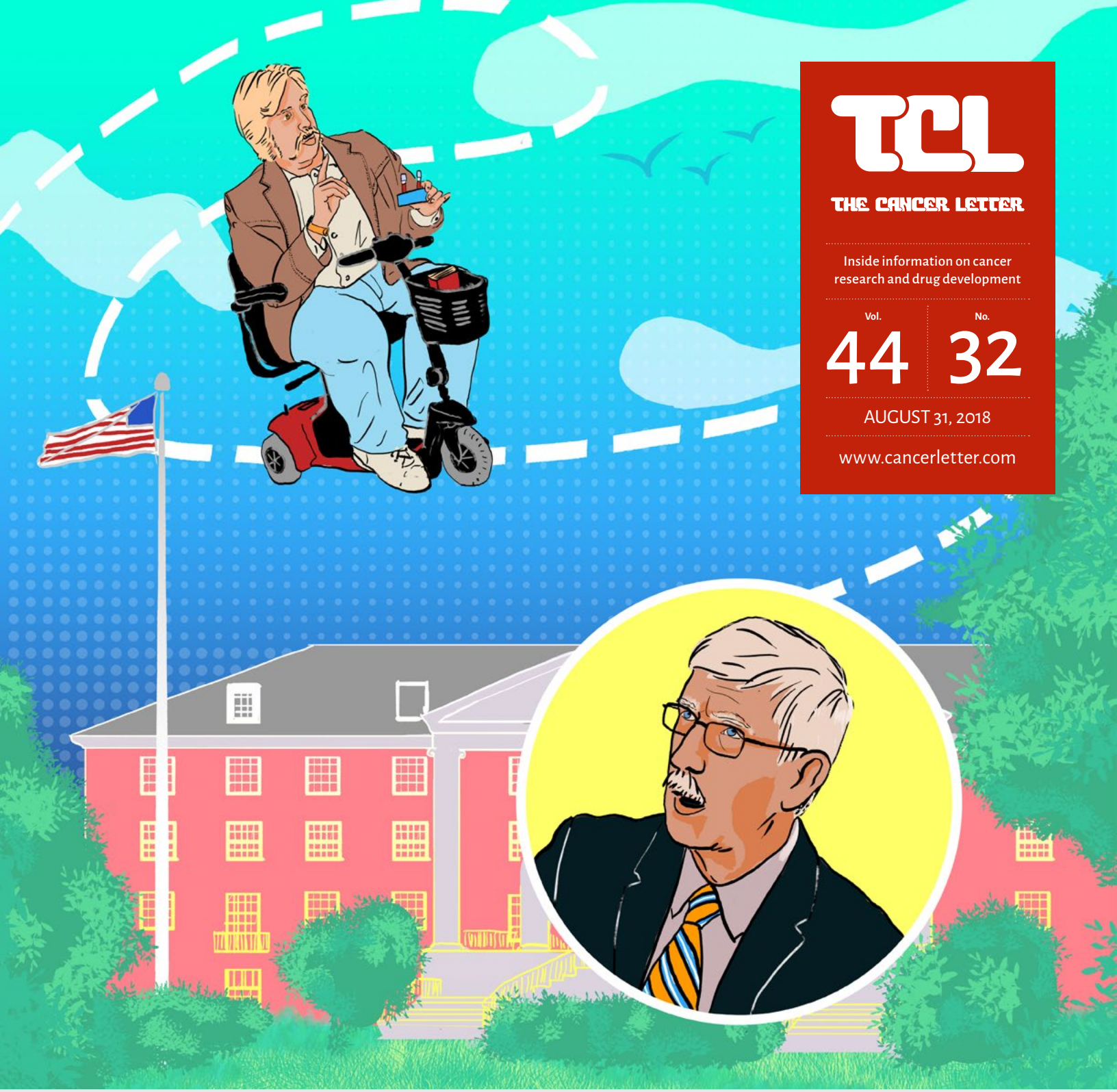

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→ PAGE 4

IT TOOK AN ELABORATE RUSE TO GET NIH DIRECTOR FRANCIS COLLINS ON SACHA BARON COHEN'S "WHO IS AMERICA?"

→ PAGE 11

SENATE SPENDING BILL GIVES NIH $2 BILLION RAISE

→ PAGE 17

IN BRIEF

ROSENBERG, JUNE AND ALLISON SHARE 2018 ALBANY PRIZE

→ PAGE 19

DRUGS AND TARGETS

IMBRUVICA + RITUXIMAB BECOMES FIRST NON-CHEMO COMBINATION FOR WALDENSTRÖM'S MACROGLOBULINEMIA

→ PAGE 27

In this issue

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COVER STORY

4 NIH Director Francis Collins tricked into debating disguised Sacha Baron Cohen on Showtime spoof "Who Is America?"

CONVERSATION WITH THE CANCER LETTER

11 It took an elaborate ruse to get NIH Director Francis Collins on Sacha Baron Cohen's "Who Is America?"

17 Senate spending bill gives NIH $2 billion raise

AN APPRECIATION

18 James D. Cox, former RTOG chair, dies at 80

IN BRIEF

19 Rosenberg, June and Allison share 2018 Albany Prize

19 Karen Knudsen named AAACI president-elect

20 Cory Wiegert named CEO of CancerLinQ LLC

20 Moffitt's chief information security officer named fellow to America's cybersecurity think tank

21 Exact Sciences, Pfizer enter into U.S. promotion agreement for Cologuard

21 MD Anderson, Accelerator Life Science form Magnolia Neurosciences

21 UCLA awarded $9.3 million to help provide prostate cancer treatment

22 Ana María López to lead medical oncology at Sidney Kimmel

22 Noriega joins Fox Chase Division of Pulmonary and Critical Care

22 Yahanda, Loaiza-Bonilla receive promotions at CTCA

THE CLINICAL CANCER LETTER

CLINICAL ROUNDUP

23 NCCN publishes first U.S. guidelines for rare cancers associated with pregnancy

23 Collection of brain cancer data accessible to global researchers

24 Comprehensive CAR T-cell therapy pediatric guidelines developed

25 University of Maryland scientists to conduct first FDA-approved study of focused ultrasound to open blood-brain barrier

26 Liquid biopsy could ease the way to immunotherapy for lung cancer

DRUGS & TARGETS

27 Imbruvica + rituximab becomes first non-chemo combination for Waldenström's macroglobulinemia

27 FDA approves lenvatinib for unresectable hepatocellular carcinoma

28 Lenvima gets European approval for advanced, unresectable hepatocellular carcinoma

28 FDA approves pembrolizumab + chemo for first-line metastatic non-squamous NSCLC

28 FDA updates prescribing information for Keytruda, Tecentriq

29 Nivolumab gets accelerated approval for third-line metastatic small cell lung cancer

29 FDA approves Kyowa Kirin's Poteligeo for mycosis fungoides and Sézary Syndrome

THE CANCER LETTER | AUGUST 31, 2018 | VOL 44 | ISSUE 32

NIH DIRECTOR FRANCIS COLLINS TRICKED INTO DEBATING DISGUISED SACHA BARON COHEN ON SHOWTIME SPOOF "WHO IS AMERICA?"

By Paul Goldberg

Billy Wayne Ruddick Jr., Ph.D., is a character eerily reminiscent of someone we know, a distant relative who picks political fights on Facebook and Twitter.

He is a big guy with a sniveling smile and bad hair. He rides a motorized scooter with a paperback of Donald Trump's "The Art of a Deal" displayed in its front basket. He is certain that global warming is a politically correct hoax, that Hillary Clinton is secretly a man, that a dark plot is afoot to make everyone transgender, and that AIDS is a myth perpetuated by what in his rendition sounds like "*Big Phurmur.*"

His accent is vaguely Southern, but misspellings in his tweets and Facebook posts are vaguely Russian.

Realistic as Billy Wayne Ruddick Jr., Ph.D., might appear, he is a fictional character portrayed by Sacha Baron Cohen in "Who Is America?" a show that has just finished its first and possibly only season on Showtime.

Last November, Billy Wayne Ruddick Jr., Ph.D., rolled into the life of NIH Director Francis Collins, M.D., Ph.D., and their sit-down interview aired on Showtime on Aug. 18.

During the episode, Billy Wayne asks Collins to illuminate the conspiracy by Big Agriculture to make Americans transgender by feeding them trans fats.

If Collins smells a rat at this point in the conversation, he doesn't show it.

"Let me unpack the word 'trans,'" he begins patiently. "'Trans' just means it's across from. It's different-than. People talk about trans fats; it turns out those aren't particularly good for you, because they give you heart attacks."

BILLY WAYNE: Because of the shock of the gender change.

COLLINS: Because they influence this whole process of building up plaque in your arteries that gives you heart attacks and strokes. It has nothing to do with gender.

That settled, the conspiracy theorist confronts the NIH director with the results of his own experiment, which he says demonstrates that AIDS is nothing but a myth.

Billy Wayne says that he paid a homeless man with AIDS $12 to draw his blood, after which—using "exactly the same needle"—he drew his own blood. How about this: if you look at the two blood samples side by side, don't they look exactly the same?

Now, Collins, who shows no emotion through the "trans" question, seems to be visibly concerned. "Oh my, didn't you worry about using the same needle that had just been in his arm?" he says as his jaw drops.

BILLY WAYNE: I did it intentionally, so there would be no discrepancy and no dispute in the scientific community.

COLLINS: You just put yourself at risk.

BILLY WAYNE: Put myself at risk of what?

COLLINS: By sharing a needle with someone who is HIV positive.

In its seven episodes, "Who Is America?" did a great deal more than Trump-bashing. The Right got beat up; the Left got beat up; sundry celebs, picked for reasons other than politics, got beat up.

Some of Baron Cohen's targets richly deserved being provoked to reveal their true nature, and, of course, one might argue that Collins didn't deserve this nonsense.

Collins is no one's political stooge. In fact, he is the only remaining Obama administration presidential appointee to remain in office.

A facile speaker who knows what he is talking about, Collins is not known for gaffes. He is also a skilled performer. He has been seen playing guitar and singing his own material before large crowds at graduations and such.

However, his job description does include confronting nonsense—and, thanks to Sacha Baron Cohen and his scooter-winged conspiracy theorist, we got a robust demonstration of what a scientist should do when confronting stupidity—and, yes, evil.

Is it still true that as long as you keep your facts straight, stay consistent, say what you mean and mean what you say, it shouldn't matter much whether you are talking to a responsible journalist or an impostor?

Tempted by Billy Wayne Ruddick Jr., Ph.D., Collins has demonstrated that this notion still holds true.

As a result, Showtime viewers got their money's worth. Taxpayers got their money's worth, too.

AGE OF REASON (working title)

Some might argue that being pranked by Baron Cohen is an honor—unless, of course, you are tricked into making a fool of yourself.

Don't count on John Burklow, NIH associate director for communications, to agree with this argument.

NIH director Francis Collins tricked onto the set of Sacha Baron Cohen's "Who is America?

> Yeah, some people have said, 'Isn't this some kind of honor?' I think we'd both gladly go back in time and give that honor back to whoever gave that to us.
>
> *– John Burklow*

"Yeah, some people have said, 'Isn't this some kind of honor?'" Burklow said to The Cancer Letter. "I think we'd both gladly go back in time and give that honor back to whoever gave that to us, but, well, it really brings up the point: Okay, so what are we going to do now? Do we do things differently?

"I would say, admittedly, I'm a bit gun shy.

"But we're not going to slow down, we're not going to stop talking to reporters, talking to the media. And put it in perspective, Francis has done well over a thousand interviews since becoming NIH director nine years ago in August."

A conversation with Burklow appears on page 11.

Should the NIH press shop have been expected to catch this caper?

Based on interviews and documents The Cancer Letter obtained under the Freedom of Information Act, the answer tilts heavily toward No.

This story begins on Oct. 23, 2017, when a gentleman named Cory Nicks contacted NIH with this request:

His email follows:

Hello,

My name is Cory Nicks, and I am working on a new project to be aired on Showtime called AGE OF REASON (working title). Our show features conversations with distinguished experts in science and public policy, highlighting the brightest and most reputable minds our country has to offer. Our show has been picked up for 6 episodes, and we are currently in production.

Our project's goal is to cut through the noise and disinformation surrounding today's most important issues in a way that's clear and accessible to everyday Americans. By sharing the knowledge and insights of people like Mr. Collins, and institutions like the NIH, we hope to make a real difference in elevating these conversations with facts and reason.

As one of our country's most decorated and well-respected scientists, we'd be thrilled to have Mr. Collins on our program. We'd like to ask Mr. Collins questions about the NIH, the current research projects he's most excited about, his history with the Human Genome Project, and the relationship between science and religion.

We have already filmed with several prominent figures from the world of politics and public policy, as well as a Fortune 20 CEO, and leaders from the tech world. Sir Jony Ive is assisting with our project as well.

Our team is tentatively scheduled to shoot on Nov. 9th, 12th, and 14th. Would Mr. Collins have time to sit down with us on any of those dates? We'd love to have him for an hour, if possible, but would be grateful for any amount of time he can spare.

Please reach out with any questions, and I look forward to speaking with you soon.

Sincerely,
Cory Nicks
cory@hereandnowtelevision.com
323-761-3413

Showtime is not known for policy wonk shows like, say, NPR or BBC, but in today's media, it's not always easy to say who is who and who does what.

Light fact-checking was done: www.hereandnowtelevision.com was in existence, and Cory Nicks had a working phone.

In retrospect, the claim that "Sir Jony Ive is assisting with our project as well" might have been worth looking into.

But, really, who would lie about collaboration with Apple's design guru? That would be unethical, perhaps even DSMable.

Had Burklow known then what he knows now, he would have used the following search words: "Jony Ive, Sacha Baron Cohen," which would have produced an episode where the comedian brilliantly spoofs the cultish behavior of Apple crazies to describe his own artistic development.

Readers with a few minutes on their hands might wish to click here.

The NIH staff came back to AGE OF REASON with several follow-up questions:

Hi Cory-

Thanks for your email. We have a few follow up questions: Can you provide more details about the show? Will each episode focus on a specific topic? How long are the episodes? Will each episode feature interviews with multiple people, or only one person? Can you share the names of those you have interviewed?

To this Cory responded:

Thanks for getting back with me.

Each episode will be 30 mins, and will feature interviews with more than one person.

I'm not sure about the final creative edit, but I believe Mr. Collins will appear in the same episode with other luminaries from the worlds of health and science. It's also possible we may use footage from interview with Mr. Collins in more than one episode, depending on the breadth of the conversation,

I'm unable to share specific names of people we've already interviewed, but they include a former US Attorney General, a Fortune 20 CEO, multiple legislators, and an accomplished Silicon Valley entrepreneur, among others. For our upcoming D.C. swing, we are also working to schedule interviews with prestigious scientific organizations like NASA, the Smithsonian, etc.

Please let me know if you have any further questions, and I'd be happy to hop on a call with yourself and my senior producer at any time.

Thanks,
Cory

Collins showed up for filming a few minutes early and was brought into the impromptu studio.

Burklow showed up on time.

While his boss was facing five cameras and one idiot, Burklow interacted with an AGE OF REASON staff member, who gave her name as Julia Harris. This Julia Harris looked and acted like an associate producer from Central Casting, from whence she might well have come.

Collins didn't recognize the prank immediately. While it's relatively easy to recognize Baron Cohen's Borat, Brüno, and Ali G characters, the character of the conspiracy theory-spouting Billy Wayne Rudick Jr., Ph.D., wasn't publicly known to exist until the show's debut in July 2018, still about nine months away.

Also, the man's costume and makeup were convincing.

> While this wasn't a conventional forum for discussing public health, if it brings people into the conversation who otherwise wouldn't be, I find value in it.
>
> *– Jim Goodwin*

Baron Cohen portrays Billy Wayne Ruddick Jr., Ph.D., a conspiracy theorist.

Duped into hostile territory, smelling a rat (actually, a confederacy of rats), Collins decided to stay on message, keeping self-control, and not storming off the set, which would have made for better television. This lasted for about an hour.

For Collins, there was no joy in it.

"I got set up somehow," he said as he came out to the waiting area. The producers—including the nice Julia Harris—acted surprised.

"Oh gosh, what's wrong? What's wrong?" she said to Collins and Burklow.

After that, the www.hereandnowtelevision.com disappeared from the web, Cory Nicks's phone was disconnected, and Julia was gone. Collins and Burklow knew they were duped, but by whom, and how badly? All Burklow could do was subscribe to Showtime and wait.

The answer emerged on July 13, two days before "Who Is America?" aired. Former Alaska governor and former vice presidential candidate Sarah Palin went on national television to report that she had been tricked by Sacha Baron Cohen in his new television show.

"It was supposed to be this big-time Showtime documentary, and it was passed on to me by a speakers' bureau, which I would assume had done some vetting," Palin said. "But this—quote unquote—comedian is obviously very good at lying, at duping people."

This is, of course, true.

Tricking people is not okay in mainstream journalism. Your first step should be to state your name and affiliation.

However, anonymity, in addition to being one of the mainstays of the web, is a way to find out what people really think, whether ugliness and ignorance lurk in their souls—and how they perform in the face of things that are, well, very bad.

Granted, being duped is nightmare for a communications pro like Burklow. But was Collins harmed? He wasn't, not in the least—because he didn't allow that to happen.

"Dr. Collins handled this well, providing a great example for any physician-scientist being interviewed: no matter what, stay on message and don't say

Collins to Baron Cohen's character: "You just put yourself at risk. ... By sharing a needle with someone who is HIV positive."

things that can't be verified," Jim Goodwin, chair of the Public Affairs & Marketing Network of national cancer centers and associate director of strategic communication at Washington University Siteman Cancer Center, said to The Cancer Letter. "While this wasn't a conventional forum for discussing public health, if it brings people into the conversation who otherwise wouldn't be, I find value in it.

"The more people who know what physicians and researchers do for us, the better."

Jeffrey Molter, director of communications at NYU Perlmutter Cancer Center, agrees.

"I think Dr. Collins did a fine job of answering the questions posed to him by the interviewer, even though they were all very odd questions about health issues," Molter said to The Cancer Letter. "Dr. Collins remained calm and composed—and presented medical facts about some untrue assertions and provided some useful health education to viewers."

The Cancer Letter reached out to Showtime, twice via phone, once via email, but there was no response.

There were no burning questions, but it might have been nice to suggest that Baron Cohen send Collins an autographed screen grab depicting the NIH director struggling mightily to maintain composure as Billy Wayne Ruddick Jr., Ph.D., brandishes two "identical" blood samples.

Q & A

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

CONVERSATION WITH THE CANCER LETTER

It took an elaborate ruse to get NIH Director Francis Collins on Sacha Baron Cohen's "Who Is America?"

"He's going to keep taking opportunities to talk about NIH and how medical research affects people's lives. And we'll have to check the makeup better on the interviewers, but other than that we're going to keep going."

John Burklow
Associate Director for Communications, NIH

Intricate deception went into luring NIH Director Francis Collins onto Sacha Baron Cohen's television show.

A production company called Here and Now Television was created, as was its website. The show's working title was priceless, in an Orwellian sort of way: AGE OF REASON. It turned out to be Showtime's "Who is America?"

The production company staff members—presumably actors all—did considerable advance work, and did it well. Their letters were good enough to convince a seasoned professional, NIH Associate Director for Communications John Burklow, that the show is worth doing.

"Even though we were tricked into the interview, Francis really wasn't pranked, so to speak," Burklow said to The Cancer Letter. "I guess he was doing an interview [that was] not the type of interview he was expecting, but unlike some other guests that you've perhaps seen on the show, he didn't say or do anything embarrassing. It's just not in him, anyway. There was never any risk of that.

"But you still don't want to be the guy who puts your boss in front of Sacha Baron Cohen."

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

Paul Goldberg: I'm actually Paul Goldberg, and I'm actually calling from The Cancer Letter. I am not one of Sacha Baron Cohen's characters.

John Burklow: Thank you. That was my first question.

I am not him in disguise. Not that you'd see a disguise, because we're on the phone. So, your boss, Francis Collins, was just on "Who Is America?" What's that like?

JB: What's that like? Well, my first thought was, "So this is how my 30-year tenure at NIH ends."

Well, yeah. You have been doing this for a long time, and I've known you for all of those 30 years. You've been through some real silliness, and we've been through some real silliness together.

JB: Together, yes.

Is this the silliest thing that ever happened to you as a press dude?

JB: I think it rates right up there, if not takes the cake.

Cool

JB: Yes. An unforgettable experience, put it that way.

Yeah, yeah. But how did it happen?

JB: Yes, how did it happen… To back up, last October we got a request from a producer, who was working on a new program for Showtime, and it was called… well, the tentative name was "Age of Reason," and the stated goal was to present facts on important issues through conversations with experts in science and public policy in a way that's clear and accessible to everyday Americans.

And so, they asked if Dr. Collins would be interviewed by a Cory Nicks; not sure if that's a real name, producer for the project. And so, we thought, "Hmm, okay."

Now, you might think, "Showtime? Why talk to Showtime?"

Well, we've noticed over the last few years that more and more people are getting involved in doing policy shows about health and science. So, it wasn't that much out of left field. And also, the streaming companies like Netflix and Amazon were getting into this area.

Also, Dr. Collins feels strongly about communicating science to the public, to broader audiences. He's had a history of going on shows that you might not think conventionally, "Oh yeah, there's the NIH director."

For example, he's been on "Wait, Wait, Don't Tell Me" on NPR. Then there was the Colbert Report; he had been on several times. So, we were expecting a serious discussion about science and medicine in America.

We said, "Okay," and we scheduled the interview. It was mid-November. They had rented space down at the Hyatt Regency in Bethesda, which, again, this stuff happens. It's not that unusual.

What was unusual was that—and again, it didn't really strike me at the time—Dr. Collins and I came from two

different locations to meet up there. He got there earlier than I did.

And when I arrived, they said, "Oh. We took Dr. Collins up to the studio, and they're already taping."

And so, I said, "Well, can I go up there?"

And they said, "Well, this will be done pretty soon, so you won't be able to go in, because they have cameras and all that."

So, I thought, "Hmm, that's not usually how it works with me."

Everybody's very knowledgeable, people talking to me very professionally, and everything leading up to this didn't give us an inkling that there was anything awry or irregular.

They had a website, they had a production company, they had all this stuff lined up. They told us they'd interviewed other people, not mentioning Dick Cheney or Sarah Palin, but other more scientific types. And so, well, okay, I wait down in the lobby, waiting for Dr. Collins.

I'm talking with the producers, who, again, are very knowledgeable, polite. And I'm guessing they're either real producers or, in retrospect, hired actors. And I keep looking at my watch, and I keep wondering, "This is going overtime."

And I'm presuming, Oh, Dr. Collins must be enjoying his conversation, because he's going longer than expected.

So, he comes down finally from the studio, and he doesn't look pleased. He looks rather irritated. And Dr. Collins almost never looks irritated, so this is not a good sign. So, I go from, "Oh, day's going well," to "Oh my goodness."

And I'm sure those were the exact words I used, I don't know.

These specific words? I would have used different words.

JB: He said something went on there. He said, "I got set up somehow."

And the producers with us were looking upset, and, "Oh gosh, what's wrong? What's wrong?"

And so, we got out of there quickly, and then tried to follow up with Showtime, tried to follow up with the Here and Now Television Company producers... All those folks, they were accessible to us for a little while, and then, all of a sudden, we couldn't even have access to them.

So, they were pretty much a Potemkin village of production companies.

I don't know how they did it, but they pretty much ghosted us after the interview. We tried to follow up with Showtime, which we did, but they pretty much said, "That's showbiz."

So, that's last November, and we weren't too happy... Nobody's happy with being tricked.

But you didn't know you were tricked. You were still not clear on this being Sacha Baron Cohen?

JB: No, but Francis had a sense that something was going on, as he was-

The person—the character—Francis was talking to was an idiot. I mean beyond the usual, even.

JB: So, as he told me later, he said he was in the studio, and then a heavyset man with sideburns and a mustache comes in on a scooter that's usually associated with somebody who has disabilities, has trouble walking. And he comes in and introduces himself, and I'm sure that Francis is taken back a bit by, he wasn't expecting this person.

But he had been told up there that he'll be interviewed by somebody who doesn't know a great deal about his world, NIH, but is very interested in learning about it. So, that's how it was set up.

And so, Billy Wayne started with some very reasonable questions. And then they veered off into comments and questions that were anything but conventional or expected.

But the joke was to get him to answer some truly idiotic questions while trying to keep a straight face. Was there any point where he recognized that he's being pranked?

JB: Yes. He told me that at some point along the way he realized he was being pranked, or this was some kind of farce, but he had to decide, "Do I stand up and pull the microphone off and give them more to videotape? Or shall I just keep going with this and play it straight, and see perhaps even in spite of the absurd

circumstances, maybe I can get across some important information."

And so, even though we were tricked into the interview, Francis really wasn't pranked, so to speak. I guess he was doing an interview [that was] not the type of interview he was expecting, but unlike some other guests that you've perhaps seen on the show, he didn't say or do anything embarrassing. It's just not in him, anyway. There was never any risk of that.

But you still don't want to be the guy who puts your boss in front of Sacha Baron Cohen.

And also, I have to hand it to the makeup crew.

I never saw him, but just watching the shows, they did an incredible job disguising him. And Francis himself was saying that he knew who Sacha Baron Cohen was, but you know, he didn't start his day thinking, "I wonder if I'm going to be pranked by Borat later today."

He went in to do a serious discussion about science and medicine, to talk about how we fight cancer and heart disease and Alzheimer's, and so on.

So, it doesn't surprise me, but Francis stayed on message. It was like a study on how to stay on message in spite of all the absurdities that were thrown at him. What was captured was, as you've seen, their one ... Billy Wayne contended that the government was trying to turn everybody transgender through the use of trans fats in their food.

And, that's the other thing, Francis is always respectful, always compassionate, always caring. That's who he is. Francis wasn't playing any role, any character. Francis was being Francis. He is a concerned physician, as you can tell as the conversation goes on.

He's very seriously explaining trans fats and the difference, and how they have nothing to do with transgender.

And then they go to the topic of AIDS. And Billy Wayne explains how he paid a homeless man $12 so he could take some of his HIV-infected blood and then he used the same needle to get his own blood. And that's when Francis said, "What? What are you talking about? You put yourself at risk for contracting HIV?"

But throughout the whole piece, so when you look back, Francis could have been talking to somebody who was asking straightforward, normal questions, and he would have conveyed about the same information.

I guess what this says is that if you have an unwavering message, it's impossible to trick you. He came out of this really not looking stupid at all.

JB: I agree. I know I work for him, but I certainly do agree. Also, if you noticed, it wasn't a wooden performance of, "Okay, I'm going to go back to my main message now. I'm going to bridge back no matter what you said."

Francis had an authentic conversation and answered all of the crazy questions. So, he actually engaged fully in the discussion, but he stayed on message, because that's what he came to talk about, and that's who he is.

There was nothing that Billy Wayne was going to uncover about Francis, or Francis' motives. Francis was just who he was. He's there to tell you all about the latest in science and how it affects people's health.

I've never seen more idiotic questions than these. And the objective was just to look at his face as he says, "No, trans fats have nothing to do with transgender. No, you should not exchange needles in the name of science." What's really funny is that Francis is not shy—he sings in public even!

This must be kind of growing on him, like a badge of honor, you know?

JB: Yeah, I'm not so sure. Well, he knew what happened in the conversation, so he's not surprised that they were able to capture what he said. But I think he's relieved, as I am, that it's behind us.

“There was nothing that Billy Wayne was going to uncover about Francis, or Francis' motives. Francis was just who he was. He's there to tell you all about the latest in science and how it affects people's health.”

Yeah, some people have said, "Isn't this some kind of honor?"

I think we'd both gladly go back in time and give that honor back to whoever gave that to us, but, well, it really brings up the point: okay, so what are we going to do now? Do we do things differently?

I would say, admittedly, I'm a bit gun shy.

But we're not going to slow down, we're not going to stop talking to reporters, talking to the media. And put it in perspective, Francis has done well over a thousand interviews since becoming NIH Director nine years ago in August.

And he probably did thousands before that. And he's going to keep going. He's going to keep taking opportunities to talk about NIH and how medical research affects people's lives. And we'll have to check the makeup better on the interviewers, but other than that we're going to keep going.

Are you going to print out a screen grab and have Sacha Baron Cohen autograph it, so you can put it on the wall of respect? I think that would be a perfectly reasonable thing to do. I'm actually not making a joke.

JB: Yeah. Yeah. I hadn't explored that option. Yeah. I was thinking, if it happens again, perhaps he could come impersonating a reporter from PBS News Hour perhaps, or something, but that-

What about The Cancer Letter?

JB: Or The Cancer Letter. Right.

Please... PBS... But, actually, as far as I'm concerned Sacha Baron Cohen is doing journalism. It's another way of doing journalism. It's an unconventional way of doing journalism, but he's getting people to respond, to reveal things beneath the surface, beneath the facts. My hat's off to him as a reporter.

JB: Yeah. Well, I'm probably not the best person to ask right now, but I have to say that he revealed what Francis had to say. Francis came in there to talk about health and science. Not just to talk about it, but if you watch how Francis engaged him, no matter what the man asked, Francis treated it like a logical, reasonable question.

And he answered it respectfully. And he was very concerned, especially when he heard that he shared a needle.

Right, right. That's really an absolutely incredible story. When did you first figure out it was Sacha Baron Cohen?

JB: I guess it was early July. I was talking to some of my colleagues here on staff, and I said, "I wonder what ever happened with that Showtime piece?" And I looked down on my phone, and Francis had sent me a note and said, "Was this possibly what I was part of?"

And we all saw it at the same time ... because it popped up on my phone as well ... the reports of Sarah Palin complaining that she was on the show. Or she was tricked into being on the show.

And so, that's how we learned that, because she said that the character being Billy Wayne interviewed her. And that was a forehead-slapping moment for me. Oh, gosh. We've been punk'd by none other than Sacha Baron Cohen.

Well that's, again, an honor. But what's really hilarious is that the joke's on the character who's doing the interview. This is not the first conspiracy theorist that Francis ever saw.

JB: Right. And this was just a small segment of a longer conversation. Francis had to field all kinds of these questions and assertions.

Another one he told me, he said, was, Billy Wayne asserted that vaccines are dangerous. His son was in a car accident on his way to getting his flu shot. But he made the conclusion that since he was in a car accident, it was ... it was almost like Henny Youngman jokes.

Well, but this is actually scary. Because how close is he to some of the folks that you run into all the time? I've written stories about people who said that there's no such thing as AIDS. So, it's not like we're completely in the world of hyperbole.

JB: No, I think that's an excellent point, that even though we might say, "Oh, trans fat, transgender." But it's really important to remind people, "No, those two things do not have anything in common, other than they start with 'trans.'" It's important to say, "Yes, AIDS

does exist. HIV does exist, and it's important not to share needles."

So, all the things you might take for granted that it's already commonly known, it's actually important to re-emphasize those messages.

And storming out would have been an absolutely disastrous act, which I guess they were hoping for.

JB: I don't know. The last words I heard from the person posing as the production assistant said that, "We will not put Dr. Collins or NIH in a negative light." And I thought, "Okay, well, let's see."

So, I had to subscribe to Showtime, and I'm watching every Sunday... there was a pit in my stomach as each Sunday night approached. And he didn't appear until the sixth of seven episodes.

And as I'm watching the others, I'm thinking, "Well at least he didn't do this. At least he didn't do that." But still—

I don't think Francis could have done what other Baron Cohen guests did.

JB: No, there's no way. No way. I wasn't afraid that he was going to do any of those things. It's just that you start thinking, "Okay. I'm sure it went well."

But I still didn't know, because I hadn't seen it.

I was kept out of the room.

Senate spending bill gives NIH $2 billion raise

By Paul Goldberg

The US Senate Aug. 23 passed a spending bill that will increase the NIH budget by $2 billion to $39.1 billion—a 5.4 percent boost over the current level.

Of the proposed $2 billion, $190 million in new money would trickle down to NCI.

NCI is slated to receive $5.747 billion, of which up to $30 million may be used for facilities repairs and improvements at the NCI—Frederick Federally Funded Research and Development Center.

The House version of the Labor-HHS spending bill proposes a $1.25 billion increase for NIH, bringing the total to $38.3 billion.

"Last week's passage of the combined Labor-HHS-Education and Defense Appropriations bills in the Senate was a great accomplishment for our policymakers in the Upper Chamber, especially when considering that it's the first time in a decade that the full Senate debated and passed the Labor-HHS-Education Appropriations Bill," said Jon Retzlaff, chief policy officer and vice president of science policy and government affairs of the American Association for Cancer Research.

"The debate and overwhelming vote in favor of these two bills that were grouped together also underscores the Senate's commitment to providing robust, sustained, and predictable annual funding increases for the National Institutes of Health. "In fact, if the $2 billion increase that's been proposed for NIH in FY 2019 becomes law, it would translate to a 30 percent increase for the NIH since FY 2016," said Retzlaff.

"We sincerely hope that this action in the Senate will provide lots of positive momentum for the Senate lawmakers as they enter into conference negotiations with their House counterparts to reconcile the Labor-HHS-Education bills, especially since lawmakers will only have roughly five weeks to hash out differences in the competing versions of the measures if they hope to avoid a short-term continuing resolution."

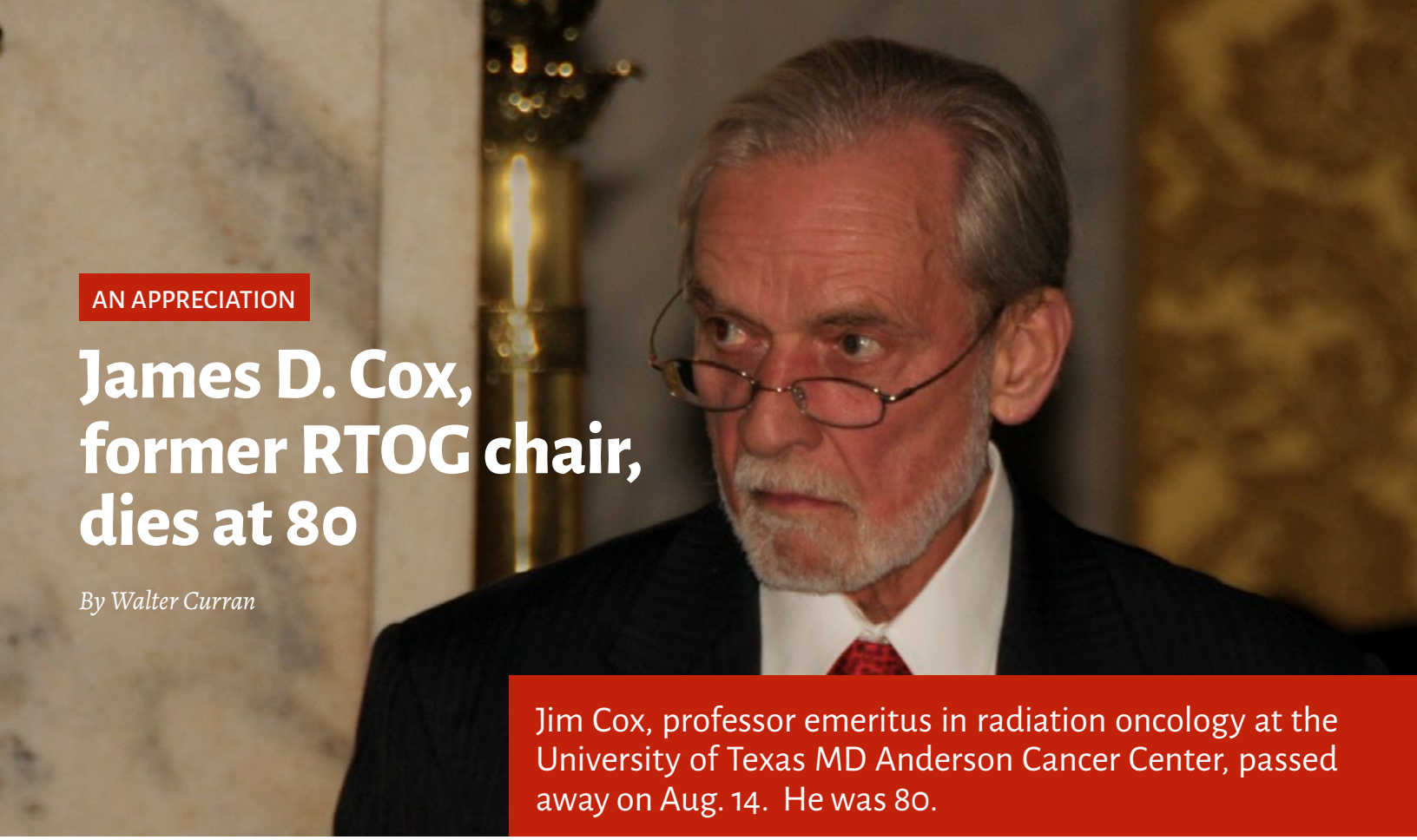
The president's budget proposal initially sought to cut NIH budget by 27 percent, but after Congress raised the spending caps, the White House largely reversed the cut, adding back $9 billion, thereby bringing NIH funding back to the FY 2017 level (The Cancer Letter, Feb. 16).

Here is how the numbers line up for NCI:

- In the Senate bill, NCI stands to receive $6.15 billion, with $400 million in Cancer Moonshot funds coming from the NIH Innovation Account. The bill also includes $30 million for NCI's facility in Frederick.
- In the House bill, NCI would receive $6.13 billion, also with the Moonshot included.
- Under the White House proposal, NCI would get $5.626 billion. This number, too, includes the Moonshot.

The 2019 appropriations package passed by an 85 to 7 vote.

"The last time that the Senate passed nine appropriations bills by the end of August was 1999," Richard Shelby (R-Ala.), chairman of the Senate Committee on Appropriations, said in a statement. "We collectively called earlier this year for a return to regular order in the appropriations process because it was broken, and the leaders on both sides—Sen. [Mitch] McConnell [(R-KY)]and Senator [Chuck] Schumer [(D-NY)]—provided us the opportunity to follow through."



AN APPRECIATION

James D. Cox, former RTOG chair, dies at 80

By Walter Curran

Jim Cox, professor emeritus in radiation oncology at the University of Texas MD Anderson Cancer Center, passed away on Aug. 14. He was 80.

A native of Ohio, Jim graduated with honors from Kenyon College and University of Rochester School of Medicine and Dentistry and completed his oncology training at Penrose Cancer Hospital of Colorado Springs, University of Chicago, and Institute Gustav Roussy Institute in France.

Jim served during his long and illustrious career as professor and founding chairman of the departments of radiation oncology at Medical College of Wisconsin and Columbia University College of Physicians and Surgeons and as professor, physician-in-chief, and division of radiation oncology head at UTMDACC.

In each of these roles, Jim had extraordinary success in mentoring younger physicians, elevating the care of cancer patients and the associated clinical and translational research, and establishing a culture of collaborative inquiry among his colleagues.

I personally came to know Jim best during his tenure (1987-1997) as Group Chairman of the Radiation Therapy Oncology Group. RTOG was at that time one of ten NCI-supported cooperative groups and was struggling in the late 1980's with its identify and core research mission.

Jim significantly expanded the core membership of RTOG to include surgeons, medical oncologists, medical physicists, translational and computational scientists, and international investigators.

The group became one of the first truly multi-disciplinary cooperative groups and began to more fully fulfill its mission of improving the lives of adults with localized or locally advanced malignancies through the conduct of its clinical trials.

I had the honor of serving as the RTOG Brain Tumor Committee Chairman and RTOG Deputy Group Chairman during the latter years of Jim's term as Group Chairman and succeeding him in that role.

Jim was an extraordinary mentor for me and for literally hundreds of other professionals he touched during his career. He had a very intuitive feel as to when to step back and when to push and when to shout out and when to remain silent, whether the issue was with other investigators, other cooperative groups, staff, or the NCI.

He was invaluable as RTOG Past Group Chairman to the group in strategizing as to how to successfully function as an undercapitalized, underappreciated research organization through a highly politicized environment.

Jim had a wonderful sense of humor, smile, and laugh, and the most melodious public speaking voice this side of Humphrey Bogart. He loved all things French and all the richness that travel and arts can bring to a great life. He was devoted to and is survived by his wife and colleague Ritsuko Komaki, MD, his children Lara and Christoph Cox, and his five grandchildren.

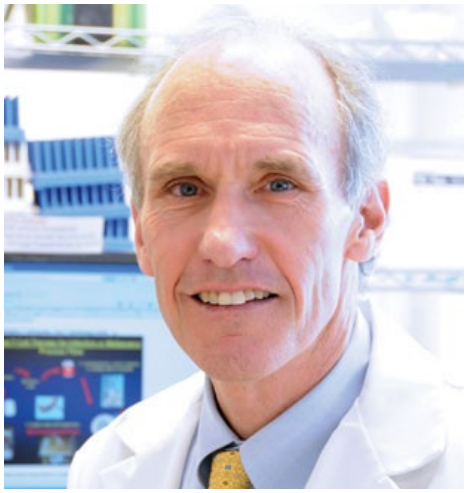
The author is the group chairman and principal investigator of NRG Oncology, formerly the Radiation Therapy Oncology Group, and executive director of Winship Cancer Institute of Emory University

IN BRIEF

Rosenberg, June and Allison share 2018 Albany Prize

Steven Rosenberg, Carl June and James Allison received the 2018 Albany Medical Center Prize in Medicine and Biomedical Research.

- Rosenberg is chief of the surgery branch at NCI.



- June is director of the Center for Cellular Immunotherapy at the Abramson Cancer Center at the University of Pennsylvania.

- Allison is chair of the Department of Immunology at MD Anderson Cancer Center.

The $500,000 award has been given annually since 2001 to "those who have altered the course of medical research."

A statement from the Albany Medical Center said the "awardees were chosen to receive the 2018 Albany Prize for their groundbreaking research in immunology, the translation of their ideas into clinically meaningful therapies for diseases, including metastatic melanoma, lung cancer and leukemia, and their leadership in moving the field of immunotherapy forward."

"We congratulate these amazing scientists for receiving this prestigious award. Their visionary work exemplifies the value of the national cancer program. Each has had a long history of NCI support and I celebrate their achievement," NCI Director Ned Sharpless said in a statement. "Dr. Rosenberg is a pioneer whose immunotherapy work has advanced cancer treatment to an immeasurable degree. His innovations have changed patients' lives."

Vincent Verdile, the Lynne and Mark Groban Distinguished Dean of Albany Medical College and chair of the Albany Prize National Selection Committee, said that "because of the work of these three researchers, the nascent field of immunotherapy has already had spectacular success, leading to effective mitigation and often cures for thousands of cancer and HIV patients whose diseases were not treatable by other methods."

The prize will be awarded during a celebration on Sept. 26, in Albany.

Karen Knudsen named AAACI president-elect

Karen Knudsen, enterprise director of the Sidney Kimmel Cancer Center–Jefferson Health, was elected vice president/president-elect of the Association of American Cancer Institutes' board of directors.

Knudsen, who has been serving as SKCC enterprise director since 2015, governs cancer research and cancer care across 14 hospitals within Jefferson Health.

Under Knudsen's leadership, SKCC recently was evaluated as "Outstanding" in its most recent NCI Cancer Center Support Grant renewal. It was one of only three cancer centers to rank "Exceptional" by the NCI for Community Outreach and Engagement.

Knudsen is also the Hilary Koprowski Chair, Department of Cancer Biology at Thomas Jefferson University, and Professor of Cancer Biology, Urology, Medical Oncology, and Radiation Oncology. Her translational research centers on prostate cancer and has contributed to new mechanisms for treatment of advanced disease.

A member of AACI's board of directors since 2016, Knudsen was program chair of the association's 2017 annual meeting. She also serves on review, advisory, and elected panels for the NIH, Department of Defense, American Society of Clinical Oncology, American Association for Cancer Research, and is editor-in-chief of the journal Molecular Cancer Research.

Knudsen's two-year term will begin Sept. 30 during the AACI/Cancer Center Administrators Forum annual meeting in Chicago.

Cory Wiegert named CEO of CancerLinQ LLC

Cory Wiegert was named chief executive officer of CancerLinQ LLC, a non-profit subsidiary of the American Society of Clinical Oncology.

Wiegert most recently served as vice president of product management for IBM Watson Health. He led the launch of major projects, including IBM's first cloud-based offerings in healthcare and the creation of new solutions from the integration of several major acquisitions.

Prior to joining IBM, Wiegert held positions with Sterling Commerce, Siebel Systems, Inc., Centura Software Corporation, and Safety-Kleen.

CancerLinQ is a big data initiative that collects and analyzes data fromcancer patients at practices nationwide, drawing from electronic health records, to inform and improve the quality of cancer care. The effort has two major components: 1) the CancerLinQ quality improvement and data-sharing platform for oncology practices, and 2) CancerLinQ Discovery, which provides access to high-quality, de-identified datasets derived from the patient data to academic researchers, non-profit organizations, government agencies, industry, and others in the oncology community.

The CancerLinQ database contains more than a million cancer patient records, making it one of the largest and most comprehensive data sets of its kind. In addition, CancerLinQ LLC has established a number of collaborations with government and nonprofit entities—including American Society of Radiation Oncology, FDA, and NCI—as well as industry through its collaborators AstraZeneca, Tempus, and Concerto HealthAI.

Wiegert replaces Richard Schilsky, who was serving as interim CEO of CancerLinQ. Schilsky will continue his role as ASCO's chief medical officer.

Moffitt's chief information security officer named fellow to America's cybersecurity think tank

Moffitt Cancer Center's chief information security officer will join a group of experts charged with protecting and enhancing national cybersecurity.

Dave Summitt has been named a Fellow of the Institute for Critical Infrastructure Technology, the nation's leading cybersecurity think tank.

The institute focuses on safeguarding national security, economic security, and national public health and safety under the Department of Homeland Security. As an ICIT Fellow, Summitt will share his expertise with the cyber and national security community by participating in thought leadership and educational engagements.

ICIT provides objective, nonpartisan advisory to the Senate, House of Representatives, and federal government leaders in civilian, defense and intelligence agencies. Research conducted in ICIT's labs, and distributed through its publications, is used by United States leaders, embassies, allied governments, and critical infrastructure operators around the globe.

Summitt has been with Moffitt since 2015. He has more than 30 years of experience in the technology field, with over 13 years working directly in cybersecurity.

Exact Sciences, Pfizer enter into U.S. promotion agreement for Cologuard

Exact Sciences Corp. and Pfizer Inc. announced an agreement through 2021 to co-promote Cologuard, the only FDA-approved non-invasive stool DNA screening test for colorectal cancer. Pfizer will join the Exact Sciences sales representatives in reaching both physicians and health systems and will also actively participate in extending and deepening the Cologuard marketing campaign.

Exact Sciences brings a sales force with expertise in colorectal cancer, the innovative science of Cologuard and a recognizable direct-to-consumer marketing campaign. Pfizer brings a large and experienced sales force and relationships integrating with the leading health systems, two areas where Cologuard is most often prescribed.

Under the agreement, Pfizer will co-promote Cologuard with Exact Sciences beginning in the fourth quarter of 2018. Exact Sciences will maintain responsibility for all aspects of manufacturing and laboratory operations of Cologuard. Pfizer will share gross profits and marketing expenses equally above an agreed upon baseline.

Cologuard was approved by the FDA in August 2014 and results from Exact Sciences' prospective 90-site, point-in-time, 10,000-patient pivotal trial were published in the New England Journal of Medicine in April 2014. Cologuard is included in the American Cancer Society's 2018 colorectal cancer screening guidelines and the 2016 recommendations of the U.S. Preventive Services Task Force and National Comprehensive Cancer Network.

Cologuard is indicated to screen adults of either sex, 50 years or older, who are at typical average-risk for CRC. Cologuard is not for everyone; not for high risk individuals, including those with a family history of colorectal cancer, a personal history of cancer or advanced adenoma, IBD, and certain hereditary syndromes. Positive Cologuard results should be referred to diagnostic colonoscopy.

MD Anderson, Accelerator Life Science form Magnolia Neurosciences

MD Anderson Cancer Center and Accelerator Life Science Partners announced the launch of Magnolia Neurosciences Corp., a company developing a new class of neuroprotective medicines, with $31 million in Series A funding. The company will develop novel therapeutics based on discoveries made by researchers in MD Anderson's Therapeutics Discovery division, including the Institute for Applied Cancer Science and the Neurodegeneration Consortium.

Magnolia Neurosciences will focus on neurodegenerative conditions, such as Alzheimer's disease and chemotherapy-induced neuropathy in cancer patients.

More than 200,000 patients each year suffer from a condition known as "chemobrain," characterized by general cognitive and memory problems, which can last for years. Additionally, roughly two-thirds of patients undergoing chemotherapy treatment develop peripheral neuropathy, in which nerve damage causes pain, numbness and tingling in the hands and feet.

Neurodegenerative diseases include a range of conditions characterized by progressive deterioration of neurons in the human brain. These conditions affect millions of Americans and are largely untreatable.

The NDC is a multi-institutional initiative launched to better understand the biology of neurodegenerative diseases and translate that knowledge into effective therapeutics interventions.

Established in 2012 by an inaugural $25 million gift from the Robert A. and Renee E. Belfer Family Foundation, the NDC brings researchers from Baylor College of Medicine, the Massachusetts Institute of Technology and the Icahn School of Medicine at Mount Sinai together with drug discovery and development experts from MD Anderson's Therapeutics Discovery division.

Investors participating in the $31 Million Series A financing include AbbVie Ventures, Alexandria Venture Investments, ARCH Venture Partners, Eli Lilly and Company, Innovate NY Fund, Johnson & Johnson Innovation – JJDC, Inc., the Partnership Fund for New York City, Pfizer Ventures, Watson Fund, L.P., WuXi AppTec's Corporate Venture Fund and 180 Degree Capital Corp.

UCLA awarded $9.3 million to help provide prostate cancer treatment

Members of the UCLA urology department received $9.3 million of funding from the state of California to help combat the financial burden of cancer treatment for men diagnosed with prostate cancer.

During the next three years, the award will directly support the 17-year-old IMPACT program, which stands for Improving Access, Counseling and Treatment for Californians with prostate cancer.

Mark Litwin, professor of urology in the David Geffen School of Medicine at UCLA and a member of UCLA Jonsson Comprehensive Cancer Center, and his team have led the efforts of the state-funded program that provides free, high-quality prostate cancer treatment to California men who are underinsured or uninsured.

While more people are signing up for health insurance, many cannot afford the costs of important health care services, especially when it comes to cancer treatments. More than one-third of insured people who have cancer and are receiving some type of therapy for their disease face out-of-pocket costs that are far greater than expected, with some paying almost one-third of their income in health care-related costs. This number is even higher for those at or below the federal poverty level.

Along with providing comprehensive care to a population that would otherwise go without, the program combines health care and public health approaches to treating the whole patient. IMPACT promotes increased self-efficacy, knowledge, and health literacy through its clinical team model, in which each patient is paired with a nurse case manager to assist with their care coordination and management.

To date, more than 2,200 men have enrolled and received prostate cancer treatment services under the IMPACT Program. Backed by more than $85 million in support from the California Department of Health Care Services since it began, IMPACT contracts with more than 600 health care providers across the state who treat men enrolled in the program, as well as with mental health professionals, local health departments, hospitals, outpatient facilities, pharmaceutical companies and others for the additional services patients need.

"Since the Affordable Care Act was passed, everybody thinks everybody is insured," said Laura Baybridge, the IMPACT program's original administrator and currently the chief administrative officer for the urology department. "What they don't recognize is that even though someone is insured, it doesn't mean they can afford their out-of-pocket expenses. We're finding people simply can't afford their insurance, so we really want those patients that don't have a safety net to call and to get enrolled."

Ana María López to lead medical oncology at Sidney Kimmel

Ana María López joined the Sidney Kimmel Cancer Center–Jefferson Health as the vice chair of medical oncology and chief of cancer services at the Sidney Kimmel Cancer Center–Washington Township.

López comes from the Huntsman Cancer Institute in Salt Lake City, where she was director of Cancer Health Equality, in addition to associate VP for Health Equity and Inclusion at the University of Utah Health; associate director of Collaboration and Engagement Services at the Utah Center for Clinical and Translational Sciences; and professor of medicine at UU School of Medicine.

She is an expert in breast and gynecological cancers, integrative medicine, telehealth and cancer disparities. Currently she is president of the Philadelphia-based American College of Physicians, which is the largest medical specialty organization in the United States. Additionally, her strong commitment to cancer disparities is reflected in her leadership of the American Society of Clinical Oncology committee on cancer disparities.

López will be based out of SKCC in Center City until the New Jersey site is remodeled. Once she moves into the new site, she will continue to collaborate with research and physician teams throughout the Sidney Kimmel Cancer Center Network and will still spend some days in Center City.

Noriega joins Fox Chase Division of Pulmonary and Critical Care

Fox Chase Cancer Center has hired Julio Noriega as an assistant professor in the Division of Pulmonary, Critical Care, and Sleep Medicine.

Noriega comes to Fox Chase from the University of Iowa Hospitals and Clinics, where he completed fellowships in both pulmonary medicine and critical care. He is board-certified in internal medicine and earned his medical degree and completed a residency in internal medicine at the Indiana University School of Medicine.

Yahanda, Loaiza-Bonilla receive promotions at CTCA

Cancer Treatment Centers of America Global Inc. announced enterprise-wide promotions:

Alan Yahanda, chief of staff at CTCA–Atlanta was promoted to chair of the Department of Surgery,

Arturo Loaiza-Bonilla, chief of medical oncology and medical director of research at CTCA Philadelphia was named vice chair of the Department of Medical Oncology.

THE CLINICAL CANCER LETTER

CLINICAL ROUNDUP

NCCN publishes first U.S. guidelines for rare cancers associated with pregnancy

The National Comprehensive Cancer Network has released new treatment guidelines for a group of rare cancers that impact women during pregnancy. Gestational trophoblastic neoplasia, also known as gestational trophoblastic disease, can occur when tumors develop in the cells that would normally form the placenta during pregnancy.

It happens in approximately one out of every 1,000 pregnancies in the U.S., though it is more common in many Asian and African countries. Due to the rare nature of this condition, and the small number of specialists worldwide, providers often are not aware of how to provide the best care for people with GTN.

"These guidelines are sorely needed," explained David Mutch, Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine, who leads the NCCN Clinical Practice Guidelines in Oncology Committee for GTN. "By compiling expert consensus, we can standardize the way this uncommon disease is treated. When treated properly, GTN can almost always be cured, but deviating from that standard can have severe consequences. Plus, by providing clear instructions for how best to treat GTN, we can streamline the insurance approval process for more efficient care."

The NCCN Guidelines for GTN details treatments for several variations of the disease. For molar pregnancy (also known as a hydatiform mole, a rare mass that can form inside the womb during early pregnancy, resulting in an abnormal fetus), surgery is the first, and often only treatment required. It is generally performed via suction dilation and curettage.

Low-risk GTN is primarily treated with single-agent chemotherapy, although additional chemotherapy or surgery may be required for persistent disease. With high-risk GTN, treatment typically involves multiagent chemotherapy, with possible radiation therapy for brain metastasis. Surgery can be used for chemotherapy-resistant disease.

Mutch was joined on the GTN Committee by John Lurain, Robert H. Lurie Comprehensive Cancer Center of Northwestern University and R. Kevin Reynolds, University of Michigan Rogel Cancer Center.

The committee is a subset of the larger NCCN Guidelines Panel for Cervical, Uterine, and Vulvar Cancers, of which all three are members.

The NCCN Guidelines for GTN bring the total number of NCCN Guidelines to 72. They are available free-of-charge online at NCCN.org or via the Virtual Library of NCCN Guidelines mobile app for smartphones and tablets.

Collection of brain cancer data accessible to global researchers

A cache of brain cancer biomedical data has been made freely available to researchers worldwide, say researchers at Georgetown Lombardi Comprehensive Cancer Center. The dataset, Repository for Molecular Brain Neoplasia Data, also known as REMBRANDT, hosted and supported by Georgetown, is one of only two such large collections in the country.

Information about the brain cancer data collection, which contains information on 671 adult patients collected from 14 contributing institutions, is detailed in Scientific Data, an open-access journal.

Already, thousands of researchers in the U.S. and internationally log on to the data site on a daily basis, and word about the resource is expected to increase its use, says Subha Madhavan, chief data scientist at Georgetown University Medical Center and director of the Innovation Center for Biomedical Informatics at Georgetown Lombardi.

The Georgetown data resource is unique in several ways. One is that it

contains genomic information, collected from volunteer patients who allowed their tumors to be sampled, as well as diagnostic (including brain scans), treatment and outcomes data. Most collections contain either one or the other.

"We want this data to be widely used by the broadest audience — the entire biomedical research community — so that imagination and discovery is maximized," says first author on the paper Yuriy Gusev, associate professor and a faculty member of the ICBI. "Our common goal is to tease apart the clues hidden within this biomedical and clinical information in order to find ways that advance diagnostic and clinical outcomes for these patients."

The REMBRANDT dataset was originally created at the National Cancer Institute and funded by Glioma Molecular Diagnostic Initiative led by co-authors Howard Fine, from New York Presbyterian Hospital, and Jean-Claude Zenklusen, from the NCI. They collected the data from 2004 to 2006.

NCI transferred the data to Georgetown in 2015, and it is now physically located on the Georgetown Database of Cancer, a cancer data integration and sharing platform for hosting alongside other cancer studies. G-DOC investigators, led by Madhavan, developed novel analytical tools to process the information anew.

The genomic data includes the specific genes within individual tumors that are either over-expressed or under-expressed as well as the number of times that gene is repeated within a chromosome. The data collection also includes information on RNA.

REMBRANDT includes genomic data from 261 samples of glioblastoma, 170 of astrocytoma, 86 tissues of oligodendroglioma, and a number that are mixed or of an unknown subclass. Outcomes data include more than 13,000 data points.

Additional co-authors of the work are Krithika Bhuvaneshwar, from Georgetown and Lei Song, from the National Cancer Institute.

Georgetown has filed a patent application related to G-DOC technology. Madhavan is the named inventor of the intellectual property protected.

The project was funded by the Georgetown Lombardi cancer center support grant (P30 CA51008) and a contract from the NCI to migrate the Rembrandt dataset to G-DOC.

Comprehensive CAR T-cell therapy pediatric guidelines developed

Almost one year after FDA approval of chimeric antigen receptor T-cell therapy for children with acute lymphoblastic leukemia, researchers at MD Anderson Cancer Center and the Pediatric Acute Lung Injury and Sepsis Investigators Network published treatment guidelines for managing the treatment in the online issue of Nature Reviews Clinical Oncology.

These guidelines outline lessons learned by leading experts in various fields to identify early signs and symptoms of treatment-related toxicity and detail ways in which to manage it.

The FDA approved the first CAR T-cell therapy for children and young adults with ALL last year. Ongoing research aims to expand its use for other cancers.

"CAR T-cell therapy has been associated with remarkable response rates for children and young adults with ALL, yet this innovative form of cellular immunotherapy has resulted in unique and severe toxicities which can lead to rapid cardiorespiratory and/or neurological deterioration," said Kris Mahadeo, associate professor of Pediatrics and Chief of Stem Cell Transplant and Cellular Therapy at MD Anderson. "This novel therapy requires the medical vigilance of a diverse multi-disciplinary team and associated clinical infrastructure to ensure optimal patient outcomes."

As CAR T-cell therapy becomes more widely used, treatment guidelines, comprehensive training of multi-disciplinary staff, and other measures should facilitate the appropriate management of toxicities that may occur following this new treatment, Mahadeo said.

MD Anderson's CAR T-cell-therapy-associated Toxicity program collaborated with PALISI and its Hematopoietic Stem Cell Transplantation sub-group in creating the comprehensive guidelines for treating children with cancer receiving CAR T-cell therapy.

By bringing together experts from many areas, including pediatric intensivists, pharmacy, neurology, and translational immunotherapy research, the guidelines offer key learnings to providers and aim to help improve the patient experience and outcome.

"CARTOX, which oversees care for MD Anderson CAR T-cell therapy patients, is the first stand-alone immune effector cellular therapy program to earn accreditation from the Foundation for the Accreditation of Cellular Therapy," said Elizabeth Shpall, professor of Stem Cell Transplantation and Cellular Therapy and one of the senior authors on the Natures Reviews Clinical Oncology paper. "The program provides oversight for more than 20 active immune effector cell research protocols and two approved standard of care therapies at MD Anderson, and it is clear these new guidelines will serve

as an important new model for care of CAR T-cell patients."

In 2017, MD Anderson's CARTOX Program published guidelines in Nature Reviews Clinical Oncology on management of adult patients receiving CAR T-cell therapy. However, early signs and symptoms of toxicity in children brought attention to pediatric-specific monitoring including escalation of care based on parent and caregiver concerns.

Some examples of the recommendations include:

- Monitoring for cytokine release syndrome using pediatric normal ranges for organ function.
- Promptly addressing parent and/or caregiver concerns as early signs or symptoms of CRS can be subtle and best recognized by those who know the child best.

MD Anderson team members who collaborated on development of the guidelines included Elizabeth Shpall; Katy Rezvani; and Partow Kebriaei; all of the Department of Stem Cell Transplantation and Cellular Therapy; Sattva Neelapu, of the Department of Lymphoma and Myeloma; Sajad Khazhal; David McCall; Demetrios Petrepolous; Joan O'Hanlon Curry; Sarah Featherston; Jessica Fogelsong; Lisa Hafemeister; Cathy Nguyen; Rodrigo Mejia; and John Slopis; all of the Division of Pediatrics; and Alison Gulbis; and Maria Mireles; of the Department of Pharmacy.

Other participating institutions included the Keck School of Medicine, University of Southern California, Los Angeles; University of Pennsylvania Perelman School of Medicine, Philadelphia; University of Washington Seattle Children's Hospital; George Washington University and Children's National, Washington D.C.; Baylor College of Medicine, Houston; Dana-Farber Cancer Institute, Harvard University, Boston; Weill Cornell Medical College Presbyterian Hospital, New York; University of Minnesota Masonic Children's Hospital, Minneapolis; Duke Children's Hospital, Duke University, Durham, N.C.; Nationwide Children's Hospital, Ohio State University, Columbus; St. Jude's Children's Research Hospital, Memphis, Tenn.; and Children's Hospital at Montefiore, Albert Einstein College of Medicine, Bronx, N.Y.

University of Maryland scientists to conduct first FDA-approved study of focused ultrasound to open blood-brain barrier

In the first such clinical trial in the United States, physician-scientists with the University of Maryland School of Medicine are investigating the use of MRI-guided focused ultrasound to open the blood-brain barrier. The trial will be conducted with patients undergoing brain cancer surgery at the University of Maryland Medical Center.

While this network protects the brain, it also limits doctors' ability to deliver effective doses of disease-fighting drugs to the brain, particularly in the case of brain tumors, which are notoriously treatment-resistant. This safety and feasibility study is a first step in attempting to overcome a major hurdle in treating these often-deadly cancers.

"The ability to temporarily disrupt the blood-brain barrier without causing tissue damage has the potential to dramatically alter the landscape of drug delivery to the brain for many diseases," said Graeme Woodworth, principal investigator, professor of neurosurgery at UMSOM and director of the Brain Tumor Treatment and Research Center at the University of Maryland Marlene and Stewart Greenebaum Comprehensive Cancer Center at UMMC.

"If successful, this approach would allow us to use chemotherapy and other therapies in the brain in ways that are currently not possible," said Woodworth, noting that 98 percent of currently approved drugs don't enter the brain because of the blood-brain barrier. "If we can selectively open the blood-brain barrier, then in the future we could give a much lower dose of powerful drugs, which would likely reduce toxic side effects and make treatments safer and more effective for patients."

The process involves injecting microscopic inert gas-filled bubbles into a patient's bloodstream and then oscillating the microbubbles with highly targeted sound waves, stretching the blood vessel walls to create temporary openings.

FDA approved the clinical trial in October 2017 after a lengthy review process. Although there are similar research studies in Canada and other countries, this was the first time the FDA approved a clinical study using this promising technology and approach.

Within a few months, University of Maryland researchers expect to open another FDA-approved clinical trial in which newly diagnosed glioblastoma patients will undergo blood-brain barrier opening prior to treatment with standard chemotherapy, temozolomide. This new ultrasound-augmented approach would target the areas where tumor recurrence would be most likely to occur.

In the initial study, researchers plan to enroll up to 15 patients with suspected glioblastoma, an aggressive brain cancer, who will undergo surgery at UMMC to remove their tumor.

The morning of the scheduled surgery, patients will undergo a standard mag-

netic resonance imaging scan as part of the preoperative planning process. Guided by this MRI, doctors will target a precise region within the tumor with ultrasound, while the injected microbubbles are circulating within the bloodstream.

The microbubbles will oscillate within the ultrasound field, causing temporary openings in the walls of the brain blood vessels, and allowing the MRI contrast agent, gadolinium, to pass into the brain tissue. The MRI scan will then be completed, documenting the extent to which the blood-brain barrier was disrupted.

The data from the MRI will be used in a system called intraoperative stereotactic neuro-navigation – an advanced 3D-guidance system that accurately localizes the tumor within the brain. After the surgery, researchers will also rigorously examine the tissue that was removed to study the potential therapeutic and other effects from the focused ultrasound procedure.

In this initial trial, the increased amount of contrast enhancement within the tumor provided by the focused ultrasound procedure may help the 3D navigation during the surgery, according to Woodworth. "The standard of care is not changing in regard to the surgical procedure. We are functionally increasing the amount of navigation data available to the surgeon," he says.

Woodworth notes that the disruption in the blood-brain barrier is not permanent, lasting about four to six hours.

The clinical trial is sponsored by InSightec, which has developed the MRI-guided focused ultrasound technology that will be used in the study. Neurosurgeons at UMMC are also using this technology to treat patients with neurological conditions, such as essential tremor and Parkinson's disease, the latter as part of a clinical research study.

Liquid biopsy could ease the way to immunotherapy for lung cancer

Researchers at UC Davis, Genentech, and Foundation Medicine are the first to show that a blood-based test to assess tumor mutational burden accurately identifies non-small cell lung cancer patients who could benefit from immunotherapies called checkpoint inhibitors.

The blood test offers a much less invasive and more repeatable alternative to tissue testing. The study was published online today in Nature Medicine.

"We wanted to know if we could transfer this TMB assay from tissue to blood," said David Gandara, who directs the Thoracic Oncology Program at the UC Davis Comprehensive Cancer Center and is first author on the paper. "We succeeded, establishing a TMB level in blood that correlates well with similar levels in tissue and was associated with favorable patient outcomes."

Checkpoint inhibitors take the molecular brakes off T cells, allowing them to attack tumors.

However, they work best in patients who exhibit certain tumor biomarkers. One of these is the PD-L1 protein. More recent is tumor mutational burden – the number of mutations found in specific genomic sequences in tumor cells of an individual patient. Patients with higher TMB are often better candidates for immunotherapy.

Translating these findings into clinical practice is now feasible. The initial laboratory research methods used to identify these biomarkers, such as exome sequencing, take a long time and are not always scalable for clinical care. In addition, as many as 30 percent of NSCLC patients have too little tumor tissue to facilitate these tests. A fast, minimally invasive blood test would be the ideal solution.

"There are patients for whom the biopsy is inadequate from the start, or the tissue is used for routine pathology and we don't have enough tissue left to do either genomic testing or tissue TMB," Gandara said. "If we can do it in blood in one test, that offers many advantages for patients who have had an inadequate biopsy."

In addition, because it's much less invasive, a blood test could be repeated to determine if a treatment is effective or provide an additional option for patients who might not tolerate a traditional biopsy in the first place.

To determine whether blood could produce TMB results as well as tumor tissue, the researchers examined more than a thousand blood samples from patients with advanced NSCLC (two or more lines of treatment) in two studies, OAK and POPLAR.

This retrospective study compared these blood samples with tumor tissue and found a strong, though not perfect, TMB correlation between the two. This was not unforeseen, as tumor tissue is heterogeneous, and the blood test is actually more sensitive.

Despite these differences, the blood test performed well, consistently predicting which patients would benefit – with improved response and progression-free survival – from the PD-L1 inhibitor atezolizumab (Tecentriq). The assay proved both accurate and reproducible.

This blood-based approach seems poised to move rapidly into the clinic. Foundation Medicine is now seeking FDA approval to incorporate it into their FoundationACT liquid biopsy. In addition, interim data from the prospective BFIRST study presented at

the recent ASCO conference confirmed that blood samples are a viable way to test TMB.

Other authors included: Sarah Paul, Marcin Kowanetz, Erica Schleifman, Wei Zou, Yan Li, Lukas Amler, Todd Riehl, Craig Cummings, Priti Hegde, Alan Sandler, Marcus Ballinger and David Shames at Genentech; Achim Rittmeyer at Lungenfachklinik Immenhausen; Louis Fehrenbacher at Kaiser Permanente Medical Center, Vallejo, California; Geoff Otto, Christine Malboeuf, Daniel Lieber, Doron Lipson, Jacob Silterra and David Fabrizio at Foundation Medicine; and Tony Mok at State Key Laboratory of Southern China.

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DRUGS & TARGETS

Imbruvica + rituximab becomes first non-chemo combination for Waldenström's macroglobulinemia

The Janssen Pharmaceutical Companies of Johnson & Johnson announced the FDA approval of Imbruvica (ibrutinib) in combination with rituximab for the treatment of Waldenström's macroglobulinemia.

The approval expands the label for Imbruvica in WM beyond its approved use as a monotherapy to include combination use with rituximab. The approval represents the first approved non-chemotherapy combination option for the treatment of WM.

Imbruvica first received FDA approval in WM as a monotherapy in January 2015 via the Breakthrough Therapy Designation pathway, making it the first FDA-approved therapy for the disease. The expanded label marks the ninth FDA approval for Imbruvica since 2013. Imbruvica is a first-in-class Bruton's tyrosine kinase inhibitor jointly developed and commercialized by Janssen Biotech Inc. and Pharmacyclics LLC, an AbbVie company.

This approval is based on results from the randomized, double-blind, placebo-controlled iNNOVATE study (PCYC-1127), the largest phase III study of a non-chemotherapy combination in WM patients. The iNNOVATE study evaluated Imbruvica in combination with rituximab versus placebo plus rituximab in 150 patients with either relapsed/refractory disease or previously untreated WM.

At a median follow up of 26.5 months, a significant improvement in the Independent Review Committee-assessed primary endpoint of progression-free survival was seen with Imbruvica plus rituximab when compared with placebo plus rituximab (30-month PFS rates were 82% vs. 28%, respectively). Patients in the Imbruvica plus rituximab treatment arm experienced an 80% reduction in relative risk of disease progression or death compared with patients treated with placebo plus rituximab (hazard ratio=0.20; confidence interval, 0.11-0.38, p<0.0001).

FDA approves lenvatinib for unresectable hepatocellular carcinoma

FDA approved lenvatinib capsules (Lenvima) for first-line treatment of patients with unresectable hepatocellular carcinoma.

The drug is sponsored by Eisai Inc.

Approval was based on an international, multicenter, randomized, open-label, non-inferiority trial (REFLECT; NCT01761266) conducted in 954 patients with previously untreated, metastatic or unresectable HCC. Patients were randomized (1:1) to receive lenvatinib (12 mg orally once daily for patients with a baseline body weight of ≥60 kg and 8 mg

orally once daily for patients with a baseline body weight of <60 kg) or sorafenib (400 mg orally twice daily). Treatment continued until radiological disease progression or unacceptable toxicity.

REFLECT demonstrated that lenvatinib was non-inferior but not statistically superior to sorafenib for overall survival (HR 0.92; 95% CI: 0.79, 1.06). Median OS in the lenvatinib arm was 13.6 months and 12.3 months in the sorafenib arm. REFLECT also demonstrated a statistically significant improvement in progression-free survival with lenvatinib as compared to sorafenib.

Median PFS was 7.3 months in the lenvatinib arm and 3.6 months in the sorafenib arm (HR 0.64; 95% CI: 0.55, 0.75; p<0.001) per modified RECIST for HCC; findings were similar according to RECIST 1.1. The overall response rate was higher for the lenvatinib arm as compared to sorafenib (41% vs. 12% per mRECIST and 19% vs. 7% per RECIST 1.1).

Lenvima gets European approval for advanced, unresectable hepatocellular carcinoma

Eisai and Merck said the European Commission granted a marketing authorization for the oral receptor tyrosine kinase inhibitor Lenvima (lenvatinib), as a single agent for the first-line treatment of adult patients with advanced or unresectable hepatocellular carcinoma who have received no prior systemic therapy.

Lenvima is the first new, first-line treatment for advanced or unresectable HCC in a decade to show an overall survival treatment effect by statistical confirmation of non-inferiority against standard of care.

Lenvima is marketed in Japan for the treatment of HCC and in the United States for the treatment of first-line unresectable HCC, and applications seeking approval for this indication have been submitted to additional countries.

FDA approves pembrolizumab + chemo for first-line metastatic non-squamous NSCLC

FDA approved pembrolizumab (Keytruda) in combination with pemetrexed and platinum as first-line treatment of patients with metastatic, non-squamous non-small cell lung cancer, with no EGFR or ALK genomic tumor aberrations.

Keytruda is sponsored by Merck & Co.

Pembrolizumab was previously granted accelerated approval for this indication in May 2017 based on improvements in overall response rate and progression-free survival for patients randomized to pembrolizumab administered with pemetrexed and carboplatin as compared with pemetrexed and carboplatin alone in the KEYNOTE-021 study.

The approval represents fulfillment of a postmarketing commitment demonstrating the clinical benefit of this product. This action is based on the results of KEYNOTE-189 (NCT02578680), a randomized, multicenter, double-blind, active controlled study enrolling 616 patients receiving first-line treatment for metastatic NSqNSCLC.

Patients were randomized (2:1) to receive pembrolizumab (or placebo) in combination with pemetrexed, and investigator's choice of either cisplatin or carboplatin every 3 weeks for 4 cycles followed by pembrolizumab (or placebo) and pemetrexed. Treatment with pembrolizumab continued until disease progression, unacceptable toxicity, or a maximum of 24 months.

The primary efficacy outcome measures were overall survival and progression-free survival, as assessed by a blinded independent committee review (RECIST 1.1.)

The trial demonstrated a statistically significant improvement in OS for patients randomized to pembrolizumab and chemotherapy (HR 0.49; 95% CI: 0.38, 0.64; p<0.00001) in a pre-specified interim analysis.

The median OS was not reached at the time of the data cut-off in the pembrolizumab plus chemotherapy arm and was 11.3 months for those in the chemotherapy arm. The trial also demonstrated an improvement in PFS for patients randomized to pembrolizumab plus chemotherapy (HR 0.52; 95% CI: 0.43, 0.64; p<0.00001). The median PFS was 8.8 months for patients receiving pembrolizumab plus chemotherapy and 4.9 months for those receiving chemotherapy alone.

The overall response rate was significantly higher (48% vs. 19%; p=0.0001) for those in the pembrolizumab plus chemotherapy arm and the median response duration was 11.2 months and 7.8 months, respectively.

FDA updates prescribing information for Keytruda, Tecentriq

FDA has updated the prescribing information for Keytruda (pembrolizumab) and Tecentriq (atezolizumab) to require the use of an FDA-approved companion diagnostic test to determine PD-L1 levels in tumor tissue from patients with locally advanced or met-

astatic urothelial cancer who are cisplatin-ineligible. FDA approved two different companion diagnostic tests, one for use with Keytruda and one for use with Tecentriq, as described below.

FDA approved the Dako PD-L1 IHC 22C3 PharmDx Assay (Dako North America, Inc.) as a companion diagnostic to select patients with locally advanced or metastatic urothelial carcinoma who are cisplatin-ineligible for treatment with Keytruda. The 22C3 assay determines PD-L1 expression by using a combined positive score assessing PD-L1 staining in tumor and immune cells.

The updated indication for Keytruda is: Keytruda is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score ≥ 10] as determined by an FDA-approved test, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.

FDA approved the Ventana PD-L1 (SP142) Assay (Ventana Medical Systems, Inc.) as a companion diagnostic test to select patients with locally advanced or metastatic urothelial carcinoma who are cisplatin-ineligible for treatment with Tecentriq. The SP142 assay determines PD L1 expression in immune cells.

The updated indication for Tecentriq is: TECENTRIQ is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- Are not eligible for cisplatin-containing chemotherapy, and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells covering ≥5% of the tumor area), as determined by an FDA-approved test, or
- Are not eligible for any platinum-containing therapy regardless of level of tumor PD-L1 expression

The FDA updated the prescribing information for both drugs to require use of an FDA-approved test for selection of patients being treated in the first-line setting who are cisplatin-ineligible. The second-line indications in urothelial carcinoma for both drugs remain unchanged. The tests used in the trials to determine PD-L1 expression are listed in Section 14 of each drug label.

Nivolumab gets accelerated approval for third-line metastatic small cell lung cancer

FDA granted an accelerated approval to nivolumab (Opdivo) for patients with metastatic small cell lung cancer with progression after platinum-based chemotherapy and at least one other line of therapy.

The drug is sponsored by Bristol-Myers Squibb Co. Inc.

Approval was based on demonstration of a durable overall response rate in a subgroup of patients from CheckMate-032 (NCT01928394), a multicenter, open-label trial in patients with metastatic solid tumors. This subgroup comprised 109 patients with metastatic SCLC, with disease progression after platinum-based therapy and at least one other prior line of therapy, regardless of tumor PD-L1 status. All patients received nivolumab 3 mg/kg by intravenous infusion over 60 minutes every 2 weeks.

The major efficacy outcome measures were overall response rate and duration of response according to RECIST v1.1 as assessed by blinded independent central review. The ORR was 12% (95% CI: 6.5, 19.5). Responses were durable for 6 months or longer in 77%, 12 months or longer in 62%, and 18 months or longer in 39% of the 13 responding patients. PD-L1 tumor status did not appear to be predictive of response.

Safety data was evaluated in 245 patients with metastatic SCLC with disease progression following platinum-based chemotherapy and received at least one dose of nivolumab.

FDA approves Kyowa Kirin's Poteligeo for mycosis fungoides and Sézary Syndrome

Kyowa Hakko Kirin Co. Ltd. said FDA has granted approval for Poteligeo (mogamulizumab-kpkc) for the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy. FDA granted Priority Review and Breakthrough Therapy Designation in late 2017.

Poteligeo is a humanized monoclonal antibody directed against CC chemokine receptor 4, which is frequently expressed on leukemic cells of certain blood cancers including CTCL. Using the proprietary Potelligent technology, the amount of fucose in the sugar chain structure of Poteligeo is reduced, which enhances the antibody dependent cellular cytotoxicity.

"Mycosis fungoides and Sézary syndrome can be disfiguring, and debilitating. MAVORIC, the largest study of systemic therapy ever conducted in MF and SS, showed that mogamulizumab prolonged progression-free survival compared to vorinostat in patients with relapsed or refractory MF or SS," said Jeffrey Humphrey, president of Kyowa Kirin Pharmaceutical Development, Inc. "We look forward to the publication of MAVORIC's primary results and to ongoing scientific

exchange within the medical and academic communities."

Because CTCL manifests itself in skin lesions, it is often mistaken for other non-critical skin conditions, which can delay conclusive diagnosis and treatment options. MF and SS are the two most common subtypes of CTCL. MF is the most common subtype, accounting for 50-70% of cases. It is a slow progressing form of lymphoma that can involve the skin, blood, lymph nodes and organs, and may be associated with severe infections. SS accounts for approximately 3% of CTCL cases and is a more aggressive, leukemic form of CTCL.

FDA approval of Poteligeo is supported by the MAVORIC (Mogamulizumab anti-CCR4 Antibody Versus Comparator In CTCL) study, which is the largest randomized trial in MF and SS and the first pivotal trial in CTCL to use PFS as a primary endpoint.

MAVORIC was a phase III open-label, multi-center, randomized study of mogamulizumab versus vorinostat in patients with MF and SS who have failed at least one prior systemic treatment. The study was conducted in the U.S., Europe, Japan and Australia, and randomized a total of 372 patients to mogamulizumab or vorinostat. The results showed that mogamulizumab demonstrated significantly superior PFS at a median of 7.6 months [95% CI: 5.6, 10.2] compared to 3.1 months with vorinostat [95% CI: 2.8, 4.0], [hazard ratio 0.53: 95% CI: 0.41, 0.69; p<0.001]. The confirmed overall response rate for mogamulizumab and vorinostat was 28% and 5%, respectively (p<0.001).

FDA granted Poteligeo Breakthrough Therapy Designation for the treatment of MF and SS in adult patients, and evaluated Poteligeo with Priority Review, which is reserved for drugs that treat a serious condition and, if approved, would provide a significant improvement in treatment safety or effectiveness.