THE CANCER LETTER

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Conversation with The Cancer Letter

Stanford Cancer Institute Earns NCI Comprehensive Center Designation

Stanford Cancer Institute earned the NCI Comprehensive Cancer Center designation, becoming the eighth institution in California to earn this highest level of recognition.

Nationwide, the number of comprehensive cancer centers now climbs to 47. Earlier this summer, the University of Maryland also received the comprehensive designation (The Cancer Letter, May 31).

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Slamming the Door

Part XIV: How AI Got It Right

By Paul Goldberg

Gilman's resignation enabled him to retain the most precious of all privileges: the ability to look at himself in the mirror.

By slamming the door loudly and publicly—and by triggering an impossible-to-ignore resignations of scientists who conducted peer review at the Cancer Prevention and Research Institute of Texas—he made it clear that the institute's scientific review was in danger of being subverted, and that its funds were at risk of being raided by politicians.

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Capitol Hill

House Appropriators Propose $1.25 Billion Budget Increase for NIH in FY 2017

By Matthew Bin Han Ong

The House Appropriations Subcommittee on Labor-HHS marked up a bipartisan spending bill July 6 that gives NIH a $1.25 billion increase in the 2017 fiscal year.

NCI is to receive a $264 million increase over FY 2016.

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Stanford Earns Comprehensive Cancer Center Designation

(Continued from page 1)

"I think our strength is having depth of basic science that hasn't yet been fully mobilized to apply to cancer," said Beverly Mitchell, SCI director and the George E. Becker Professor of Medicine. "[SCI] has a broad, multidisciplinary group of really creative and innovative people; the word 'innovation' comes up a lot here. I think that's probably a distinction."

Mitchell, who became the SCI director in 2008, spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

Paul Goldberg: *The name Stanford comes with a certain level of prestige in all endeavors—science, healthcare, arts, humanities—why did this designation not happen, say, 25 years ago?*

Beverly Mitchell: There's an interesting history at Stanford. Years ago, Henry Kaplan wanted a cancer center, and the chairs of many departments thought that it wouldn't be advantageous to necessarily have a separate group responsible for cancer.

It really was Dean Phil Pizzo, who came from the NCI, who had this vision and who made it happen. He recruited myself and Dr. Karl Blume, a bone marrow transplant expert and wonderful person and leader, who unfortunately died three years ago.

Dr. Blume started this process, then he and Dr. Pizzo recruited me from UNC.

PG: *There was of course a consortium cancer center a few years ago. You've been director since 2008. How did you make this designation happen?*

BM: It was really a matter of simply building on the existing talent—there was expertise in most areas, perhaps not as strong in population science.

So it was a matter of recruiting some key leaders in clinical research and population science, recruiting some other very skilled faculty and then catalyzing their interactions, which is pretty much what cancer centers are supposed to do.

But the talent here was remarkable to start with, so that was definitely an advantage.

PG: *That's certainly putting it in a nutshell. What was your war chest for making this happen?*

BM: In the beginning, we frankly had some wonderful community support. Then three years ago, we had received a large gift from a group of anonymous donors that was intended to transform the care of cancer patients.

It has been applied to improving coordination of care and overall attention to how patients are treated in the clinic, as well as to translational research and how to improve patient outcomes.

PG: *How much money was it?*

BM: The total for both patient care and translational research was $125 million.

PG: *And that's over a fairly short period of time.*

BM: Yes. Frankly, we started with not a very big war chest, but people in the community have been very supportive.

PG: *Is there number—is it $125 million-plus?—to make the designation happen?*

BM: We still have some of that, so I don't really have a number. I would hesitate to attribute it all to dollars. Although it does help in some of the recruitments, obviously.

PG: *Your clinical center has always been very busy and full of great docs, though I've been told by friends that it hasn't really had a major PR machine, a bragging machine. And you have recruited some clinical stars—George Sledge, Doug Blayney, to name a couple. Am I missing anybody? Do you want to point to anyone who helped make this designation happen?*

BM: Mark Pegram, another breast cancer and translational research who's head of our clinical research programs now. And Robert Hale came from USC to lead our population science programs. I think those were two really important recruitments. I should mention another—I guess that recruitment happened after the comprehensive designation—but we've also recruited Crystal Mackall from the NCI who is a fantastic immunotherapy person.

PG: *What's the value of a comprehensive cancer*

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PROUD TO BE RECOGNIZED AS ONE OF THE NATION'S BEST.
We are now an NCI-designated *Comprehensive* Cancer Center.
University of Maryland Greenebaum Comprehensive Cancer Center has achieved the National Cancer Institute's highest designation. While this is an honor, what's more important is the progress we are making in fighting and preventing cancer:
NCI
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• Discovery of galeterone, an FDA fast-tracked compound developed to treat hormone-resistant prostate cancer
• Invention of GammaPod™, a radiotherapy system for treating breast cancer in a prone position to better protect the heart
• Immunotherapy trials that train patients' own T cells to attack blood and lung cancers
• Population health-related discoveries with risk and prevention implications for cervical cancer
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MEDICINE ON A MISSION

designation to Stanford? Is it the value of the core grant or is it something that you need to stay competitive in this environment?

BM: I think we were feeling as if we should be among the comprehensive cancer centers in the state, which are quite a few. We we are on par with them.

It's really helped us to achieve the stature we believe we deserve, in the state of California and nationally.

PG: *How is Stanford different from other cancer centers nationwide or in California or Northern California?*

BM: I think our strength is having depth of basic science that hasn't yet been fully mobilized to apply to cancer. [SCI] has a broad, multidisciplinary group of really creative and innovative people; the word 'innovation' comes up a lot here. I think that's probably a distinction.

PG: *I think that segues to the next question; I'm going to generalize shamelessly, so just throw something at me. Stanford recruits and develops people who are smart and independent, and a friend of mine said that this is probably why it took so long to get a cancer center put together. How do you get these folks to understand the value of teamwork?*

BM: Mobilizing people with really good ideas to meet and come together—we have the traditional seed grant programs where we give interactive groups some amount money to work together; that always helps.

But everybody here is very collaborative, it's just that there had never been a structure in place to set and pursue priority research areas. It's always been from the bottom up. Some of the resources have gone toward encouraging people to do more collaboration, but, truthfully, it's a very collaborative environment. That part is not too difficult.

The rewards at the level of promotion at Stanford are still very much for individual achievement, but I think that's changing a little bit.

PG: *Is there anything we've missed? Anything you'd like to add?*

BM: I've been here 10 years, so it's been quite a journey. It's a very exciting place and we're pleased with the recent acknowledgement of that.

Slamming the Door

Part XIV: How Al Got It Right

(Continued from page 1)

"I built something I am proud of, and now it's being taken apart," Gilman said to me at the time. "I can't work for people who are pushing their own interests at the expense of the interests of cancer patients.

"A wise and experienced friend said to me: 'This is always the way it works when you put a large amount of public money on the table. The vultures and the hyenas lie low for two or three years to see how the system really works. And then they come in for their feast.'"

Gilman accepted the fact that he had no control over the events that followed his exit. He believed that two changes would have to be made for the institute to become viable again:

(1) Bill Gimson, the executive director who shepherded MD Anderson incubator proposal through peer review, would need to go, and

(2) The politically appointed CPRIT Oversight Committee would need to be jettisoned as well.

Anything short of that would be insufficient. But of course, nothing of the sort could possibly happen, he said initially. By then I knew that in the case of Al Gilman, the verbs "said" and "believed" could be used interchangeably.

Initially, Gilman thought the chance of either of these events occurring was somewhere around zero. Even if a good scientist is found to replace him as chief scientific officer, this person will have to battle politicians.

His refrain: "Never underestimate the power of Texas politicians to fuck things up."

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If anything, following Gilman's resignation, Texas politicians seemed to be strengthening their control over CPRIT.

In October 2012, immediately after Gilman's resignation, Gov. Rick Perry, House Speaker Joe Straus and Lt. Gov. David Dewhurst sent a letter to CPRIT officials urging them to pursue more commercialization projects.

"CPRIT laid a solid foundation for this endeavor by focusing its efforts and funding predominantly on basic scientific research," they wrote. "It is now time for CPRIT to take further steps to fulfill its statutory mission and expedite innovation that will deliver new cancer treatments to patients within three to five years."

Charles Tate, a Houston venture capitalist and member of the oversight committee who engineered the loophole in review of technology incubators, and then worked to have the MD Anderson incubator funded, said CPRIT needed to switch its emphasis to commercialization.

"There's no question in the minds of the…oversight committee that development/commercialization activities are allowed under the legislation," Tate said to the Texas Tribune. "The only people who disagree on that are all the people who want all the money spent on research."

To put Tate's statement in perspective, Gilman pointed to an earlier statement by the politically active Texas entrepreneur. When the MD Anderson-Rice incubator was first announced, Tate said in a Rice press release that the problem with research is not the absence of scientific breakthroughs but the lack of commercialization expertise.

"One of the biggest obstacles to getting life-saving treatments to patients is not a lack of good ideas or good science, but a lack of business expertise," he said in a Rice University press release. http:// bit.ly/ HyeC0d "CPRIT is proud to support a center that will ensure the best cancer-fighting technologies can make it to market and into the hands of the people who need them the most."

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Yet, in part due to Gilman's continuing efforts, events didn't develop in accordance to the plans Texas politicians may have devised. They solidified their grip on CPRIT, but the place continued to crumble.

First, a routine audit showed that Jerald Cobbs, CPRIT's chief commercialization officer, had failed to conduct peer review before awarding an $11 million grant to Peloton Therapeutics Inc., a Dallas-based company (The Cancer Letter, Nov. 30, 2012).

Cobbs was a key player in awarding an $18 million grant to a Houston-area biotechnology incubator led by Lynda Chin, scientific director of the MD Anderson Cancer Center Institute for Applied Cancer Science and wife of the center's president, Ronald DePinho (The Cancer Letter, May 25, 2012).

Gilman flagged the Peloton proposal for CPRIT, but recused himself immediately and was as surprised as anyone else to learn that the proposal wasn't subjected to formal review by CPRIT. The company didn't seek special treatment and would likely have passed any review.

Cobbs would later become the only CPRIT official charged and tried in connection with the explosion of widely publicized scandals. He was charged with securing execution of a document by deception, a first-degree felony punishable by imprisonment of five to 99 years and a $10,000 fine.

Gilman believed Cobbs was eager to please his bosses, and while he clearly screwed up by failing to review the Peloton application, this error could be explained: CPRIT was just getting going, and the company's science was well reviewed by the Column Group, a California-based venture capital firm that had skin in the game. The magnitude of Cobbs's error didn't merit a felony charge, and the prospect of becoming a life-long guest of the state government.

Cobbs was ultimately acquitted.

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CPRIT officials were forced to look for Gilman's successor in the midst of exploding scandals and probes by the legislature and law enforcement authorities.

I was surprised that they wanted to replace Gilman with another reputable scientist.

The job was first offered to Raymond DuBois, who had just left his job as provost at MD Anderson. DuBois had demonstrated both courage and integrity under very difficult circumstances at MD Anderson and there was no reason to expect that he would become anyone's stooge.

After DuBois said no-thanks, CPRIT recruiters went after Margaret Kripke, DuBois's predecessor as provost at MD Anderson.

"I read in The Cancer Letter and other news publications about what was going on, and it was very clear that the agency was in danger of losing the money—that the legislature was angry enough about what was happening that they could very well have lost the money," Kripke said to me recently. "I just got so angry over that issue, because it would have been such a lost opportunity; $2 billion were left at that time. It would have been $2 billion for cancer research wasted at a time when NIH money was so hard to come by. I just thought I shouldn't sit around and watch that happen."

Another statistic: CPRIT's contribution to cancer research in Texas was roughly equal to all NCI funds received by scientists in the state. Moreover, the institute sponsors recruitment and relocation of top-tier cancer scientists to Texas institutions.

Kripke had stepped down as MD Anderson's provost five years earlier, in 2007, and retired completely

in 2009. "I had colleagues who urged me to do it, since I had just retired, I wasn't really doing much of anything," she said.

Kripke had another reason to consider taking the job.

"I have thought for a long time that we needed to be spending more of the cancer research portfolio on prevention and early detection, so that was also an opportunity for to try to change the funding a little bit, tweak in the direction of cancer prevention," she said to me. "Those were really the two factors for me to jump in and throw my hat in the ring for this position."

Kripke and Gilman weren't acquainted.

"I called him as soon as I was appointed," Kripke said. "He was absolutely most gracious. He said he would be willing to help me in any way he could, and to please call him if I needed any advice for anything. He couldn't have been nicer and more supportive. Which was really terrific. That was a real positive for me because he was of course all of the reviewers were very loyal to Al, and having him be supportive I knew would be very important in terms of helping rebuild the review committee."

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Just after 11 a.m. on Dec. 11, 2012, CPRIT sent out a press release announcing Kripke's hiring.

A little more than an hour later, the same office sent out another bit of news: the resignation of Bill Gimson, CPRIT's executive director, the official ultimately responsible for the MD Anderson and the Peloton fiascos.

In his letter of resignation, Gimson accepted no blame for the events that caused CPRIT to bleed out its scientific credibility and brought it to the edge of a precipice (The Cancer Letter, May 25, 2012, Oct. 12, 2012, Oct. 19, 2012, Oct, 26, 2012).

"The last eight months have been extremely difficult for those at CPRIT—during this time they have not been able to do their jobs due to wasted efforts expended in low value activities that do nothing to advance cures for cancer," Gimson wrote.

"Unfortunately, I have also been placed in a situation where I feel I can longer be effective. After considerable thought, and in the hope that my fellow CPRIT workers will finally be able to get back to what is important, I hereby tender my resignation as CPRIT Executive Director."

A couple of hours after this epistle was released to reporters, Kripke took questions at a telephone press conference, arranged by CPRIT officials.

The first question was entirely predictable: what can you say about Gimson resigning?

"Since I learned about it a few minutes ago, I haven't had an opportunity to digest it yet," Kripke said. "I am, of course, sorry to hear it, because he seemed to be doing a reasonably good job, and I am waiting to see what the board is going to do about his letter."

"So, Dr. Kripke, whom are you reporting to?" asked another reporter. "I have no idea at this juncture," Kripke said. "Until Jan. 17, I am reporting to Mr. Gimson, because he will stay on until then. After that, I don't know what happens. As you know, I haven't started yet, so I am in the dark about what's happening." Kripke was expected to begin work Jan. 7.

In our recent conversation, Kripke reflected on that day's strange events.

"I remember you asked me what does that feel like, and I said I have no idea," Kripke said. "It just happened I haven't even had time to process this yet. It was quite strange to have the person who had hired me to resign on the day that my appointment was announced."

Being happily retired, Kripke could look at that day's events with healthy detachment.

"There was a third issue in my taking the position which was that I really had nothing to lose," she said. "I figured that if it didn't work out and the thing collapsed, I didn't have a gigantic investment in moving to Austin or doing anything like that. For me it wasn't a major issue, it would work out or it wouldn't. I would've happily gone back to my state of retirement if things did not work out.

"I didn't know any of the people involved and I wasn't involved in what was going on in any substantive way. I didn't have a side to be on—at least that's how I viewed it.

"I don't know if it was perceived that way."

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Kripke initially thought that her top priority would be to get reviewers to return.

At the time, only one of the seven members of the CPRIT Scientific Review Council did not resign.

Richard Kolodner, head of the Ludwig Laboratory of Cancer Genetics and distinguished professor of cellular and molecular medicine at the University of California San Diego, stayed to wait and see how events played out. Gilman supported Kolodner's strategy.

For one thing, with six of the seven council members gone, there was nothing left to resign from. And if Texas officials decided to restore CPRIT to its

former glory, Kolodner's presence would give the effort credibility.

Meanwhile, CPRIT had additional problems. A moratorium was imposed on making new grants, and there were audits, an inquiry by the legislature as well as civil and criminal investigations. Questions were raised about the structure of CPRIT foundation and the purchasing of furniture for a CPRIT offshoot. The institute was too exposed to remain a target for the "vultures and the hyenas" Gilman spoke about.

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Though more than half of CPRIT's 100 or so scientific reviewers had departed, Kripke was being precluded from starting recruitment.

"I expected to go right to work rebuilding the committee, but the first thing that happened to us was that the governor imposed a moratorium," Kripke said. "I couldn't do anything in terms of recruiting people or rebuilding the review panels, because we were on notice that we might not survive."

Gimson was replaced by Wayne Roberts, an expert in public finance and budget. His job immediately prior to CPRIT was as associate vice president for public policy at the University of Texas Health Science Center at Houston.

Roberts was a no-nonsense budget guy who spent 18 years at the Legislative Budget Board, served as a deputy and acting budget director for Gov. George W. Bush, and later worked for Gov. Rick Perry in a variety of jobs, including drafting legislation that created the Texas Emerging Technology Fund.

Roberts's expertise was in workings of state agencies, their budgets and process. It wasn't limited to health or health administration. By way of comparison, his predecessor, Gimson, had spent 35 years in administrative positions at the Centers for Disease Control and Prevention.

"To some, Wayne seemed an odd choice, as he had no experience in cancer research, patient care or prevention, nor had he ever headed a state agency," said Tom Kleinworth, vice president for government relations at the Baylor College of Medicine. "What the leadership correctly saw, however, is that to survive the agency would need someone who fully and deeply understood Texas state government. They needed someone who understood state budgeting. They needed someone who understood both the appropriations process and the legislative process. And most of all they needed someone who had a reputation for honesty and integrity.

"That was Wayne."

Another insider, former Texas Deputy Comptroller Billy Hamilton, was hired as a senior advisor to Roberts and the Oversight Committee. Hamilton at the time was a private consultant. But prior to 2007, he was the chief deputy comptroller of public accounts of Texas.

CPRIT was under orders to stop funding grants, investigations were underway, the blueprints for the state budget didn't contain any funds for the institute, and the state auditor was preparing what would turn out to be a scathing 99-page report.

Instead of disputing the findings of the state auditor's report, Roberts decided to implement it in its entirety—all 42 recommendations.

"This in itself was a monumental task, as many of the board members understandably were defensive," Kleinworth said in an email. "However, he convinced them it was the right thing to do and then, working with the very capable members of the CPRIT staff, quickly and fully implemented the auditor's recommendations.

He was similarly open to hearing any ideas from legislators. "He convinced them not only that he was open to making any and all changes," Kleinworth said. "More importantly, he convinced them that CPRIT should continue in existence--that the work it was doing in cancer research, in commercialization and in cancer prevention was and would continue to be beneficial to the people of Texas."

Two state legislators, Sen. Jane Nelson (R-Flower Mound) and Rep. Jim Keffer (R-Eastland), in effect saved the institute by crafting complex legislation that instituted tighter controls and—just as importantly—got rid of the members of the oversight committee.

Nelson and Keffer had collaborated on the 2007 legislation that created CPRIT. Under the new bill, which saved CPRIT, the staggered terms of existing members ended on the day the new bill went in effect.

Though former members of the Oversight Committee could have been reappointed, they weren't.

Can Gilman be given credit for the committee's ouster?

I can say that he never claimed credit in our conversations. However, he did mention speaking with Nelson, Keffer and their staff members, and as a citizen and, of course, scientist he owed them his unvarnished opinion and advice.

I say Al won.

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The auditors' findings affected Kripke's work.

"There were a lot of issues that the auditors were unhappy about," she said. "I don't think there was anything done maliciously. It was a matter of not dotting all the I's and crossing all the T's when they got the agency up and running

"We were not allowed to do anything that looked like we were restarting or returning to business as usual.

"We spent the first year rewriting and implementing all the new rules. It was both pretty difficult and unexpected because that's not really what I went there for; at least I didn't think so, but that's what we did," Kripke said. "I was in Austin once a week for two to three days a week. For a lot of the time the first year.

"Rewriting the rules meant working out all the details about how appointments were made, the criteria for appointing people to review panels. There were a lot of things that were never really codified, because people were busy trying to get the agency up and running and trying to get grant money flowing. There were a lot of things put in place that were actually never put down on paper. I certainly was involved in the rules regarding the review panels and how the honoraria were paid, and so on."

Basically, the task amounted to taking the workings of CPRIT and translating them into rules.

Kripke invited Kolodner to become head of the Scientific Review Council.

"He was quite close to Al and spoke with him on a regular basis, so he stayed and because he history with the process, I asked him to be the head of the Scientific Review Council," Kripke said. "He did discuss that with Al before he accepted."

Sanjiv "Sam" Gambhir, another member of Gilman's council, also returned, bringing back his reviewers. Gambhir is the chair of the Department of Radiology at the Stanford University School of Medicine, director of the Canary Center at Stanford for Cancer Early Detection, director of the Molecular Imaging Program at Stanford, and a professor in Stanford's Department of Radiology, Bio-X Program and the Department of Bioengineering.

Kripke couldn't have reconstituted the peer review committees without Gilman's support.

When she invited Tom Curran, to serve as chair of a basic research panel, he checked in with Gilman.

"Al spoke at great length on the phone about how wonderful CPRIT was and strongly encouraged me to accept," said Curran, chief scientific officer and executive director of the Children's Mercy Children's Research Institute. "I am very glad that I did as it has been one of my most enjoyable reviewing experiences (not at all like NIH Study Sections). The committees continue to function according to Al's design with the primary focus on scientific excellence and impact on cancer. I have not encountered the slightest hint of politics in the decision-making process. CPRIT has helped recruit numerous spectacular scientists to Texas and it continues to fund top quality science. I just wish more states would emulate Texas (which is not something I would normally say)."

Kripke added a review panel on prevention, so that grants in prevention might have an opportunity to get reviewed by people who knew something about prevention.

However, Kripke didn't think that setting up a threshold of spending on prevention was a good idea. Gilman's vision of funding the best science—whether prevention or any other area—made sense to her.

Next, Kripke worked on establishing strategic priorities:

"We did it within the peer review system," she said. "We put out requests for applications in specific areas: childhood cancers, prevention, early detection, computational biology—but we didn't set aside funds specifically to fund those. They had to compete successfully with the other applications. It's a matter of trying to emphasize certain areas without disturbing the prioritization based on peer review.

"In truth, there was very little of substance that was changed from what Al did," Kripke said. "He pretty much got it right the first time around."

Capitol Hill

House Proposes $1.25 Billion Budget Increase for NIH in 2017

(Continued from page 1)

The measure boosts the NIH budget to $33.3 billion and now moves to consideration by the full House appropriations committee.

The Senate Committee on Appropriations June 9 marked up a spending bill, which would provide a $2 billion funding increase for NIH and $216 million increase for NCI in FY 2017 (The Cancer Letter, June 10).

The White House proposed a $33.1 billion appropriation for NIH in 2017. An $825 million infusion included $680 million for Biden's moonshot and $100 million for the Precision Medicine Initiative, and $45 million in new money for the BRAIN Initiative.

For the 2016 fiscal year, NIH received a $2 billion raise for a total of $31.3 billion, and NCI's budget was increased from $4.95 billion to $5.2 billion (The Cancer Letter, Feb. 12).

"This bill achieves its goal of reducing discretionary spending by more than half a billion dollars, all the while prioritizing where funding is needed the most," Rep. Tom Cole (R-Okla.), chairman of the Labor-HHS Subcommittee, said in a statement. "Several important programs through the Centers for Disease Control and the National Institutes of Health that benefit many Americans receive a substantial increase in funding, often well beyond the amount [President Barack Obama] requested in his budget."

For NIH, the House subcommittee bill includes:

• $300 million for the Precision Medicine Initiative, an increase of $100 million;

• $1.26 billion for the Alzheimer's disease research initiative, a $350 million increase;

• $195 million, for the BRAIN Initiative, a $45 million increase;

• $12.6 million for the Gabriella Miller "Kids First" initiative, for pediatric cancer research;

• $165 million for the National Children's Study;

• $511.5 million for Clinical and Translational Science Awards, and

• $333.3 million for Institutional Development Awards (IDeA) programs.

The legislation includes a total of $7.8 billion for the Centers for Diseases Control and Prevention—$605 million above the enacted FY 2016 level. This includes $6.9 billion in appropriated funds, as well as $908 million in transfers from the Prevention and Public Health Fund. The bill also provides $390 million in research funds for the Zika virus.

The measure provides $3 billion for Centers for Medicare and Medicaid Services program management and operations, which is $576 million below the FY 2016 enacted level, and $1 billion below Obama's budget request.

The bill continues the longstanding prohibition against using federal funds for gun control research, and contains several provisions to stop the implementation of the Affordable Care Act—including rescinding prior-year mandatory funds and prohibiting the use of any new discretionary funding to implement the ACA.

The boost in funding will help continue advances in big data, precision medicine, and clinical trials and translational research, said Daniel Hayes, president of the American Society of Clinical Oncology.

"ASCO is encouraged by comments from Rep. Cole who referred to the increase in NIH funding 'as a floor, not as a ceiling, for biomedical-research funding,'" Hayes said in a statement. "As Congress works through its appropriations process, we'll continue to advocate for funding levels more closely aligned to the $2 billion included in the Senate version of the bill.

"Federal funding for medical research has remained flat for most of the past decade, and while the boost in funds in 2016 was a critical step forward, more is needed to reverse the trend and regain ground in the fight against cancer."

The medical research advocacy community needs to "work extremely hard" to ensure the FY 2017 appropriations reflect the support for NIH in both chambers of Congress, said Jon Retzlaff, managing director of the Office of Science Policy and Government Affairs at the American Association for Cancer Research.

"Of course, while it's very clear that Congress will need to pass a continuing resolution in September to fund the federal government at least through the November elections, we are increasingly optimistic that when the final decisions on the FY 2017 appropriations process are made, NIH will receive its second major annual funding boost in a row after twelve years of stagnant funding," Retzlaff said to The Cancer Letter.

The proposed increase for the NIH is impressive, said AACR President Nancy Davidson.

"Chairman Cole is one of the key reasons that the NIH received its biggest boost in funding in 12 years in last year's appropriations bill, and we are deeply grateful to him for his ongoing commitment to providing robust, sustained, and predictable funding

increases for medical research," Davidson, director of the University of Pittsburgh Cancer Institute, said in a statement. "We look forward to working with Chairman Cole, his staff, and his colleagues throughout 2016 to help secure an increase for FY 2017 that builds upon the positive foundation that began in FY 2016."

Budget cuts are "ill advised" at a time when health care delivery research is critical to improving health care and patient safety, said Mary Woolley, president and CEO of Research!America.

"We are heartened that for the first time in four years funding for the Agency for Healthcare Research and Quality was not eliminated," Woolley said in a statement. "These cuts are moving our nation in the wrong direction. Research supported by AHRQ is addressing waste and inefficiencies in the health care system, medical errors and rising health care costs. Increased funding for the CDC to combat Zika virus and find solutions to prescription drug abuse is a positive development.

"The sooner resources are deployed to address these health threats, the better. But we are concerned that the spending bill continues to prohibit gun prevention research supported by the CDC."

NIH needs steady budget increases to keep up with biomedical inflation and public health and research needs, said David Pugach, president of United for Medical Research.

"It is essential that Congress continue the momentum begun last year to put the NIH back on a growth path after more than a decade of flat funding," Pugach said in a statement. "NIH research is an engine for innovation, a pathway to hope for patients and an economic catalyst, supporting $60 billion annually in economic activity.

"UMR will work with the House and the Senate to ensure maximum funding for NIH for FY17."

In Brief

Socinski Named Medical Director At Florida Hospital Cancer Institute

MARK SOCINSKI was named executive medical director of the **Florida Hospital Cancer Institute**. He will oversee the coordination of clinical cancer services for the Florida Hospital network. He will also be a member of the institute's Thoracic Oncology Program.

Socinski comes from the University of Pittsburgh Medical Center, where he served as professor of medicine and cardiovascular surgery; director of the Lung Cancer Section for the Division of Hematology and Oncology; co-director of the Lung Cancer Center of Excellence; and co-director of the Lung Cancer Program. Prior to joining UPMC, Socinski served as professor of medicine at the University of North Carolina. His research focuses on clinical trials in thoracic cancers.

THE AMERICAN SOCIETY FOR RADIATION ONCOLOGY named 10 members as ASTRO Fellows, in the 10th year that the designation has been awarded. The 2016 class will be recognized at an awards ceremony during ASTRO's annual meeting Sept. 25-28, in Boston.

Fellows have been an active or emeritus member of ASTRO for at least 15 years, giving the equivalent of 10 years of service to ASTRO through committee service and similar activities. With the addition of the 2016 class, a total of 269 ASTRO members have received the FASTRO designation since 2006.

"The individuals in this class of ASTRO Fellows demonstrate both talent and commitment across multiple aspects of radiation oncology, particularly in clinical care, research, service and education," said ASTRO Chair Bruce Minsky. "As is the case for our other fellows, the clinicians and researchers in the 2016 cohort show a clear dedication to improving patients' lives and advancing our field, especially through service to ASTRO and its initiatives."

The new ASTRO Fellows are:

• **H. Joseph Barthold**, Beth Israel Deaconess Hospital-Plymouth

• **Jennifer Bellon**, Dana-Farber Cancer Institute and Harvard Medical School

• **Laura Dawson**, Princess Margaret Cancer Centre, University of Toronto

• **Theodore DeWeese**, Johns Hopkins University

• **Shalom Kalnicki**, Albert Einstein College of Medicine Montefiore Medical Center

• **Nancy Mendenhall**, University of Florida, Gainesville

• **William Mendenhall**, University of Florida, Gainesville

• **Todd Pawlicki**, University of California San Diego

• **Timothy Solberg**, University of California San Francisco

• **John Suh**, Cleveland Clinic

THE UNIVERSITY OF MICHIGAN Comprehensive Cancer Center and **Trovagene Inc**. initiated a collaborative research program focused on the Trovera KRAS ctDNA liquid biopsy test in pancreatic cancer.

"KRAS gene mutations occur in over 90 percent of pancreatic carcinomas. There is an urgent need for targeted therapies and a precision diagnostic test to identify who would benefit from these therapies," said Diane Simeone, director of the Pancreatic Cancer Center at the University of Michigan Comprehensive Cancer Center. "As part of this research collaboration, Trovagene's ctDNA urine and blood tests will be utilized as noninvasive diagnostic tools to enable early detection and rapid monitoring of patient response to therapy. The Trovagene assay will allow us to quickly test multiple therapies to determine which one will be most effective in treating an individual patient's tumor."

Drugs and Targets

European Commission Approves Kyprolis for Multiple Myeloma

The European Commission approved a variation to the marketing authorization for Kyprolis (carfilzomib) to include use in combination with dexamethasone alone for adult patients with multiple myeloma who have received at least one prior therapy. The extended indication marks the second approval for Amgen's Kyprolis by the EC in less than a year.

"In the phase III head-to-head trial, Kyprolis in combination with dexamethasone doubled the time patients lived without their cancer progressing, as well as the rates of complete response compared to bortezomib and dexamethasone," said Sean Harper, executive vice president of Research and Development at Amgen.

The EC approved the extended indication for Kyprolis based on data from the ENDEAVOR trial: patients with multiple myeloma treated with Kyprolis plus dexamethasone achieved superior progression-free survival of 18.7 months compared to 9.4 months in those receiving bortezomib plus dexamethasone (HR=0.53; 95% CI: 0.44, 0.65; p <0.0001). Kyprolis also demonstrated improvement in secondary endpoints, including rates of complete response or better, which were double in patients treated with Kyprolis, at 12.5 vs. 6.2 percent (p <0.0001).

The most common adverse reactions that occurred in greater than 20 percent of patients treated with Kyprolis were anemia, fatigue, diarrhea, thrombocytopenia, nausea, pyrexia, dyspnea, respiratory tract infection, cough and peripheral edema.

Kyprolis was first approved by the EC in November 2015 for use in combination with lenalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy based on results of the ASPIRE study. Today's approval by the EC follows the FDA's approval of a supplemental New Drug Application based on the ENDEAVOR results in January.

FDA granted seribantumab, also known as MM-121, a Fast Track designation for development in patients with heregulin-positive, locally advanced or metastatic non-small cell lung cancer, whose disease has progressed following immunotherapy.

Merrimack Pharmaceuticals, the drug's sponsor, is conducting the SHERLOC trial, a global clinical study of seribantumab in combination with docetaxel or pemetrexed in heregulin-positive patients with NSCLC that is designed to support a Biologics License Application to the FDA. Seribantumab is Merrimack's wholly owned, fully human monoclonal antibody that targets ErbB3.

"Heregulin-positive cancer cells are characterized by their ability to escape the effects of a broad range of cancer therapies and potentially contribute to accelerated disease progression. The SHERLOC trial is designed to advance the development of a much-needed treatment option for patients with heregulin-positive NSCLC after they progress on immunotherapies. This is important because we find that more than 50% of patients with NSCLC are heregulin-positive," said Akos Czibere, vice president of clinical development at Merrimack.

SHERLOC is an open-label, multi-center, phase II study. Merrimack expects to enroll approximately

280 heregulin-positive patients who will be randomized to receive seribantumab in combination with either docetaxel or pemetrexed versus docetaxel or pemetrexed alone. Patients will be screened for heregulin status using a fully validated RNA-ISH assay. Eligible patients for the study must have failed prior treatment with no more than three lines of therapy including prior anti-PD-1 or anti-PD-L1 immunotherapy. The study's primary endpoint is overall survival with secondary endpoints including progression free survival, objective response rate, and safety and quality of life measures.

FDA granted 510(k) clearance to the HARMONIC HD 1000i ultrasonic surgical device, developed by Ethicon, for use in open and laparoscopic procedures.

The shape of the device mimics a mechanical dissector, reducing the need to use a separate dedicated dissecting instrument, according to Ethicon. HARMONIC HD 1000i is designed for use in numerous procedures and specialties including hepato-pancreato-biliary, thoracic, colorectal, and gynecologic oncology.