THE CANCER LETTER

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Conversation with The Cancer Letter

Sequestration Hurts Kids With Cancer

Sequestration is forcing the Children's Oncology Group to confront a profound ethical dilemma.

Doctors who develop treatments for children's cancer may have to choose between initiating new trials and continuing current studies, said Peter Adamson, chair of the Children's Oncology Group and chief of the Division of Clinical Pharmacology and Therapeutics at the Children's Hospital of Philadelphia.

"Do we delay or not pursue new studies, versus waiting to get the complete studies and get the answers from the ongoing studies?" Adamson said in a conversation with Paul Goldberg, editor and publisher of The Cancer Letter.

"It sets us back, and it sets the outcomes for children with cancer back if we can't move our highest-priority ideas forward into the clinical research and answer these important questions."

A recording of the conversation is available on The Cancer Letter website.

Paul Goldberg: *Will sequestration affect pediatric trials in the same way that it will affect adult trials?*

Peter Adamson: I think there is going to be some similarities, but there is also going to be some added challenges that we face in pediatric trials.

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Appropriations

Continuing Resolution Expires March 27; NIH, NCI Hope for Budget Compromise

By Matthew Bin Han Ong

Washington is barreling toward another landmark in the ongoing fiscal crisis: March 27, the end of the continuing resolution that funds the operations of the federal government.

Unless a budget compromise is reached by this deadline, the government will shut down. The actual deadline could be even closer: March 22, the day members of Congress are scheduled to take a two-week spring recess.

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In Brief

Nature Editorial Criticizes NCI OCE Spending

NCI's spending on cancer communications is high enough "to make even bureaucratically hardened Washington, DC, insiders gasp," the journal Nature says in an editorial March 13.

Citing coverage by The Cancer Letter, the Nature editorial noted that the institute's Office of Communications and Education had the budget of nearly $45 million in fiscal 2012, spending a total of $381.2 million between 2006 and 2012 on OCE.

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Funding Cuts Force COG Into Ethical Dilemma

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To understand the difference, I think one has to look at the funding landscape for clinical research in the country. As you know, about 60 percent of clinical research that occurs is funded from the private sector. This is not just in cancer—I'm talking about the spectrum of clinical research.

The 60 percent of funding for clinical research comes from the biopharmaceutical industry, and, overall, about 25 percent of the research dollars come from NIH.

For childhood cancer, that's not the case.

Virtually all our funding comes from the NCI, and the reason for that is that childhood cancers are a collection of rare and ultra-rare diseases. So the economic models for industry to get into drug development and research for pediatric cancer simply isn't there.

The reason that is all important for sequestration is—for the research that we do—our portfolio is heavily skewed toward federal funding.

Thus, when there is a cut in federal dollars across the board, it's in essence magnified for childhood cancer, because we don't have a balanced portfolio. We don't have the level of industry funding that occurs in medical oncology.

So, from that standpoint, the impact will be greater for us.

PG: *What kind of money are you getting from NCI, and what kind of cuts do you anticipate? Both worst-case and best-case scenarios.*

PA: Right now it's anybody's guess as far as what's going to happen with cuts.

But I think the NCI budget is projected, with sequestration, to be cut somewhere on the order of 4.5-5 percent. How that gets applied is not clear, at least certainly to anyone outside the NCI—because the NCI has fixed costs and existing obligations. Looking at a best guess, we think our cut is going to be somewhere in the 3 to 8 percent range. But that's really a guess at this point.

"The impact will be greater for us."

PG: *In terms of money, what's 3 to 8 percent?*

PA: We are fortunately supported by more than one NCI grant, so across the board that's probably going to be somewhere around $1.5 million, depending where it falls.

PG: *How does one make cuts in a clinical trials organization? I'm really thinking about the ethics of the thing. How ethical is it to cut expenses in a trial or stop a trial for financial reason, when you owe patients an answer, or else why did you accrue them to the trial? It's a loaded question, I'm sorry.*

PA: It's an important question.

We had a cut last year as well, as did others. So the first place we looked, and we've made significant changes, is really to trim down our central administration.

It wasn't by any means too large, but we really looked at essential functions, and how to align personnel with essential functions and what areas that we could forgo development in, as far as trying to improve our systems and streamline clinical research.

The first thing we did is make cuts centrally.

Having done that, we really do not need to absorb budget cuts by cutting infrastructure. As you know, there is critical infrastructure to conduct research from regulatory to data management to oversight and it's going to be quite difficult to make further cuts given what we've gone through in the past year and a half.

What we are then looking at is the impact on the clinical research portfolio, and there, it is a real challenge. We have ongoing studies, as you alluded to. We are obligated to complete those studies. We don't want to enroll children with permission from their parents on research if we can't see it through. So we take that obligation very seriously and we are absolutely committed to completing trials.

With that said, science is advancing at a pretty

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rapid pace, and we have a number of studies that we are developing and we anticipate opening. And these are studies that bring novel therapeutics, new discoveries, and new treatment approaches for a variety of childhood cancers.

And so, in the balance, is: do we delay or not pursue new studies, versus waiting to get the complete studies and get the answers from the ongoing studies?

Either way, I think it sets us back and it sets the outcomes for children with cancer back if we can't move our highest-priority ideas forward into the clinical research and answer these important questions.

"We don't want to enroll children with permission from their parents on research if we can't see it through."

It's difficult to make these very hard choices, especially when one doesn't know the true magnitude of the costs.

And, importantly, not only the magnitude of the costs, but what's the duration of this fiscal change going to be? Are we simply going to be functioning at a lower funding level for the upcoming years? Is this something that may work back to its baseline level? All those variables then turn into a decision of where does one make the cuts.

PG: *Plus the cuts have to be made probably over a concentrated period. So it's not like you've been cutting a certain amount per month. This would have to be done in half a year.*

PA: Regarding the decisions on where to save resources, it's not something one can truly stretch out.

A decision to delay the opening of a study is just that, it's the delay of opening of a study. The decision to close a study early, which is something we certainly want to avoid, is also essentially just that.

You know, 3 to 8 percent, whatever it may be, it may not seem like a significant amount of money. But when one has been dealing with flat funding or decreases—and streamlining operations, and making decisions—it becomes a cut that will have a real impact.

PG: *Is it too early to say what your strategy will be, in a nutshell?*

PA: This is going to involve discussions with the leadership throughout the Children's Oncology Group. These are difficult decisions; it's not a decision for any one person. I think the discussion would also have to involve the NCI—they are our partner in this.

We would do our best to prioritize, and the leadership includes parent advocates. No one wants to trade off one disease for another; or one trial for another. But the hope is that we can—worst-case scenario—delay the opening of a very limited number of studies, with the hope that the budget issues get resolved.

But we are operating now as the NCI is, without actually knowing what our budget is. And one can do that for a period of time. But without even that knowledge, it becomes a true management issue.

PG: *So there is just no way to strategize. Have the conversations begun?*

PA: The conversations, in broad strokes, have begun. But we've realized that, depending on when the fiscal challenges hit home, it will depend on the decisions.

We are always developing and opening select studies at any moment in time. We are meeting our accrual targets on a number of studies and our data safety monitoring committees are always monitoring our trials to make sure they're accruing appropriately. All of those variables, at any point in time, have to get assessed.

And then the real challenge is, if it really comes down to it, if this is a study, or these are studies that get delayed—we have to balance what the impact for the children we care for is going to be. What's the current outcome? How common a cancer is it? Those get to be very challenging discussions.

"The frustration here is that this is a crisis that was created."

There is no question that any time we launch a study, the reason we do that is with a clear commitment to improve the outcome. And one never wants to back away from that commitment.

PG: *Again, just pulling one program out of thin air, but are your biorepositories safe?*

PA: Right now I think the funding cut will impact our biobank. Do I think that the biospeciments there are protected? Yes I do.

I think that although there are costs associated with those, the greater costs happen to be in new biospecimens coming in the door, as well as existing biospecimens going out to researchers. That's where the major costs are.

PG: *Would that be cut?*

PA: Well, all the funding is going to get cut.

So there will be a cut to the biobank as well. And we think it's on the same magnitude. The most likely place that we would, if we had to make the decisions there, would be rather on what gets sent out the door, as opposed to what we take in, because what we take in, we can't go back on. Those are opportunities we can't miss.

So I don't envision a situation where we would have to make those cuts.

But if the head of the biobank tells me, "We are down a [full-time equivalent position]," and what that might mean is the person who usually is involved in identifying biospecimens, quality control, and getting them shipped out to investigators—that's going to be a decision that gets made obviously with the leadership of the biobank.

"Virtually all our funding comes from the NCI, and the reason for that is that childhood cancers are a collection of rare and ultra-rare diseases."

So I think we have more of a margin there. It's not good, but, again, it will come down to, ultimately, are we going to be doing less research? If the answer is yes, we are going to be doing less research, then the organization downsizes—hopefully to a very limited degree—but obviously it's not a situation we want to be facing.

PG: *I guess I can't think of anything more horrifying than taking hope away from kids with cancer. Can you?*

PA: We try to keep it in perspective, Paul. Obviously, we've come a long way in improving the outcome for children with cancer.

I'm obviously biased, but I think the NCI investment in childhood cancer and the return on that investment is probably unparalleled.

As you know, when the NCI started investing, some 50 years ago, less than 10 percent of children with cancer survived. Now, the five-year survival rates across the board are about 80 percent. There hasn't been a return on investment as far as life-years saved—and taking once incurable diseases and curing them—that I can think of that really parallels childhood cancer.

But despite all that progress, childhood cancer remains the leading cause of death by disease in children. It's still a significant problem. And the price that children pay for cures, not only during therapy but for lifelong late effects, is far too high.

We know we have a lot of work left to do. We haven't solved childhood cancer, we have a lot of work left to do, and what's perhaps most frustrating is that we are in a scientific era of remarkable discovery.

The pace of discovery now was unimaginable even five, and certainly 10 years ago. And during that discovery is when you want to increase investment. This is where we have these discoveries, and if we don't turn those discoveries into better cures, then we'll have failed a generation. And in order to do that, you actually want to increase your investment in childhood cancer research.

And the prospect of seeing that investment decrease is obviously short-sighted, but will have a real impact. It's hard to defend that, given what's at stake.

PG: *Well, I don't think it's yours to defend. In fact, I was about to suggest, has anyone thought of taking this out on the road? This is a story that people should know as they vote.*

PA: It is. I think pediatric oncologists as a whole tend to be extremely optimistic.

It's just a remarkable group of individuals who are dedicated to caring for children with cancer. And so the optimistic side of this is we have supporters across the political spectrum. If there was ever a non-partisan issue, it's probably childhood cancer.

"And the prospect of seeing that investment decrease is obviously short-sighted, but will have a real impact. It's hard to defend that, given what's at stake."

PG: *And yet you are getting squeezed pretty hard.*

PA: Well, everybody is. As far as if there is a political way to solve this, it's an issue that doesn't divide. So, hopefully, as we come up against one fiscal crisis after the next, what will emerge is a consensus.

Do I think that the NIH budget should be restored?

Of course. I think the investment in the NIH globally has been some of the best investments that our government has ever made.

Am I particularly interested in the NCI budget being restored?

Yes, and the childhood cancer component of that, of course. You never want to pick one disease

against the next or necessarily one area of important research against the next. But fortunately for childhood cancer—at least I think from the White House through Congress—it's not an issue that divides. How that can get translated into fixing this problem is probably beyond my expertise

PG: *I was just wondering whether the pediatric oncologists could bring it out as a separate issue.*

PA: I think for a good number of advocacy organizations for childhood cancer it's something that's high on their radar screen, and I think everyone is looking for a path forward. We are very early into this sequestration.

And I think there are so many moving parts that it's not exactly clear what strategies might be most effective.

The impact of sequestration, at least for us, is not felt instantly—and that's true for a lot of areas. But it is coming. We know it's coming. It's not going to be a year from now, it's going to be weeks to months. So I think you'll see increasing mobilization of the advocacy community to make these issues known and the impact known.

PG: *I guess this is more of an NCI question: NCI has been talking about prioritizing all clinical trials across the indications. Could that exercise be sped up, to decide which trials are least promising or least important? We both heard the presentation [at the Clinical Trials and Translational Research Advisory Committee meeting] today [March 13].*

PA: I think you know the way at least the cooperative group research portfolios, from the adult groups and now from the COG, there is now a greater level of peer review for every study.

So I think that a trial that emerges through that process is likely to be high-quality science and important and merit resources. If it goes through that process and then has to undergo another prioritization, I think that it gets exceedingly difficult.

Certainly, for what we do, we wouldn't want our experts and our advocates—if we have to make these hard choices, we would want to lead that discussion. But it won't be done in the absence of NCI input for any of the cooperative groups, because of how we are structured in the partnerships that we have with NCI to conduct this research.

PG: *So you are embracing the challenge of making the cuts and taking responsibility?*

PA: Well, not enthusiastically, but it's part of our responsibility. We face situations and challenges not only day-to-day in caring for children with cancer, but in research.

We know there are variables that occur that are beyond our control, and in some circumstances, anyone's control. So part of our job as leaders of the COG is to manage these situations, and always do the best we can to put the interests of children first, the interests of science first, and make these decisions.

The frustration here is that this is a crisis that was created.

And, not to delve into the politics, but I think everyone will agree that this is not a crisis due to natural causes or due to circumstances that were unpredictable. This is a crisis that was self-imposed, and that does make it more frustrating by a significant degree to manage.

PG: *As you said, pediatricians are optimistic. What's the most optimistic scenario you can now come up with?*

PA: Well, I think that on the near term, is that we end up with a flat budget. I wouldn't say that's the most optimistic, but perhaps the most optimistic, realistic outcome. I think the likelihood of that, and you know Washington better than I, is probably small.

"Now we are really getting backed into a corner that is going to impact the research itself."

And thus we are hoping for the smallest possible cut achievable. We've made changes—we've relocated our operations to a significantly less expensive off-campus office building. We've made a lot of changes to save costs.

These were important changes, and we are glad we made them. It allowed us to move resources from overhead into research. We can't put our people in a tent. We've made those cuts. Now we are really getting backed into a corner that is going to impact the research itself.

PG: *So your most optimistic scenario doesn't really sound that optimistic.*

PA: Well, it's all perspective.

In the current environment, a flat budget this year is something we are confident we could manage without impacting the clinical research portfolio. Will we be able to pursue initiatives that we would otherwise thing are important? Not all of them by any means. But that's the current environment.

That to us would be an optimistic outlook.

And it is true—optimism now is very much tempered by the realities in Washington.

Appropriations

NIH, NCI Now Wait for Congress To Compromise on 2013 Budget

(Continued from page 1)

The House of Representatives passed its version of the continuing resolution, March 6, which funds the government through the remainder of the 2013 fiscal year.

Considering that Congress and the White House recently demonstrated a remarkable tolerance for fiscal disasters, the possibility of a complete shutdown appears to be as reasonable as any other outcome of the continuing crisis that has, so far, produced the across-the-board spending cuts known as sequestration.

In the best-case scenario, Congress may find a way to apply cuts more selectively.

This is being attempted in the House continuing resolution as Republicans seek to retroactively protect defense and veterans' programs from sequester cuts.

The Senate is working on its own version of the continuing resolution. Recently, Sen. Tom Harkin (D-Iowa) proposed an increase in the Labor HHS Education bill, hoping to get the bill into the Senate version of the resolution.

Barring a last-minute reprieve, NCI and NIH are preparing to adjust spending to sequestration levels, which technically went in effect March 1. NIH would be subjected to a 5.1 percent cut, or $1.553 billion, and NCI would get a 4.4 percent, or $219 million, cut (The Cancer Letter, March 8).

"I think at this present time—and this is a big if—if at the end of the month there is a budget, or at least if there is a continuing resolution, then there won't be any furloughs at NIH," said James Doroshow, director of the NCI Division of Cancer Treatment and Diagnosis, at the Clinical Trials and Translational Research Advisory Committee March 13.

"The intention is to not be in any furloughs based on the sequester," Doroshow said. "If there is no budget, then we'll all be on vacation—unpaid."

Should sequestration continue, Doroshow said that NCI will make every effort to try and sustain the number of research grant awards at about 13.5 percent, the 2012 success rate.

Other NCI programs will be cut back to maintain the number of competitive awards if a budget deficit deal is not achieved before March 27.

NCI recently submitted a preliminary proposal to NIH, spelling out how the estimated $219 million cut would be managed.

"I can tell you, even that document, if I had it even on a slide, you wouldn't know where you stand, because it was very high-level in terms of where things would be cut," said Doroshow. "The truth is that, until we get to the end of this month, we won't actually know or hopefully will have an appropriation.

"We have to know exactly what the appropriation is going to be before it can be portioned in any reasonable way."

In an email to the NCI-supported scientific community March 7, NCI Director Harold Varmus said that to "achieve this goal, we need to make reductions, modest but significant, in virtually all of our extra- and intramural programs, including noncompetitive (type 5) grant renewals, cancer centers, and research contracts."

A Congressional Compromise

Both chambers of Congress are poised to begin negotiations on a final continuing resolution that will fund federal agencies through the end of the current fiscal year.

The House's resolution included appropriations bills that increased Pentagon funding for related agencies and priority programs.

"[The Senate continuing resolution] includes some very limited changes to fix pressing problems," said Mikulski. "These are called anomalies. The Senate version totaled $1.043 trillion, equal to the House continuing resolution.

"So the top line is the same. It's how we achieve our national goals. It is equal to the House Continuing Resolution. And it is the same as required by the Budget Control Act [which created the sequester deadline]. We are in absolute compliance with the Budget Control Act.

"Now, sequester mandates another $85 billion in cuts. That comes over what we do, and that solution is to be negotiated by the President and the leadership, with the concurrence of both bodies," Mikulski said. "Sequester needs a balanced solution and we will be listening and awaiting their ideas."

One particularly important amendment offered by Harkin, chairman of the Senate Labor HHS Appropriations Subcommittee, would increase NIH funding by $211 million, tripling the $71 million increase in the Senate version of the 2013 omnibus spending bill.

The amendment would not "change the sequestration, with the result that NIH would still be cut by $1.3 billion rather than $1.5 billion, a modest improvement, but one that is needed," wrote James Bernstein, director of government and public affairs

for the American Society for Pharmacology and Experimental Therapeutics, in an email to the society's members.

"If this amendment is offered and passed, it could provide some momentum to further remedy a difficult situation."

Cancer Centers, Coalitions Sound Off on Sequestration

A survey conducted by the Community Oncology Alliance showed that sequestration cuts to Medicare reimbursements for cancer drugs and services would cause 72 percent of community oncology practices to stop seeing new Medicare patients.

These practices would not treat any Medicare patients without secondary insurance or send Medicare patients elsewhere for treatment.

The survey polled 331 office-based practices, hospital-based clinic or outpatient departments, and university-based cancer care centers. In total, that represents 2,349 oncologists and 901 mid-level practitioners, who see close to 1.2 million patients per year.

The sequestration cuts would end up costing Medicare an estimated $2 billion per year or more, due to the shift to more expensive treatment settings, according to the COA.

The impact is substantial because approximately 50 percent of all cancer patients are covered by Medicare. The COA says that splitting the sites of care and treatment will increase patient access problems and lead to higher costs for Medicare seniors.

"The sequestration cut is a blunt axe to cancer care that will have a devastating effect on patients," said Mark Thompson, COA president and an oncologist at the Zangmeister Center in Columbus, Ohio. "In some areas, particularly rural communities, practices will simply be driven out of business and close their doors, causing access problems.

"Others will be forced to send patients to hospitals for chemotherapy, if the hospital will treat them, or simply merge into the hospital, resulting in higher costs for both patients and Medicare—the exact opposite of the intent of healthcare reform."

"We Cannot Afford to Experience Such Loss"

The impact of sequestration has also begun to affect the conduct of research at the Winship Cancer Institute of Emory University, said the institute's director, Walter Curran.

Curran testified March 13 before the House Appropriations Subcommittee on behalf of the Association of American Institutes, focusing on the relationship between NIH and the nation's cancer centers.

"A budget cut to NIH, and ultimately the NCI, will decrease funding to cancer research in all parts of the country and impact many of the research teams working on new treatments and new cures," Curran said. "Rebuilding such teams, even after a short break in funding, could take years.

"Immediate effects will be felt in our research labs, with promising research slowed or even shut down, pending projects wiped off the boards, the next generation of bright young researchers unable to learn cancer research at the side of experts, and layoffs among trained cancer staff, including those who coordinate clinical trials that test new cancer therapies."

The text of Curran's testimony follows:

I believe that our nation's leaders should visit cancer centers in order to witness the vital role our institutions play in the health of their constituents as they face a battle with cancer.

Chairman [Jack] Kingston [R-Ga.], your support of Winship's recommended National Cancer Institute (NCI) funding level as well as your backing of our recent application to become a Lead Network Participating Site for NCI's National Clinical Trials Network (NCTN) is also appreciated. I hope your colleagues take the time to visit the cancer centers in or near their own districts and states to observe the outstanding work my colleagues do at their institutions.

As you are well aware, the NCI is one of the NIH's institutes. NCI awards its designation to cancer centers who demonstrate expertise in laboratory, clinical, and behavioral and population-based cancer research through the successful competition for a Cancer Center Support Grant (CCSG). Winship first received NCI designation in 2009; joining a prestigious group of then 64 NCI-designated cancer centers.

Winship just successfully renewed its designation and CCSG through a competitive renewal process, receiving a rating of "Outstanding" by a panel of our peers. Winship is the first and only NCI-designated cancer center in Georgia. Today, Georgia is the 8th most populous state in the nation and is home to 3.2 percent

of the entire U.S. population.

While Congress continues to debate the remainder of the FY2013 budget, NIH and NCI have prepared for cuts through FY2021. NIH will suffer a cut of $1.6 billion, of which NCI will lose approximately $250 million. These cuts will have a real impact on progress against cancer at Winship and other cancer centers across the country.

Continued progress in cancer research is dependent on the sustained efforts of highly skilled research teams working at cancer centers across the country and supported by the NCI. A budget cut to NIH and ultimately NCI will decrease funding to cancer research in all parts of the country and impact many of the research teams working on new treatments and new cures. Rebuilding such teams, even after a short break in funding, could take years.

As an example, Winship has an outstanding research team making real progress understanding how to target newly discovered mutations causing lung cancer, the type of cancer causing the most deaths in our country.

We are observing an increase in the number of lung cancer patients who have little or no tobacco use history, and we are just beginning to understand the genetic and genomic risk factors of such individuals for developing lung cancer. A break in funding support of this and other projects could delay finding new and effective therapies for thousands of patients by years.

Our nation's cancer patients deserve greater research attention to this deadly disease. In Georgia, we rank the 36th state for health outcomes overall. More than 1.6 million Americans were diagnosed with cancer in 2012, with more than 570,000 people dying from the disease.

With 25 percent of all deaths in America caused by cancer—almost 1,600 deaths per day—the disease is the nation's second leading cause of death. NCI estimates that 41 percent of individuals born today will receive a cancer diagnosis at some point in their lifetime.

At Emory's Winship Cancer Institute, we are excited about the new proton beam therapy facility that is now under construction in Atlanta as well as the increasing number of our patients being enrolled on cancer clinical trials. We see that the impact of budget cuts through FY2021 has already begun to affect our progress in research.

Immediate effects will be felt in our research labs, with promising research slowed or even shut down, pending projects wiped off the boards, the next generation of bright young researchers unable to learn cancer research at the side of experts, and layoffs among trained cancer staff, including those who coordinate clinical trials that test new cancer therapies.

At Winship, we enrolled over 700 cancer patients on trials testing new treatments in 2012 from all across the state of Georgia and beyond, each of whom has his or her own amazing cancer journey to tell. We aspire to increase the number of cancer patients that we can offer such hope, but we need sustained support to achieve this. The reduction of funding to the CCSG program will directly impact our ability to provide the critical infrastructure necessary for a robust research program.

We are particularly excited about Winship's and other cancer centers' ability to offer new and promising therapies to our patients in what we refer to as our phase I unit. This is our specialized center, which allows us to carefully study all the beneficial and any harmful effects of these therapies. We have offered such groundbreaking phase I treatments to nearly 200 patients per year at Winship.

In addition to cancer centers, the NCI supports cancer research in all of your communities through the National Clinical Trials Network and its newly reorganized five cancer cooperative groups. I have the great honor of co-leading one of these five research groups, and we have dedicated volunteer physicians and staff in every state and every congressional district in the nation offering hope to our cancer patients through a menu of over 200 cancer clinical trials.

Twenty to twenty-five thousand patients choose to participate in these network trials each year, and this research has defined many of the best treatments for today and tomorrow's cancer victims among us. This research is well coordinated with our cancer centers and is necessary for outreach beyond our research universities into community medical practices and for finding answers to some of the toughest cancer research questions as quickly as possible.

It is through this network that patients in such locations as southeastern Georgia are able to enroll in these cancer clinical trials with their community oncologists. Unfortunately, NCI support for these cancer cooperative groups has remained flat for over a decade. Sustaining this support is critical in providing your constituents the best access to the outstanding cancer care available through their participation in NCI-supported clinical trials.

NIH plays a vital role in our cancer centers' research and also impacts our nation's overall economy. A United for Medical Research analysis released in January of 2013 projected the nation's life sciences sector, which includes cancer research, would

lose more than 20,500 jobs and $3 billion in economic output due to cuts to NIH.

These serious consequences for biomedical jobs and local economies mean that funding cuts will undermine U.S. competitiveness, at a time when other nations are aggressively boosting their investments in research and development. We risk driving an entire generation of young cancer physicians and researchers either abroad, to seek opportunities to practice their craft and advance their careers, or out of the field altogether.

At Winship this threat is real and we cannot afford to experience such loss. Such declines in funding will prevent Winship and other centers from quickly moving to a broader platform of personalized cancer care and research. This personalized approach requires a time- and resource-intensive approach to every patient's cancer to best understand what is the very best approach to each patient's care.

This effort is well underway at Winship and other centers and will require a sustained and significant level of support to yield the positive results that we expect.

NIH's full support of NCI-designated centers and their programs remains a top priority for our nation's cancer centers. We are on a clear path to dramatic breakthroughs, both at Winship and cancer centers throughout the country.

We have come too far in cancer research progress to lose Congress' full support of NIH, and ultimately, NIH's funding of NCI-designated cancer centers and the National Clinical Trials Network.

Your constituents deserve the best NIH, NCI, and our cancer centers have to offer in order to provide life-saving treatment.

In Brief

Nature Publishes Editorial Critical of NCI's PR Budget

(Continued from page 1)

"There is no doubt that education of patients is crucial for cancer care and for clinical-trial recruitment," the editorial states. "But the institute can surely continue to educate while tightening its belt, perhaps by consolidating the OCE's other administrative tasks. It must evaluate outside contracts and consider partnering with philanthropic groups to produce educational materials. In an era of ambitious goals and shrinking resources, that could free up much-needed money for research."

The Nature editorial is available without charge.

Stories in The Cancer Letter's series focused on the cost of cancer communications appeared Dec. 7, 2012, Feb. 1, and March 1.

All three issues are now available free of charge.

URBAN MEYER, head coach of **The Ohio State University**'s football team, and his wife, Shelley, launched a fund to raise a $2 million endowment to establish a chair at Ohio State's Arthur G. James Cancer Hospital and Richard J. Solove Research Institute.

The fund was established in memory of Meyer's parents, both of whom had cancer. His father, Urban Meyer Sr., was a bladder cancer survivor. His mother, Gisela, was treated for breast cancer at OSU while her son was the assistant football coach to Earl Bruce. Funds raised above the $2 million goal will support the new chair.

The Meyers will be donating sports memorabilia

from Meyer's personal collection to a Gisela and Urban Meyer area within the new James Cancer Hospital and Solove Research Institute, as a part of the Wexner Medical Center expansion.

"As anyone who has dealt with cancer knows, there can be a lot of time spent in waiting rooms," said Meyer. "If Shelley and I are able to provide something that others might find as interesting as we have over the years, then we are profoundly honored to do so."

HARLAN LEVINE has joined **City of Hope** as chief executive of the City of Hope Medical Foundation, a sister organization to City of Hope and Beckman Research Institute of City of Hope.

Levine was a former executive vice president at WellPoint Inc. He will oversee the ambulatory practice on City of Hope's main campus and at all community clinics.

Prior to WellPoint, Levine served chief medical officer of United Health Group's Optum Health Care Solutions; the national practice leader for Towers Watson's health management practice; regional medical director of PacifiCare of California; and chief medical officer and executive vice president for Adesso Health Care Technologies. He also served as president and CEO of Logic Health Systems, a division of Salick Health Care/AstraZeneca.

Levine has held appointments on IBM's Watson Healthcare board of advisors and the Patient Centered Primary Care Collaborative board of directors.

AVICE MEEHAN was appointed vice president of communications at **Memorial Sloan-Kettering Cancer Center**.

As chief communications officer, Meehan will lead the center's public affairs and marketing projects.

Meehan previously served as the center's vice president of public affairs from 1994 to 2002, and is returning after ten years as vice president for communications and public affairs at the Howard Hughes Medical Institute.

Prior to her work at HHMI and Memorial Sloan-Kettering, Meehan worked as a reporter and editor for newspapers in New York and New England for more than a decade. In 1990, she joined Lowell Weicker Jr.'s campaign for governor of Connecticut, and served as his communications director and press secretary from 1991 to 1994.

JENNIFER SIZEMORE was named vice president of communications at **Fred Hutchinson Cancer Research Center**. She will begin April 17.

Sizemore, a journalist, most recently served as vice president and editor-in-chief of NBC News Digital, formerly msnbc.com.

Previously, she was deputy managing editor of news at the Houston Chronicle and assistant managing editor at the Seattle Post-Intelligencer. At NBC, she oversaw editorial content and financial management.

PATRICK FLYNN was honored with the **Association of Community Cancer Centers**' David King Community Clinical Scientist Award for his service, leadership and commitment to the oncology community.

In addition, **JIMMIE HOLLAND** was presented with the ACCC's Achievement Award.

Flynn is director of research at Minnesota Oncology Hematology, and medical director of Autologous Bone Marrow and Stem Cell Transplant at Abbott-Northwestern Hospital. He is also adjunct associate professor of medicine at the University of Minnesota Medical School.

Holland is recognized as the founder of the subspecialty of psycho-oncology. She is the Wayne E. Chapman Chair in Psychiatric Oncology at Memorial Sloan-Kettering Cancer Center.

The awards were presented at the ACCC's annual meeting.

Under Flynn's tenure, clinical trial accrual has risen from 50 to 500 patients per year, through a consortium of physicians, clinics and hospitals that cover the entire metropolitan Twin Cities.

His research areas include autologous peripheral blood stem cell transplantation; hematology, including bleeding and clotting disorders; and colorectal cancer. King Award winners become lifetime members of the ACCC National Academy of Community Oncology Scientists.

Holland has been at the forefront of efforts to delineate the prevalence and nature of the psychological and psychiatric implications of cancer for patients,

their families and healthcare professionals. She has worked on ways in which counseling, psychosocial interventions and medications can reduce the distress experienced by cancer patients and their families.

Holland was the first chair of Memorial's Department of Psychiatry and Behavioral Sciences, and the founding president of both the International Psycho-Oncology Society and the American Psychosocial and Behavioral Oncology Society.

In 2000, she published a book for patients titled The Human Side of Cancer. In 1995, she became a fellow of the Institute of Medicine. In addition, she has served on many national committees for the American Cancer Society and the NCI.

THE KNIGHT CANCER INSTITUTE at Oregon Health & Science University and CEPHEID today announced a collaboration to develop advanced molecular diagnostics to be performed on the GeneXpert system.

The collaboration will focus on the development of clinical oncology tests for the GeneXpert system and will establish a system for clinically validating the tests through the Knight Diagnostic Laboratories, a division of the institute. The alliance includes an exclusive license to OHSU intellectual property in prostate cancer and intellectual property co-developed by Lawrence Berkeley National Laboratory and OHSU in breast cancer.

The collaborative research will be led by Joe Gray, associate director of translational research for the Knight Cancer Institute, and Michael Bates, Cepheid's vice president for oncology research and development.

Initial projects will focus on breast and prostate cancers, including development of Xpert Breast Cancer Signature, a diagnostic test designed to predict the risk of recurrence in newly diagnosed patients, and Xpert Prostate Cancer Recurrence Risk, a test designed to predict the likelihood of recurrence in patients following surgery, as well as other prostate cancer applications.

UNIVERSITY OF ARIZONA CANCER CENTER broke ground for a planned outpatient facility at St. Joseph's Hospital and Medical Center/ Dignity Health in downtown Phoenix.

Located on the Phoenix Biomedical Campus, the center is expected to open in 2015. The university is leasing the land from the City of Phoenix.

The 220,000-square-foot, five-story, $100 million facility will offer comprehensive cancer services, including infusion, radiation oncology, diagnostic imaging, endoscopic/interventional radiology, a women's center, specialized cancer clinics, patient wellness and support services, a prevention/executive health clinic, clinical lab space and other related support spaces.

St. Joseph's will operate inpatient clinical cancer services at its main hospital campus and outpatient services at the new downtown facility. Until the new facility opens the hospital will continue to provide outpatient services.

FDA Approvals

Lymphoseek Approved For Imaging Lymph Nodes

FDA approved Lymphoseek injection, a radioactive diagnostic imaging agent that helps doctors locate lymph nodes in patients with breast cancer or melanoma who are undergoing surgery to remove tumor-draining lymph nodes. It is not a cancer imaging drug.

Lymphoseek (technetium Tc 99m tilmanocept) is the first new drug for lymph node mapping to be approved in more than 30 years. Other FDA-approved drugs used for lymph node mapping include sulfur colloid (1974) and isosulfan blue (1981).

"To use Lymphoseek, doctors inject the drug into the tumor area and later, using a handheld radiation detector, find lymph nodes that have taken up Lymphoseek's radioactivity," said Shaw Chen, deputy director of the Office of Drug Evaluation IV in the FDA's Center for Drug Evaluation and Research.

Lymphoseek's safety and effectiveness were established in two clinical trials of 332 patients with melanoma or breast cancer. All patients were injected with Lymphoseek and blue dye, another drug used to help locate lymph nodes.

Surgeons subsequently removed suspected lymph nodes for pathologic examination. Confirmed lymph nodes were examined for their content of blue dye and/ or Lymphoseek. Results showed Lymphoseek and blue dye had localized most lymph nodes, although a notable number of nodes were localized only by Lymphoseek.

The most common side effects identified in clinical trials was pain or irritation at the injection site.

Lymphoseek is marketed by Navidea Biopharmaceuticals Inc.