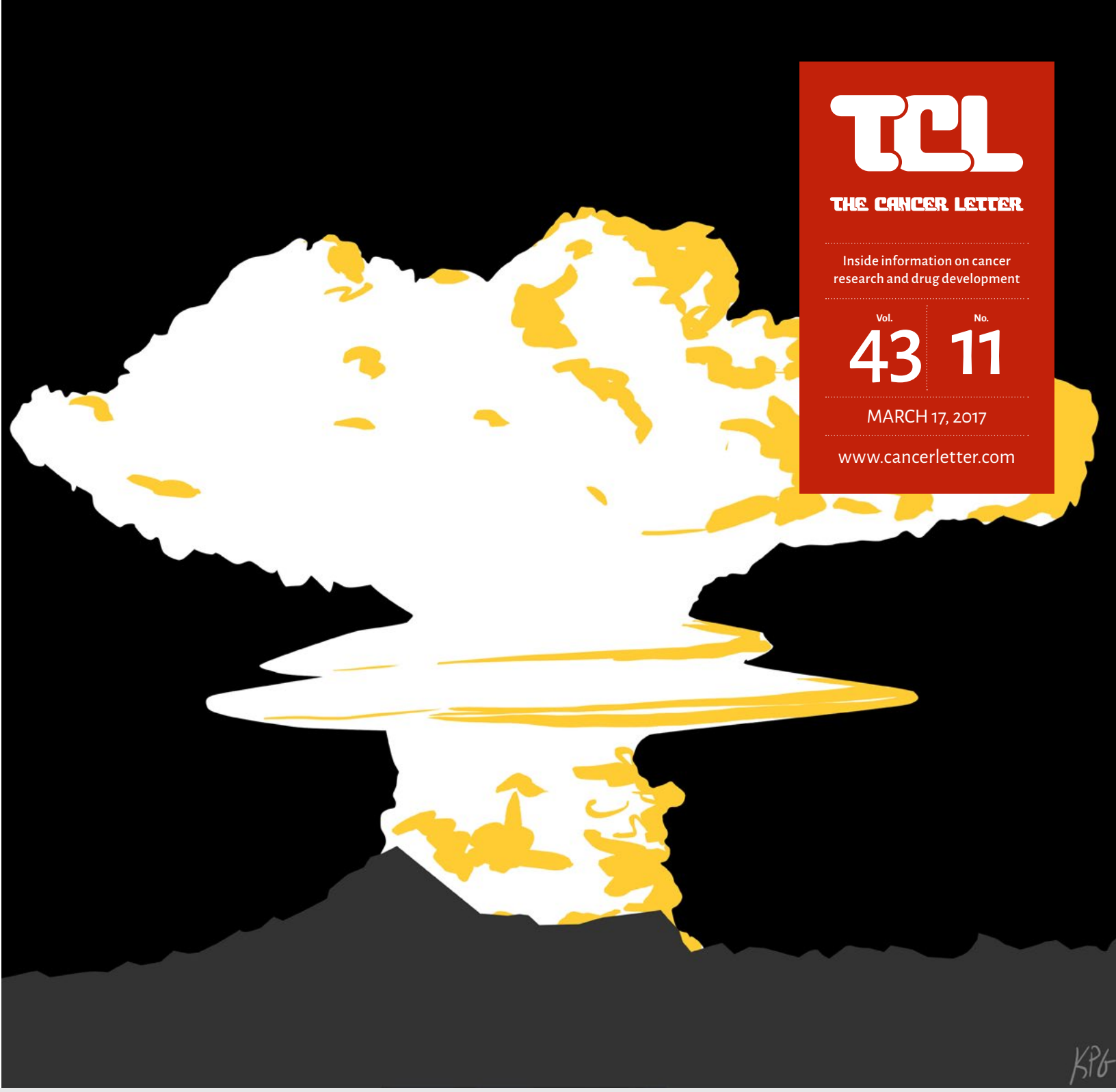


TCL
THE CANCER LETTER
Inside information on cancer research and drug development
Vol. 43 No. 11
MARCH 17, 2017
www.cancerletter.com

TRUMP'S PROPOSED 2018 BUDGET LAUNCHES A SURPRISE ATTACK ON NIH

FDA may have escaped the devastating cuts in President Trump's first budget proposal, while NIH ended up taking the brunt of its fury.

→ PAGE 4

THE CANCER LETTER | MARCH 17, 2017 | VOL 43 | ISSUE 11

Paul Goldberg
Editor & Publisher,
The Cancer Letter

White House "vision" would cripple NIH

Dear Reader,

This issue of The Cancer Letter is free. Send this link to your colleagues.

Share it because on March 16, while America slept, the White House launched a surprise attack on biomedical research. Share it because the entire enterprise of cancer research—and yes, the lives of cancer patients—are under a clear threat. Share it because good things happen when good people are informed.

The package of stories in front of you provides comprehensive coverage of President Donald Trump's proposal to cut the NIH budget by over 18 percent in FY 2018. This would drop federal funding for NIH below the 2003 level.

The year 2003 marked the completion of the doubling of the NIH budget. John Porter, a former House appropriator who spearheaded the doubling, is now one of the people shocked by Trump's proposal. "It will take us below the baseline that we achieved by doubling," Porter said to me. "That doesn't even take inflation into account.

"If you want to make America great, you don't take America's worldwide scientific lead and cut it."

These proposed cuts came as a surprise to folks who usually get warning of impending catastrophes.

According to the White House, NIH needs to be reconfigured because—to quote Sean Spicer—its research is riddled with "duplicity." The much-lampooned spokesman may have meant "duplication," or he may not have.

Suppose four or eight years from now, another administration comes in and decides that biomedical research is good.

If Trump's vision prevails, an entire generation of researchers will have moved on to less hostile work environments, said Blase Polite, chair of the Government Affairs Committee of the American Society of Clinical Oncology.

"Medical research isn't something that you can turn on and off like a faucet," said Nancy Davidson, president of the American Association for Cancer Research.

It would be appropriate to disclose The Cancer Letter's editorial vantage point. We are nonpartisan. Our job is to keep institutions accountable. The Cancer Letter is now in its 43rd year of exposing deviations from solid, evidence-based policy.

Leaf through the 10,000-word package of stories before you. This is Day One coverage of the president's budget proposal—establishing the record, letting questions percolate.

Is this proposal the beginning of a new era in cancer politics? Will opposition endure? Will the voices of cancer scientists and cancer patients be heard on Capitol Hill? Most importantly, who has the capacity to lead this fight?

Former Vice President Joe Biden was the last person to galvanize the cacophony of voices that make up oncology. He did this in a bipartisan manner, without bruising too many egos and hardly ever overpromising. Can Biden do this? Should he? Will he?

Joe, are you reading this?

In this issue

Editor & Publisher
Paul Goldberg

Reporter
Matthew Bin Han Ong

General Manager
Angela Spring

Designer
Jacqueline Ong

Illustrator
Katherine Goldberg

Editorial, Subscriptions and Customer Service
PO Box 9905 -
Washington, DC 20016

T 202-362-1809
F 202-379-1787
W www.cancerletter.com

Subscription $425 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd.

IN BRIEF

DRUGS & TARGETS

THE CANCER LETTER | MARCH 17, 2017 | VOL 43 | ISSUE 11

TRUMP'S PROPOSED 2018 BUDGET LAUNCHES A SURPRISE ATTACK ON NIH

By Paul Goldberg and Matthew Bin Han Ong

FDA may have escaped the devastating cuts in President Trump's first budget proposal, while NIH ended up taking the brunt of its fury.

Consider two "bullets" in the President's Budget Proposal for fiscal 2018, released March 16, and you might agree that the second of the two—the one flying toward the NIH campus in Bethesda—is more akin to a literal, lead bullet than a typographic device:

- [The President's Budget Proposal] reduces the National Institutes of Health's spending relative to the 2017 annualized CR level by $5.8 billion to $25.9 billion. The budget includes a major reorganization of NIH's Institutes and Centers to help focus resources on the highest priority research and training activities, including: eliminating the Fogarty International Center; consolidating the Agency for Healthcare Research and Quality within NIH; and other consolidations and structural changes across NIH organizations and activities. The budget also reduces administrative costs and rebalance federal contributions to research funding.

- Recalibrates Food and Drug Administration medical product user fees to over $2 billion in 2018, approximately $1 billion over the 2017 annualized CR level, and replaces the need for new budget authority to cover pre-market review costs. To complement the increase in medical product user fees, the budget includes a package of administrative actions designed to achieve regulatory efficiency and speed the development of safe and effective medical products. In a constrained budget environment, industries that benefit from FDA's approval can and should pay for their share.

Insiders in both sides of the aisle say they were surprised by the magnitude of the cut the president proposed for NIH—18.3 percent below the current continuing resolution level of $31.7 billion.

Even without accounting for inflation, this would knock the budget to $1.2 billion below the FY 2003 level, the year when the doubling of funding for NIH was completed. The budget document doesn't include numbers for NCI and other institutes.

Many predicted flat funding or, at worst, a small cut, that—of course—would have run into vigorous opposition on Capitol Hill.

In his address to a joint session of Congress, President Trump had lambasted FDA for being "slow and cumbersome," but, as far as anyone could remember, he hasn't slammed NIH in public (The Cancer Letter, March 3).

Last week, Trump nominated Scott Gottlieb, a physician who has worked on Wall Street and done stints at FDA and CMS to lead FDA.

In naming Gottlieb, who is seen as a solid choice by many patient groups and the industry, Trump had refrained from selecting an FDA-basher. The more optimistic observers saw the Gottlieb appointment as a signal of the new administration's sober attitude toward science.

America First

A Budget Blueprint to Make America Great Again

Office of Management and Budget

WHITE HOUSE SPOKESMAN SEAN SPICER SAID PROPOSED BUDGET AIMS TO REDUCE "DUPLICITY" AT NIH. WATCH AN EXCERPT OF THE PRESS CONFERENCE HERE.

The only explanation for slashing the NIH budget was offered on March 16, when Press Secretary Sean Spicer repeatedly referred to "duplicity" at NIH. Presumably, he meant "duplication."

"There's this assumption in Washington, that if you get less money, it's a cut, and I think the reality is, is that in a lot of these, there's efficiencies, duplicity, ways to spend money better," Spicer said at the media briefing. "And I think if you're wasting a lot of money, that's not a true dollar spent.

"And I think when you look at [the Office of Management and Budget] Director [Mick] Mulvaney and the president's approach to this budget, it was, 'Can we ask, can we get more with the same dollar? Can we find duplicity?'"

The text of Spicer's explanation appears on page 26.

Many insiders declared that Trump's budget proposal, titled America First - A Budget Blueprint to Make America Great Again, was dead on arrival.

"I don't think the budget that the President sent is serious at all," said John Porter, an advocate for biomedical research and a former House appropriator who led a successful push to double the NIH budget. "It's playing to his base. It just says what his base wants to hear. I don't think Congress has any intention to adopt it and support it. So, I am not overly concerned that the things that he is proposing in his budget would happen. I think that's very remote."

However, Porter urges advocates for science to take the document as a serious threat and make their voices heard on Capitol Hill. "What has to happen is that people have to protest—loudly! They have to let their representatives know that these are all bad things," Porter said.

A conversation with Porter appears on page 12.

A few short months since the Obama administration's popular cancer moonshot program and the passage of the 21st Century Cures Act, the cancer groups will have to fight like hell in what will surely be a free-for-all to maintain research funding that has been won over decades of hard work.

"I think we have to hope that the members of the current Congress will be very much like the members of the last Congress, who were very supportive in a bipartisan way of the importance of medical research and cancer research," said Nancy Davidson, president of the American Association for Cancer Research.

A conversation with Davidson appears on page 15.

Trump's proposed cuts would turn the United States into a "second-rate scientific country," said Blase Polite, chair of the American Society of Clinical Oncology Government Relations Committee.

"Let's look at the one that probably worries me more than anything else, from a big-picture perspective: this is a generational-level cut, and what I mean by that is, a cut of this magnitude will basically devastate what we could see 15, 20 years down the road," said Polite, associate professor of medicine and associate director of the Center for Clinical Cancer Genetics at the University of Chicago. "I mean, it's going to have immediate impact, but the research that should've been done that won't be done, we can't even contemplate what the effect of that is going to be.

"And most importantly, who's going to get hurt by this? You're going to kill the young scientists. That crop of innovative, energetic young scientists who are thinking about going into basic science research or going into research along this line, and all of a sudden, a cut of this magnitude where you're going to be funding 5 percent of grants, 7 percent of grants? Who in the right mind is going to go into that field? It would kill it."

A conversation with Polite appears on page 21.

"I just think there's nobody there that has an appreciation, candidly, at the White House, who is passionate about these issues, or understands biomedical research," said Ellen Sigal, founder and chair of Friends of Cancer Research. "We've seen budget cuts and we've seen decreases and we've seen people that feel that NIH or FDA is not efficient, but we've never seen anything like this.

"This is wanton disregard for medicine and public health. But, again, I want to stress, the impact of this won't only be felt in academic institutions. Patients will feel the impact, and that's whom I care about."

A conversation with Sigal appears on page 18.

Beth Caldwell, a patient with metastatic neuroendocrine breast cancer, said her life now depends on investigational drugs. She is undergoing treatment at the Fred Hutchinson Cancer Center.

"People like me will die because of these [budget] cuts," said Caldwell, who spoke at a Fred Hutch news conference broadcast via Facebook Live. "We just spent all this effort getting the 21st Century Cures Act passed, which slated more funding for research, including into cancer. And to see that undone, I feel like our government will have blood on its hands if these cuts go through. The only treatments left for me are going to be ones that are experimental."

Caldwell's comments appear on page 28.

The impact of these proposed cuts would be exacerbated by the repeal of the Affordable Care Act, said Patricia Goldsmith, president and CEO of CancerCare.

> "What has to happen is that people have to protest—loudly! They have to let their representatives know that these are all bad things."

"I would see a huge impact, because it's also coupled with the repeal of Obamacare," Goldsmith said. "We looked at what the Congressional Budget Office has put out and, also, what seems to be the statistics of showing many, many, many individuals, perhaps, 10 to 20 million losing their insurance coverage. We also are seeing that Medicare funding could be jeopardized.

"If you put all of this together, of repealing a system—Obamacare is not perfect, and it has its flaws, and it has its warts. But on the other hand, it has provided some insurance for many millions of people. I think that there will be a decrease in those individuals that are insured, there will a decrease in funding of Medicaid, decrease in funding of research. I would say that it's a bleak future if all these things actually converge in a way that I understand it at this moment."

A conversation with Goldsmith appears on page 24.

While the White House submits its funding proposals, Congress is responsible for drafting appropriations bills, and cancer research clearly has support on both sides of the aisle.

Insiders say the $25.9 billion Trump proposes likely includes the nearly $500 million NIH was slated to receive in fiscal 2018 under the 21st Century Cures Act, which makes the cut even more devastating. It's unclear how the current functions of the Agency for Healthcare Research and Quality would be incorporated into NIH and what impact this would have on its budget.

At NIH, the Trump administration has asked NIH Director Francis Collins to stay in office—at least for now. If he stays, he will likely have to defend the proposed budget.

This is not some remote, hypothetical situation. Collins is scheduled to get his first opportunity to do so on March 21, at a hearing of the House subcommit-

> This is wanton disregard for medicine and public health. But, again, I want to stress, the impact of this won't only be felt in academic institutions. Patients will feel the impact, and that's whom I care about.

tee on Labor, HHS, Education, and Related Agencies.

While it appears that the FDA budget has been left alone, this is by no means certain. The White House states only that revenues from user fees would be doubled. This provision is puzzling, said Ryan Hohman, vice president of public affairs at Friends of Cancer Research.

"I don't think anyone quite understands this," Hohman said. "The White House budget references it as $2 billion in 2018 and $1 billion in 2017. User fees, in the latest agreement, are $1.9 billion, so arguing to reopen the user fee agreement, for $100 million—is the president saying then that he will reduce FDA's budget by $100 million and make up for it with that extra user fee money?

"You almost can't react to it; it's so unclear. It shows a baseline misunderstanding—or not understanding—of how the FDA functions."

The Centers for Disease Control and Prevention can expect to be refocused on the needs of each state. The budget proposal reads:

> "Reforms key public health, emergency preparedness, and prevention programs. For example, the budget restructures similar HHS preparedness grants to reduce overlap and administrative costs and directs resources to states with the greatest need. The budget also creates a new Federal Emergency Response Fund to rapidly respond to public health outbreaks, such as Zika Virus Disease. The budget also reforms the Centers for Disease Control and Prevention through a new $500 million block grant to increase state flexibility and focus on the leading public health challenges specific to each state."

Several Republican leaders were lukewarm on the budget request. Sen. Marco Rubio (R-FL) said the president's proposal should be seen as no more than a statement of the administration's priorities.

"While this budget blueprint offers insights into the president's thinking about what's important to his administration and the American people, it is Congress that will actually set the nation's policy priorities and fund them," said Rubio, who serves on the Senate Committee on Appropriations and the Special Committee on Aging. "I will continue to review all the details of this budget proposal for areas of common interest we can work on together."

Rep. Nita Lowey (D-NY), ranking Democrat on the House Appropriations Committee, said that "the lack of detail in the President's 2018 budget request would be embarrassing for an administration with basic competence.

"Congress writes the appropriations laws that fund the federal government, and Democratic votes will likely be needed to enact these laws, just like in the 114th Congress when Republican majorities were larger in both chambers," Lowey said. "The goal of this administration is to help the most fortunate at the expense of working families, seniors, and other vulnerable populations."

Join Our Team

MASSEY CANCER CENTER VCU

Virginia Commonwealth University Massey Cancer Center is seeking exceptional mid-career to senior scientists and physician-scientists to join our growing team of more than 265 world-class physicians and researchers. These tenure-eligible faculty positions will be a part of Massey's leadership team with appointments in the appropriate academic home departments at the VCU School of Medicine. These positions offer a competitive salary, start-up and relocation package.

VCU Massey Cancer Center, headquartered on the MCV Campus in Richmond, Virginia, is one of only two NCI-designated cancer centers in the state. Founded in 1974, Massey is dedicated to discovering, developing, delivering and teaching effective means to prevent, detect, treat and cure cancer. Massey conducts cancer research at every level: basic science, translational, clinical and prevention and control research. Major strengths for Massey are in facilitating the translation of research discoveries into improved treatments, patient care and approaches to prevention and control, as well as in studying disparities and ways to reduce cancer incidence and mortality among minorities. Massey leads Virginia in offering the largest cancer clinical trials menu as a Minority/Underserved-NCORP lead academic site, and Massey's multidisciplinary cancer care is provided by nationally ranked and award-winning hospital, VCU Medical Center. Massey Cancer Center is part of Virginia Commonwealth University, one of the nation's top public research universities, and VCU Health, a leading academic health system. Learn more about Massey at **masseycancercenter.org**.

> Associate Director, Basic Research

- Position #F51620
- Provides oversight, development, implementation and evaluation of basic science-related programs and initiatives
- Conducts research planning
- Manages planning of all-member scientific retreats
- Encourages multidisciplinary collaboration and translational research

> Program Co-Leader, Cancer Molecular Genetics

- Position #F36090
- Provides oversight, development, implementation and evaluation of cancer molecular genetics-related programs and initiatives
- Partners with leadership to enhance scientific goals and objectives
- Facilitates multidisciplinary collaboration and translational research
- Conducts research to be translated into improved approaches for diagnosis, prevention and treatment of neoplastic diseases

> Senior Physician-Scientist (Solid Tumors) - Director, Cancer Immunotherapy Program

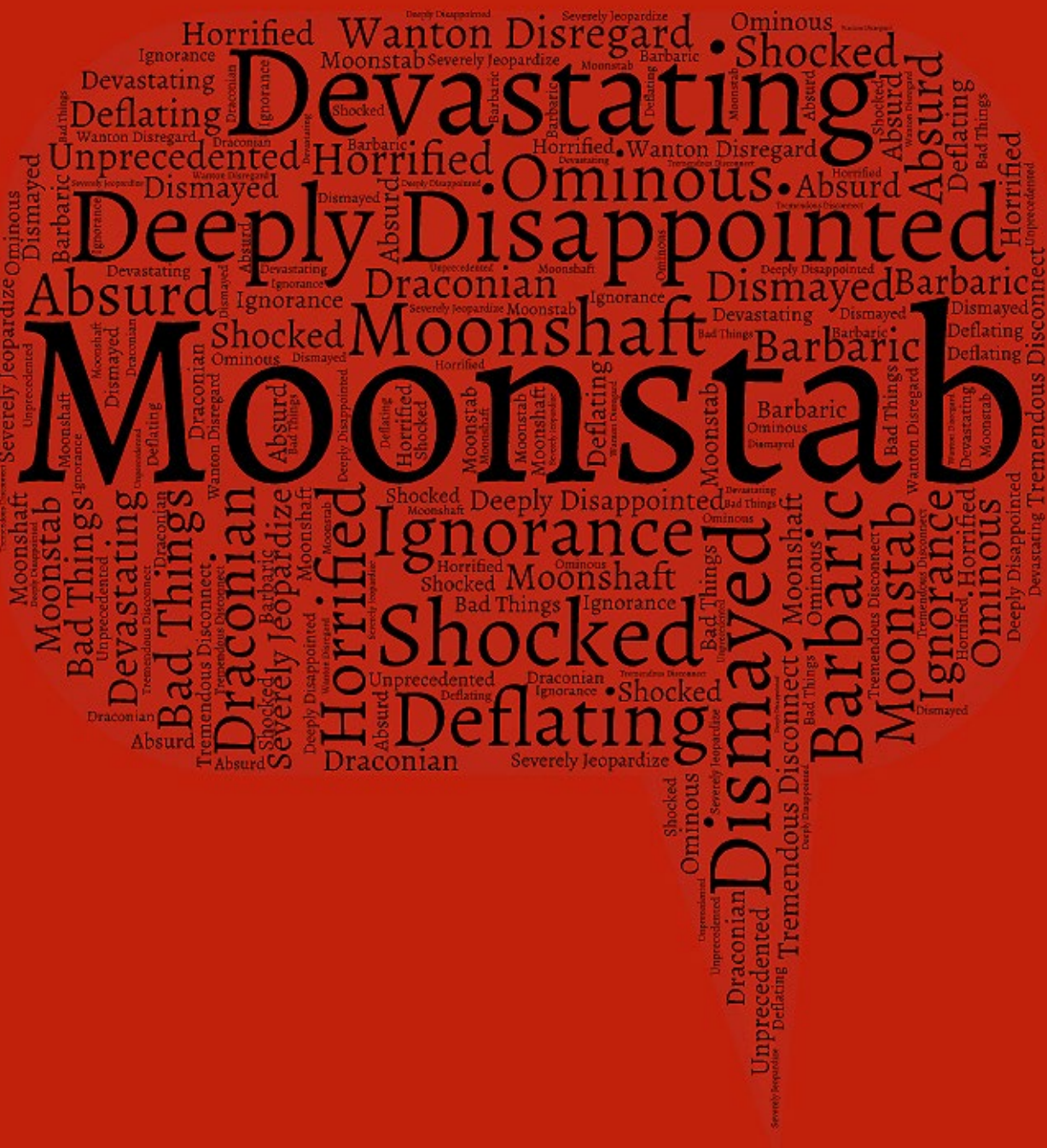
- Position #F16770
- With the substantial institutional commitment of resources to support clinical and translational research in cancer immunotherapy, builds and leads cancer immunotherapy program with a multidisciplinary approach
- Develops investigator-initiated trials (IIT) focused on cancer immunotherapy
- Has a clinical and translational research focus in solid tumors (e.g., lung, breast, prostate or GI cancer)

Join Virginia's premier cancer resource and enjoy the benefits of living in the Richmond metropolitan area with a low cost of living, rich history, beautiful James River, acclaimed restaurants, cultural amenities, outdoor recreation, magnificent architecture, minimal traffic congestion and short commutes.

Apply online >> vcujobs.com

VCU is an Equal Opportunity/Affirmative Action Employer and Educator

Q & A


Moonstab
Devastating
Deeply Disappointed
Ignorance
Horrified
Wanton Disregard
Shocked
Deflating
Unprecedented
Dismayed
Absurd
Barbaric
Draconian
Moonshaft
Ominous
Bad Things
Tremendous Disconnect
Severely Jeopardize

THE CANCER LETTER | MARCH 17, 2017 | VOL 43 | ISSUE 11

CONVERSATION WITH THE CANCER LETTER

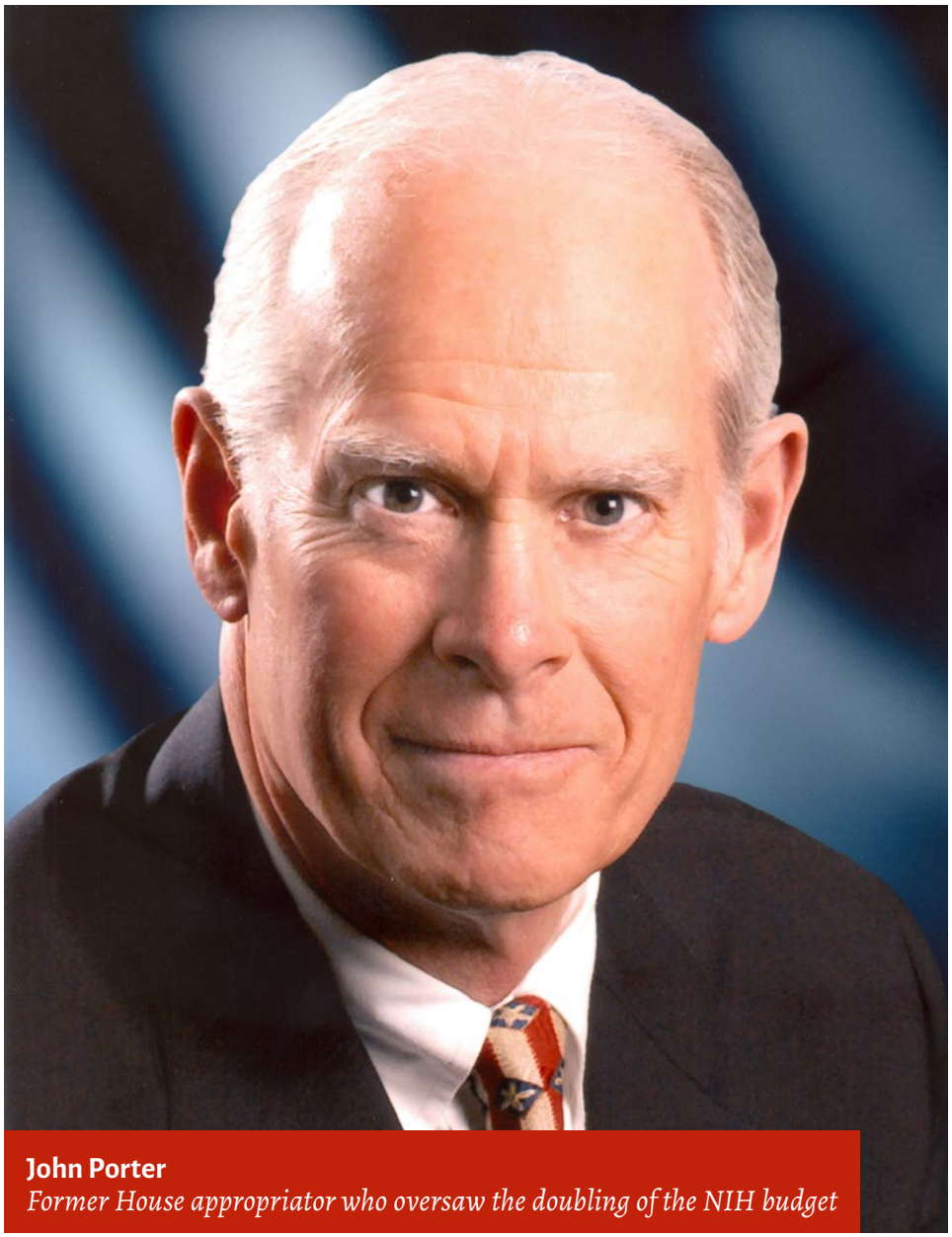
John Porter: If you want to make America great, you don't take America's worldwide scientific lead and cut it

As former chairman of the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, then-Rep. John Porter (R-IL) oversaw the doubling of the NIH budget over five years.

Now, President Trump's budget proposal seeks to drop the NIH budget to $25.9 billion. That's $1.2 billion below the FY 2003 level, the year when the doubling was completed. These are absolute numbers. Adjusting for inflation will erode these funds even more.

Porter, who has been a vocal supporter of funding for biomedical research after leaving Congress in 2001, noted that cancer research has strong support on Capitol Hill. Nonetheless, cancer groups must come out and make certain that their voices are heard. Porter said.

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



John Porter
Former House appropriator who oversaw the doubling of the NIH budget

> I just don't see this as having any legs whatsoever. I think there is no support for it in Congress. It illustrates to me this president's ignorance of government, and his lack of discipline to even begin to study how things work. It's just more campaigning.

I was there when you were fighting to double the NIH budget, sitting at the press table, hoping you would succeed. This is a terrible reporter question: How does this feel?

John Porter: I don't think the budget that the President sent is serious at all. It's playing to his base. It just says what his base wants to hear. I don't think Congress has any intention to adopt it and support it. So, I am not overly concerned that the things that he is proposing in his budget would happen. I think that's very remote.

Support for medical research is totally bipartisan. And [Sen.] Roy Blunt [(R-MO), chair of the Senate appropriations subcommittee on Labor, HHS, Education and Related Agencies] and [Rep.] Tom Cole [(R-OK) chair of the House appropriations subcommittee on Labor, HHS, Education and Related Agencies] both are big supporters of medical research.

In the Labor-HHS bill, there are about 800 line items. Forty of those are NIH. If you have one high priority in the bill—and that's their high priority in the bill—the rest of it doesn't matter. Even if you get a low allocation, you can plus-up that account and not plus-up the others.

I stepped down as chair of Research!America last night after 12 years and got a chance to talk about it, and I said, "I am optimistic. I don't see that there is going to be any big cut in medical research. In fact, there could well be a $1 billion or $2 billion increase, depending upon the allocations."

Presidents propose things, but their budgets have no weight in legislation. It's the Congress that writes budgets. I just don't see this as having any legs whatsoever. I think there is no support for it in Congress.

It illustrates to me this president's ignorance of government, and his lack of discipline to even begin to study how things work. It's just more campaigning.

Hearing this, I am worried that people will take this as an assurance that "Oh well, it's going to be okay," and that's how bad things happen.

JP: Oh, no! No, no, no! What has to happen is that people have to protest—loudly! They have to let their representatives know that these are all bad things.

Another area where I am very concerned, which has nothing to do directly with science is the Corporation for Public Broadcasting. He proposes zeroing that out. I think it's some of the best spent money in government. PBS is a national treasure, and I think people should go up to their representatives and say, "Don't you dare cut that!"

What about cancer centers? If you think about it, in any congressional district, the cancer center is one of the jewels, one of the pillars, politically. How does he think that the House and Senate members are going to forsake their cancer centers?

JP: Ha! Well, he just doesn't understand the support for cancer research out there, which is universal. I talked with Joe Biden last night. He actually did a 45-minute speech, and focused on the cancer initiative that he was in charge of.

I just think that people have to have their voices heard. They should have had their voices heard in the last election. Maybe the outcome would have been different. People have to get up off their chairs and really get involved in the process, and their elected representatives will then understand. That's what counts.

How do we do this? Who is leading the charge right now? During the 1998 March [The March--Coming Together to Conquer Cancer, a gathering of 250,000 people on the National Mall and a million more in grassroots events nationwide], you were in charge of a lot of it. Who is doing this? Are you going to lead the charge?

JP: Well, you know, there is a march for science, coming up on April 22. All the organizations that I know of are involved in it, including Research!America. That sends its own message, if people participate. If they stay home and say, "Oh well," that's a message.

All the organizations—and there are many of them—have to get out and be heard. Especially cancer groups, like you.

I am just a dog-faced reporter; what do I know? Except I was there when you were trying to get the doubling done. And, by the way, the magnitude of this cut isn't too far off from the raise that you got for NIH.

JP: I know. It will take us below the baseline that we achieved by doubling. That doesn't even take inflation into account.

Amazing.

JP: You can't just dismiss it as a political document. You have to go out there and protest every little bit of it.

There are protests at town halls that Congress men and women hold. That's a great place to send a message. People have to go out and go to those things and say, "Wait a minute, this is wrong, this is one we shouldn't be doing!"

If they sit home, that's another message.

Also, thinking deeper about this, when you were working on the doubling, science was in a very different place than it is now. And here we are, cutting science when it's actually producing very interesting outcomes.

JP: If you want to make America great, you don't take America's worldwide scientific lead and cut it. You support it and increase it.

You know, it's incredible!

"I just think that people have to have their voices heard. They should have had their voices heard in the last election. Maybe the outcome would have been different."

Nancy Davidson: This is the time for investment, not for retreat

CONVERSATION WITH THE CANCER LETTER

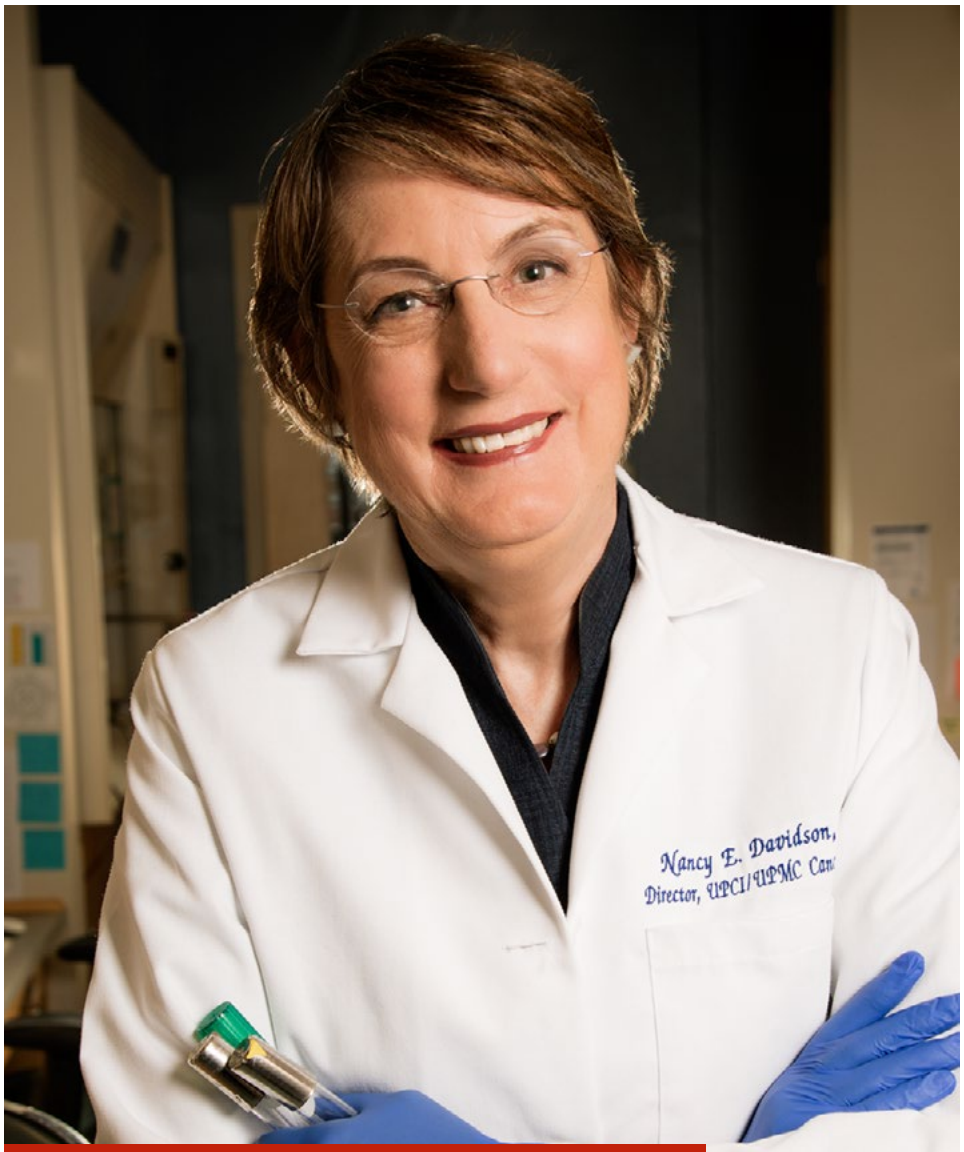
First, Congress should follow through on increasing the NIH budget by $2 billion in fiscal 2017, said Nancy Davidson, president of the American Association for Cancer Research.

Second, the House and the Senate should craft appropriations bills that will provide robust, sustainable, and predictable increases for fiscal 2018, said Davidson, executive director and president at Seattle Cancer Care Alliance, senior vice president and director of the Clinical Oncology Division at Fred Hutchinson Cancer Research Center, and professor and Head, Division of Medical Oncology at the University of Washington School of Medicine.

While some insiders declare Trump's budget proposal dead on arrival, Davidson said AACR will not be complacent.

"We are taking this incredibly seriously. I don't think we have any choice but to do so," Davidson said. "This is the first budget from the Trump Administration. I think it gives us some ideas about the priorities. I think we need to take the strongest possible stance right now."

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



Nancy Davidson
President of the American Association for Cancer Research

As you look at this budget proposal, what do you think?

Nancy Davidson: I am horrified. I think we are all horrified. The magnitude of these cuts is really shocking, Paul. Particularly when you look at this time at our ability to really capitalize on cancer research moving into improved cancer care. To me, there is tremendous disconnect between what we have seen in this budget and what the opportunities are. And I think that this budget would severely jeopardize the progress we are making right now to prevent and treat cancer.

What do you see happening at your institution if this budget were adopted?

ND: At the Fred Hutch, we are one of the top cancer centers in the country. We are one of the most reliant on federal funding, which has allowed us to accomplish so much. So, I think we would see a substantial decrease in some of the efforts that we are trying to fund things like cell-based therapies.

This would inevitably have negative effects on patients. I don't think that we can expect that the private sector or the philanthropic sector are going to be able to fill in these gaps. This is really the responsibility of the federal government to make these investments, because they lead to improvement of health for all of our citizens.

Let's say four years from now or eight years from now, when a new administration comes in and decides to recapture the lost ground, would that even be possible?

ND: I think it would be extremely difficult, Paul. You know, medical research isn't something that you can turn on and off like a faucet. The teams that are brought together to do this kind of sophisticated work—once you disaggregate them, it's very hard to bring them together again.

The other important thing is that we have a pipeline of investigators, doctors, researchers that we have to continuously develop. And you can't take a break from that pipeline and then anticipate that four years from now or eight years from now, when the faucet is turned back on, you will be able to regain that lost momentum.

This is very heavily dependent, of course, on ideas from people, and these ideas develop from having sustained, robust and predictable funding from NIH.

Our AACR position for this year is that we would like Congress to provide a $2 billion increase for NIH in FY 2017, this spring. And we obviously call on Congress to be firmly against the budget proposal that we have just seen.

Are you being assured that this budget proposal is dead on arrival, that this will not pass?

ND: Assured by whom?

By folks in Congress. Are you taking this so seriously that you believe that there is an actual possibility that this will become the budget?

ND: We are taking this incredibly seriously. I don't think we have any choice but to do so. This is the first budget from the Trump Administration. I think it gives us some ideas about the priorities. I think we need to take the strongest possible stance right now.

As you know, over the past few years, Congress had been working in a bipartisan fashion very supportive of medical research and cancer research specifically. We hope that we continue to be in that same place and that Congress will also be strongly opposed to this budget and we could figure out ways to undo this potential damage.

So, there is hope?

ND: Paul, we are oncologists. There is always hope. But hope requires resources, and resources in this case means that we are reliant on substantial funding from NIH and NCI to improve the health of Americans.

How does AACR intend to respond to this?

ND: We've already been out today with what we think is a very strong statement. We had the good fortune that we will be in Washington, D.C., in just two weeks for our annual meeting. This is our 110th anniversary meeting.

It's an opportunity for over 20,000 people to be in Washington to talk about the progress that we have made in cancer, the opportunities that are out there, and how we can capitalize on them.

It's also an opportunity for us to reflect on what will be lost with the kind of cut we are talking about. I hope we will be able to articulate the importance of NIH funding in all this, that it's an investment in our future, and that it's critical to improve and extend lives.

And I also hope we will be able to articulate that the cost of cancer is billions of dollars, and we think that cancer research is a way of trying to reduce these costs that are associated with cancer.

I want to remind you that AACR also plays a key leadership role in the Rally for Medical Research Hill Day, which will be held on Sept. 14. I think that will be an opportunity for the entire medical community to come together and ask Congress to push back on this FY2018 proposal and to really articulate the importance of robust, sustainable and predictable funding increases.

This proposal starts a war on multiple fronts—can't even count them all—foreign policy, EPA—everything. So, it's going to be a war on all fronts against the administration's budget. The level of lobbying that will be taking place on the Hill is going to be astonishing.

ND: We'll be there. We obviously believe that human health has to be an absolute priority for any administration.

Just a few months ago, Congress passed the Cures act, and was looking seriously enough at the moonshot.

ND: I think we have to hope that the members of the current Congress will be very much like the members of the last Congress, who were very supportive in a bipartisan way of the importance of medical research and cancer research.

Today, at the White House press briefing, Sean Spicer noted "duplicity" at NIH. He repeated that several times. I think he might have meant "duplication." You are an insider. You've been a reviewer, an advisor. Do you see either duplicity or duplication at NCI?

ND: I don't think that there is any evidence to suggest that there is duplicity. Nor do I think that there is any duplication except, you might appropriately hope, for replication, which is, of course, one of the tenets of evidence-based science.

Let me read to you from the budget proposal:

"The budget includes a major reorganization of NIH's Institutes and Centers to help focus resources on the highest priority research and training activities, including: eliminating the Fogarty International Center; consolidating the Agency for Healthcare Research and Quality within NIH; and other consolidations and structural changes across NIH organizations and activities. The budget also reduces administrative costs and rebalance federal contributions to research funding."

Where is that idea coming from—that there is a need to consolidate and reshuffle the institutes? Is this coming from the inside of the scientific establishment, or is it coming from some ideological sources?

ND: I am not familiar with the information that would lead to those statements. I would return to the message that, if anything, these important places are underfunded at a time when we have such great opportunity for advance.

So rather than cutting in order to "restructure," I think we have to come back and ask Congress for a $2 billion increase for NIH for FY 2017 and to push back on the 2018 budget.

This is the time for investments, not for retreat.

> "This would inevitably have negative effects on patients. I don't think that we can expect that the private sector or the philanthropic sector are going to be able to fill in these gaps."

THE CANCER LETTER | MARCH 17, 2017 | VOL 43 | ISSUE 11

CONVERSATION WITH THE CANCER LETTER

Ellen Sigal: This is not a grasstops issue anymore, this is really grassroots

Over decades, Ellen Sigal has emerged as a Washington insider in oncology, someone who has the ability to convene key players in academia, industry and government.

Her work at Friends of Cancer Research is now largely focused on FDA. Last year, Sigal, chair and founder of Friends, worked the Beau Biden Cancer Moonshot and the 21st Century Cures Act to consolidate the FDA oncology portfolio into a single cancer center at the agency (The Cancer Letter, July 1, 2016).

Sigal said cancer groups must adopt aggressive advocacy tactics in response to Trump's budget proposal.

"I think this is going back to the advocacy of what we used to see with the HIV community and the breast cancer community in the early days," Sigal said to The Cancer Letter.

Sigal and Ryan Hohman, vice president of public affairs at Friends, spoke with Matthew Ong, a reporter with The Cancer Letter.

Ellen Sigal
Chair and founder of Friends of Cancer Research

> It's also going to be the cancer center directors saying to their members of Congress, 'What the hell, do you understand what this is going to do to the economy of our local district?'

Ryan Hohman
Vice president of public affairs at Friends of Cancer Research

What came to mind when you saw the budget proposal?

Ellen Sigal: Dismayed, deeply disappointed. Those were words that came to my mind. That was really my immediate reaction.

Does this proposal have political legs in Congress?

ES: I think, traditionally, the president's budget sets a tone but does not always translate into policy.

Everyone knows there is bipartisan support for the NIH and the FDA, but this does set a deeper tone and deeper discord that what we've had before, and it is very concerning, and I think the biggest issue for me is the impact on patients and on public health and the devastation this will cause.

We're in a very promising area where we just came off the elation of the 21st Century Cures and bipartisan efforts to really focus on research and promising immunotherapies, the moonshot, personalized medicine, the BRAIN Initiative, and all these things—and after two-and-a-half years of hard work, the Cures Act was an enormous victory.

And then, all of a sudden, to see this? It's just deflating.

What would the impact be on patients and public health if these drastic cuts were made?

ES: This is for patients who are living and who need help every single day. The ramification of this for patients, for people who will be deeply impacted, are really draconian, because right now, the science is breathtaking, but we have a huge amount of work to do. We're not finished.

We're just starting to understand precision medicine and immunotherapy and all these clinical trials that are going to make a difference, and we finally, after years and years of low budgets, finally got to some equilibrium and to some incentive to really increase the funding.

Now, all of a sudden, this just sends a very ominous message. It shows you something about values, values for patients, and values for people who are suffering.

And, the impact will be devastating, because it will cost more money. Research, we know, saves money ultimately. The great advocate Mary Lasker once said, "If you think research is expensive, try disease."

Why did the White House propose doubling of the user fees? I'm not sure I quite understand the justification for the move.

Ryan Hohman: I don't think anyone quite understands this.

The White House budget references it as $2 billion in 2018 and $1 billion in 2017. User fees, in the latest agreement, are $1.9 billion, so arguing to reopen the user fee agreement, for $100 million—is the president saying then that he will reduce FDA's budget by $100 million and make up for it with that extra user fee money?

You almost can't react to it; it's so unclear. It shows a baseline misunderstanding—or not understanding—of how the FDA functions.

ES: And also, at the moment, the White House proposal didn't touch the FDA budget, but we don't know what that means.

You know, after the elation of Cures, after the victory, after we all worked together—all diseases—and worked for years, bipartisan effort by everyone, and to get this right on the heels of such a victory for health and patients and science, it makes no sense. It's just draconian and hard to understand or to grasp.

I think the community is going to have to get out there—and I mean community centers and the academic centers—this is not a grasstops issue anymore, this is really grassroots.

Congress needs to understand what this really means in their communities.

What are your next steps?

RH: We want clarity on the FDA and understanding what the White House means, because the budget proposal is going to be interpreted in different ways.

What President Trump did with NIH is tone-deaf politically, because the impact it has at the congressional level, at the Senate level—a cut of almost 20 percent—is going to impact all districts.

We'll obviously work with ACS, ASCO, AACR, but I think what their power is going to be not only—like Ellen said, she's exactly right, the grassroots issue—get on the Internet, get on Twitter, get people to call the Hill. It's also going to be the cancer center directors saying to their members of Congress, "What the hell, do you understand what this is going to do to the economy of our local district?"

Fifty days in, with health care on shaky ground, and [HHS] Secretary Tom Price's being tested so early on, these numbers add uncertainty for our community.

ES: I just think there's nobody there that has an appreciation, candidly, at the White House, who is passionate about these issues, or understands biomedical research.

We've seen budget cuts and we've seen decreases and we've seen people that feel that NIH or FDA is not efficient, but we've never seen anything like this.

This is wanton disregard for medicine and public health.

But, again, I want to stress, the impact of this won't only be felt in academic institutions. Patients will feel the impact and that's whom I care about.

Any closing remarks?

ES: This is a different world, different administration. We have to use better tactics. This is not marching 20 physicians or 20 researchers to the Hill. Those are not the tactics.

I think this is going back to the advocacy of what we used to see with the HIV community and the breast cancer community in the early days.

“Research, we know, saves money ultimately. The great advocate Mary Lasker once said, ‘If you think research is expensive, try disease.’”

Blase Polite: This was put together by folks who have no sense of how research is done

CONVERSATION WITH THE CANCER LETTER

If Congress follows the fiscal 2018 budget priorities outlined by the White House, the United States will lose its standing as the powerhouse of biomedical research, said Blase Polite, chair of the American Society of Clinical Oncology Government Relations Committee.

"If that science doesn't happen, the drug companies never come up with these drugs, and so, you're going to devastate future cures, and you're going to devastate our talent pool of young researchers that do that science," said Polite, associate professor of medicine and associate director of the Center for Clinical Cancer Genetics at the University of Chicago.

"That will make us a second-rate scientific country. That shouldn't be acceptable to anybody."

Polite spoke with Matthew Ong, a reporter with The Cancer Letter.

Blase Polite
Chair of the American Society of Clinical Oncology Government Relations Committee

> You're going to devastate future cures, and you're going to devastate our talent pool of young researchers that do that science. That will make us a second-rate scientific country. That shouldn't be acceptable to anybody.

What was your initial reaction when you saw the White House budget proposal this morning?

Blase Polite: Shocked. Literally. I mean, I saw it this morning at about 6:30 a.m. and I was absolutely shocked.

Several of my colleagues filled in my basket with equal shock—and these are folks who come from across the political spectrum—that these numbers came out the way they did.

It's almost an impossible number to even wrap your head around, that they would be looking at this level of cut at NIH.

Did you have any indication ahead of the release that this would be the outcome?

BP: No, we didn't know that it was going to look like that. You almost had to check it twice to make sure that you weren't missing something. So yes, shocked, and feeling that this was absurd.

That's probably the second reaction to this, and really, the feeling that this was put together by folks who really have no sense of how the biomedical research infrastructure works in this country.

Have you gotten a sense of how the administration is justifying these proposed cuts?

BP: No, I have not seen anything other than what they've put out, and that they're talking about reorganizing and reprioritizing NIH. But what that means, I don't know.

What's the chance that Congress might listen to the White House on this?

BP: Zero. I mean, if you look at where the 2017 budget is looking to come out, right, when the Senate passed the $34 billion NIH appropriations—the thought that they would go down to $25 billion?

There's not a single appropriator on the House or Senate side that would even put that number down on a piece of paper.

I think they would view it as just a naïve budget that needs some education from Congress to the administration about how the biomedical infrastructure works.

In a hypothetical scenario where this budget proposal comes true, what's going to happen to the cancer research enterprise and patients?

BP: Let's look at the one that probably worries me more than anything else, from a big-picture perspective: this is a generational-level cut, and what I mean by that is, a cut of this magnitude will basically devastate what we could see 15, 20 years down the road.

I mean, it's going to have immediate impact, but the research that should've been done that won't be done, we can't even contemplate what the effect of that is going to be.

And most importantly, who's going to get hurt by this? You're going to kill the

young scientists. That crop of innovative, energetic young scientists who are thinking about going into basic science research or going into research along this line, and all of a sudden, a cut of this magnitude where you're going to be funding 5 percent of grants, 7 percent of grants? Who in the right mind is going to go into that field? It would kill it.

Those folks will go off, they'll go into industry. You'll produce something in industry, but you're never going to produce the basic science work that leads to the breakthroughs.

I mean, you look at where we are now with immunotherapies. All of that stuff, anything that we're doing now, all these drugs that are coming that so many of us have seen have tremendous impact—all have their genesis in basic science, NIH-funded research from 20, 25, 30 years ago.

If that science doesn't happen, the drug companies never come up with these drugs, and so, you're going to devastate future cures, and you're going to devastate our talent pool of young researchers that do that science.

That will make us a second-rate scientific country. That shouldn't be acceptable to anybody.

What are the next steps for ASCO?

BP: Once everybody gets past the shock phase, I think it's really to get a reality check, talk to our friends on the Hill, and I think what we will quickly learn is that this is going to be, essentially, ignored.

I don't think it's going to be, "We're going to start from the president's budget and then negotiate," up to some number, I think we're going to negotiate from the 2017 budget, which, again, we hope comes out at the $34 billion, and then we will be doing our negotiations from there, not from the president's budget.

I suspect, when all the smoke clears, this is just going to be absolutely ignored, and we're going to go on like we would've gone on, even though we haven't come up with our consensus number yet, because the process is all the groups get together to come up with a consensus for NIH's number.

That's a process we follow for good reason, for many years, because we don't want this to be disease against disease. That's not a winning fight for anybody, and so we come up with what we believe biomedical research funding should be.

We'll come up with a target number and we will all be up on the Hill preaching that number to the folks on the Hill.

At the end of the day, I think this is just going to be a lot of sound and a lot of noise that will end up meaning nothing.

Have you heard from the rank-and-file Republicans on the Hill and what they might think of this?

BP: Not yet. I have not yet been on with them. We've got our folks up on the Hill today; I haven't heard anything back yet.

But again, having been with them and enough discussions with them over the last 10 years, I can't imagine that their reaction is going to be any different from the one that I just gave you.

And I remember doing this in 2010 when the Tea Party wave came in, and there was a lot of resistance to NIH, and it took several years of many of us—and many of the organizations you're talking to—going up on the Hill and educating them on biomedical research, letting them understand that the impact that this money has on the local economy, the jobs that are provided by this etc. to get the point where, when we were back up there two years later, 2012, 2013, these folks got it. Tea Party, not Tea Party, left wing, right wing, didn't matter. Everyone got NIH.

So it takes a bit of education, and I think that's probably where the administration is right now.

I think there's a group of people putting together budgets that are looking at numbers and don't really understand the critical importance of biomedical research, again, not just for, of course, our patients and the cures that won't happen if you do this kind of cuts, but also for our position as a first-world country.

If you kill this type of research and if you do this kind of stuff to NIH, you will not be a competitive country, going forward.

If you cannot compete in the biomedical sciences, you cannot be a first-rate country in the future. I say there is no question about that.

Once that sets in, and people understand that, then they quickly get to this point, where I think they all will even back off this, once they understand it better.

THE CANCER LETTER | MARCH 17, 2017 | VOL 43 | ISSUE 11

CONVERSATION WITH THE CANCER LETTER

Patricia Goldsmith: This is the "Moonstab," or, maybe, the "Moonshaft"

Patricia Goldsmith
CEO of CancerCare

Coupled with the repeal of the Affordable Care Act, the administration's proposed cuts to the NIH budget would be devastating for cancer patients, said Patricia Goldsmith, CEO of CancerCare, an organization that provide counseling, support groups, education, and financial assistance.

"Congress can fight over this, but the bottom line is the leader of our country has communicated his priorities, and those priorities set us back decades," Goldsmith said.

Goldsmith spoke with Matthew Ong, a reporter with The Cancer Letter.

You've worked with patients and researchers through many administrations, have you seen anything like this?

Patricia Goldsmith: Never. Never. This move is unprecedented. And the fact is, I read all of the articles today and watched the press, there is only one word that came to mind about what is being released under the Trump administration, and that word is: barbaric. It is absolutely barbaric.

Would Congress be amendable to the White House proposal?

PG: I think we're facing a brave new world right now, so I really don't know what the actions of Congress will be. I don't know what the reaction is. Just to review a couple of facts, as I understand them:

First, NIH, it is suggested, is going to get a 18.29 percent decrease in funding, which is the biggest funding decrease in the history of the NIH, as I recall. In addition, what I understand is this is going to translate into a $1 billion decrease for cancer research at the NCI.

Yes, that's what I understand has been suggested. If that's correct, that's the largest reduction in the history of the National Cancer Institute.

In addition, I applaud President Trump's nomination of Scott Gottlieb to head the FDA. I also understand that there's going to be a doubling of the user fees at the FDA. I'm not exactly sure what that's for. What do we get for the doubling of the fees at the FDA?

Yes, we all want to make sure that we get drugs to patients faster, that we go through a process that allows that to happen, but I don't see anything articulated in the proposal as to what that directly translates into, with respect to doubling of the user fees. And, doubling the user fees has to have a major impact on the manufacturers of these products.

So, well, I see the numbers of the doubling of the user fees—I don't understand how that translates into a better process, a more expeditious process, and at the end of the day, the bottom line: a better way to get medications to patients.

Assuming Congress approves these cuts, what do you think would happen in your work with cancer patients?

PG: I would see a huge impact, because it's also coupled with the repeal of Obamacare.

We looked at what the Congressional Budget Office has put out and, also, what seems to be the statistics of showing many, many, many individuals, perhaps, 10 to 20 million losing their insurance coverage. We also are seeing that Medicare funding could be jeopardized.

If you put all of this together, of repealing a system—Obamacare is not perfect, and it has its flaws, and it has its warts. But on the other hand, it has provided some insurance for many millions of people.

I think that there will be a decrease in those individuals that are insured, there will a decrease in funding of Medicaid, decrease in funding of research.

I would say that it's a bleak future if all these things actually converge in a way that I understand it at this moment.

What other initiatives might be jeopardized?

PG: There's been so much talk, so much discussion, and so much hype about the [Beau Biden Cancer] Moonshot, and the fact that this was something that was under the then Vice President Joe Biden—and now may be taken into the private sector, one would hope—but when I think about the promise of the moonshot, there's absolutely no antonym to the moonshot.

I think about the "moonstab," perhaps, at least in terms of what we have heard today, because there's just no antonym. So it is the "moonstab" or, maybe, the "moonshaft." Those are the only things I can think of.

The last thing I'd like to say: as you recall, in my last interview with The Cancer Letter, I invited President Trump, who was then President-Elect Trump, to come to our offices to meet with cancer patients, and hear exactly what they're struggling with and what their hopes are.

I would like to reiterate that invitation, because it would be very enlightening to a man that doesn't understand cancer and doesn't understand the ramifications of what he's doing for our progress.

The president has sent a message about what he believes and what his priorities are.

Congress can fight over this, but the bottom line is the leader of our country has communicated his priorities, and those priorities set us back decades.

THE CANCER LETTER | MARCH 17, 2017 | VOL 43 | ISSUE 11

"Duplicity" at NIH? White House spokesman Sean Spicer says the cut isn't really a cut

White House spokesman Sean Spicer said the cuts proposed by the administration will help eliminate inefficiency and duplication at NIH. At a White House press briefing March 16, Spicer was asked to justify his boss's proposal to gut biomedical research funding:

Reporter:

I want to ask you about the decision to cut the National Institutes of Health budget by 19 percent. As you know, it's a very important part of the government funding medical research.

Sean Spicer: Yup.

Budget Director [Mick] Mulvaney yesterday acknowledged that the private sector can't fill that gap. When there are rare diseases, we do need a robust government presence. The president invited a rare disease patient to his speech to Congress to talk about medical innovation and new cures. How do you square those things when you are cutting NIH by 19 percent? And many conservatives actually want to increase the budget.

SS: I think director Mulvaney…somebody asked him during the Q&A period the same question, and…

My outtake from listening to him yesterday was that it wouldn't be cut.

SS: But then again, there's this assumption in Washington, that if you get less money, it's a cut, and I think the reality is, is that in a lot of these, there's efficiencies [sic], duplicity [sic], ways to spend money better. And I think if you're wasting a lot of money, that's not a true dollar spent.

And I think when you look at Director Mulvaney and the president's approach to this budget, it was, "Can we ask, can we get more with the same dollar? Can we find duplicity?

"Can we find efficiencies? Can we combine facilities in some cases at NIH to enhance a better experience whereby we actually have an outcome that reduces savings?"

But to assume that because you spend a ton of dollars, you're going to get a better outcome? I mean, with all due respect, you look at the District of Columbia, they spend, by far, more per capita than any other city in the country on education.

And I think they have tremendous issues that are constantly being dealt with in our education system. So to assume that just because you throw money at a problem, it's somehow magically solved is a very Washington way of looking at a budget problem.

…a fifth of the NIH budget…

SS: I understand.

…is a lot…

SS: I think part of the issue is that we're working, as the director outlined a couple of weeks ago during the passback process, is to work with them, to talk to each of these agencies and departments about how to walk through their budget in a way that ensures that they can continue to do their core functions if they want, while finding ways to reduce ways, get rid of … enhance efficiencies, and get rid of duplicity.

But that is a very Washington way of looking at a problem when you say, "Let's just look at how much we spend as a measure of how much we care or how much we're going to get done."

And I think that the president's been very clear as to what his priorities on this budget are, and the outcomes that we expect from every dollar that we spend.

So, for being in office for 55 days, or 50-some days, whatever it has been, we've had a unique ability to go far, to go forward so far and make a very strong commitment to enhancing our national security to protect the country and keep America safe and its citizens safe, while at the same time making sure that we don't ask for people to work harder to send more to Washington, that gets ultimately wasted.

I just don't see how that's showing respect to the American people or the American taxpayer, especially when so many people are working two, sometimes three, jobs, or both parents are working just to get by, pay the mortgage, and we're saying, "Hey, don't worry, keep sending more money to Washington, and we're not going to take the time."

But there should be a review of all these agencies. Director Mulvaney was pointing out how many unauthorized agencies and departments and programs we have throughout the government.

If we're going to do that, at some point there should be a debate on whether or not these agencies and programs are achieving their mission. And if they are, then great, fund them. But if they're not, we shouldn't be asking hardworking American taxpayers to send more money to Washington to fund things that don't further those goals.

Beth Caldwell: People like me will die because of these cuts

Beth Caldwell, a patient with metastatic neuroendocrine breast cancer, has more to lose than anyone else in the controversy over President Donald Trump's proposed cuts to the NIH budget.

Caldwell, who is undergoing treatment at the Fred Hutchinson Cancer Center, spoke at a news conference broadcast live on the cancer center's Facebook page.

The text of her remarks follows:

My name is Beth Caldwell and I have metastatic neuroendocrine breast cancer. I was diagnosed in March of 2014. I found a lump in my breast and I was 37, too young to be getting mammograms yet, and it turned out that it had already spread to my bones, which means that it's incurable, currently. And I'd like to add that currently, the more research we do, the more likely it is that I'm going to live to see my children into adulthood.

My children right now are five and nine. My goal when I was initially diagnosed was to see my youngest start kindergarten, and she will in the fall. I would really like to set some new goals, but it's hard to do that when we see research funding cuts happening.

I've lost—I can't even tell you—how many friends with metastatic cancers within the time since I've been diagnosed. I lost one this week. Another friend told me today she was just diagnosed with brain metastases, which means that her expected life span just shortened by quite a bit. And it's not okay. It's just not acceptable that people will die because of these cuts.

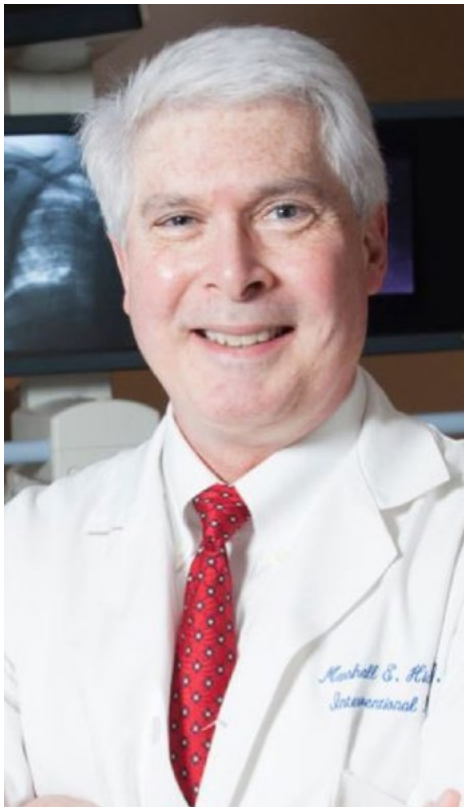
And I'm going to say that again—people like me will die because of these cuts. We just spent all this effort getting the 21st Century Cures Act passed, which slated more funding for research, including into cancer. And to see that undone, I feel like our government will have blood on its hands if these cuts go through. I frankly would love to watch my children grow into adulthood but I think currently, that's not likely to happen.

The only treatments left for me are going to be ones that are experimental. I've been through all the regular treatments already in the past three years and they've all stopped working, which is what happens when you have metastatic cancer. You take a drug until it stops and then you take a new one. And if there aren't new ones, then you die.

So we need this funding for NIH. We need funding for research to keep patients alive longer, to keep them alive longer with a quality of life that's acceptable. And so I desperately hope that people will begin to contact their members of Congress and demand that this budget with these cuts to NIH not be passed.

IN BRIEF

Marshall Hicks named interim president of MD Anderson Cancer Center



Marshall Hicks was named interim president of MD Anderson Cancer Center.

The appointment, announced by the UT System Chancellor William McRaven, will become effective March 21, "following Dr. Ronald A. DePinho's retirement as president on March 20."

Earlier this month, when DePinho announced his resignation, he said that he had been asked to remain in his job through the end of the Texas legislative session, which is scheduled to end on May 29 (The Cancer Letter, March 10).

According to the announcement that was distributed to MD Anderson faculty and staff March 8, "discussions between Dr. DePinho and Chancellor McRaven are ongoing to coordinate the details and timing of his transition."

According to an MD Anderson spokesperson, DePinho had communicated to MD Anderson's faculty and staff March 13 that McRaven accepted his request that March 20 be his final day as president. He will transition to past president and become a member of the faculty.

Hicks, 59, has served as Division Head of Diagnostic Imaging at MD Anderson since 2010. According to the cancer center, he has "played a leading role in the development of the institution's Shared Governance Committee."

"Dr. Hicks is a widely respected leader within the MD Anderson family, with nearly 20 years of service on the faculty," McRaven said in a statement. "When we discussed potential candidates for the interim presidency, Dr. Hicks' name came up time and time again. His colleagues throughout the institution have great trust and confidence in him."

Dr. Hicks specializes in interventional radiology and served nationally as former president of the Society of Interventional Radiology. He has been a collaborator in many clinical research studies of a wide range of different types of cancers, including, among other sites, those involving the lung, liver, colon, head and neck.

"I am honored to be asked to serve MD Anderson as its interim president," Hicks said. "This extraordinary institution holds a special place in the hearts of its patients and their families, our outstanding faculty and trainees, our dedicated staff, the Houston community and people across the world."

Recently-appointed Chief Operating Officer Stephen Hahn, said Hicks is "one of our most seasoned leaders on campus and he has been a great partner with me in our efforts to position MD Anderson for the challenges and opportunities ahead. He has a calming and reassuring style that will help us through the leadership transition."

While serving as interim president, Hicks will appoint an interim head of the Division of Diagnostic Imaging to serve until he returns to that position, MD Anderson officials said.

A national search for a permanent president would launched soon and will include the appointment of a search advisory committee, MD Anderson offocoals said. The committee will aim to recommend top candidates to the UT System Board of Regents by the end of 2017.

"Given the national prominence of MD Anderson, we expect significant interest in this position from the most renowned cancer experts in the country," UT System Executive Vice Chancellor for Health Affairs Raymond Greenberg, said in a statement.

Greenberg said the search advisory committee "would look for an established leader with proven skills in managing a large and complex health care organization, ideally with both clinical and research expertise."

THE CANCER LETTER | MARCH 17, 2017 | VOL 43 | ISSUE 11

Stupp named associate director, strategic initiatives at Lurie Cancer Center

Roger Stupp, a Swiss neuro-oncologist, was named associate director for strategic initiatives at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University.

An expert in the treatment of primary and metastatic brain cancer, Stupp will join Northwestern Medicine in April as a professor of neurological surgery. He will work at the Division of Neuro-Oncology in the Department of Neurology and Lurie Cancer Center's Northwestern Brain Tumor Institute.

In 2005, Stupp led clinical research demonstrating that chemotherapy with the drug temozolomide in conjunction with radiotherapy increases survival for patients with glioblastoma. Later, Stupp and colleagues showed that electromagnetic waves called tumor treating fields can substantially improve outcomes for patients suffering from glioblastoma. These breakthrough discoveries led to the last two FDA-approved treatments for the disease.

"The 'Stupp Protocol' is a standard of care for patients with malignant glioma around the world," said Maciej (Matt) Lesniak, chair of the Department of Neurological Surgery. "Northwestern is fortunate to have recruited an international leader in the field who will champion the development of new therapies for patients with brain cancer."

Stupp went on to discover a predictor of response to his chemotherapy-radiation treatment: Patients who carry an inactivated MGMT gene respond better to the combination therapy. Stupp's ongoing research touches not only primary and secondary brain tumors, but also head and neck tumors and lung cancers.

Stupp serves as president of the European Organization for Research and Treatment of Cancer and section editor of the European Journal of Cancer. His honors and awards include the European Society for Medical Oncology's Hamilton Fairley Award and the Society for NeuroOncology's Victor Levin Award.

City of Hope vice provost to focus on faculty growth initiatives

Arti Hurria, City of Hope's new vice provost, plans to focus on faculty growth and development, including fostering faculty career development and ensuring more diverse voices are represented.

Hurria, a geriatrician and oncologist who has been at City of Hope for 10 years, is also its director of Cancer and Aging Research Program. As vice provost, she will have primary oversight of academic and faculty affairs for physicians in the clinical professor series.

She will support City of Hope's mission to increase the diversity of clinical faculty, and is responsible for designing, implementing and assessing various programs to address faculty diversity, recruitment, retention and advancement.

Hurria's goals toward those ends include developing pilot grant awards for junior faculty, organizing a regular meeting for women leaders in the oncology field to share experiences and advice with female faculty, informing faculty of career development opportunities outside City of Hope, and supporting diversity at all levels.

"As the daughter of Indian immigrants and doctors, I am particularly passionate about ensuring that diverse voices are represented at the table," Hurria said.

"One of the opportunities that truly helped me grow was serving as chair of the ASCO Professional Development Committee, where I was able to strategically plan professional development activities for members. I realized just how many opportunities there are within our own field to help foster the careers of individuals within our own profession. As vice provost, I will work to bring those opportunities to City of Hope and develop programs that can foster the career development for all of our faculty members."

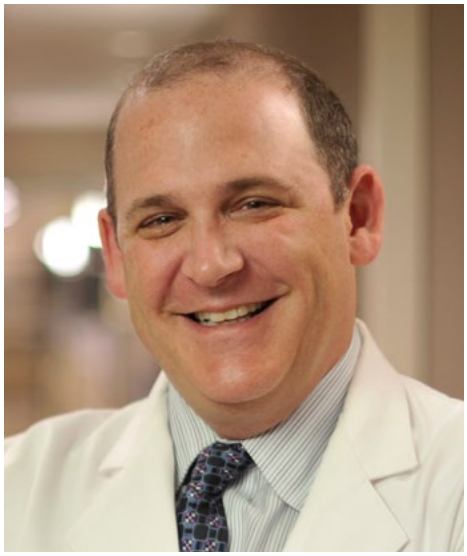
Nichols named LLS chief medical officer

Gwen Nichols was named chief medical officer of the Leukemia & Lymphoma Society.

A physician and scientific researcher, Nichols has advanced cures for cancers through a unique combination of clinical, academic and pharmaceutical experience. AS CSO, she will oversee LLS's scientific research portfolio, patient access services and policy and advocacy initiatives.

Most recently, Nichols was oncology site head of the Roche Translational Clinical Research Center, where she worked to develop new cancer therapies, translating them from the laboratory to clinical trials. Prior to joining Roche in 2007, Nichols was at Columbia University for more than ten years, where she served as the director of the Hematologic Malignancies Program.

Penson named chair of Science & Quality Council at American Urological Association



David Penson was named chair of the Science & Quality Council at the American Urological Association. He will assume the role of chair-elect on June 1 and begin his two-year term as chair on June 2018.

As council chair, Penson is expected to provide strategic oversight to shape and execute the broad science, quality, and data agenda of the AUA. This includes supporting and expanding the AUA Quality Registry, and developing and disseminating evidence-based guidelines, patient safety and quality improvement initiatives, physician performance measures and white papers.

He will also oversee the activities of the following AUA committees: Data, Practice Guidelines and Quality Improvement & Patient Safety.

Penson is the former chair of the AUA Public Policy Council and previously held leadership positions on the AUA Quality Improvement and Patient Safety Committee and AUA Practice Guidelines Committee. He was also the AUA representative to the American College of Surgeons Commission on Cancer and the National Quality Forum.

NCI selects ATCC to provide end-to-end cancer epidemiology services

NCI awarded ATCC a five-year indefinite-delivery/indefinite-quantity contract to support the Division of Cancer Epidemiology and Genetics' Molecular Epidemiology Assay Support program.

DCEG's mission is to conduct population and multidisciplinary research to discover the genetic and environmental determinants of cancer and new approaches to cancer prevention. The MEAS program provides support services for studies on the genetic and other cellular events that influence the onset of different types of cancer.

Under the contract, ATCC will provide collection supplies to study sites; perform aliquoting and advanced molecular assays; and provide short-term storage for human biospecimens and environmental samples obtained through family and population-based collection efforts, both domestically and internationally. ATCC will track all specimens using a customized biospecimen inventory and resource management system, ensuring that specimens are safeguarded appropriately for use in long-term epidemiology research projects.

"We understand that the proper collection, tracking and storage of specimens is of critical importance to cancer research, and take pride in maintaining and distributing these unique samples to the global research community," said Joseph Leonelli, vice president for ATCC's Microbiology and Government Solutions business.

ILO delays vote on whether to cut ties with tobacco industry

The International Labour Organization voted on Wednesday to delay the decision on whether to cut ties with Big Tobacco until November.

The decision could remove one of the tobacco industry's final avenues of influence in the United Nations. Most other UN agencies developed firm policies against collaboration with the tobacco industry after the negotiation of the World Health Organization Framework Convention on Tobacco Control, the global anti-tobacco treaty.

The vote was originally scheduled due to public health, labor, and human rights communities escalating their call for the ILO to extricate itself from

Big Tobacco, one of the deadliest industries on the planet.

Since 2015, the ILO has received more than $15 million USD from Japan Tobacco International and other tobacco corporations for programs that boost the industry's public relations yet do little toward the ILO's stated purpose of curbing child labor violations in tobacco fields, a problem largely caused by the tobacco industry itself.

"The ILO cannot address major human rights violations by collaborating with the perpetrators," said Laurent Huber, executive director of Action on Smoking and Health, who helped negotiate the global tobacco treaty. "Working with the tobacco industry on child labor is like inviting the fox to consult on how best to guard the henhouse."

United Nations officials, including the Secretariat of the FCTC, have also called on the ILO to distance itself from the tobacco industry. The ILO's coziness with the tobacco industry violates a core tenet of the FCTC, which establishes a firewall between the tobacco industry and public health policymaking.

Child labor in tobacco production is not a problem limited to the developing world. The U.S. government has acknowledged the risks of tobacco farming to children, which includes exposure to carcinogens and acute nicotine poisoning.

DRUGS & TARGETS

Kisqali gets FDA approval as first-line treatment for HR+/HER2- metastatic breast cancer in combination with any aromatase inhibitor

FDA approved Kisqali (ribociclib, formerly known as LEE011) in combination with an aromatase inhibitor as initial endocrine-based therapy for treatment of postmenopausal women with hormone receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) advanced or metastatic breast cancer.

Kisqali is a CDK4/6 inhibitor approved based on a first-line phase III trial that met its primary endpoint early, demonstrating statistically significant improvement in progression-free survival (PFS) compared to letrozole alone at the first pre-planned interim analysis. Kisqali was reviewed and approved under the FDA Breakthrough Therapy designation and Priority Review programs.

FDA approval is based on the superior efficacy and demonstrated safety of Kisqali plus letrozole versus letrozole alone in the pivotal phase III MONALEESA-2 trial. The trial, which enrolled 668 postmenopausal women with HR+/HER2- advanced or metastatic breast cancer who received no prior systemic therapy for their advanced breast cancer, showed that Kisqali plus an aromatase inhibitor, letrozole, reduced the risk of progression or death by 44 percent over letrozole alone (median PFS not reached (95% CI: 19.3 months-not reached) vs. 14.7 months (95% CI: 13.0-16.5 months); HR=0.556 (95% CI: 0.429-0.720); p<0.0001).

More than half of patients taking Kisqali plus letrozole remained alive and progression free at the time of interim analysis, therefore median PFS could not be determined. At a subsequent analysis with additional 11-month follow-up and progression events, a median PFS of 25.3 months for Kisqali plus letrozole and 16.0 months for letrozole alone was observed. Overall survival data is not yet mature and will be available at a later date.

"In the MONALEESA-2 trial, ribociclib plus letrozole reduced the risk of disease progression or death by 44 percent over letrozole alone, and more than half of patients (53%) with measurable disease taking ribociclib plus letrozole experienced a tumor burden reduction of at least 30 percent. This is a significant result for women with this serious form of breast cancer," said Gabriel Hortobagyi, professor of medicine, Department of Breast Medical Oncology, MD Anderson Cancer Center, and MONALEESA-2 principal investigator.

"These results affirm that combination therapy with a CDK4/6 inhibitor like ribociclib and an aromatase inhibitor should be a new standard of care for initial treatment of HR+ advanced breast cancer." Kisqali was developed by the Novartis Institutes for BioMedical Research under a research collaboration with Astex Pharmaceuticals.

Prescribing information for Kisqali is posted at https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/kisqali.pdf

Keytruda gets accelerated approval for classical Hodgkin lymphoma

FDA granted an accelerated approval to Keytruda (pembrolizumab) for the treatment of adult and pediatric patients with refractory classical Hodgkin lymphoma (cHL), or those who have relapsed after three or more prior lines of therapy.

Keytruda is sponsored by Merck & Co. Inc. Approval was based on data from 210 adult cHL patients enrolled in a multicenter, non-randomized, open-label clinical trial. Patients had refractory or relapsed disease after autologous stem cell transplantation (ASCT; 129 patients) and/or brentuximab vedotin (175 patients), and received a median of four prior systemic therapies (range: 1, 12). With a median follow-up of 9.4 months (range: 1-15), the overall response rate was 69% (95% CI: 62, 75). This included partial responses in 47% of patients and complete responses in 22%.

The estimated median response duration was 11.1 months (range 0+ to 11.1). Efficacy in pediatric patients was extrapolated from results observed in adults. Safety was evaluated in 210 adults with cHL. In adults, the most common (at least 20%) adverse reactions were fatigue, pyrexia, cough, musculoskeletal pain, diarrhea, rash and hypertransaminasemia. Additional common adverse reactions (at least 10%) included dyspnea, arthralgia, vomiting, nausea, pruritus, hypothyroidism, upper respiratory tract infections, headache, peripheral neuropathy, hyperbilirubinemia and increased creatinine. Other immune-mediated adverse reactions occurring in 0.5%-9% of patients included infusion reactions, hyperthyroidism, pneumonitis, uveitis, myositis, myelitis and myocarditis. Fifteen percent had an adverse reaction requiring systemic corticosteroid therapy.

Pembrolizumab was discontinued due to adverse reactions in 5% of patients, and treatment was interrupted due to adverse reactions in 26%. Safety was also evaluated in 40 children with advanced melanoma, PD-L1 positive solid tumors, or lymphoma. The safety profile in the pediatric patients was similar to that observed in adults. Adverse reactions occurring at a higher rate (difference of 15% or greater) in children than adults included fatigue, vomiting, abdominal pain, hypertransaminasemia and hyponatremia. Pembrolizumab exposure in these pediatric patients at a dose of 2 mg/kg every 3 weeks was comparable to that seen in adults. FDA has required the sponsor to evaluate pembrolizumab's long-term safety in pre-pubertal patients, and those who have not completed pubertal development.

A new "Warning and Precaution" was added for complications of allogeneic hematopoietic stem cell transplantation (allo-HSCT) after pembrolizumab. Transplant-related deaths have occurred, and health care professionals should follow patients closely for early evidence of transplant-related complications, such as hyperacute graft-versus-host-disease (GVHD), severe (grade 3 to 4) acute GVHD, steroid-requiring febrile syndrome, hepatic veno-occlusive disease (VOD), and other immune-mediated adverse reactions. FDA has required the sponsor to further study the safety of allogeneic HSCT after pembrolizumab therapy. The recommended dose and schedule of pembrolizumab for cHL is 200 mg every 3 weeks for adults and 2 mg/kg (up to 200 mg) every 3 weeks for pediatric patients.

Full prescribing information for pembrolizumab is available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125514s015lbl.pdf

FDA granted pembrolizumab Orphan Drug Designation for the treatment of HL, and Breakthrough Therapy Designation for the current indication. This application also received priority review status and accelerated approval.

FDA extends Keytruda PDUFA date for microsatellite instability-high cancer

FDA extended the action date for the supplemental Biologics License Application for Keytruda (pembrolizumab) for previously treated patients with advanced microsatellite instability-high cancer.

The drug is sponsored by Merck & Co. Inc. The company recently submitted additional data and analyses to the FDA related to the pending application. The submission of additional data is considered a major amendment to the sBLA under the Prescription Drug User Fee Act (PDUFA), thus extending the target action date by three months.

The new FDA target action date is June 9.

Mylan announces settlement, license deals with Genentech and Roche on Herceptin

Mylan N.V. announced that the company has agreed to the terms of a global settlement with Genentech, Inc. and F. Hoffmann-La Roche Ltd. in relation to patents for Herceptin (trastuzumab),

which provides Mylan with global licenses for its trastuzumab product.

The global license will provide a clear pathway for Mylan to commercialize its trastuzumab product in various markets around the world, commencing on the license effective dates, which are confidential. The licenses pertain to all countries except Japan, Brazil and Mexico.

In addition to eliminating any legal uncertainty over the launch of Mylan's trastuzumab, the settlement eliminates further patent litigation expenses associated with Genentech and Roche. Mylan has agreed to withdraw its pending Inter Partes Review (IPR) challenges against two U.S. Genentech patents (patent numbers 6,407,213 and 6,331,415) as part of the settlement.

Following this settlement and the recent acceptance of Mylan's application for its proposed biosimilar trastuzumab with the FDA, Mylan anticipates potentially being the first company to launch a biosimilar to Herceptin in the U.S. Mylan's proposed biosimilar trastuzumab is one of the six biologic products co-developed by Mylan and Biocon for the global marketplace. Mylan has exclusive commercialization rights for the proposed biosimilar trastuzumab in the U.S., Canada, Japan, Australia, New Zealand and in the European Union and European Free Trade Association countries. Biocon has co-exclusive commercialization rights with Mylan for the product in the rest of the world.

In the U.S., Mylan's Biologics License Application for proposed biosimilar trastuzumab is under review by FDA. The anticipated FDA goal date set under the Biosimilar User Fee Act is Sept. 3.

Mylan markets its trastuzumab products in 14 emerging markets and has submissions pending in the European Union and several additional emerging markets, in addition to the U.S.

Oncoceutics expands DRD2 research collaborations with NIH

Oncoceutics Inc. announced research collaborations with various groups within the NIH to study DRD2 as a novel therapeutic target in oncology.

DRD2, a member of the dopamine receptor family that is part of the G protein-coupled receptor superfamily, is a well-known drug target but one that has not been explored previously as a target for clinical oncology. As a result of recent work by Oncoceutics with its cancer drug candidate called ONC201 that selectively antagonizes DRD2 and is in phase II clinical trials, Oncoceutics has generated interest by multiple institutions within the NIH to study basic, translational, and clinical research opportunities for both ONC201 and other related drug candidates called imipridones.

In addition to Oncoceutics' relationship with NCI, the company has recently expanded its collaborations throughout NIH institutions to include:

- Preclinical and clinical evaluation of ONC201 in advanced breast and endometrial cancers by a team led by Stanley Lipkowitz, chief of Women's Malignancies Branch at the NCI;
- DRD2 receptor pharmacology and signaling studies of imipridones by the laboratory of David Sibley, chief of the Molecular Neuropharmacology Section at the National Institute of Neurological Disorders and Stroke; and
- Translational evaluation of ONC206 (a related drug candidate also under development by Oncoceutics) as a potent and selective DRD2 antagonist for neuro-oncology by a team of investigators led by Mark Gilbert, at the Neuro-oncology branch that itself is a collaboration between NCI and NINDS.

NCI also continues to support clinical investigation of ONC201 as a single agent in recurrent glioblastoma through a small business innovation research grant, and discussions are underway with the NCI regarding the clinical evaluation of ONC201 in combination with targeted agents.

"The unique pharmacology and mechanism of action associated with ONC201 and other imipridones that has come to light in the past year opens up an exciting new arena for basic and clinical investigations," said Joshua Allen, vice president of research and development at Oncoceutics. "We are delighted to work with these expert multi-disciplinary teams to continue to elucidate the elegant and complex basic biology of this receptor, how imipridones uniquely target this receptor, and how we assimilate this information to maximize the clinical benefit offered by imipridones to cancer patients."

"True medical breakthroughs in oncology and other diseases are driven by the introduction of novel classes of therapeutic targets," said Keith Flaherty, director of Developmental Therapeutics at Massachusetts General Hospital.

"We have seen this in recent history with oncogene targeted therapies that have been followed by immune checkpoint inhibitors, and the question is what realm of therapeutic targets will be the next to drive a quantum leap. G protein-coupled receptors are a befitting family of druggable receptors that are dysregulated in cancer and control broadly important signal transduction pathways."