely with the Secretary of HHS, Sylvia Burwell. She has been terrific. She's participated, they're fully engaged, and whether it's working with [NIH Director] Francis Collins or [FDA Commissioner] Margaret Hamburg, we have welcomed their support—they're full participants in the hearings and roundtables all around the country.

We're working with researchers, the innovators in the private sector who are investing in the future of cures, and I'm sure our colleagues, particularly our new colleagues to the Congress, and to our committee—they are going to be fully engaged in what we're trying to do, and we want to obviously continue to work well with you.

At our committee, we've held four or five D.C.-based roundtables in the last couple of months. We've had eight committee hearings, Francis Collins has been all over the country with us; he's been terrific. Dean Kamen, Michael Milken has just been wonderful, obviously, Commissioner Hamburg, and others like Secretary Burwell, [former NCI Director] Andy von Eschenbach. I mean, all of them have been truly helpful to try and encourage us to do the right thing.

We've done more than a dozen, across the U.S.—from Pennsylvania, to out west, the south, even in this great town called Kalamazoo, Michigan, which happens to be my where my plane will land a little bit later this morning.

We've had a number of white papers. I would encourage you to go to our website at our committee to look at them. We've got, I want to say, four or five pretty extensive white papers, generating ideas and thoughts. We want input on how we can better utilize digital medicine, asking patients about their diseases so that we know how we can help.

The basic framework pillars of what we want to see our goals are these five:

• Keep patients at the center of the decision-making process

• Modernize clinical trials

• Foster 21th century digital medicine by facilitating data sharing and the use of medical apps

• Encourage young scientists to enter the research world—the reduction, inflation and everything else, younger scientists are getting into that queue, losing interest, we've got to bring that back up.

• Incentivize new drugs and devices for unmet medical needs.

Those are our five goals. We have to have an ongoing collaborative effort. It has to be all-hands-on-deck, and we're going to need your help.

After we sit down in January, our goal is to introduce legislation within a couple of weeks. I'm a regular order guy, which means I actually changed the rules of our committee to encourage more bipartisanship.

Our goal is, again, to have a discussion draft by mid-January or so, not too late after that. Then, after we sit down with Ellen, introduce the bill. Our idea is to move it through the committee before the end of March and have it on the floor before Memorial Day. We're reaching out to the Senate.

We're going to need, particularly, the patient groups and all of the stakeholders that we've been

working with to really help us, because there are some bumps out there, and we also know that the political season gets into high energy, particularly with 2016 right around the horizon.

We want to get this bill enacted next year. That is our goal. And that means we need a big vote in the House to help with the Senate—there are different rules over there—be able to work out the differences; hopefully there's not going to be all that many. I don't expect real problems to get to the president's desk by the end of next year.

We're really excited about what we're going to be able to do to change the process and save a lot of lives, and the secondary effect is we're going to bring a lot of those jobs back to America, and that's not a bad thing.

Advocates Prepare to Face Republican-led Congress

By Matthew Bin Han Ong

The 113th Congress staggered through its final spending bill, approving $1.1 trillion in a massive "cromnibus" Dec. 13, keeping most of the federal government funded through September 2015, and locking in a half-percent increase for NIH and NCI in FY2015.

Biomedical research advocates bemoaned the modest increase in funding—$150 million for NIH and $27 million for NCI—and questioned Congress's commitment to scientific progress (The Cancer Letter, Dec. 12).

"In times of constrained funding, any increase is both welcomed and appreciated. But a half a percent increase when biomedical research inflation is two percent is not enough to sustain even current progress," said Jennifer Zeitzer, director of legislative relations at the Federation of American Societies for Experimental Biology, a coalition that represents 27 scientific societies and over 120,000 researchers worldwide.

The 2013 and 2014 fiscal years were years of dysfunction for the federal government.

Congress regularly log-jammed on funding issues: by activating the sequestration set in the Budget Control Act, which cut the federal budget by 5.1 percent; and by forcing a government shutdown in October 2013.

Lawmakers consistently failed to jump through the hoops of the regular appropriations process, lumping funding bills into large omnibuses and enacting emergency continuing resolutions as stopgap measures to create opportunities for fiery debates.

The time has come, advocates said, for the incoming Republican majorities in both chambers of Congress to legislate and appropriate in an orderly fashion.

"Congress continues to completely shock me with how dysfunctional they can be. They continue to lower the bar, and I admire that commitment," Zeitzer said to The Cancer Letter. "But we get to start over with a clean slate anyway next year. That might help—clearing out the old. This is an opportunity for Republicans to show that they can govern. Let them take control. We've tried doing that under Democrats."

A conversation with Zeitzer appears on p. 7.

Republicans have at times been generous to NIH, said Jon Retzlaff, managing director of science policy and government affairs at the American Association for Cancer Research.

"It's important to remember that the last time there was a Republican-dominated Congress and a Democrat in the White House, from 1994 to 2000, the process of doubling NIH's budget began, which included multiple years of 15 percent annual increases," Retzlaff said to The Cancer Letter. "Of course, today's fiscal and political environment is different in many ways—the research opportunities which currently exist, as well as our ability to translate medical science discoveries into improved treatments for patients, are even that much greater than they were in the mid-1990s."

But advocates will need to step up efforts to raise awareness, Retzlaff said.

"There's definitely a unique opportunity, in spite of the obvious challenges, for all of us in the medical research advocacy community to increase our activities to raise awareness on Capitol Hill about the importance of robust and sustained federal investments in medical research," Retzlaff said. "And because it is so vitally important to bring predictability and growth to the NIH budget, we may also need to increase our advocacy in 2015 for some of the alternative funding mechanisms—outside the regular appropriations process—that have been proposed for funding the NIH and NCI."

Advocates said the Budget Control Act, which caps all federal spending, plays a bigger role in limiting federal investment in scientific progress. The deep 5.1 percent cuts across-the-board went into effect March 1, 2013, slashing the NIH budget by $1.553 billion and NCI's by $219 million. (The Cancer Letter, March 22, 2013).

The Republican majority is unlikely to reverse the cuts, advocates say.

"Some of NIH's greatest champions have been, and continue to be, Republican members of Congress," said Carrie Wolinetz, president of United for Medical Research and deputy vice president for federal relations

at the Association of American Universities. "For example, Sen. Jerry Moran (R-Kan.), who is likely to be the next Senate Labor-HHS appropriations subcommittee chair, cares deeply about NIH.

"Unfortunately, the current challenge is the limiting impact of the overall budget caps, which make it difficult to provide adequate funding to NIH and other federal research programs, and which seem less likely to be alleviated under a Republican majority."

The caps are set to gradually increase over the next decade, but advocates said the scheduled increases could be seen as another reason to not aggressively fund NIH.

"The problem is the caps are working, in the sense that the deficit has been reduced," Zeitzer said. "We are holding down spending, and so I don't think there is much of an incentive for either side to bust the caps.

"The other thing, too, is even for those who do want to bust or readjust the caps, they are facing a pretty solid wall of opposition from the fiscal conservatives in the House and the Senate.

"If I'm a fiscal conservative like Sen. Jeff Sessions (R-Ala.), and some advocate comes to me pleading for more money for NIH, and says the caps are too tight, I'd look at the chart and say, 'But they're going up! So it's your job to make your case, fight for what you think you need, but don't talk to me about increasing the caps, because they're going up.'"

Advocates said legislators have called for renewed commitment to action in the wake of the November elections.

"We are cautiously optimistic that the new Congress will support incremental increases for federal science agencies, especially given the reality that research has no party affiliation," said Mary Woolley, president and CEO of Research!America. "Bipartisan proposals to advance medical progress, such as the 21st Century Cures initiative, and to increase National Institutes of Health funding, such as the Warren-Hatch bill, are perhaps our best prospects in this new political climate."

Half-Percent Raise Is Not Enough

The Cancer Letter asked leaders of science and cancer advocacy groups to comment on the half-percent increases in federal funding for NIH and NCI in fiscal 2015, and on the prospects of science funding when Republicans take control of Congress in January.

Their responses follow:

Peter Paul Yu, president of the American Society of Clinical Oncology

The federal budget process over the past decade has created severe instability for medical research funding.

If we are going to build on the major progress that we have made in every area of cancer care, Congress must provide predictable increases in funding for the National Institutes of Health and the National Cancer Institute that at least keep pace with the rate of biomedical inflation.

ASCO looks forward to working with this Congress and will continue to urge members on both sides of the aisle to provide long-term financial support to our nation's cancer research infrastructure that corrects years of underfunding.

Richard Schilsky, chief medical officer of ASCO

We're encouraged that Congress passed an omnibus budget rather than another short-term continuing resolution, and we appreciate the hard work of many lawmakers to ensure that the bill includes an increase for NIH and NCI.

However, this small increase isn't enough to build a robust future for America's cancer research enterprise and combat the continued decreasing purchasing power of the NCI.

Jon Retzlaff, managing director of science policy and government affairs at the American Association for Cancer Research

While we are disappointed that the FY 2015 budget increase for NIH will result in the continued erosion in the agency's ability to support lifesaving research (which is because the small increase in funding won't allow NIH to keep pace with the biomedical inflation rate for FY 2015), we are pleased that Congress passed the bill, as opposed to funding NIH and NCI through a full-year continuing resolution, which would have eliminated the $150 million increase for the NIH ($27 million increase for the NCI).

It's just paramount that if we are to help build

on our nation's prior investments in medical research, ensure that our nation is able to respond to emerging health and research needs, and train the future generation of scientists, our leaders in Congress must prioritize NIH funding by providing sustainable budget increases above the biomedical research inflation rate.

We recognize that the FY 2016 appropriations process is once again going to be quite challenging, especially because the rigid defense and nondefense spending caps will continue unless Congress passes a law to provide sequestration relief for discretionary programs.

However, with the medical research advocacy community united in its commitment to do more to convince Members of Congress to prioritize NIH funding, we will have opportunities to make our case in 2015.

For example, the Rally for Medical Research Capitol Hill Day, which we anticipate will include more than 300 national organizations coming together to call on our nation's policymakers to make funding for the NIH a national priority, will take place again (in September 2015).

It's also important to remember that the last time there was a Republican-dominated Congress and a Democrat in the White House (1994-2000), the process of doubling NIH's budget began, which included multiple years of 15 percent annual increases.

While, of course, today's fiscal and political environment is different in many ways, the research opportunities that currently exist, as well as our ability to translate medical science discoveries into improved treatments for patients, are even that much greater than they were in the mid-1990s.

In addition, since supporting NIH is a non-partisan issue and one that has historically been championed by both Republicans and Democrats, this particular message may resonate with a Congress that is likely to identify specific priorities to support.

Therefore, our job is to make sure that Congress recognizes the importance of robust and sustained Federal investments in medical research. And because it is so vitally important to bring predictability and growth to the NIH budget, we may also need to increase our advocacy in 2015 for some of the alternative funding mechanisms (outside the regular appropriations process) that have been proposed for funding the NIH.

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Mary Woolley, president and CEO of Research!America

The tiny increases included in the "cromnibus" bill for the National Institutes of Health and our nation's other health research agencies are just that. The underwhelming support for the NIH, the Centers for Disease Control and Prevention, the National Science Foundation and the Food and Drug Administration following years of stagnant funding and budget cuts begs the question—how low can we go, given health threats the likes of which stand to bankrupt the nation?

And the decision to flat-fund the Agency for Healthcare Research and Quality does not provide what it takes to reduce the much-complained of inefficiencies in our health care system. The pain and economic drain of one disease alone—Alzheimer's—is not going to be effectively confronted without stronger investments in research.

In the wake of the election we hear a renewed commitment to action. We are cautiously optimistic that the new Congress will support incremental increases for federal science agencies, especially given the reality that research has no party affiliation.

Bipartisan proposals to advance medical progress, such as the 21st Century Cures initiative, and to increase National Institutes of Health funding, such as the Warren-Hatch bill, are perhaps our best prospects in this new political climate.

All stakeholders for research—and by that I mean every American who has known illness directly or indirectly and every business leader who understands the importance of the public-private partnership essential to medical innovation and its significance to our economy—should work shoulder to shoulder to make sure NIH and our other federal science agencies are among the short list of priorities as our nation's leaders discuss their agendas for the 114th Congress.

Carrie Wolinetz, president of United for Medical Research and deputy vice president for federal relations at the Association of American Universities

Congress has missed a major opportunity to fund advances in science and medicine that improve our nation's health and economic outlook, with nearly flat funding for the National Institutes of Health in its FY15 omnibus bill.

With millions of deaths annually from disease, millions more receiving devastating diagnoses every day and a decade of declining funding slowing the progress of scientists in research labs across the country, we call on Congress to renew its effort to fund vital medical

research supported by NIH.

Sustained increases to the NIH budget are necessary to close our nation's innovation deficit—the widening gap between the current medical research funding levels and the investment required to ensure the U.S. remains the world's innovation leader.

Some of NIH's greatest champions have been, and continue to be, Republican members of Congress. For example, Senator Moran, who is likely to be the next Senate Labor-HHS appropriations subcommittee chair, cares deeply about NIH.

Unfortunately, the current challenge is the limiting impact of the overall budget caps, which make it difficult to provide adequate funding to NIH and other federal research programs, and which seem less likely to be alleviated under a Republican majority.

Conversation with The Cancer Letter

Is Republican Control Better Than Two-Party Stalemate?

As Congress goes into recess and Democrats relinquish their eight-year control of the Senate, advocates for biomedical research are rethinking their approaches to a political reality not observed in nearly a decade: a Republican-controlled Congress.

Jennifer Zeitzer, director of legislative relations at the Federation of American Societies for Experimental Biology, a coalition that represents 27 scientific societies and over 120,000 researchers worldwide, says she is optimistic about prospects for science funding in the 114th Congress.

The reason: both sides have learned that stalemates benefit no one.

"The last two years have not been great for anybody, for either party, for advocates, for America at large. Congress has been largely dysfunctional," Zeitzer said to The Cancer Letter. "We shut down the government; very little got done."

True, the funding landscape continues to look bleak: sequestration caps are unlikely to be lifted, and fiscal conservatives—bolstered by incoming freshman Republicans in the Senate—will keep spending at a minimum.

Advocates need to continue to do their best to make the case for a sustained increase in federal investment, Zeitzer said.

"Funding for biomedical research has always been a bipartisan endeavor," Zeitzer said. "We can't forget that the beginning of the doubling of the NIH budget started under the Republican chairman of the Labor, Health and Human Services Committee in the House, and that was [Rep.] John Porter [R-Ill.].

"I'm not overly concerned, because we have both Republican and Democrat champions for science."

Zeitzer spoke with Matthew Bin Han Ong, a reporter with The Cancer Letter.

Matthew Ong: *How will the new GOP-led Congress affect science funding?*

Jennifer Zeitzer: Congress continues to surprise me with what they do and do not do regardless of who's in charge. That being said, the incoming committee chairs are going to have a bigger role and a big influence in Congress, especially in the Senate.

[House] Majority Leader Kevin McCarthy (R-Calif.) also issued a memo saying that he intends to return more power to the committees.

Starting with the Senate, because I think that's the bigger story here, Sen. Thad Cochran (R-Miss.) is in line to chair the full Appropriations Committee. He would take over from Sen. Barbara Mikulski (D-Md.). Sen. Cochran has been an appropriator—he knows what he's doing—he's been supportive of funding for the NIH in the past, and I don't expect that position to change.

Sen. Mikulski is expected to become the top Democrat on the Appropriations Committee. She and Sen. Cochran have served together on the Appropriations Committee for years, so my understanding is that they have a working relationship—that could be good news, moving forward.

Getting the appropriations process back to regular order is a key goal of theirs. It's critically important. You've got to get Congress back in the business of deciding what the budgets are going to be for the federal agencies, whether it's NIH or the Department of Education.

On the appropriations subcommittees that fund research, for example, the Labor, Health and Human Services Subcommittee that funds NIH, I don't know who is going to take over that subcommittee from Sen. Tom Harkin (D-Iowa).

If you look at the seniority list from the subcommittee, the next person in line is Sen. Jerry Moran (R-Kan.), who has been a very vocal NIH advocate in the entire time he has been in the Senate. He's finishing up his first term now, he's up for reelection in two years. He's been the top Republican on that subcommittee for the last two or three years now, and he's always spoken up on behalf of NIH. He has, in fact, offered amendments during the process of writing the bills to increase funding for NIH above what Democrats

have recommended.

Sen. Moran's challenge—and everyone else's—is how to make the numbers work within the strict Budget Control Act caps.

I'm hearing that if Sen. Moran takes over that subcommittee, his counterpart on the Democratic side will likely be Sen. Patty Murray (D-Wash.), who will be phenomenal.

She's a huge NIH champion and she really understands the issues. She's got the budget experience as well—let's not forget that she and [House Budget Committee] Chairman Paul Ryan (R-Wis) negotiated the deal that gave us some relief from sequestration and the budget caps.

I'm hearing that she is a very strong contender to take over the top Democratic spot on that subcommittee.

On the Commerce, Justice, Science, and Related Agencies Appropriations Subcommittee, which funds the National Science Foundation, the person who's in line to take that chairmanship is Sen. Richard Shelby (R-Ala.), who is a big fan of science funding, particularly as it relates to NASA. Now, I don't know if he will go ahead and take that or take something else, because he's got such seniority. It is not clear who the top Democrat will be on that subcommittee.

The other committee that has jurisdiction over research issues, although not funding, is the Health, Education, Labor and Pensions Committee. It was just announced that Sen. Murray will become the top Democrat on that committee, which will be great.

On the Republican side, it's Sen. Lamar Alexander (R-Tenn.) who will be first in line in seniority for the HELP committee. It remains to be seen who the Republican chair of the HELP committee will be. But even if it was Sen. Alexander, he is a huge champion for the physical sciences agencies, and that could work out very well for agencies like NSF.

MO: *If I'm hearing you correctly, it sounds like the future of science funding in the forthcoming term is a little brighter.*

JZ: I guess I'm more optimistic than some people, and I'm optimistic for a couple of reasons. I think the last two years have not been great for anybody, for either party, for advocates, for America at large. Congress has been largely dysfunctional. We shut down the government; very little got done with the exception of, perhaps, the Ryan and Murray deal, but it took the government shutdown to get us there.

So in some respects, we get to start over with a clean slate anyway next year. That might help—clearing out the old. This is an opportunity for Republicans to show that they can govern. Let them take control. We've tried doing that under Democrats.

Sen. [Mitch] McConnell (R-Ky.) has recently given a couple of speeches and he's talking about buckling down and getting some work done, and working with the other side, and reaching across the aisle on areas where they can find agreement.

Funding for biomedical research has always been a bipartisan endeavor. We can't forget that the beginning of the doubling of the NIH budget started under the Republican chairman of the Labor, Health and Human Services Committee in the House, and that was John Porter (Ill.).

I'm not overly concerned, because we have both Republican and Democrat champions for science.

The biggest issue that we still face, that did not get changed at all on Election Day, was our budgetary woes and what's going to happen, moving forward. For better or for worse, it seems like the Budget Control Act is here to stay. I have not spoken to anybody on Capitol Hill—in the last six to eight months—who thinks that we need to get rid of that, unfortunately. Sequestration continues to be very unpopular, but who knows?

In order to get rid of sequestration, we need Congress—Democrats and Republicans—to come together and address the larger budget picture and budget issues that are affecting the long-term outlook for the deficit, and that is the entitlement side of things, as well as raising revenue. And neither side has really shown much of a willingness to do that, and I'm not sure the election changes that calculus, especially with the 2016 presidential race starting soon.

It's a matter now, really, of doing our best as advocates to make the case for increasing and sustaining the investment in biomedical research, even given the current budget picture. And if Congress would be willing to increase the caps a little bit to make room for some high priority items, it's our job as advocates to make sure that funding for research is one of the high priority items. And that's what we're going to be doing moving forward.

MO: *Will the Republicans be more likely than the Democrats to consider loosening the budgetary caps?*

JZ: I really don't know. There's a contingent of folks on Capitol Hill, both from the House and the Senate, who don't like the fact that the caps are really holding down the line on defense spending as well, and they want to see defense spending increase.

But the problem is the caps are working, in the sense that the deficit has been reduced. We are holding down spending, and so I don't think there is much of

an incentive for either side to bust the caps.

The other thing, too, is even for those who do want to bust or readjust the caps, they are facing a pretty solid wall of opposition from the fiscal conservatives in the House and the Senate. Sen. Jeff Sessions (R-Ala.), a member of the Budget Committee, has made it very clear in chapter and verse, and in every comment that he's made since the Budget Control Act was passed, that he does not believe that they should renegotiate that or change the caps, and he's got support behind him on that.

Sessions has support from fiscal conservatives like Mike Lee (R-Utah) and Ron Johnson (R-Wis.)—who would actually like to lower those caps and cut even more spending. And there is a contingent of very fiscally conservative members in the House who have given the speaker a hard time on a lot of things in the last two years, one of which is that the budget caps still allow for too much spending.

The same group that was happy to shut down the government—or at least was blamed for shutting down the government—part of their mantra was, "Washington is still spending too much."

That's why I don't think there's going to be any leeway. I think what Patty Murray and Paul Ryan were able to do this time last year in getting that deal to raise for FY14 and FY15 spending caps slightly and providing some relief from sequestration—that was tied very much to America recovering from the horrible aftermath of the government shutdown.

Also, we've been dealing with near constant fiscal crises for the last couple of years. What we need is a Congress that will get to work to make up for the recent lack of productivity.

It's going to be interesting to see moving forward. Some of those same fiscally conservative members of Congress who also support defense spending have already said that they are willing to sacrifice defense spending in order to keep the caps. They don't care if it hurts DoD, or defense, or our military. They do not want to increase spending in any way, even for something like defense.

When you put all of that together, it doesn't really bode well for a productive conversation.

MO: *But the caps do increase.*

JZ: The other thing that people have not really focused on is that, yes, the caps do increase for FY16, 17 and beyond. Not by much, but they do increase by a very small amount. So I think that's out there as well, too, in terms of an argument.

If I'm a fiscal conservative like Sen. Sessions, and some advocate comes to me pleading for more money for NIH, and says the caps are too tight, I'd look at the chart and say, "But they're going up! So it's your job to make your case, fight for what you think you need, but don't talk to me about increasing the caps, because they're going up."

MO: *Do you think this election has shifted Congress more into the fiscally conservative spectrum?*

JZ: That's hard to tell. I'll be honest and say that I don't know very much about the incoming freshman class of the House of Representatives. I didn't pay very much attention because I was more focused on the Senate.

On the Senate side, some of the new members coming in are Joni Ernst (R-Iowa), Thom Tillis (R-N.C.), and Tom Cotton (R-Ark.). Cotton is extremely conservative. He's coming over from the House.

I don't know much about Tillis. I've heard he is more conservative.

Joni Ernst—she talks about "making Washington squeal." I'm not quite sure what she really stands for, but some of her rhetoric—she talks about getting Washington out of our lives and making government smaller—so she might be another one who says, "Hey, let's stop spending money."

That being said, the new senator from West Virginia, Shelley Moore Capito (R), is much more moderate, a big fan of NIH, so we are glad to see her moving over to the Senate because that brings another NIH champion into the discussion. And she does happen to be from the majority party, so that couldn't hurt.

MO: *I see. What can we conclude, then, about Congress in the next term?*

JZ: Congress continues to completely shock me with how dysfunctional they can be. They continue to lower the bar, and I admire that commitment.

But I'm optimistic that this gives everybody, the whole country, a chance to sort of reset things, get past the dysfunction of the last two years, and move forward with making important decisions about how to run this country.

As an advocacy community, we've made a strong case for continuing the investment in biomedical research, and we just need to continue to do that. We need to reach out to the new members of Congress from both parties, we need to work with the new leadership in the Senate, and continue to make that case.

So I'm feeling somewhat optimistic that we can perhaps get past the gridlock and identify some priorities for this country.

It's just so hard to tell at this point, but so far I've been impressed with the way that Mitch McConnell, the incoming Senate Majority Leader, has been proactive—he said that they're ready to govern, and if that's the case, it could mean good things moving forward.

Bontrager Viewed as Overseer Of ACS Move to Centralization

(Continued from page 1)

Bontrager was also believed to have been a candidate to succeed Seffrin, who took the top job in 1992 and recently announced plans to retire (The Cancer Letter, Jan. 24). Seffrin offered to stay on until a successor is found.

Bontrager joined ACS in 1988 as director of development for the former Michigan Division. According to the ACS tax forms for 2013, his total compensation was $767,000. His sudden departure is likely a sign of the board taking a greater role in running the society.

In 2007, before Bontrager became COO, the society's total support from the public was at its historic high point of $1.05 billion. In 2013, support from the public was $884.6 million.

ACS spokeswoman Tara Peters said Bontrager's departure was a part of the transition. "I don't think it's uncommon for that sort of change to be made," Peters said to The Cancer Letter. "His departure provides maximum flexibility for the incoming CEO to continue transforming and leading the society into the future."

The text of Seffrin's announcement of Bontrager's departure—which was sent to the society's staff and volunteers—follows:

Dear Colleagues,

I'm writing to inform you of a leadership change. As you know, our Board of Directors continues to make progress in its Chief Executive Officer selection process. As part of this natural evolution and anticipated transition to a new CEO in early 2015, Greg Bontrager has tendered, and I have accepted, his resignation as President and Chief Operating Officer, effective Jan. 31, 2015.

Greg began his career at the American Cancer Society in 1988, as the Director of Development for the Michigan Division. Twenty-six years later he is leaving as President and Chief Operating Officer of a united enterprise. The very fact that we can now speak of one enterprise is due, in great part, to his vision and leadership. What many of you may not know is

Gregory Bontrager

that Greg came to what was then the National Home Office to be the Chief Mission Officer for Pat Felts, who was taking over as Chief Operating Officer from Don Thomas. When Pat suffered a serious stroke and was unable to continue working, I asked Greg to step in. He had not expected such responsibility, but he accepted my request, and I found a true partner. Greg's intelligence and his gift for communicating are well known, and I have appreciated both, but what I value most is his integrity, loyalty and his friendship. He will be sorely missed.

Greg's departure further positions the organization for the arrival of a new CEO, and provides the maximum degree of freedom and latitude for the incoming CEO to continue transforming and leading the Society into the future. While Greg's departure completes the Transformation chapter he and I began as partners, together with you, I remain absolutely confident and excited about the solid foundation we have built for the future of the organization.

To maintain our continuity and commitment to ACS Transformation during this interim period and through the transition to a new CEO, I have established an Operating Council comprised of Joe Cahoon, senior executive vice president, Field Operations; Catherine Mickle, chief financial officer; and Dr. Richard Wender, chief cancer control officer. This Operating Council will work closely with me and with Carol Richard, deputy to the president & COO, who will transition to my deputy. I will remain fully engaged leading the Society until my CEO successor is in place.

Through a century of our history we have one common thread that hasn't wavered and that is our exceptionally talented and passionate staff and volunteers. Millions of lives are counting and depending on us to deliver on our mission of alleviating suffering and saving more lives from cancer each and every day.

Thank you for your continued support during this time of transition—and always.

ODAC To Advise FDA on First Biosimilars Application Jan. 7

The FDA Oncologic Drugs Advisory Committee will meet Jan. 7, 2015, to discuss a biologics license application for a proposed biosimilar to Amgen Inc.'s Neupogen (filgrastim).

The biosimilar application, submitted by Sandoz Inc., will be the first such application to be filed and discussed by an FDA advisory committee.

The meeting will likely clarify the standards for approval of biosimilar biologics, which are likely to cost less than their branded counterparts.

The proposed indications for this product are:

• To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever;

• For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with acute myeloid leukemia;

• To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation;

• For the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; and

• For chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

The Affordable Care Act amended the Public Health Service Act to create an abbreviated licensure pathway for biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product.

This pathway is provided in the part of the law known as the Biologics Price Competition and Innovation Act. Under the act, a biological product may be demonstrated to be biosimilar if data show that, among other things, the product is highly similar to an already-approved biological product.

FDA's resources are:

• Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations.

• Guidance for Industry: Reference Product Exclusivity for Biological Products Filed Under Section 351(a) of the PHS Act (Draft Guidance)

NCI Board Approves 3 Concepts

At a meeting Dec. 2, the NCI Board of Scientific Advisors approved three concepts during a joint meeting with the National Cancer Advisory Board.

The approved concepts are:

1. The Innovative Molecular Analysis Technologies Program, which supports the development, testing, and validation of high-risk and high-impact multidisciplinary, cancer-relevant technologies for the molecular and cellular analysis of cancer.

The program seeks to support technology-focused applications unlikely to be competitive through existing funding opportunities.

The program's request for reissuance of four RFA solicitations was approved 20 to 0, with one abstention.

The four RFAs are:

• Early-Stage Innovative Molecular Analysis Technology Development for Cancer Research (IMT R21)

• Advanced Development and Validation of Emerging Molecular Analysis Technologies for Cancer Research (EMT R33)

• Early-Stage Innovative Technologies for Cancer Biospecimen Sciences (BSP R21)

• Advanced Development and Validation of Emerging Technologies for Cancer Biospecimen Sciences (BSP R33)

The RFAs will support 34 to 39 new awards per year, and would cost about $11 million in the first year.

The IMAT program, a trans-divisional initiative involving all extramural divisions of NCI as well as the Office of the Director and the Center to Reduce Cancer Health Disparities, has solicited applications every year since 1998.

To date, 3,914 applications have been received, with a total of 478 new competitive awards. As of November 2014, 97 projects are active.

2. The Experimental Therapeutics Clinical Trials Network of clinical trial sites and infrastructure that conducts earliest clinical studies of Investigational New Drugs sponsored by NCI.

The ETCTN is composed of two clinical components: phase I UM1 grant program and Phase 2 N01 contract program.

According to officials, the expiration of contracts for the phase II program is an opportunity to develop ETCTN into a unified grant program to adapt to the era of targeted therapies.

The reissuance of the RFA for the phase II component of ETCTN was approved 20 to 0, with one abstention.

The proposal for reissuance seeks to incorporate the phase II study expertise that currently resides in the contract program sites into the phase I UM1 grant program to create a single early therapeutics program for the early clinical development of these agents.

In addition, a pilot collaboration between the ETCTN and the NCI Cancer Centers Program called the NCI Early Therapeutics Opportunity Program, would allow NCI Cancer Centers not affiliated with the ETCTN through the UM1 grant program to have limited participation in the ETCTN, with opportunities for physician-scientists to develop studies and for patients to enroll in select phase II studies.

The proposal seeks an annual allocation of $10 million per year, with $9 million for UM1 supplements and $1 million for the NCI Cancer Centers pilot collaboration with ETCTN.

The ETCTN is run out of the Cancer Therapy Evaluation Program.

3. The NCI Small Business Innovation Research Program, which provides a funding opportunity called the SBIR Phase IIB Bridge Award, which supports projects in the areas of cancer therapeutics, imaging technologies, interventional devices, diagnostics and prognostics.

The proposal for a third reissuance of the RFA for the Bridge Award program was approved 20 to 0, with one abstention.

According to officials, the program is designed to fund the critical milestones necessary for companies and projects to successfully navigate the so-called "Valley of Death"—the time gap between the end of the SBIR Phase II award and the subsequent round of financing needed to advance a product or service toward commercialization.

The funds requested cover awards of up to $1 million a year for three years. Competitive preferences and funding priority is given to applicants who are able to secure independent third-party investor funds that equal or exceed the NCI award.

The NCI monies are set aside from the SBIR budget and are not drawn from the R01 pool. The request covers annual reissuance of the RFA for the next three years.

The program has funded 18 Bridge Awards since its inception in 2009 for $43 million in NCI dollars. Private investors have committed $86 million, averaging about $2 of private investment per each dollar awarded by the NCI for those same projects.

The program initially funded new therapies and cancer imaging technologies, but the program scope was expanded in 2010 to include interventional devices, diagnostics and prognostics.

FDA News

FDA Expands Cyramza Label To Include Metastatic NSCLC

FDA expanded the approved use of Cyramza (ramucirumab) to treat patients with metastatic non-small cell lung cancer.

The drug is intended for patients whose tumor has progressed during or following treatment with platinum-based chemotherapy, and it is to be used in combination with docetaxel. Cyramza's application was reviewed under the agency's priority review program.

On April 21, the FDA approved Cyramza, sponsored by Eli Lilly & Co., as a single agent to treat patients with advanced stomach cancer or gastroesophageal junction adenocarcinoma. On Nov. 5, FDA expanded Cyramza's use to treat patients with advanced gastric or GEJ adenocarcinoma to include paclitaxel.

The approval of Cyramza plus docetaxel for metastatic NSCLC is based on a clinical study of 1,253 participants with previously treated and progressive lung cancer. Study participants were randomly assigned to receive Cyramza plus docetaxel or a placebo plus docetaxel. Results showed that half of the participants treated with Cyramza plus docetaxel survived an average of 10.5 months from the start of treatment,

compared to an average of 9.1 months from the start of treatment for half of the participants who received placebo plus docetaxel.

FDA approved Somatuline Depot Injection (lanreotide) for the treatment of patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors.

Somatuline was previously approved for the long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. Somatuline is sponsored by Ipsen Pharma.

The approval was based on demonstration of improved progression-free survival in a multi-center, international, randomized, double-blind, placebo-controlled study that enrolled 204 patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic, non-functioning GEP-NETs. Fifty-five percent of patients had neuroendocrine tumors arising outside the pancreas.

Patients were randomized to receive either Somatuline 120 mg or placebo subcutaneously every 28 days.

The trial demonstrated a significant prolongation of PFS for the Somatuline arm (HR 0.47 [95% CI: 0.30, 0.73]; $p < 0.001$; log-rank test). The median PFS in the Somatuline arm had not been reached at the time of the final analysis and will exceed 22 months. The median PFS in the placebo arm was 16.6 months.

FDA approved Lynparza (olaparib) capsules as monotherapy for the treatment of patients with deleterious or suspected deleterious germline BRCA mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. FDA also approved a molecular companion diagnostic.

The approval of Lynparza, sponsored by AstraZeneca Pharmaceuticals LP, is based on objective response rate from the international single-arm trial in patients with deleterious or suspected deleterious gBRCAm advanced cancers. The trial enrolled 137 patients with measurable, gBRCAm-associated ovarian cancer treated with three or more prior lines of chemotherapy.

Of the 137 patients, 93 percent had an ECOG performance status of 0 or 1. Deleterious or suspected deleterious gBRCAm status was verified retrospectively in 97 percent (59/61) of the patients for whom blood samples were available. The trial results demonstrated an ORR of 34 percent (95% CI: 26, 42). The median response duration was 7.9 months (95% CI: 5.6, 9.6).

FDA concurrently approved the BRACAnalysis CDx companion diagnostic, for use in conjunction with Lynparza.

BRACAnalysis CDx, developed by Myriad Genetics Inc., represents the first FDA-approved companion diagnostic for use with a PARP inhibitor.

The molecular test identifies deleterious or suspected deleterious mutations in the BRCA1 and BRCA2 genes, using DNA obtained from a blood sample. The test was proven in clinical studies to effectively identify patients with BRCA mutations who would be candidates for Lynparza. The approval follows a multiyear scientific collaboration between Myriad and AstraZeneca in ovarian cancer.

FDA granted 510(k) clearance to Narrow Band Imaging, developed by Olympus Medical Systems Group, for targeting biopsies not seen under white light and visualization of tumor boundaries in non-muscle-invasive bladder cancer patients.

NBI can be used for NMIBC in the office/clinic for cystoscopy and in the O.R. or ambulatory surgical center for resection.

Based on a weighted average, aggregated studies show NBI has visualized NMIBC lesions in: 17 percent additional patients when compared with white light; 24 percent additional tumors; and 28 percent additional carcinoma in situ.

NBI uses endoscopic light technology without the use of dyes or drugs, and is not intended to replace histopathological sampling as a means of diagnosis. NBI enhances visibility of vascular structures on the mucosal surface. Unlike white light, which uses all colors in the spectrum, NBI uses only blue and green. Blue and green light are strongly absorbed by blood and appear darker than normal tissue. Blue light highlights shallow capillaries and green light highlights deeper veins.

FDA cleared an Investigational New Drug application to conduct a phase I/II clinical study to evaluate the combination of **ADXS-PSA** (ADXS31-142) with Keytruda (pembrolizumab), marketed by Merck & Co., Inc., in patients with previously treated, metastatic castration-resistant prostate cancer.

The clinical trial will be the first-in-human study of Advaxis's lead Lm-LLO immunotherapy candidate in prostate cancer, and is expected to begin patient enrollment in early 2015.

The open-label trial is designed to evaluate the

safety and efficacy of ADXS-PSA as a monotherapy and in combination with Keytruda, the first anti-PD-1 therapy approved in the U.S.

The phase I part of the study will be a dose-escalating study designed to establish the maximum tolerated dose of ADXS-PSA when used alone and in combination with Keytruda. The phase II portion will assess the safety and efficacy of the combination immunotherapy regimen. Advaxis and Merck will collaboratively oversee the conduct of the study and will use the results from the trial to determine the future clinical development program for the combination.

Genentech, a member of the Roche Group, **submitted a New Drug Application for cobimetinib** to the FDA for treatment, in combination with Zelboraf (vemurafenib), for people with BRAF V600 mutation-positive advanced melanoma.

The submission is based on results of the coBRIM phase III study, which showed that cobimetinib plus Zelboraf significantly increased progression-free survival compared to Zelboraf alone.

Cobimetinib and Zelboraf reduced the risk of disease worsening or death by half (HR=0.51, 95% CI 0.39-0.68; p<0.0001), with a median PFS of 9.9 months for cobimetinib plus Zelboraf compared to 6.2 months with Zelboraf alone.

The results were presented at the European Society of Medical Oncology 2014 Congress and published in the New England Journal of Medicine. Roche has already submitted the coBRIM data to the European Medicines Agency.

Cobimetinib is designed to selectively block the activity of MEK, one of a series of proteins inside cells that make up a signaling pathway that helps regulate cell division and survival. Cobimetinib binds to MEK while Zelboraf binds to mutant BRAF, another protein on the pathway, to interrupt abnormal signaling that can cause tumors to grow.

In Brief

Calvo Named Chief Scientific Officer of Cancer Core Europe

FABIEN CALVO was named chief scientific officer of **Cancer Core Europe**.

Calvo is currently a professor of pharmacology at the University of Paris Denis Diderot Medical School and a physician at Saint Louis Hospital in Paris. He specializes in genomics and the biology of metastatic disease, translational research, preclinical pharmacology and early clinical trials in hematology and oncology.

Previously, from April 2007 to September 2014, Calvo was deputy director general of the National Cancer Institute of France. Calvo was also director of the Cancer Multi-Organization Institute of the National Alliance for Life Sciences and Health, which includes INSERM, CNRS, CEA, INRA, INRIA, IRD, Pasteur Institute, Universities and University hospitals. He also helped launch the International Cancer Genoma Consortium in 2008 and the global alliance for genomics and clinics.

Launched in July, Cancer Core Europe is a consortium comprising of six European cancer centers: the Gustave Roussy Cancer Campus Grand Paris; Cambridge Cancer Research UK Centre; the Karolinska Institutet in Stockholm; the Netherlands Cancer Institute; the Vall d'Hebron Institute of Oncology in Barcelona; and the German Cancer Research Center and its National Center for Tumor Diseases.

THE OHIO STATE UNIVERSITY Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute opened in a new hospital building, following a four-phase transition that involved 700 staff and volunteers, spanning three days.

The move began at 6 a.m. Dec. 12 with critical care patients. All other acute care patients were transitioned Dec. 14 during overlapping patient moves that start every six minutes.

Sixteen transport teams will move patients the estimated quarter mile between the hospital's current location to the new home of The James. The tightly orchestrated plan is the result of two years of planning. With 21 floors and more than 1.1 million square feet, the new James is the largest single construction project in the history of The Ohio State University.

Sending and receiving command centers were created to manage the move. The receiving command center will give all James staff one telephone number to call and triage situations that arise during the transition process – everything from medication administration, food delivery and equipment/staff needs. The command center will be staffed 24/7 for two weeks after the initial move into the new hospital. Patient move packets were developed that include the most recent assessment, and a checklist of key facts and medications that will be required for administration within two hours of the planned move.

The move included nearly 300 spotters positioned at key points along corridors so the patient is always in sight, with resuscitation bays positioned along the route to ensure any emergency situation is responded to immediately. Elevator time studies were performed to ensure proper timing of move schedule and weekly patient census scenario drills to confirm accuracy of move timing based on projected patient volumes.

MD ANDERSON CANCER CENTER and **UnitedHealthcare** launched a pilot program for a cancer care payment model for head and neck cancers using bundled payments.

The bundled payment method reimburses a care provider or hospital for a defined episode of care under a single fee or payment. This is a shift away from the common fee-for-service structure in which a care provider is paid for each treatment, drug, appointment or test.

The three-year pilot will be conducted in MD Anderson's Head and Neck Center for up to 150 patients newly diagnosed with cancers of the salivary glands, oral cavity, throat and larynx, and who are enrolled in certain employer-sponsored benefit plans insured or administered by UnitedHealthcare.

The program is based on MD Anderson's mapping of tests, treatments, follow-up care and supportive services required for the most common head and neck cancer diagnoses. This is expected to improve patient outcomes, lower costs and increase patients' quality of life.

UnitedHealthcare launched a similar pilot in 2010 involving 810 breast, colon and lung cancer patients who were treated at five medical oncology groups around the U.S. The July 2014 issue of Journal of Oncology Practice featured the results of that study, which showed cancer costs were cut by a third and quality was improved.

THE OHIO STATE UNIVERSITY Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute named the winners of its 2014 **James Hope Award**.

The winners are Ohio State Sen. **Scott Oelslager** and **Robert Massie**, operating board chair of the James Cancer Hospital. The award recognizes the center's community partners, and is named for The James' Statue of Hope in Legacy Park outside the new hospital and institute.

Oelslager sponsored legislation to ensure oral chemotherapy agents have parity in insurance coverage with intravenous chemotherapy agents. The bill ended the practice of charging greater pharmacy co-payment amounts for oral chemotherapy medications than lesser office co-payment amounts for intravenous therapies. Oelslager also co-authored a bill that ended the practice of directly sending medications to cancer patients that cannot be self-administered and must be injected.

Massie is former president, CEO and director of Chemical Abstracts Service. He is the former chair of University Medical Center Partners, a nonprofit corporation that develops commercial enterprises for OSUMC research. He also donated the lawn of Chemical Abstracts Service to host the original starting point for Pelotonia, a bike ride event that raises funds for cancer research.

THE WASHINGTON UNIVERSITY School of Medicine in St. Louis received a $25 million pledge from philanthropists James and Elizabeth McDonnell for the schools genomics institute. With the gift, the institute will be named **The Elizabeth H. and James S. McDonnell III Genome Institute**.

The gift will fund research into the genetic origins of multiple diseases, including cancer.

In 2000, the McDonnells joined with Anne and John McDonnell and the JSM Charitable Trust to fund the construction of the McDonnell Pediatric Research Building on the Washington University Medical Center campus.

James McDonnell began his career in 1963 as an aerodynamics engineer at McDonnell Aircraft, the firm his father founded in 1939 in St. Louis that later became McDonnell Douglas Corp. He served as a vice president from 1973 until his retirement in 1991, and was a director of the corporation until its merger with Boeing Co. in 1997. He is director of the board of the Children's Discovery Institute, a joint initiative of the School of Medicine and St. Louis Children's Hospital.

THE GEORGE WASHINGTON UNIVERSITY Cancer Institute received a $150,000 memorial gift from the **Center for Advancing Health** to support a new patient engagement center.

"This gift will expand our focus on patient-centered care to create informed, engaged patients, and advocate for supportive health care systems," said Mandi Pratt-Chapman, director of the GW Cancer Institute. In addition to the memorial gift, the institute will receive numerous intellectual assets from CFAH.

The new Center for Patient Engagement at the GW Cancer Institute will use the bequest—honoring the late **Jessie Gruman**, CFAH's president and founder—to provide resources to disseminate CFAH materials to patients, public health practitioners, and health care professionals through webinars and the GW Cancer Institute's new resource repository; use patient-centered outcomes research; and advocate for a more patient-centered health care system in policy forums.

THE ROBERT H. LURIE Comprehensive Cancer Center of Northwestern University, the **Northwestern Medicine Developmental Therapeutics Institute**, and **NeoGenomics Inc**. entered into a research agreement with plans to initiate a translational program focused on expanding the use of genomic profiling technologies.

The Lurie Cancer Center and NMDTI expect to conduct a broad range of research studies with NeoGenomics that will expand current protocols focused on matching cognate agents with targets identified by the NeoTYPE line of cancer profiling tests.

NeoGenomics operates a network of CLIA-certified clinical laboratories that specialize in cancer genetics testing, including cytogenetics, fluorescence in-situ hybridization, flow cytometry, immunohistochemistry, anatomic pathology and molecular genetic testing.

OREGON HEALTH & SCIENCE UNIVERSITY and **FEI** expanded their Living Lab for Cell Biology agreement that includes the installation of a complete correlative microscopy workflow in the new Collaborative Life Sciences Building on the OHSU campus. This expansion adds a new instrument, the FEI CorrSight, to the OHSU-FEI correlative light and electron microscopy suite.

The CorrSight is an advanced light microscope that integrates multiple sample preparation protocols for correlative experiments and enables researchers to observe live cell dynamics using visible light microscopy and quickly fixes those cells for follow-on light and electron microscopy when a targeted event or structure is identified. The system will be used to develop correlative light and electron microscopy assays for high-content drug screening applications.

CANCER TREATMENT CENTERS OF AMERICA selected **WIRB-Copernicus Group** to help expand its clinical research program. WCG will assist CTCA in the centralization of its regulatory and ethical review process.

WCG Oncology, which includes three dedicated institutional review boards, will partner with CTCA in this process; CTCA will also centralize its own IRB. This CTCA panel is fully accredited by the Association for the Accreditation of Human Research Protection Programs through Western IRB.

Editorial

A Record-Breaking Year For The Cancer Letter

(Continued from page 1)

• We catalogued all 40 years of back issues of The Cancer Letter, placing them online. I invite you to click around.

• We redesigned The Cancer Letter logo, paying homage to its 1970's design sensibility, and we've added illustrations, photos, infographics, videos and cartoons.

• We developed a new web advertising program, which immediately attracted ads from the most important organizations in cancer research and cancer care.

Today, on our website you will find ads from the American Society of Clinical Oncology, the National Comprehensive Cancer Network, Friends of Cancer Research, and Physicians' Education Resource. Emory University, the Cleveland Clinic, Georgetown University, California HealthCare Foundation and the National Breast Cancer Coalition have placed ads earlier this year.

As editor and publisher, I start every morning by checking how many people came to The Cancer Letter website and how many pages they've read. These numbers tell me whether our readers consider our coverage worthy of their time, and whether our readership is growing.

Here is one of the metrics I see this morning, on Dec. 19:

In 2014, we logged 1.05 million page-views. This amounts to a 48-percent boost in readership from 2013, when the total number of page-views was 711,000.

Our readers include key players in oncology. Many of them access The Cancer Letter through more than 100 institutional and group subscriptions, and hundreds of individual subscriptions.

Most major health care organizations and pharmaceutical companies now have institutional subscriptions.

Our publications now reach more junior members of the faculty and staff at institutions that make the switch to institutional subscriptions. As a result, more people learn where the funds are—and where they aren't. More people understand what happens at other corners of their profession. And I'm told water cooler conversations on Friday afternoons are changed fundamentally.

In 2014, The Cancer Letter continued to cover the news in the same way it always has: independently, thoroughly.

This year, our coverage focused on:

• Changes in the way FDA approves cancer drugs—and the quality of applications the agency receives. Are cancer drugs getting better? FDA's Cancer Czar Richard Pazdur told me that the answer is yes.

Will FDA get involved earlier in the development cycle of some cancer drugs? The answer is, again, yes.

• The pricing of cancer drugs and evolution of distribution channels.

• The challenges of a switch to precision oncology as they affect FDA, CMS, NCI and the industry.

• Controversies at MD Anderson Cancer Center, including debate over the declining faculty morale and a dispute over tenure of two professors and the institution's seven-year "term tenure" appointment. Our 2013 coverage of conflicts of interest at the cancer hospital won a 2014 Dateline Award from the Washington, D.C. Professional Chapter of the Society of Professional Journalists.

• Restructuring of the NCI network for conducting clinical trials.

• Pinpointing how persistent decline in federal funding has affected top-tier institutions conducting cancer research.

• Persistent shortages of generic drugs and the expansion of the 340B drug discount program.

• Development of CMS coverage for CT screening of lungs of former and current heavy smokers.

• The hazards of power morcellation, a widely used surgical procedure known to upstage undetected uterine tumors.

The number of readers who come to our website has been going up month after month.

In 2014, the number of unique visitors to our website stands at 149,000. This is a 60 percent leap from 95,800 visitors in 2013

The number of visits in 2014 is 298,000. This is a 69 percent leap from 2013, when the number of visits stood at 182,900.

The number of visitors has been growing at an increasing rate through the year.

Since July, the number of visitors on The Cancer Letter's website has averaged more than 1,000 per day.

August was an exception. That month, we logged 46,300 visits—3,000 more than the number of people who came to the 2014 annual meetings of the American Society of Clinical Oncology and the American Association for Cancer Research combined.

The number of readers who access our coverage via mobile devices has increased by about 50 percent over the past year.

I have managed to report and write as much as I have since joining The Cancer Letter staff full-time in 1992.

This year, my lieutenant, Matthew Bin Han Ong, has taken the lead on key stories of his own making, expanding the scope of coverage. Just as importantly, Lt. Ong took the lead in redesigning the website, often making me feel like The Cancer Letter's Luddite-in-Chief.

Conor Hale has been focusing on writing, editing, copyediting, production and billing systems, an enormous and hugely important job, considering The Cancer Letter's expansion, as well as publishing the monthly issues of The Clinical Cancer Letter.

In another highlight of 2014, interns Tessa Vellek, a third-year student at Duke University, and Will Craft, a fourth-year student at the University of Chicago, spent the summer in our offices in Northwest Washington.

Tessa and Will's enthusiasm and their great work reminded me what a privilege it is to be a journalist.

Thank you for your support this past year and best wishes for 2015.