THE CANCER LETTER

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Sequestration

Deep Budget Cuts Poised to Kick in March 1; Hill Insiders See Little Hope for Deal

By Paul Goldberg

As President Barack Obama delivered the State of the Union address Feb. 12, federal agencies, including NIH, braced for draconian budget cuts scheduled to take effect March 1.

The once unthinkable across-the-board cuts, called "sequestration," will affect the entire federal government—and medical research, Medicare, FDA and the Department of Defense will not get special exemptions.

"The greatest nation on Earth cannot keep conducting its business by drifting from one manufactured crisis to the next," Obama said in the speech.

"Let's agree, right here, right now, to keep the people's government open, pay our bills on time, and always uphold the full faith and credit of the United States of America," Obama said. "The American people have worked too hard, for too long, rebuilding from one crisis to see their elected officials cause another."

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Conversation with The Cancer Letter

Swain: "Shattering Impact on Cancer Enterprise"

The Cancer Letter asked Sandra Swain, president of the American Society of Clinical Oncology, to discuss the impact the sequestration will have on the practice of oncology and cancer research.

Swain, medical director of the Washington Cancer Institute of the Washington Hospital Center and professor of medicine at Georgetown University, spoke with Paul Goldberg, editor of The Cancer Letter.

PG: *What's your thinking about what sequestration is going to do?*

SS: I think it's very clear that sequestration will have a shattering impact on the entire cancer enterprise in the United States.

The cuts would be really far-reaching and widely felt, and—ultimately—it's the cancer patient, fighting for his or her life, who's going to feel the most profound impact from reductions in clinical cancer research, slowdowns in the

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In Brief

Weiner Elected President-Elect of AACI

GEORGE WEINER was elected vice president and president-elect of the **Association of American Cancer Institutes**.

Weiner is director of the Holden Comprehensive Cancer Center at the University of Iowa. He is also the C.E. Block Chair of Cancer Research,

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Sequestration Would Cost NIH $1.58 Billion; NCI, $265 Million

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In the Republican response to the address, Rep. Marco Rubio (R-Fla.) didn't mention either research or NIH. However, other Republican leaders have been predicting that the sequestration cuts would, in fact, take effect.

Congress designed sequestration in 2011, gambling that the prospect of swallowing so bitter a pill—a trillion-dollar across-the-board cut over a decade—would force the right and the left to agree to a deficit reduction deal.

However, Capitol Hill insiders said to The Cancer Letter that the cuts are now likely to take effect.

"It's extremely difficult to be optimistic today," said Jon Retzlaff, managing director of science policy and government affairs at the American Association for Cancer Research. "There doesn't seem to be any movement, any willingness to compromise. It's absolutely crazy, and it's going to be devastating."

The cuts will hurt the entire field of oncology, said Sandra Swain, president of the American Society of Clinical Oncology.

"The cuts would be really far-reaching and widely felt, and—really—ultimately it's the cancer patient who is fighting for his or her life that's going to feel the impact from these reductions in cancer research, in the drug review process," Swain said to The Cancer Letter. A Q&A with Swain appears on page 1.

The fallback best-case scenario now looks like this: the sequestration cuts kick in March 1, and Congress finds a way undo the damage within the following weeks.

However, Capitol Hill insiders aren't optimistic about this, either.

"You need to have the ability and desire to compromise, and so far we have seen nothing that gives any indication that there is that willingness," Retzlaff said to The Cancer Letter.

Currently, NIH is operating on a continuing resolution, which expires on March 27.

Sequestration would cut the NIH budget by about 5.1 percent, current estimates show. (Recently, NCI Director Harold Varmus said the cuts could be as high as 6.4 percent.) At the 5.1 percent level, sequestration would amount to a $1.58 billion reduction in funds for NIH and about $265 million for NCI during the current fiscal year, which ends Sept. 30.

Cuts Compressed to Second Half of Fiscal Year

"With a 5.1 percent cut to NIH's budget in FY 2013, you could see a 25-percent reduction, as compared to FY 2012, in the number of new investigator-initiated grants NCI and NIH are able to fund for the remainder of this year," Retzlaff said. "We are already at a point where it's been 10 years of, in effect, declining budgets and opportunities to fund life-saving research. Specifically, NIH's ability to fund research has declined by 20 percent since 2003, when taking inflation into account."

Officials at NCI, NIH and FDA say they have drawn up plans for managing the cuts, but these plans aren't being sent to rank-and-file staff or being made public. Similarly, cancer centers and other institutions, which depend on NIH funding, are preparing for impact.

A conversation with Donald Trump, president and CEO of Roswell Park Cancer Institute, will appear in next week's issue of The Cancer Letter.

"There are many scenarios under discussion, both at the NCI and the NIH, on how we would cope with these difficulties," Varmus said to the National Cancer Advisory Board at its meeting Feb. 8.

A video recording of Varmus's remarks to NCAB is posted at The Cancer Letter website, and an excerpted text appears in this article.

"Our goal is to maintain a reasonable number of new grants," Varmus said to NCAB. "That would be the thing that would go most rapidly if we simply took a hit in the money that is made available each year by expiration of grants.

"We are trying to envision ways in which sharp reductions in our budget, those that would result

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from enactment of the sequester, would be taken. It's premature to release any information about that, because we haven't reached a firm conclusion.

"I would point out that, as far as I can tell, the sequester would not just be for one year, it would be in our base, and that would be something we would need to think about very clearly.

"We already have a community that's under stress. Reduction that could be as high as 6.4 percent could have a really detrimental effect on what we are trying to do—at a time when science is more expensive, there are more well trained people trying to do this great work, and the costs of doing the research have gone up well in excess of not just regular inflation, but the biomedical research and development price index.

"So how much is being done to try to prevent the sequestration? You've been reading statements from many of our leaders who would like it not to happen. There have been a number of strong statements, and briefings by many of our advocates. There is some political action plan, some of it not until April, when the show will be over, at least for this year.

"I would like to think that more of our advocates and scientists—and those who are affected by a sharp reduction of our budget—would be calling their members of Congress. In some ways, that's the most effective thing that can be done.

But right now, we're simply waiting to hear what is going to happen.

"We are also, of course, waiting for the pass back of the FY 2014 budget," Varmus said. "Usually by now we are further along in that planning process."

Sen. Ben Cardin: Long-Term Deal Unlikely

"We are getting to March 1," Sen. Ben Cardin (D-Md.) said at a town hall meeting at NIH Feb. 8. "These across-the-board cuts were never intended to take effect, but we are at the Day of Judgment, and they will take effect—to out national defense budget and our domestic budget."

Cuts to NIH alone will cost about 100,000 jobs, Cardin estimated.

Ideally, Congress should come to a deficit-reduction deal that would span a decade, he said. "What is the prognosis for getting this done by March 1?" Cardin said. "It's not likely."

The possibility of short-term relief is still viable, he said, but short-term solutions are harmful to research, Cardin said.

"Predictability is critically important for work you do here, to know that the funding will be here not for two months, but for a long time," he said.

Cardin's talk is available on C-Span.

The American Cancer Society Cancer Action Network earlier this month published a report that focused on impact of federally-funded cancer research.

"Sequestration could cost us a decade of progress in medical research leaving the next breakthroughs in the fight to defeat cancer to languish in the labs," said John Seffrin, CEO of the American Cancer Society and ACS CAN. "Lawmakers should act to avoid these indiscriminate cuts and make the fight to defeat a disease that still kills 1,500 people a day in this country a national priority."

United for Medical Research, an umbrella group of research organizations, similarly published a report on impact of sequestration.

The report found:

• At current funding levels, NIH supports roughly 402,000 jobs and $57.8 billion in economic output.

• A 5.1 percent sequester is estimated to cut the total number of jobs supported by NIH extramural spending by more than 20,500 and reduce new economic activity by $3 billion.

The report also states that the real impact of sequestration on NIH will be amplified by the fact that the cuts will take effect in the middle of the fiscal year and will need to be absorbed over a truncated budget calendar.

Obama's State of the Union address specifically mentioned medical research:

"If we want to make the best products, we also have to invest in the best ideas. Every dollar we invested to map the human genome returned $140 to our economy. Today, our scientists are mapping the human brain to unlock the answers to Alzheimer's; developing drugs to regenerate damaged organs; devising new material to make batteries ten times more powerful. Now is not the time to gut these job-creating investments in science and innovation.

"Now is the time to reach a level of research and development not seen since the height of the space race."

At the Department of Defense, sequestration would cut over $46 billion in cuts over seven months.

Obama didn't suggest any specific way to avoid sequestration.

"These sudden, harsh, arbitrary cuts would jeopardize our military readiness," he said. "They'd devastate priorities like education, energy, and medical research. They would certainly slow our recovery, and cost us hundreds of thousands of jobs. That's why Democrats, Republicans, business leaders, and

economists have already said that these cuts, known here in Washington as 'the sequester,' are a really bad idea.

"Now, some in this Congress have proposed preventing only the defense cuts by making even bigger cuts to things like education and job training; Medicare and Social Security benefits.

"That idea is even worse."

Varmus's Remarks to NCAB

In his remarks to NCAB, Varmus focused primarily on financial matters.

Excerpted text of his remarks follows:

One thing is certain: we avoided the New Year sequester. That's the good news.

We also got through Congress and signed a bill for disaster relief for Hurricane Sandy—which is, of course, an NIH-relevant matter, because many of our grantees were affected institutions—especially NYU, but others as well—and we hope that some of the money that was appropriated by that disaster relief bill will be used for repairs that affect NIH projects.

However, we are much less certain on a continuing resolution that lasts until March 27 of this year at the FY 2012 level.

We are still awaiting news—either waiting for an appropriations bill, or more importantly, the March 1 sequester. That could produce a cut in the NIH budget overall of about 6.4 percent.

I really don't know about what's going to happen more than you do if you're loyal readers of the New York Times, the Financial Times, The Wall Street Journal, The Washington Post, etc.—or thousands of blogs on the topic.

There are many scenarios under discussion, both at the NCI and the NIH, on how we would cope with these difficulties. Our goal is to maintain a reasonable number of new grants. That would be the thing that would go most rapidly if we simply took a hit in the money that is made available each year by expiration of grants.

We are trying to envision ways in which sharp reductions in our budget, those that would result from enactment of the sequester, would be taken. It's premature to release any information about that, because we haven't reached a firm conclusion.

I would point out that, as far as I can tell, the sequester would not just be for one year, it would be in our base, and that would be something we would need to think about very clearly.

We already have a community that's under stress. Reduction that could be as high as 6.4 percent could have a really detrimental effect on what we are trying to do—at a time when science is more expensive, there are more well trained people trying to do this great work, and the costs of doing the research have gone up well in excess of not just regular inflation, but the biomedical research and development price index.

So how much is being done to try to prevent the sequestration? You've been reading statements from many of our leaders who would like it not to happen.

"Our goal is to maintain a reasonable number of new grants."

There have been a number of strong statements, and briefings by many of our advocates. There is some political action plan, some of it not until April, when the show will be over, at least for this year.

I would like to think that more of our advocates and scientists—and those who are affected by a sharp reduction of our budget—would be calling their members of Congress. In some ways, that's the most effective thing that can be done.

But right now, we are simply waiting to hear what is going to happen. We are also, of course, waiting for the pass back of the FY 2014 budget. Usually, by now we are further along in that planning process.

No hearings have been scheduled for appropriations for FY14, and I think that's understandable, given the dramatic uncertainty of where we are going to be in FY13.

Let me say a couple of things about the new Congress:

We have a bit of additional news about our committees. I would just mention a couple of things about things that have been assembled by deliberations by both parties. On the Senate side, as you know, Sen. Daniel Inouye (D-Hawaii), chairman of the full appropriations committee, died last year and he will be replaced by Sen. Barbara Mikulski (D), a long-term friend of the NIH and a Maryland senator.

That's good news.

Our appropriation subcommittee for the NIH has not yet assigned members. We assume that Sen. Tom Harkin (D-Iowa) will remain chairman, but, as many of you know, Sen. Harkin has declared that he will not be seeking reelection in 2014.

That will be a moment of concern because Sen. Harkin has been a very stalwart supporter of the NIH and the NCI in particular. His loss from the Senate will be a significant one for us.

Sen. Harkin remains until he leaves the Senate as the chair of Health, Education, Labor and Pensions—the so-called HELP committee, which is at least our authorizing committee.

As for appropriations, the ranking member is Sen. Lamar Alexander (R-Tenn.), a friend of the NIH. A new member of the HELP committee that you may want to take note of is Sen. Elizabeth Warren (D) from Massachusetts, a state that's quite important to the NIH.

On the House side, the committee chair of Appropriations will be Rep. Hal Rodgers (R-Ky.). The ranking member is Rep. Nita Lowey (D-N.Y.), who is a very loyal friend of the NIH.

We have a replacement as chair of our appropriations subcommittee, the so-called Labor-H—you'll recall that Rep. Dennis Rehberg (R) from Montana ran for the Senate, lost his House seat as a result and then was defeated in his bid a Senate seat. The ranking member of that committee remains Rep. Rosa DeLauro (D-Conn.).

"We are making too few grants, the success rate is too low, and the grants themselves, in my view, are too small to carry out research with the kind of support that NIH should be providing."

The other committee worth mentioning, the Energy and Commerce Committee, which also has a number of interactions with us, will continued to be chaired by Rep. Fred Upton (R-Mich.), a Republican very friendly to the NIH. And Rep. Henry Waxman (D-Calif.) is the ranking member, another long-term friend.

Of course, we are waiting to see the list of members of the appropriations subcommittee in the Senate, because there are a number of Democratic vacancies that need to be filled.

Under the current circumstances of funding, we are continuing to be cautious in the way we move forward. We are making new grants. And we are paying competitive renewals at less than the full value, expecting to make adjustments as is appropriate once we have news of sequester and our appropriation for this year.

At the last meeting in November, I presented some of the results of our funding of grants in 2012.

That information is available on the web, and I would urge any of you who hear from your colleagues about success rates, which are frequently reported as being low, or about the process in which we awarding grants to look at those graphs—they reveal a story that suggests to me that, under rather unfortunate circumstances, we're conducting this process of grant making taking into consideration the review by peers and the priority scores, but also using programmatic evaluations to make final decisions.

I think it's been a pretty fair process—but I hasten to point out that the fact that the process is fair does not negate the fact that we are making too few grants, the success rate is too low, and the grants themselves, in my view, are too small to carry out research with the kind of support that NIH should be providing.

I don't think the picture is pretty.

But I think we are doing a reasonably good job under these circumstances.

Let me mention a few other things that are related to Congress.

Last time, we discussed the history of the Recalcitrant Cancer Act that was ultimately passed by both houses of Congress as an amendment to the armed services bill then signed by the President.

That bill proscribes that we carry out two studies of recalcitrant cancers, according to their definition. And to my mind, only two cancers fit that definition:

Pancreatic ductal adenocarcinoma, in which we had a planning workshop way before the bill was signed, anyway—and you heard last time from Jim Abbruzzese [chair of the Department of Gastrointestinal Medical Oncology and Digestive Diseases at MD Anderson Cancer Center], the chair of the so-called Clinical Translational Advisory Committee, that the written version of that report that he presented here is now under final review and will soon be sent to the [HHS] Secretary and the Congress.

It recommends more intense activity in certain areas that you heard discussed last time. Some progress has already been made toward those goals.

The second cancer that meets that definition is small-cell lung cancer. A working group is being formed by John Minna [the Max L. Thomas Distinguished Chair in Molecular Pulmonary Oncology, Sarah M. and Charles E. Seay Distinguished Chair in Cancer Research] of UT Southwestern, and we will soon have another workshop that I hope was as successful as the workshop that we had on pancreatic ductal adenocarcinoma.

Let me mention a few other initiatives that have been going on for the past month or so since we last met.

You'll have recalled that we're spending a lot of time thinking about the activities that go on at Frederick,

Md., especially the contract program which is now officially designated the Frederick National Laboratory for Cancer Research.

An advisory committee, headed by Zach Hall [former executive vice chancellor for research at UCSF and former president of the California Institute for Regenerative Medicine], has been meeting regularly

"One of the things that will be on the table is a discussion about how we fund the centers."

to give us advice. And at the suggestion of Joe Gray, who used to be there we met this time at the Lawrence Berkeley National Lab to see how they do their business through contract awarded by the Department of Energy to the University of California.

I believe we were there Monday, and some of my colleagues around the table were there. We learned a lot of interesting things—it's a remarkable institution, profiting tremendously from a very strong relationship with the University of California, especially with the University of California, Berkeley.

There is a cohort of outstanding scientists that are taking responsibility for building new programs, completing for money that's being made available within the contract program, with a reasonable turnover of projects.

They receive about 10,000 visitors a year. Other scientists who have come to work there temporarily are now thinking about an additional campus in Richmond that will help unite science in the Bay Area.

We got a lot of useful tips for how to make a national lab run through a contract program successful. And we will be following up on some of those ideas that emerge. No two national labs are the same.

The situation in Frederick is not quite the same thing being a few yards up the hill from University of California, Berkeley, but there are things that could be done to include interactions between universities and the Frederick National Lab, and we're thinking about some of those.

Cheek-by-jowl with that meeting was a meeting we held in San Francisco the next day.

To discuss one of the new so-called megaprojects that we hope to initiate at the Frederick National Lab as an emblematic, aspirational activity—that is to take on the question of how we work more effectively to kill cancer cells that are driven by mutant RAS genes.

And this workshop I co-chaired with Frank McCormick [director, UCSF Helen Diller Family Comprehensive Cancer Center, associate dean, UCSF School of Medicine, and David A. Wood Distinguished Professorship of Tumor Biology and Cancer Research] who is deeply involved in this effort.

And over the course of about eight hours on Monday night and Tuesday, we heard from folks who are taking a variety of approaches based on cell signaling and chemistry, protein structure, immunology, and screens for new targets for therapeutics—a lot of enthusiasm among the 45 or so investigators who were on hand a lot of new ideas put on the table.

We are envisioning a program that will operate as a hub at the Frederick National Lab, with lots of spokes radiating out to subcontractors at universities and institutions around the country and around the world. Many of these specific proposals of what to do at the hub facility are much less clear than what we should be doing in those radiated spokes.

SAIC, the contractor at Frederick, is actively working under the direction of David Heimbrook [CEO of SAIC-Frederick Inc., a subsidiary of SAIC] to build a pivot program that will a move a lot of resources money people facilities to undertake this program. You'll hear much more about this in due course, but we're very optimistic about getting this first project underway.

Last time I talked briefly about a workshop that we had held on data replication, a concern that is generally shared throughout the NIH—that is, many of our published findings supported by NIH money are not actually replicable science, and we had a discussion about that last time.

Can I just point out that we had a discussion at the institute directors meeting not long ago and [NIH

"We are envisioning a program that will operate as a hub at the Frederick National Lab, with lots of spokes radiating out to subcontractors at universities and institutions around the country and around the world."

Director] Francis Collins asked that we form a group of institute directors, chaired by [Director of the National Institute of Neurological Disorders and Stroke] Story Landis, who has taken an active role in this, as have we.

I'm a member of that committee and we'll be meeting next week to talk about some specific actions to take—ranging from checklists on grants, checklists in journals, better guidelines for using statisticians more

appropriately in various kinds of preclinical work, and a number of other things we discussed here last time.

There is much discussion going on about computing—how we are going to be storing and using the genetic information and related clinical information that's coming from studies of cancers.

There are discussions being held in the committee headed by Dan Mathys, who is advising [NCI Center for Biomedical Informatics and Information Technology] and was helpful in bringing to a close the caBIG program—about whether the NCI should be undertaking some kind of trial program in cloud computing.

A number of institutions interested in building a worldwide alliance to do computing in this vein met in New York in January.

I was there, Francis Collins was there, as were a number of other folks, and that again is a work in progress about which I hope to report to this group sometime in the next couple of months, perhaps when we have our joint meeting when we meet with the BSA.

Next week, we have a meeting with the NCI-designated cancer centers. One of the things that will be on the table is a discussion about how we fund the centers. Clearly, under these financial conditions it's not possible for us to grow the cancer center program financially.

I would still like to see some growth in the numbers of centers, and I was particularly pleased last year to see the addition of University of Kansas Cancer Center to that group, bringing it to 67 centers.

A small group of leaders got together to discuss some new guidelines we put in place to keep the growth of those budgets under control, so that the expectation would no longer be if you did well and got a satisfactory review, you'd get a 10 or 20 percent increase—that's just not palatable at this time; it's not possible at this time.

So we are trying to develop some clearer criteria for funding and I've seen a preliminary report of the deliberations, and those will be further discussed next Wednesday at the cancer center director's meeting.

I would point out to those of you who are following the judicial proceeding on the so-called Myriad [Genetics] case, the determination on whether genes and gene mutations can be patented, that case will almost certainly be heard by the Supreme Court in mid-April.

That's a case of immense concern to the NCI. I'll just draw your attention to that, we'll be reporting back on that at the next meeting.

Francis and I and some others here at the NIH have been called upon by the Department of Justice and the ACLU to help with the formulation of briefs. [Oral arguments in the case are set for April 15.]

Conversation with The Cancer Letter

Swain: Sequestration Presents "Triple Threat" to Cancer Patients

(Continued from page 1)

drug review and approval process, and the oncologists being squeezed by cuts to reimbursement.

PG: *Have you looked at the numbers at each of the stages that you have just outlined?*

SS: New research projects will be dramatically affected by a 5.1 percent cut to NIH under sequestration.

PG: *I've seen the number 6.4 percent as well.*

SS: Well, 5.1 percent is what they are saying today on the Hill. ASCO feels that this is a triple threat to individuals with cancer, because of three different issues: Biomedical research, based on the numbers, we have will have an estimated $1.5 billion budget reduction. Cancer care providers will have a two-percent reduction in reimbursement from Medicare, so that would decrease access to care, and that's an $11 billion cut, and these numbers were checked again today, so they are current. And then there is already an underfunded drug review process, as you know, and FDA would have to absorb a $200 million to $245 million cut.

PG: *That's pretty horrific.*

SS: It is. And on the second point, you probably know that 60 percent of cancers occur in Medicare enrollees. So that's a huge problem for those patients.

PG: *As you take the temperature on the Hill, what does it look like?*

SS: I think it doesn't look good. It looks like they are serious about this, and it's really coming down to the wire. I am not sure which way it's going to go, but ASCO is working every day to make sure members of Congress fully understand the impact sequestration will have on people with cancer.

I think that the troubling part, not only for patient care, but for research is just really incredible. NIH not only funds critical clinical trials, which helps a lot of young investigators get started in their research careers, but it also supports jobs. NIH supported 432,000 jobs in 2011. So this 5.1 percent cut will decrease that.

It will also decrease the number of grants that can be funded. Before the fiscal cliff legislation, estimates reported that the number of NIH grants would be cut by at least 700 in FY2013. The actual number could be even higher.

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PG: *Have you looked at the NCI and NIH success rates?*

SS: The payline for 2012 was 7 percent, which is already very low.

PG: *They haven't released any projections at this point.*

SS: Right. But we know that the NIH budget, adjusted for inflation, is 20 percent lower than it was a decade ago. So it's already lower, and with the 5-percent sequestration cut, it will have a devastating impact on biomedical research—which I think is egregious.

All the tremendous cancer advances that have been made—the basic research that has been funded through federal grants, the drugs that have been approved—all those things are going to grind to a halt.

PG: *What happens if this is reversed, which it might be within a few weeks? Would the damage go away?*

SS: The damage would already be done and felt for the remainder of the year.

[ASCO is tracking sequestration at http://ascoaction.asco.org.]

Guest Editorial

Interlocking Tragedies: Lance Armstrong and CPRIT

By Leonard Zwelling

On Jan. 15, the Houston Chronicle reported that the initial Texas biennial budget reduced the allocation for CPRIT, the taxpayer-approved and funded Cancer Prevention and Research Institute of Texas. This two-year budget reduction was from $600 million to $10 million. Should this preliminary allocation not be restored to its prior higher level, CPRIT will surely be over, and a superb opportunity to create a center for cancer research and development in Texas will have been lost. This would be tragic.

The CPRIT trouble is predicated on the awarding of two large grants that together constitute a very small percentage of the total CPRIT funding distributed to date. Unfortunately, the rules established for awarding the two commercialization grants were ignored (investigations are still on-going). Then many people resigned or lost jobs. Worthy projects that CPRIT initiated may never be finished. This all occurred because the true goals for CPRIT were all too vague, thus left in the eyes of many different beholders. CPRIT's oversight was the responsibility of the very people who might benefit from the awards and who established a parallel funding vehicle (the CPRIT Foundation) to augment salaries within a government agency. Scientifically, CPRIT was great. Administratively, it was a mess.

This same week we heard about another Texas tragedy, one that is related to CPRIT. Lance Armstrong admitted to the long-standing allegations that he "doped" in winning his seven Tours de France. The yellow jersey and matching rubber wrist band that not only branded him an American hero but allowed Livestrong, his cancer fighting foundation, to grow and prosper represented a lie. Interestingly, CPRIT's birth would not have occurred without the backing of Armstrong. I was privileged to testify in support of CPRIT right next to him in 2007, and I had no illusions about whose voice was heard most clearly that day from among the many of us who spoke to the Legislature. Lance carried the day.

This is a true Texas two-step tragedy, for both ideas—CPRIT and Livestrong—were superb in concept and, in the end, poorly executed. The similarity is that, in both cases, those overseeing the integrity of a critical process and those who might benefit from the process and its attendant wealth were the same people.

Cycling was governed by people whose power was growing with every Armstrong victory. Team Armstrong strong-armed the entire higher echelon of the cycling community into becoming a group of athletes more dependent on the latest breakthroughs in pharmacology and avoiding the detection of the anti-doping squad than in any progress in training techniques.

To this day, CPRIT is governed by an oversight board of political appointees. Some of these people and some of the potential grant recipient organizations have contributed to the CPRIT Foundation that enhanced the salaries of the professionals hired to run CPRIT in a fair and unbiased fashion. Much as was the case in the cycling world, incestuous oversight is not a recipe for integrity, and now both CPRIT and the career of someone once considered an American hero and medical miracle incarnate lie in ruins.

I cannot comment on where Lance Armstrong goes from here.

CPRIT, on the other hand, can be salvaged. To do so will require the Legislature and the governor to decide whether it is about finding a cure for cancer through scientific research or it is an outgrowth

and augmentation of the Emerging Technology Fund to build businesses in Texas. Of course, commercialization of any scientific discovery is key to making that breakthrough a useful product. Someone may well get rich. But the science has to come first and despite the publicity heaped upon genetic, molecular and so-called personalized medicine as the cure for cancer, the pursuit of the cancer cure is still a scientific one, not a technical one. It is not like going to the moon was in 1962.

The 41 years since the war on cancer began when President Richard Nixon signed federal legislation launching it indicates this is a bit of a harder problem to crack than a moon landing, which took only eight years to accomplish because it was basically an engineering triumph based on Newtonian physics.

The cancer agency needs to start again with a much clearer elucidation of what it is, a more realistic communication to the people of Texas of what to expect from their $3 billion investment and oversight of the program free from any interference from the executive branch of the Texas state government. Rather, it should be overseen by the people's representatives in the Legislature, preferably via a committee of Texans of high accomplishment and unquestioned integrity from the worlds of biomedical science, scientific commercialization, cancer clinical trials and cancer prevention. After all, it's the people's money.

CPRIT can be and ought to be saved. To do so will require a few new Texas heroes with science, not wealth, on their minds.

Zwelling is a Houston physician. This editorial was published Feb. 12 in the Houston Chronicle and is reprinted with permission.

In Brief

Weiner Elected Vice President And President-Elect of AACI

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a professor of internal medicine, and a faculty member in the Interdisciplinary Graduate Program in Immunology.

In a statement, Weiner said he would focus his presidency on the role that academic cancer centers play in cancer patient care and research.

He will become AACI president in the fall of 2014. He served as a member of the board of directors from 2004-2007 and currently chairs the AACI New Initiative committee.

Weiner has been a faculty member at the University of Iowa since 1989, is currently president of the board of directors for the Iowa Cancer Consortium, and recently completed a term as chair of the governmental affairs committee for the American Society of Hematology.

GARTH POWIS was appointed professor and director of the cancer center at **Sanford-Burnham Medical Research Institute**. He will also assume the Jeanne and Gary Herberger Leadership Chair in Cancer Research.

Powis previously held leadership positions at MD Anderson Cancer Center. He will join Sanford-Burnham's faculty May 1.

Powis will replace Kristiina Vuori, who has served as director since 2005. Vuori is currently Sanford-Burnham's president and interim CEO. She also holds the Pauline and Stanley Foster Presidential Chair.

Powis served as deputy chair of pharmacology at the Mayo Clinic; as director of basic research at the University of Arizona Cancer Center; and most recently as chair of experimental therapeutics and director of the Center for Targeted Therapy at MD Anderson.

FDA News

FDA Approves Pomalyst For Multiple Myeloma

FDA granted accelerated approval for Pomalyst (pomalidomide) for patients with relapsed or refractory multiple myeloma.

Pomalyst is intended for patients who have received at least two prior therapies, including lenalidomide and bortezomib, and whose disease did not respond to treatment and progressed within 60 days of the last treatment.

Pomalyst is a pill that modulates the body's immune system to destroy cancerous cells and inhibit their growth.

Safety and effectiveness were evaluated in a trial of 221 patients with relapsed or refractory multiple myeloma. The trial was designed to measure objective response rate. Patients were randomly assigned to receive Pomalyst alone or Pomalyst with low-dose dexamethasone, a corticosteroid.

Results showed 7.4 percent of patients treated with Pomalyst alone achieved objective response. The median duration of response has not yet been reached in these patients. In patients treated with Pomalyst plus low-dose dexamethasone, 29.2 percent achieved objective response with a 7.4-month median duration of response.

Common side effects include neutropenia, anemia, thrombocytopenia, fatigue and weakness, constipation, diarrhea, upper respiratory tract infections, back pain and fever.

Pomalyst is marketed by Celgene Inc.

FDA granted priority review for two drugs for the treatment of patients with locally advanced or metastatic non-small cell lung cancer with an epidermal growth factor receptor mutation: **afatinib** and **Tarceva (erlotinib)**.

The NDA submission for afatinib is supported by the trial LUX-Lung 3, the largest phase III trial conducted to date in first-line EGFR mutation-positive, locally advanced or metastatic NSCLC patients. Afatinib was recently granted an orphan drug designation.

Afatinib is an irreversible ErbB family blocker that specifically inhibits epidermal growth factor receptor (EGFR or ErbB1), human epidermal receptor 2 (HER2 or ErbB2) and ErbB4. It is currently in phase III trials in advanced NSCLC, head and neck and breast cancer. Afatinib is not approved by the FDA; its safety and efficacy have not been established.

In Europe, the drug's sponsor, Boehringer Ingelheim Pharmaceuticals Inc., submitted a Marketing Authorization Application to the European Medicines Agency seeking approval of afatinib as a treatment for patients with EGFR (ErbB1) mutation-positive NSCLC.

Boehringer Ingelheim and QIAGEN are partnering on a companion diagnostic for afatinib. The Therascreen EGFR RGQ PCR kit is being developed to identify patients with EGFR mutation-positive tumors.

An FDA decision regarding Tarceva is expected in the second quarter of 2013. A pre-market approval application for a companion diagnostic, the cobas EGFR Mutation Test, developed by Roche Molecular Diagnostics, has also been submitted to the FDA.

The Tarceva sNDA submission is based on results of the international EURTAC trial, a phase III trial evaluating the first-line use of Tarceva versus platinum-based chemotherapy in patients with EGFR activating mutation-positive advanced NSCLC.

Tarceva is sponsored by Astellas Pharma US Inc.

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