

THE CANCER LETTER

Sept. 23, 2016

www.cancerletter.com

Vol. 42 No. 35



No Moonshot Funds In House & Senate FY17 Appropriations Bills

By Matthew Bin Han Ong and Tessa Vellek

The National Cancer Moonshot Initiative is not slated to receive funding in fiscal 2017—neither the House nor Senate appropriations bill includes the \$680 million the White House proposed for Vice President Joe Biden's project.

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Obituary

Dan Sargent, Mayo Biostatistician and Clinical Trialist, Dies Unexpectedly at 46

By Paul Goldberg

Dan Sargent, one of the world's foremost experts in oncology clinical trials, died unexpectedly on Sept. 22. Sargent died from an acute illness, Mayo officials said. He was 46.

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Conversation with The Cancer Letter

OHSU Seeks to Raise another \$1 Billion; Keith Todd Describes the Strategy

After raising \$1 billion for Knight Cancer Institute, the Oregon Health and Science University fundraising team set out to raise another \$1 billion over five years—before 2020.

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No Moonshot Funds In FY17 Appropriations Bills

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Despite great bipartisan breast-beating in support of boosting the NCI and NIH budgets, Congress has not dedicated funding for the moonshot, a broad scientific and public health effort focused on improving clinical trials, data sharing, and streamlining regulatory processes for oncology products at FDA.

Congress hasn't reached a compromise on appropriations, and with the end of the fiscal year just a week away, lawmakers will likely pass a continuing resolution that would last at least through December. Insiders say it's not surprising that funding for the moonshot wasn't included in the short-term, stopgap bill as well.

Congress is expected to renegotiate the appropriations bills before the 2016 calendar year ends.

"Vice President Biden is working with his former colleagues on Capitol Hill to explore all potential vehicles for funding the Cancer Moonshot," a spokesperson for the Office of the Vice President said to The Cancer Letter.

Biomedical research advocates, oncology professional societies, and federal agencies say they "remain optimistic" about the moonshot's funding prospects, citing NCI's Blue Ribbon Panel recommendations (The Cancer Letter, [Sept. 9](#)).

"We are very fortunate that Congress has shown strong bipartisan support for cancer research, and, based on the FY17 House and Senate Labor-HHS

subcommittees' bills, we are hopeful that this support will result in increased funding," NCI Acting Director Doug Lowy said to The Cancer Letter. "The Cancer Moonshot Blue Ribbon Panel Report reflects unprecedented consensus across the cancer community for where we can make rapid progress if we have the necessary resources and sustained increases in the coming years."

The White House's funding plan for the moonshot, which would involve diverting funds from NIH, is one reason why the program lacks specific funding in the current appropriations bills, NCI officials said [in a legislative update](#).

"This is not surprising, based on both the specifics of the President's budget request and the lukewarm reaction that the appropriators have had to the proposal itself," the NCI legislative update states. "It is important to note that the President's budget proposal did not request additional funding for the Cancer Moonshot from the appropriations committees. To the contrary, the budget requested a \$1 billion decrease in the NIH appropriation, while simultaneously requesting an even larger increase in mandatory funding, of which \$680 million was specified for the Cancer Moonshot."

"The appropriations committees manage the distribution of discretionary funds, they do not create new mandatory funding streams or disperse mandatory funds. Mandatory spending, such as Medicare and Social Security, are controlled by legislative committees (authorizers) and must be authorized by law."

Clinton: "I Will Take Up the Charge"

The Senate Committee on Appropriations slated an increase of \$2 billion for NIH—matching last year's increase—which would boost the NIH budget to \$33.3 billion in FY17. The bill provides \$5.43 billion for NCI, \$216 million above the FY16 level.

The House version of the bill gives NIH a \$1.25 billion increase, with NCI receiving a 2.4 percent increase in funding to about \$5.34 billion, falling short of the 13 percent increase proposed by the White House.

An amendment to add \$750 million to fully fund the moonshot initiative, introduced by Rep. Rosa DeLauro (D-Conn.), was defeated.

"In order to continue our momentum and build on the impressive work that is already underway to fight cancer, Congress needs to provide robust and sustainable funding to the NIH and a specific boost to NCI for the Moonshot," Daniel Hayes, president of the American Society of Clinical Oncology, said to The Cancer Letter. "ASCO is on Capitol Hill [Sept. 22] urging Congress to take action to provide funding for the Moonshot

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202-362-1809 Fax: 202-379-1787
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Subscription \$420 per year worldwide. ISSN 0096-3917.
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to significantly expedite our nation's progress against cancer. I remain optimistic that Congress will fund the Moonshot and sustain robust funding levels for the NIH as a whole before the end of their legislative session.

“In just nine months, the Moonshot Initiative has unveiled dozens of initiatives to improve research and treatment of cancer, building on the impressive work that is already underway to fight cancer,” said Hayes, who is also professor of internal medicine, the Stuart. B Padnos Professor in Breast Cancer, and the clinical director of the Breast Oncology Program at the University of Michigan Comprehensive Cancer Center. “ASCO applauded the Blue Ribbon Panel for their report highlighting ten additional areas where funding and effort is needed, and we’re looking forward to seeing the recommendations still to come from Vice President Biden and the Task Force.”

Democratic presidential nominee Hillary Clinton [has pledged to support the moonshot](#) if she wins the November elections.

“To start, Congress should fulfill the administration’s request for moonshot funding next year,” Clinton said in a statement. “Cancer does not discriminate, and I believe leaders of both parties can come together to tackle this disease as part of a comprehensive effort to improve medical research across diseases, both by restoring robust funding to the NIH, including the NCI, and by harnessing the power of the private sector.

“And we will continue to build on Vice President Biden’s work to mobilize the cancer community, make sure that scientists work together, and enable more patients to enroll in clinical trials. By combining new funding with creative approaches, we will not only catalyze progress against cancer: We will strengthen the nation’s entire scientific enterprise.

“I could not be prouder to stand with Vice President Biden in this fight, and as president, I will take up the charge. My administration will carry out the mission the vice president has set, and continue to call on his advice, leadership, compassion, and sheer strength of will. Together, we will seize this moment. Together, we will make cancer as we know it a disease of the past.”

Republican nominee Donald Trump has not issued a statement on the moonshot. His campaign didn’t respond to emails from The Cancer Letter.

“American Cancer Society Cancer Action Network urges Congress to seize the opportunity to boost funding for the NIH and NCI in their final FY17 budget,” ACS President Chris Hansen said in a statement. “We are at the cusp of so many promising new developments in diagnostic tests and treatments that now is the time to

re-invest and accelerate that research.

“Earlier this month, nearly 700 volunteers from every state went to Capitol Hill to make clear that funding the Moonshot and reducing death and suffering from cancer should be a top national priority. When the FY 2017 budget process resumes after the election, we trust that members of Congress will remember the conversations with our volunteers and supporters and will take action to fully fund the cancer moonshot.”

Funding the 21st Century Cures Act

There is another way to fund the moonshot, aside from appropriations: Congress can channel dollars through the 21st Century Cures Act, legislation passed by the House in July 2015 that seeks to modernize clinical trials and speed up the drug approval process (The Cancer Letter, [July 10, 2015](#)).

“The American Association for Cancer Research is strongly advocating for the FY17 Labor-HHS-Ed Appropriations bill to include the necessary funding to support the programs and projects that are required to help advance the Administration’s National Cancer Moonshot Initiative, such as the recently released recommendations from the Cancer Moonshot’s Blue Ribbon Panel,” AACR President Nancy Davidson said to The Cancer Letter. “In fact, we believe that by implementing the innovative Blue Ribbon Panel recommendations, we will transform the way we prevent and treat cancer, and improve the outlook and quality of life for cancer patients.

“The wealth of scientific opportunities also underscore the importance of robust and sustained budget increases for the NIH and NCI, and highlights why we are also calling on Congress and the Administration to finalize a Senate version of the House-passed 21st Century Cures Act,” said Davidson, who is also director of the University of Pittsburgh Cancer Institute. “We believe that the 21st Century Cures legislation is an excellent mechanism for supplementing NIH and NCI funding, particularly for National Cancer Moonshot-associated programs and projects.”

On Sept. 22, AACR, ASCO and over 300 national organizations convened in Washington, D.C. for the fourth annual Rally for Medical Research, to lobby for sustained budget increases to NIH.

The budgets for NIH and other federal health agencies have largely been flat for about a decade, and are now recovering from the 5.1 percent across-the-board budget cuts in the 2013 sequester.

The moonshot is unprecedented in the history of cancer research in the U.S.—a rare national opportunity

to expedite progress, said Ellen Sigal, chair and founder of Friends of Cancer Research.

“Through the Moonshot, Vice President Biden challenged us all to further commit ourselves and do all we can to accelerate the advancement of cancer research,” Sigal said to The Cancer Letter.

“The entire community answered the Vice President's call and has already put forth bold new ideas changing how we think about research, how we collaborate, and improve how we evaluate new treatments.

“Congress must now do its part, and rise to the challenge that we all have, by not only appropriating the necessary funding for NCI, NIH, and FDA, but by also passing the pivotal 21st Century Cures legislation into law. If Congress does not take action, the incredible opportunities before us, to find better treatments, make them safely available to patients faster, and improve the ability to detect and prevent cancer at earlier stages, will be lost.”

It's not too late to secure funding for the moonshot, said Ellie Dehoney, vice president of policy and advocacy at Research!America. “It should be a priority of Congress to put resources behind an effort that could well make what was impossible, possible,” Dehoney said to The Cancer Letter. “Members should look to the Cures initiative and the appropriations wrap-up in December, utilizing both vehicles to help fuel the moonshot.”

Appropriations must be completed as soon as the November elections are complete, said Jennifer Zeitzer, deputy director of public affairs and legislative director at the Federation of American Societies for Experimental Biology.

“The lack of funding for the Cancer Moonshot is just one of many issues Congress needs to resolve over the next few months, and is a clear example of why it's absolutely critical that they come back after the election and pass an omnibus appropriations bill,” Zeitzer said to The Cancer Letter. “Without an NIH budget, funding for all research, including cancer, faces a very uncertain future.”

Advocates Push for Short-Term CR

A long-term CR would postpone the budgeting process and delay funding for new programs, including the NCI's Blue Ribbon Panel recommendations and other projects in the National Cancer Moonshot Initiative.

This is not new: in the past 19 years, Congress has used two to 21 continuing resolutions per year to keep

the federal government open. The last time Congress passed all spending bills on schedule was in 1996.

“This is the same movie script that we've seen for many years now in terms of they haven't been able to agree on the appropriation bills by the time they need to, Oct. 1, so we go into this continuing resolution,” said Jon Retzlaff, managing director of the Office of Science Policy and Government Affairs at the American Association for Cancer Research.

“It's like Groundhog Day, where you see the same thing over and over again in terms of Congress not being able to get its work done by the end of the regular fiscal year, so it requires a continuing resolution,” Retzlaff said to The Cancer Letter.

“There is a lot of momentum right now for NIH to receive robust, sustained, and predictable budget increases,” Retzlaff said. “We hope that that method will translate or will be adopted by whomever is in office and whatever changes take place in Congress and in the White House.”

AACR issued a statement commending Clinton's pledge, and urged Trump to express support and commitment to continuing the moonshot, should he be elected president.

Though Congress might pass a CR that extends into March, the federal government will most likely be operating on a three-month CR, said Matthew Hourihan, director of the R&D policy program at American Association for the Advancement of Science.

“That's what Democrats favor, that's what Republican leadership favors, but a minority of Republicans are pushing for a longer CR,” Hourihan said to The Cancer Letter. “Congress definitely seems interested in getting things done before the end of the calendar year.

“So while the election outcomes may influence the negotiations to some extent, it's not as though we're in a situation where appropriations may carry into the new Congress, which would mean the new Congress would have responsibility for making those decisions.”

Research advocates and defense organizations are teaming up to pressure Congress to complete the FY17 spending bills, instead of passing a long-term CR.

“We urge you to ensure FY17 funding decisions are crafted to advance the best interests of the American people and the strategic interests of the United States,” Research!America and the Aerospace Industries Association said in a joint letter. “No priorities more concretely meet these imperatives than sustaining a strong and nimble national defense and rebuilding the inflation-eroded budget of the NIH.”

AACR is advocating for a shorter CR, Retzlaff said. “There’s so much uncertainty that happens in the scientific community when you don’t know what the budget is going to be, you don’t know how your grant is going to be funded,” Retzlaff said. “With all that uncertainty, it’s best to get this resolved in the calendar year 2016.”

This uncertainty comes as the National Cancer Advisory Board voted Sept. 7 to support increased appropriations for the moonshot and the Blue Ribbon Panel’s recommendations.

“Appropriators have said they are waiting for more detailed information from NIH before they allocate that funding,” Hourihan said. “The moonshot task force did release their goals and prioritizations last week, so that’s one piece of the puzzle.

“Appropriators may feel that provides enough detail to provide additional funding, but they may also ... want to hold out for even more detail from NIH. They certainly have signaled support for the moonshot in principle, but they want to know how funding is to be allocated and what the funding will be used for.

“The Senate did not specify a particular number, but NCI got an even bigger increase in the Senate than in the House, so it’s safe to assume that some of that funding in the Senate bill will be used for the moonshot,” Hourihan said. “It’s not a question of whether it will be funded or not; it is getting some funding. The question is how much it will end up with in the final appropriations.”

In addition to the \$2 billion increase proposed in the Senate bill, Retzlaff said AACR “would like to see the authorization bills—the [21st Century] Cures bill and the Senate Innovation Act—include those dollars for NIH, which could probably help fund the Cancer Moonshot Initiative.

“Consistent growth can bring some certainty in the scientific community in terms of expectations and young researchers feeling as though they have a chance when they submit a grant,” Retzlaff said. “To take advantage of all the unprecedented scientific opportunities that currently exist today requires additional funding because the ideas are building on top of the ideas, and that requires more dollars.”

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Obituary

Sargent, Mayo Biostatistician, Dies Unexpectedly at 46

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“This is a tremendous loss to Mayo Clinic as well as the national and international cancer research community. Dan has given so much to so many,” said Robert Diasio, director of the Mayo Clinic Cancer Center. “We are deeply saddened by his passing. Our thoughts and prayers are with his wife and family.”

Sargent joined Mayo Clinic Rochester after earning his PhD in biostatistics from the University of Minnesota in 1996. At the time of his death, he was the Ralph S. and Beverley E. Caulkins Professor of Cancer Research, and the Chair of the Division of Biomedical Statistics and Informatics in the Department of Health Sciences Research at the Mayo Clinic.

He was also the principal investigator for the statistics and data management program at the Alliance for Clinical Trials in Oncology.

Monica Bertagnolli, chair of Alliance, said that research group “would not have been created if it were not for Dan’s efforts and particular talents.”

In 2010, Sargent was elected to serve as Group Statistician for Cancer and Leukemia Group B, linking CALGB to the North Central Cancer Treatment Group (The Cancer Letter, [Aug. 3, 2010](#)). At the time of this election, NCCTG and ACOSOG had been operating together since 2006, and had partially harmonized their data collection. Sargent said the groups used “two-and-a-half data systems.”

“We have half-way integrated ACSOG and NCCTG,” Sargent said. “We have to finish that and integrate the CALGB system into those that we have here at Mayo.”

“Dan’s election to become CALGB Group Statistician was the catalyst that led to the 2011 merger of CALGB, NCCTG, and the ACOSOG to create the Alliance,” Bertagnolli said to The Cancer Letter. “The cancer cooperative groups are characterized by the tremendous loyalty of their members, and by the great passion that they bring to clinical trials research.

“As a result, it would have been impossible to merge three exceptional groups to create a new identity without the understanding that the whole would be greater than the sum of the parts. Dan’s wonderful collaborative personality and the uncompromising quality of his team gave everyone the confidence to proceed.”

Sargent’s numerous publications—there are 189

on MedLine—focus on the treatment of colorectal cancer, predictive biomarkers, and optimal clinical trial design and endpoints.

He led many international data pooling and analysis consortia, including ACCENT in adjuvant colon cancer, the prospective IDEA international pooled analysis testing the duration of therapy in stage III colon cancer, and the FLASH international consortia in Follicular Lymphoma.

Sargent co-chaired a joint NCI-EORTC committee on methodology for tumor marker studies, was a member of the FDA panel on endpoints for colon cancer clinical trials, and currently sat on the NCI Clinical Trials Advisory Committee, which oversees all cancer clinical trials in the U.S. He was a member of the U.S. Gastrointestinal Cancer Steering Committee, and has co-chaired the Gastrointestinal committee for the NCI Common Data Elements Project.

“The world has lost one of its stars,” Axel Grothey, a colorectal cancer expert at Mayo, wrote to a group of colleagues. “We always say that everyone is replaceable, Dan is an example that this statement is not true.”

Ellen Sigal, chair and founder of Friends of Cancer Research, said she worked closely with Sargent on many initiatives. “He was a superb scientist and human being who dedicated his life to science and making the world better for patients,” Sigal said. “He was creative and he lived his life according to his principles.”

Alliance’s Bertagnolli describes Sargent as a “rare mentor and friend to so many.”

“His faculty members benefited by his approach of leading by guidance rather than by direction,” she said. “He widely shared his love of research, his dedication to family, and his pleasure in getting good friends together for a meal. The quality of every facet of a full life was just better when Dan was around. He leaves behind many who will try very hard to follow his example.”

He is survived by wife Becky, and his children, Alec and Paige.

There will be a memorial service for Sargent on Nov. 4, during the Alliance Group meeting in Chicago.

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Conversation with The Cancer Letter **OHSU to Raise another \$1B; Keith Todd Describes Strategy**

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Some of the money—at least \$200 million—would go to cancer, but the rest is slated to support research and patient care in other areas of medicine, including neuroscience, HIV, heart disease, blindness, and child health.

“Our internal goal is to raise about \$800 million to \$1 billion, yes, over basically a four-and-a-half year period,” said Keith Todd, president of the OHSU Foundation. “It’s basically the same amount of money we raised in two years in a real sprint, and a matching gift grant, but with no matching gift this time.

“So if you want to do the math on the metrics, it’s really raising the money almost in the same amount of time. You’re doubling what you raised and you’re doubling the amount of time.”

The OHSU \$1 billion campaign for cancer began when Nike co-founder Phil Knight and wife Penny Knight pledged \$500 million to the OHSU Knight Cancer Institute, requiring the institution to raise the same amount in matching funds (The Cancer Letter, [June 26, 2015](#)). OHSU raised \$1.2 billion over the course of the Knight Cancer Challenge, with \$1 billion of that going toward cancer uses and \$200 million going toward other OHSU uses.

Here is a rough breakdown on how money raised during the Knight Cancer Challenge will be invested:

- \$450-500 million for the launch of the precision early detection program operations. Approximately 1/3 will fund initiatives that will broadly support Knight Cancer Institute investigators.
- \$250 million for an endowment—this money will be invested to create a future cash flow.
- \$100 million for clinical research—funding about 20 to 25 physicians and their teams, including nurses, data analysts, and study coordinators.
- \$100 million to \$200 million to support other research and outreach priorities.

Todd spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

Paul Goldberg: *So you’ve raised \$1 billion for cancer research, what’s next?*

Keith Todd: When I came here, we were raising \$90 million to \$100 million a year—so how bold of us to think that we could raise \$1.2 billion. Of course,

almost half of that is one gift from one couple, the \$500 million from the Knights.

When we started adding everything up, we saw that while we're riding some momentum, we could probably raise \$800 million to \$1 billion over the next five years.

PG: *Correct my math, you're basically talking about continuing to raise money at a constant rate.*

KT: Our internal goal is to raise about \$800 million to \$1 billion, yes, over basically a four-and-a-half year period. It's basically the same amount of money we raised in two years in a real sprint, and a matching gift grant, but with no matching gift this time. So if you want to do the math on the metrics, it's really raising the money almost in the same amount of time. You're doubling what you raised and you're doubling the amount of time.

PG: *That's not insane.*

KT: One of my friends called me up and said you can't keep up that pace, Keith. But we have to take advantage of the space we've earned. We don't want to just give it away. We have things that we do very well, and we want the world to know. And we want philanthropists to know.

PG: *When was the clock set to go? When did you turn on the meter?*

KT: We wrapped up the Knight challenge in the last week of June 2015, and we essentially on July 1 kicked off the next phase of this campaign and went public with it in October. We seem to do everything a little faster here.

PG: *Are you on the mark? You should have about \$150 million?*

KT: We are at right about the number we want. We're on target.

And it's actually pretty amazing for us when you're talking about the two-year sprint. It was pretty hard. We targeted around the \$140-150 million range. I think we'll be pretty darn close to where we want to be.

PG: *That really is amazing. How much of the new \$1 billion goes to cancer?*

KT: About \$150-200 million over five years.

The good thing about this is since we did something everybody didn't think we could do, we earned a few chips to be a little creative and different.

PG: *What are you doing that's creative and different in terms of fundraising?*

KT: I think one of the big things that academic medicine—well let me refer to it more globally:

University fundraising is usually very alumni-based and -centric, we're not a very alumni-based program. We've raised a couple of million dollars a year

from alumni, but when you're raising \$200-\$300 million that's not going to be the backbone for your program.

Right away, we start off differently. I would say we act a lot more like a disease-centric organization in its fundraising approach. In that regard, we consider everyone, including you, Paul, a prospect for us to impress and invite to be a part of what we're doing. In that way, we're a little different. We're not captured by the traditional college and university way of thinking.

PG: *Where will the next \$1 billion be spent?*

KT: It will be split between several programs.

We'll continue to raise money in cancer, clearly, and we're also working with Louis Picker, [professor of pathology/molecular microbiology and immunology in the OHSU School of Medicine and head of the Division of Pathobiology and Immunology], who is on our West Campus, where he's doing a lot of work in our primate center with HIV and a TB vaccine. We've gotten some funding over the last three or four years—we've gotten investments from the Gates Foundation to extend his work, and we'll continue to do that. We're also looking at the Casey Eye Institute and their gene therapy and research innovation. And then we have some research projects [in other areas]and [construction of] our guest house, and then the neurosciences.

I think the thing that pulls all those things together is, quite frankly, that they're the parts of our institution that are the most collaborative and they work more horizontally than vertically. Our work in neurosciences is, quite frankly, the greatest science we do here. We have something called the Vollum Institute, and it's a very niche program, mind you, but it's basically the place where people come to study the brain synapses—it's the leading authority on the brain synapses in the world.

In most places where I've worked in the past, and I won't mention them, because that's not fair, I see not quite as much collaboration. Here, it's more horizontal application.

For example, advanced imaging is one of the areas where we're becoming world-class. And it goes from cancer to cardiovascular to the neurosciences, so we're going to continue to invest in those places, those places that cross membranes, to use a biology term.

We're also building a new guest house--our version of a Ronald McDonald House, as some people refer to it--for our patients who are going to be traveling from all across the Northwest and across the country. Half of that house is going to be for adult patients, most likely cancer-related trials. The other half is going to be for the Doernbecher Children's Hospital.

PG: *What's the rationale for one state to launch a war not just on cancer, but the whole range of diseases?*

KT: It's part of—I call it integrating into NIH funding, or the lack of NIH funding.

We like to think of Portland and Oregon as the Pioneer State, and we do things a little differently. One of the things we try to think about is, given the right amount of philanthropy to feed that innovation and that pioneer spirit, we're hopefully driving what we call cool science—the science that's not necessarily the safest science. The science that, if you go to NIH, they want you to have two-thirds of your results done before you even come to them. And [funding is] also going down.

One of the things we're trying to do is use philanthropy to drive cool science that then, over time, we hope will do the very things that other really nice, prestigious, branded universities have, which is—they have that reputation and brand that anything they touch is now gold; right? We want to try to use philanthropy in the same way, and leverage the strength that we have in the neurosciences, cancer, and immunology, with what Louis Picker is doing.

PG: *So how will you raise money, and what do you do that is different from what NIH is doing. I guess you're going towards less-safe science.*

KT: The Howard Hughes [Medical Institute] scholars have the highest rate of breakthrough science, and they have the highest rate of failure. But people know the Howard Hughes scholars as really bright, up-and-coming smart people who are doing great work. We're kind of fashioning ourselves in that arena, as opposed to a staid, solid, conservative, plod-along science. All science plods, don't get me wrong—but we're trying to help our researchers and faculty to test some of those things that they believe or want to investigate, but really understand that if they don't have private philanthropy, they're just not going to do it.

PG: *You raised the first half-billion from one couple, and \$200 million came from the state. Is there something similar in the new endeavors in the next five years?*

KT: Well, no, we don't see that. We have some creative partnerships, for example, we're doing some things in Klamath Falls in southern Oregon, about five hours from here. There's no easy way to get there to be honest. But we have an obligation as the state's academic medical center to ensure that there's access to care. We've now done something that most places wouldn't even think about.

We have a public-private partnership with the

medical center in that community to build out a \$50 million facility and position us to help consistently deliver the right amount of care in that community, specifically some specialty care that you just can't get in rural parts of Oregon.

PG: *And that is part of your broader campaign?*

KT: We had a campaign kickoff last October and, candidly, we announced a campaign and didn't announce what number we were trying to raise. I had a couple of people call me and say you're just about crazy enough to pull that off. And I would say, pull what off? And they would say no one believed that you were going to raise \$500 million in two years to get the Phil Knight challenge, so I guess, of course, you're going to be one of the few people to announce a major comprehensive campaign for your institution and not tell anybody what your goal is.

Well, my goal is not money—our goal is to solve human health problems. [For example,] we're delivering care in Klamath Falls through the philanthropy that we raised, and it prevents kids from having to come up here, be Life-Flighted up here, that's what we're accomplishing.

PG: *Are the people your usual prospects—are you seeing them still respond? Or are you seeing some fatigue?*

KT: I would say that in the cancer program, very specifically, I think we saw just a bit of fatigue that we're starting to come out of. Another thing is we've hired Sadik Esener, [director of the Center for Early Detection Research and Wendt Family Endowed Chair in Early Cancer Detection] to take over the early detection program. We're kind of reentering the public market, if you will, with what we've accomplished.

Sometimes the fatigue on donors is that they give you money, but the science takes a while; right? They're waiting for what we're going to do next.

We're going to present what we've done in a packaged and consumable way, so I think we're going to start seeing some of that fatigue dissipate, because people will get excited.

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In Brief

AACR Cancer Progress Report Calls for Annual Increases in Research Funding

THE CANCER PROGRESS REPORT released by the **American Association for Cancer Research** argues that although funded research continues to spur progress against cancer, accelerating the pace of progress will require robust, sustained, and predictable annual funding increases for NIH, NCI, and FDA.

The report also makes a case for continued funding for the National Cancer Moonshot Initiative.

Progress highlighted in the AACR Cancer Progress Report 2016 includes the following:

- The number of cancer survivors living in the U.S. rose by 1 million from 2014 to 2016, reaching an estimated record 15.5 million.

- Between Aug. 1, 2015, and July 31, 2016, FDA approved 13 new anticancer therapeutics and new uses for 11 previously approved anticancer therapeutics.

- Four of the 13 new anticancer therapeutics are immunotherapeutics, revolutionary treatments that are increasing survival and improving quality of life for patients with an increasing number of types of cancer.

- Research discoveries continue to advance precision medicine: Four of the 13 new anticancer therapeutics are molecularly targeted agents.

- During the same period, one new cancer screening test, two new diagnostic imaging agents, and a new medical device also received cancer-related FDA approvals.

The report emphasizes that although significant advances are being made against cancer, the disease continues to exert an immense personal and economic toll, both nationally and internationally, and that the burden of cancer is expected to grow in the coming decades.

According to the report:

- More than 595,000 people in the United States are projected to die from cancer in 2016.

- Cancer is the number one cause of disease-related death among U.S. children.

- The number of new cases of cancer in the United States is predicted to rise from 1.7 million in 2015 to 2.4 million in 2035.

- Many population groups continue to suffer disproportionately from cancer and its associated effects--most notably certain racial and ethnic minority groups, individuals with low socioeconomic status,

residents in certain geographic locations, and the elderly.

- It is estimated that the direct medical costs of cancer care in the United States in 2010 were nearly \$125 billion, and that these costs will rise to \$156 billion in 2020.

The report highlights the recommendations of the National Cancer Moonshot Initiative Blue Ribbon Panel for accelerating the pace of progress in cancer research. It also calls for Congress and the administration to:

- Support the Senate Appropriations Labor, Health and Human Services, Education, and Related Agencies Subcommittee's FY17 bill, which proposes to provide an increase of \$2 billion for the NIH.

- Finalize a Senate version of the House-passed 21st Century Cures Act to support the National Cancer Moonshot Initiative and other important NIH-related strategic research initiatives.

- Support an FDA budget in FY 2017 of \$2.85 billion, \$120 million above its FY 2016 level, to ensure support for regulatory science and the timely approval of therapeutics that are safe and effective.

- Readjust the discretionary budget caps for FY 2018 and beyond, which would allow our nation's policymakers to continue to provide robust, sustained, and predictable funding increases for the NIH, NCI, and FDA in future years.

90 CANCER GROUPS AND CANCER CENTERS, in a sign-on letter, urged the **Center for Medicare & Medicaid Services** to rescind proposed reimbursement cuts for lung cancer screening in its proposed rule on the 2017 Hospital Outpatient Prospective Payment System. The proposal lowers the reimbursement for low-dose CT lung cancer screenings by 44 percent, from \$112.49 to \$63.33, and the associated shared decision making sessions between patients and providers by 64 percent, from \$69.65 to \$25.09.

The letter notes that early detection is key to successfully treating lung cancer, which is responsible for the most deaths of any cancer in the United States.

“Quite simply,” the letter argues, “if the reimbursement rates for the shared decision making visit and corresponding LDCT scan are too low, it will be cost prohibitive for hospital outpatient departments and many will not be able to afford to offer these services at all. Furthermore, if the services are unavailable in the outpatient setting, qualifying patients will be unable to receive annual screens and

the battle to combat lung cancer mortality will be severely undermined.”

THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY awarded Rep. Michael Burgess (R-TX), with its first-ever **ASCO Congressional Leadership Award** for his work to support policies related to cancer research and treatment.

The new, annual award honors a member of Congress who is a consistent champion for patients and survivors of cancer, their families, and health care teams.

Burgess was a leader in repealing the Sustainable Growth Rate and ushering in the Medicare Access and CHIP Reimbursement Act (MACRA) to replace the SGR.

Burgess has been a supporter of the 21st Century Cures Act, legislation that would advance initiatives related to interoperability, big data, and precision medicine to spur development of promising new treatments for people living with cancer. He introduced legislation (H.R. 293) to protect continuing medical education by clarifying that peer-reviewed journals, medical textbooks, and other medical education texts should be excluded from reporting requirements under the Sunshine Act.

SPECTRUM PHARMACEUTICALS INC. is under investigation by national securities law firm **Faruqi & Faruqi LLP** for potential securities fraud.

The firm said it's investigating whether the company and its executives violated federal securities laws by issuing materially misleading information about the company. Specifically, on Sept. 14, the FDA Oncologic Drugs Advisory Committee (ODAC) voted against approval of Qapzola (Cancer Letter, [Sept. 16](#)).

During the meeting, FDA officials said that in a December 2012 meeting Spectrum officials were advised against filing a New Drug Application for the company's bladder cancer drug. Despite that, the company told investors in a May 2015 conference call that "we took this data, met with the FDA, and our understanding is and our decision is that we can go ahead and file the NDA with this drug."

COLUMBIA UNIVERSITY and **New York-Presbyterian** said that their shared medical campus in Washington Heights will now be called **Columbia University Herbert and Florence Irving Medical Center** and **New York-Presbyterian/Columbia University Irving Medical Center** for donors

Herbert and Florence Irving.

The Irvings' donations and commitments over time to Columbia University Medical Center and New York-Presbyterian will exceed \$300 million. Most recently, the Irvings donated new gifts to support Columbia's precision medicine initiative which, in partnership with New York-Presbyterian, is addressing the genetic and genomic basis of cancer and other life-altering diseases.

Herbert Irving is a co-founder and former vice chairman of Sysco Corporation, the nation's largest food distributor. Florence Irving has served in leadership positions on the boards of several non-profit institutions, including The Metropolitan Museum of Art where she is a trustee emeritus. They have been married for 74 years.

SHIRLEY JOHNSON was named senior vice president of Nursing & Patient Care Services and chief nursing officer of the **Roswell Park Cancer Institute**.

Johnson was most recently senior vice president and Chief Nursing and Patient Care Services Officer at City of Hope. She has been recognized with the American College of Surgeons Commission on Cancer Award for Distinguished Service, in 2006, and the California State Legislature 2013 Woman of the Year distinction. She is a member of the American Society of Blood and Marrow Transplantation.

THE DR. RALPH AND MARIAN FALK MEDICAL RESEARCH TRUST awarded \$485,000 to research teams from the **Icahn School of Medicine at Mount Sinai** and **Thomas Jefferson University** in Philadelphia to study the effects of key genetic mutations in uveal melanoma. There are no FDA-approved therapies for metastatic UM and patient survival is poor.

Julio Aguirre-Ghiso, professor of medicine, hematology, and medical oncology at the Icahn School of Medicine at Mount Sinai, associate director for basic shared resources and director of Head and Neck Cancer Basic Research at The Tisch Cancer Institute, will lead the Mount Sinai team and is co-recipient of the award with **Andrew Aplin**, professor of cancer biology at TJU and principal investigator of the study.

THE AMERICAN BRAIN TUMOR ASSOCIATION awarded **16 grants** to support brain tumor research. This year's funded projects focus on areas such as potential new therapies, novel imaging approaches, immunotherapy and metastatic disease.

The American Brain Tumor Association Discovery Grant is a one-year, \$50,000 grant supporting approaches that have the potential to change current diagnostic or treatment paradigms for either adult or pediatric brain tumors. The 2016-2017 Discovery Grant recipients are:

- **Anita Bellail**, Henry Ford Health System, Detroit, MI. "Development of Potent SUMO1 Inhibitors as Anticancer Drugs for Glioblastoma Therapy."

- **Vivian Gama**, Vanderbilt University, Nashville, TN. "Targeting Mcl-1 to Disrupt Glioblastoma Stem Cells."

- **Xi Huang**, The Hospital for Sick Children, Toronto, Ontario. "Targeting Potassium Channel KCNB2 in High Risk Medulloblastoma."

- **Peter LaViolette**, Medical College of Wisconsin, Milwaukee, WI. "Brain Cancer Radiohistomics."

- **Josh Neman**, University of Southern California, Los Angeles, CA. "Role of Cerebellar Microenvironment in Medulloblastoma Development."

- **Jiangbing Zhou**, Yale University, New Haven, CT. "A Nanotechnology Platform for Systemic Delivery of Chemotherapy to Malignant Gliomas."

The recipients of the **Basic Research Fellowships** are postdoctoral fellows conducting brain tumor research. This two-year, \$100,000 grant provides recipients the opportunity to be mentored by world-class scientists in renowned institutions, in an effort to provide the research, scientific, management and other guidance necessary to foster their career development. The 2016-2018 Basic Research Fellowship recipients are:

- **Christopher Alvarez-Breckenridge**, Massachusetts General Hospital, Boston, MA. "Characterization of Tumor and Immune Cell Clonal Evolution in Response to Immune Checkpoint Blockade for Metastatic CNS Disease."

- **Lan Hoang-Minh**, University of Florida, Gainesville, FL. "Investigation of the Human Glioblastoma Ciliome."

- **Giedre Krenciute**, Baylor College of Medicine, Houston, TX. "Genetically Engineered T-Cells as Therapy for Glioblastoma."

- **Francisco Puerta-Martinez**, MD Anderson Cancer Center, Houston, TX. "Targeting Immunotherapy to Gliomas and Brain Metastases Enhancing Oncolytic Viruses with Immune Checkpoint Modulation."

- **Zhaohui Wang**, Duke University, Durham, NC. "Investigating the Impacts of PPM1D Mutations on Brainstem Gliomagenesis and Evaluating Therapeutic

Efficacy for Targeting PPM1D Mutations in Brainstem."

ABTA Medical Student Summer Fellowships are \$3,000 grants awarded to deserving medical students who wish to spend a summer conducting a brain tumor research project under the guidance of esteemed scientist-mentors. Through this award, the ABTA seeks to encourage motivated physician-scientists to enter and remain in the brain tumor research field.

- **Abdul-Kareem Ahmed**, Brigham and Women's Hospital, Boston, MA. "Immune Suppressive Mechanisms of Extracellular Vesicles in Glioblastoma Treated with Gene-Mediated Cytotoxic Immunotherapy."

- **Raymond Chang**, Weill Cornell Medical College, New York, NY. "Convection-Enhanced Delivery of a Novel Combinatorial Chemotherapy in a Mouse Model of Diffuse Intrinsic Pontine Glioma."

- **Patrick Flanigan**, University of California, San Francisco, San Francisco, CA. "Role of Monocyte Chemotactic Protein-1 Upregulation in Anti-Angiogenic Therapy Resistance."

- **Tyler Lazaro**, Massachusetts General Hospital, Boston, MA. "Identification of Therapeutic Targets in Posterior Skull Base Meningiomas."

- **Adela Wu**, Johns Hopkins University School of Medicine, Baltimore, MD. "Elucidating the Mechanism of Anti-TIM-3 and Anti-PD-1 in Reversing T-Cell Exhaustion and Prolonging Survival in a Murine Glioblastoma Model."

The ABTA is accepting applications for three research funding opportunities. Requests for funding are posted on the [website](#) and applications will be accepted until Wednesday, Oct. 5 at 12:00 noon CDT.

Drugs and Targets

Dignity Health, Catholic Health Initiatives Launch Precision Medicine Alliance

DIGNITY HEALTH and **Catholic Health Initiatives** announced the launch of the **Precision Medicine Alliance LLC**, which will offer patients from both health care systems faster and more accurate diagnostic and treatment protocols based on their genetic and molecular profile information.

The program will be available at nearly 150 hospitals and care centers across the U.S., serving approximately 12 million patients annually, creating the largest community-based precision medicine

program in the country.

The Alliance will initially focus on advanced diagnostic tumor profiling in cancer treatment and will later expand into other areas such as cancer and cardiovascular risk, and pharmacogenomics. The program will also support oncology research by populating a database that will become the largest collection of clinical cancer data ever compiled by a single organization.

“The Precision Medicine Alliance will provide community physicians with access to a wide range of diagnostic technology that is currently only available in academic medical centers. This will provide more accurate diagnoses, with personalized therapies tailored to each patient through community providers, where the vast majority of care happens,” Lloyd Dean, president and CEO of Dignity Health, said in a statement.

The Precision Medicine Alliance will also integrate electronic medical records into a data-management infrastructure that will allow quick access to the right clinical expertise and clinical trial information.

ELI LILLY & CO. said that the **European Medicines Agency's Committee for Medicinal Products for Human Use** issued a **positive opinion recommending the granting of a conditional marketing authorization** for **olatumab**, in combination with **doxorubicin**, for the treatment of adults in the European Union with advanced soft tissue sarcoma not amenable to curative treatment with radiotherapy or surgery and who have not been previously treated with doxorubicin. The CHMP reviewed olatumab under EMA's accelerated assessment program. If approved, olatumab will be marketed under the trade name **Lartruvo**.

This is the first regulatory step in the world towards approval for olatumab. The CHMP positive opinion is now referred for final action to the European Commission, which grants marketing authorization in the EU. The Commission usually makes a decision on marketing authorization within two to three months of the CHMP issuing its recommendation.

As part of a conditional marketing authorization, Lilly will need to provide results from an ongoing Phase III study. This study, **ANNOUNCE**, is fully enrolled. Until availability of the full data, the CHMP will review the benefits and risks of olatumab annually to determine whether the conditional marketing authorization can be maintained.

EMA previously granted olatumab with Orphan Drug Designation for the treatment of soft tissue sarcoma in the EU.

GOLDEN MEDITECH HOLDINGS LTD., a Hong Kong-based healthcare enterprise, and **MD Anderson Cancer Center** announced the creation of **Cellenkos Inc.**, a start-up enterprise focused on umbilical cord blood derived T-regulatory cellular therapies.

Cellenkos, to be based in Houston, is funded with an initial investment of \$10 million with warrants to purchase an additional \$10 million worth of shares by Golden Meditech and an independent strategic investor.

The agreement covers technologies arising from the laboratory investigations of Simrit Parmar, associate professor in the Department of Stem Cell Transplantation and Cellular Therapy at MD Anderson. Cellenkos will build on Parmar's existing and potential future pre-clinical and clinical research to develop various T-reg-based therapies for clinical use in treating autoimmune diseases where the patient's T-reg cells are often defective and/or lower in number.

ST. JUDE CHILDREN'S RESEARCH HOSPITAL and **The Wellcome Trust Sanger Institute, UK**, agreed to a full exchange of cancer mutation data to support the discovery and understanding of genetic mutations causing cancers.

The agreement will provide regular updates and exchanges of data between both institutions to ensure the best support for research in all areas of cancer, and will be freely available to researchers in all areas of science.

THE ONCOLOGY RESEARCH INFORMATION EXCHANGE NETWORK (ORIEN) and **HudsonAlpha Institute of Biotechnology** announced a new collaboration to advance cancer research and care called **The ORIEN Avatar Research Program**.

Under the agreement, HudsonAlpha will provide DNA sequences for 20,000 patient samples, tumor and non-tumor, by 2019 to identify the genetic disturbances and mutations of each patient's cancer. Their team will perform whole exome sequencing and RNA sequencing to learn more about the genetic makeup of cancerous tumors.

Health informatics solution company **M2Gen** is leading the ORIEN Avatar Research Program.