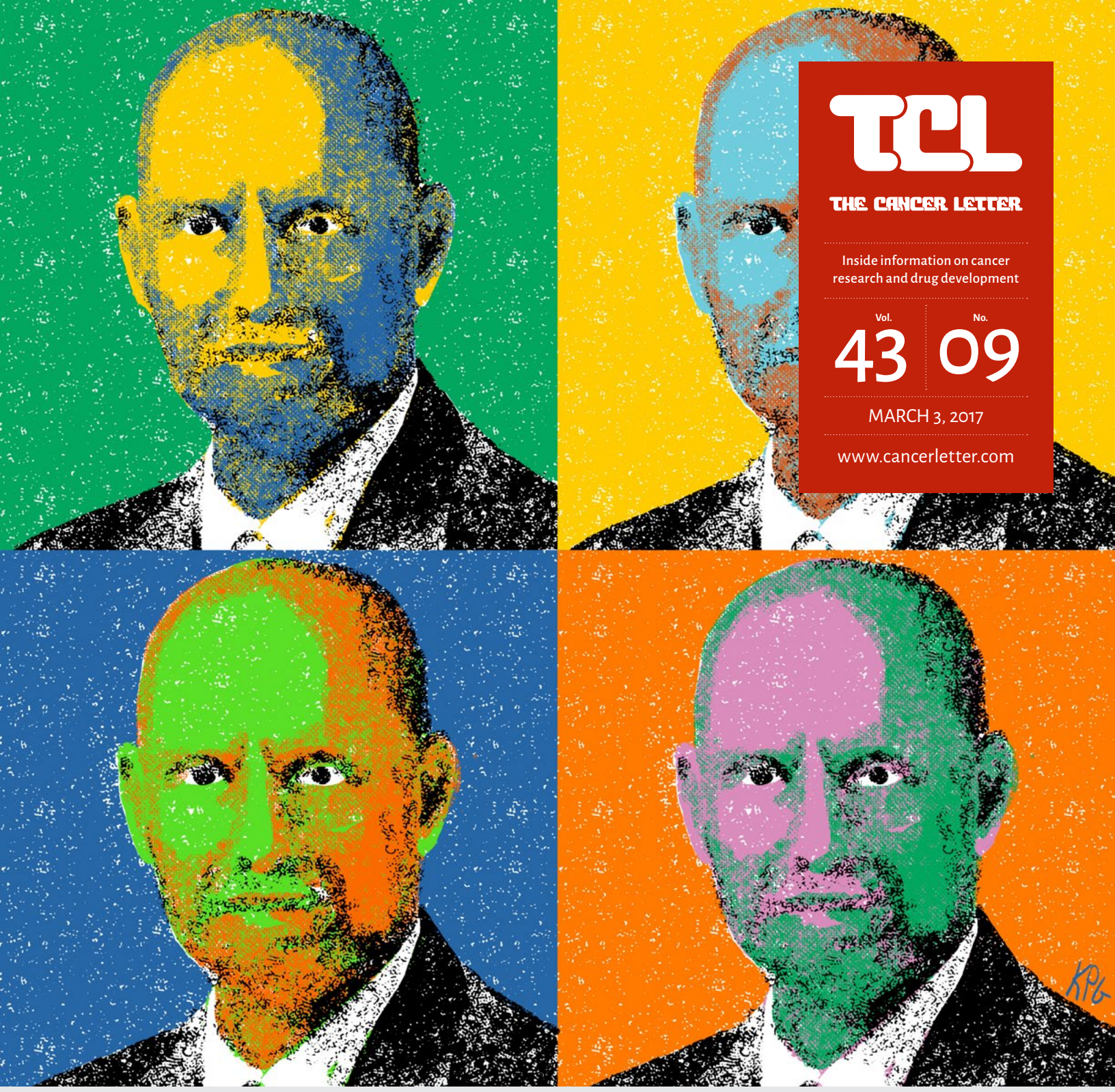

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THE CANCER LETTER
Inside information on cancer research and drug development
Vol. 43 No. 09
MARCH 3, 2017
www.cancerletter.com

STEVE HAHN AND HIS PLAN FOR RESCUING MD ANDERSON

Steve Hahn didn't apply for the job of Chief Operating Officer at MD Anderson Cancer Center. In fact, there was no COO job to apply to, and conversations that preceded the announcement of his new role took less than a week.

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IN BRIEF

DRUGS & TARGETS

STEVE HAHN AND HIS PLAN FOR RESCUING MD ANDERSON

Steve Hahn didn't apply for the job of Chief Operating Officer at MD Anderson Cancer Center. In fact, there was no COO job to apply to, and conversations that preceded the announcement of his new role took less than a week.

CONVERSATION WITH THE CANCER LETTER

> Ron has told me, and it's been put in writing for me, that when he is not here, I act on his behalf, knowing full-well where he wants to go, and his vision, but for the areas of operations, clinical operations internally, financial connection there, and the network, he's delegated those responsibilities to me.

Hahn, chair of the Department of Radiation Oncology, has been working closely with the Faculty Senate and the administration as they struggled with the Houston institution's growing operating deficits, the plunging morale, staff cuts, and the logjams created by a precipitous switch to electronic medical record.

How is Hahn, a relative newcomer to MD Anderson, going to rescue his new institution from its years of troubles? In an in-depth interview with The Cancer Letter, Hahn described functioning within a new administrative layer, formally reporting to MD Anderson President Ronald DePinho, but keeping UT System Chancellor William McRaven in the loop.

Occupying an office on the 20th floor of the T. Boone Pickens Building and the penultimate box in the MD Anderson box diagram, Hahn, whose other title is deputy to the president, is now literally the guy everyone reports to.

"Ron has told me, and it's been put in writing for me, that when he is not here, I act on his behalf, knowing full-well where he wants to go, and his vision, but for the areas of operations, clinical operations internally, financial connection there, and the network, he's delegated those responsibilities to me," Hahn said to The Cancer Letter.

Importantly, he is also in charge of representing the administration in the shared governance process, which means interaction with the Faculty Senate.

"The answer to your question would be the folks who would report up to Ron are the same people who would be facing me as well," Hahn said.

Will there be personnel changes on the 20th floor, which houses the top layer of MD Anderson administration?

Hahn said he is thinking about it. "My job is to make that assessment and make those recommendations. I won't hold back from doing that if personally I think that's in the interest of the institution," Hahn said.

Asked how he was chosen for this role, Hahn said he can only go but what he has been told.

"What I was told was when Ron and the chancellor looked around the organization and talked to folks in various constituencies—administration, faculty, Faculty Senate, and division heads—I was told that my name came up a couple of times, and that they sort of vetted that internally and thought that that would make a good choice—or I would make a good choice... Whatever...," Hahn said. "Our challenges won't be solved on the 18th and 20th floors. Our challenges will be solved in collaboration from the 18th and 20th floor with the folks at the front line, but also in leadership positions, Faculty Senate, department chairs, division heads, and our operational administrative team as well."

Asked to explain how MD Anderson's financial problems came about, Hahn pointed to the institution's decision to adopt the Epic system.

"When we did the Epic install, the largest Epic install in the history of Epic—we did a couple things that were sort of the big bang, if you will," he said. "We did inpatient, we did outpatient, and we did the billing system—all at once. "

The key to resolving MD Anderson's problem is to provide value.

"I really don't want the message to the faculty to be: 'Make money. Make money. Make money.' I want, 'What's best for our patients? What's best for taking care of them? Let's be careful about what we spend. Let's be prudent about the way that we approach our operations so that we can be more efficient, but at the same time deliver high-quality care and be very patient-centric,'" Hahn said.

Q & A

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

Can you tell me how you became the chief operating officer of MD Anderson? Did you apply for that job or..., what happened?

Steve Hahn: Sure, that's a very funny question Paul. I did not apply for it. Ron approached me about this, and the context was that, given many of his external-facing responsibilities, which are significant, interaction with the legislature, UT System, fundraising, the sort of Washington aspects of the job—NCI, et cetera.

He felt that there was a gap and a need to be filled internally, so internally-facing, in the organization from the president's office, to manage the clinical-slash-financial aspects of things as well as our network, which as you know extends from our Houston area locations all the way to our international sites and our new UT system collaborations.

He mentioned to me that he wanted to consider me for that, and would I consider such a position? That's how the conversation started, and subsequently progressed from there.

How long was that in the works?

SH: Before he contacted me?

Yeah

SH: I don't actually know the answer to that question, because I wasn't part of those conversations, but it was end of January, where that discussion took place, and over a week's period of time, with discussions that were really three-party discussions between Ron and myself and the folks in UT Austin, we sort of came to an agreement then.

I'm sure you know it was announced on Feb. 3.

Okay, so it was less than a week, and was the [UT System] chancellor [William McRaven] involved?

SH: Yeah. The chancellor was. The chancellor gave me a call and asked me if I'd be willing to serve the institution, and I told him yes.

Okay, so the offer really came from the chancellor?

SH: Well, I mean, I think, technically, the offer came from Ron, because Ron's the first person who approached me. I think my understanding is that Ron asked the chancellor to contact me to give further backup that this was something that UT Austin was also very interested in.

That's how I understood that this went, and that's where my discussions went forward.

Did they explain why you are the COO as opposed to someone else ... What do you think happened? What lead to it?

SH: I'll just give you the straight shot as to what I was told.

They felt that this was something that needed to be filled on a relatively quick basis, that this was a new position that was created.

They were cognizant of the fact that we were in a financial crisis, if you will, and that we had to move in a certain direction. I can tell you my philosophy about this, but it's basically the direction of value-based healthcare.

We had to consider significant changes in the institution to move in that direction, given the changes in healthcare. There was some urgency to move on that, because of that issue, and so that was sort of the context of the situation, and what I was told was when Ron and the chancellor looked around the organization and talked to folks in various constituencies—administration, faculty, Faculty Senate, and division heads—I was told that my name came up a couple of times, and that they sort of vetted that internally and thought that that would make a good choice—or I would make a good choice... Whatever...

I guess I should probably just ask directly. Do you report to [MD Anderson President] Ron [DePinho] or do you report to the chancellor?

SH: I report to Ron.

Are there constant communications with the chancellor? How does that work?

SH: Everybody's aware of this. One of the things that was put in my domain and this role is to make sure that there was constant communication with the UT System.

I set up regular calls, which I'll actually start this week, Paul, with the UT System, just to give them updates on what's going on in the institution from an internally-facing perspective.

It's like anything in big complex organizations. More communication is probably better, and I mean, as you probably know, lots of information gets disseminated. To have a consistent messenger about what's going on that is, in fact, consistent with what is actually going on is a good thing.

I'm really happy to play that role, both internally and also externally-facing to UT System.

My many friends on the faculty have very nice things to say about you.

SH: You know what? I have to tell you, this was a dream job when I took the division head job two years ago, because I'd been at Penn for 18 years, and I have such admiration for this institution and what it does for our patients, and I have, again, I mean, I love this place, and I love the faculty, and I love the staff.

I have said many times that you will never find a place—and, Paul I think you and I mentioned this when we talked before—where people are so committed to our mission of curing cancer and taking care of cancer patients—and it's infectious and you cannot buy that commitment.

You can't pay people to do that. It's just not possible. Why not come to a place like this and do your best to try to forward the mission? To me, it's just the bottom line. It's all about what the institution needs to do that mission.

Where is your office? Are you on the 20th floor? [The 20th floor of the T. Boone Pickens Building is the location of the administrative offices.]

SH: I do have an office on the 20th floor. Ron has asked me to keep my role as a division head. It's a little bit of a challenge.

We're putting a structure in place in the division, because I'm really sensitive to the fact that I came here to do that job, and I really want the division and our patient care mission and our safety and quality mission to be taken care of, so we're putting in a structure there, and I've kept some sort of temporary quarters there, so that I can go up and down and meet with those leaders and make sure that things are being taken care of there.

We have terrific people in the division of radiation oncology, and I'm confident that when that structure goes in place things will be taken care of. I do feel an obligation to that division, to my division, if you will, and to our patients.

I'm going to continue to see patients, and I just want to make sure that folks are taken care of there.

Are you transitioning out of that job, or do you think you're going to be able to keep both jobs?

SH: Again, I think … What I spoke to Ron and the chancellor about is that I'd like the opportunity to reassess in three and six months.

I'm glad, again, in the future to have another conversation with you about that when that reassessment takes place. I doubt it's of huge interest to people, but I'm really glad to have that conversation, and we'll see how both the COO job and things are going in the division, and then make a decision at that point.

Again, I really think we should do what's best for the institution and our patients, and although I love the Division of Radiation Oncology, truly love that job, and love those folks, if the right thing is for me to be elsewhere, then that's the right decision to make, and we'll start a search for the division head of radiation oncology.

If the right thing for me to do is to move back, I'd be very happy to do that.

Do you see making personnel changes on the 20th floor, the senior personnel?

SH: I'm just getting my feet wet in this.

You know, it's not a secret that we have our challenges. We have our challenges around decision-making, and, just like any big organization, we have our challenges around governance.

I think these are areas that the faculty and the staff expect to be addressed so that we can become as effective as possible. To the extent that sometime in the future personnel changes, wherever that happens to be, need to take place, because that's the right thing for the institution, we have to have the courage to talk about those and decide.

Ultimately, that's the president's decision, not my decision. But my job is to make that assessment and make those recommendations. I won't hold back from doing that, Paul, if personally I think that's in the interest of the institution.

These are folks that report to you, right? Because there's nobody, really who doesn't. Is there anyone who doesn't? Everybody reports to you?

SH: Yeah. Ron has told me, and it's been put in writing for me, that when

he is not here, I act on his behalf, knowing full-well where he wants to go, and his vision, but for the areas of operations, clinical operations internally, financial connection there, and the network, he's delegated those responsibilities to me.

The answer to your question would be the folks who would report up to Ron are the same people who would be facing me as well.

I see. They just kind of go through you, which means that governance is a work in progress. Is that a fair way of saying it?

SH: That is so fair. You know what? Paul, nothing's perfect in the world. I'm a cancer doctor, for goodness sake; right?

We all know that, but it is a work in progress, and I'm really interested in making sure that we make the right decisions, that we move forward on decision-making and governance, but I also want to make sure that in the process of doing that that we take care of all the people in the institution: staff, faculty, even up to the 18th and 20th floors, so to me that does require more than just a week to sort of make assessments and decisions about things, because I think the institution deserves better than sort of rushing into things.

I guess it depends on what sort of perspective you have; right? One could argue that maybe this isn't rushing, but from my perspective in this job, I feel like it needs a little bit of time to make those assessments.

How do you see the shared governance with the faculty continuing to function?

SH: That's another area that Ron has asked me to sort of assume for the present, and I am very enthusiastic about it.

There is a subcommittee of the shared governance that is now quite active that has proposed a mechanism for agenda-setting.

I think it's a great idea. Ron has approved moving forward with that, and I will provide the president's office blessing of the agenda, and we're going to move forward with confidential, but open discussions, where people are not afraid to discuss how they feel and we get a true vetting of these topics, and I have to tell you the collaboration with my division head colleagues, so Marshall Hicks [head of the Division of Diagnostic Imaging], and Steve Swisher [head of the Division of Surgery], and David Tweardy [head of the Division of Internal Medicine], and with Julie Izzo [chair of the MD Anderson Faculty Senate], and Osama Muwlawi [a Faculty Senate member who sits on the shared governance committee and serves as the chief of the Nuclear Medicine Physics Section], and Tadd Pullin [senior vice president, institutional advancement].

I count them among sort of—I'm sorry about the military expression—but sort of soldiers in arms in our mission. We're right next to each other.

I think we all feel the same way about being up-front with each other and transparent about the issues and all the risks and benefits of decisions, but I said this as I've got around the organization the last two weeks: Our challenges won't be solved on the 18th and 20th floors. Our challenges will be solved in collaboration from the 18th and 20th floor with the folks at the front line, but also in leadership positions, Faculty Senate, department chairs, division heads, and our operational administrative team as well.

It is only through that partnership that we move forward. I know it sounds like mom-and-apple-pie, but it really is true, and to folks who have felt like they haven't had a voice and haven't been heard, I think it's really important that we listen and that we engage and that we allow and we enable and we multiply all the good efforts that people have on the ground at this institution, because it's a huge strength of ours.

Shame on us if we don't use that for the good of our mission.

The chancellor has been saying that without the faculty being on board you're sunk. We keep using these naval terms here. Right?

SH: I think what I just said is exactly along those same lines. I hope I communicated it well. I am probably not as eloquent as the chancellor.

It's really important and you see this time and time again, and you have 20,000 employees, many thousands of faculty, 1,200, 1,400, depending on how you count, and the bottom line is it's a big constituency who have passion and a stake in our mission, and what a shame if we don't rally those people for the mission in a positive way and get them engaged.

What are your plans for dealing with the financial problems, which I guess if we've been talking about it, I might as well just ask it directly.

SH: Oh, yeah. You bet.

It's no secret around the country that lots of institutions are facing financial

pressures, and you probably know and report about them more than I could even list them, but—

Wait… I'm going to have to interrupt you, because I don't think any of the big cancer centers are having the problems you're having. Memorial is in the black. Fred Hutch is in the black. I just went through sort of a list of them, just to see, but nobody's really in the red.

SH: Yeah, and I guess I wasn't … Sorry, Paul. I wasn't specifically talking about being in the red, because, certainly that is an issue. Losing $405 million dollars over the last 11 months—that is a huge issue, and you're right.

I guess what I meant was the factors that put pressures on academic health systems, they were true at Penn, where I was before, and I think there was recently an article in the Harvard Business Review about Cleveland Clinic.

A lot of people are facing those pressures. I'll just give you my perspective on the issues here, and I'm going to tell you what I've told the faculty and the staff when I met with them.

When we did the Epic install, the largest Epic install in the history of Epic—we did a couple things that were sort of the big bang, if you will. We did inpatient, we did outpatient, and we did the billing system—all at once.

Some folks staged that. We decided not to.

The pain associated with an Epic install is real for many places for a variety of reasons. It's just a new way of doing things, but the virtuous part of Epic is that it uncovers processes that have been in place for years that need to be revised—that maybe you weren't aware of need to be revised.

When I was at Penn and we did the Epic install that was very true. We sort of found things that we were like, "Oh. We need to do things a different way," and Epic gives you that opportunity. It's not just Epic, but an electronic medical record does. It uncovered processes that, sort of situations, that we had to get better.

How we account for deductions from gross revenue? Literally how we do things like bring a patient through the door, do financial clearance, see them in the clinic, what a doctor versus a nurse versus an MA does in the clinic? In radiation oncology, what a therapist does versus a dosimetrist?

All of those issues and processes become exposed.

It slows you down, because you have to reassess how you do things, and you become less efficient and anybody who's done the big bang of Epic, I think, has realized that that makes you slow down and inefficient.

We just did it, I think, in a more dramatic fashion.

What we are playing catch-up on now is how do we address those and fix those. In answer to your question of how are we going to address those, we have to look at a couple of things:

What are we doing from a process point of view on all those areas I just talked about that are inefficient and affect how we might care for patients? Because in the literature as well as I think other folks' experiences with this is that there is a relationship with processes that need to be fixed, efficiency, and this concept of value.

If you fix those processes, you can actually make it more efficient. You get more patient satisfaction, more provider satisfaction, you make the care less costly, and you provide greater value. What we want to do is move in that direction, and there's components of that that can be addressed specifically, but at the same time make sure that we still maintain the high quality of care that we deliver.

Thankfully, our faculty and staff won't let us do otherwise. That's a really good thing. That's a wall that we will never cross, because folks won't put up with that.

We have to figure out what's the right way, within MD Anderson and the culture of our faculty and staff, to move forward in a way that helps us change some of our processes to become more efficient and less costly, and I think that will also have a positive effect in our networks, insurers, how we face and treat insurers on the government side.

I think all those issues have come to face us as an institution, and you can argue about the rightness or wrongness of a big bang Epic install, but it did allow us to look at these things.

The great news is there is a lot of interest, by the faculty in particular, but also the staff, to ask where are we seeing these inefficiencies, where are we seeing these challenges that we have to address?

I asked faculty and staff to send me emails, when you see things about charge capture, that inefficient processes, where there might be waits. We're trying to collect those and address those not just at the 18th and 20th floor, but throughout the organization.

Is it going to happen in two weeks? No.

This is a long-term project, and, Paul, I think we're thinking one to two to three to five years to get to that value proposition.

I'm convinced we have the quality side of things. That I'm convinced about in terms of the labor of care, but it's the other side of the equation that is counting in the current environment.

Sorry for the longwinded answer.

What are the targets now in terms of financials? There was a point where I was told early on this year that you will end the year in the black. I don't think anybody's saying that. Now the word is that it's going to be in the black for months, during, by the end of the year. How much do you expect to lose? How long can this go on? What are your thoughts on the projections?

SH: We set a budget, you probably know this, of a positive margin at the end of the year of $25 million. As you know—our financials are public record—so we had a very good January, and our current negative margin variance was reduced substantially, because of our positive margin in the month of January.

Some of that, as you know, is due to the Medicare true-up that we have, but, in fact, if you took that away, we still had a positive operating margin, I think around, and you can check these numbers, Paul, and sorry, but I think around $26 million dollars was left if you took away the Medicare. Something in that range. I took a great deal of hope from that.

We reduced our operating loss year to date from $169.4 million to $77.3 million. It's a good-news story. Medicare was about $63.4 million of that, so the positive variance we still accounted for was somewhere around a $28.7 million.

We have been holding the line on expenses, and we expect to continue to see the benefit of expense reduction moving forward.

In fact, we haven't seen the full force of our expense reduction that we've been going through. In February, so far, it looks like our clinical activity has been holding as well.

Only time will tell, but the message, and I think the truth of this, is that we have to continue to pay attention to allowing the patients who are appropriate to come to MD Anderson to come through the door, to do the appropriate assessment.

I really don't want the message to the faculty to be: "Make money. Make money. Make money." I want, "What's best for our patients? What's best for taking care of them? Let's be careful about what we spend. Let's be prudent about the way that we approach our operations so that we can be more efficient, but at the same time deliver high-quality care and be very patient-centric," and I'm convinced if we make it easy for the patients who are appropriate to come through the door to come to MD Anderson that we will continue to have positive operating margins.

I don't have a crystal ball about February, March, April, but I think it's trending in the right direction.

You may actually end up with the year in the black?

SH: We could. We could. Steve Hahn's not making that prediction. That's for sure, Paul, but I'm encouraged by what we're seeing.

Listen, I'm glad to have an ongoing conversation with you about this.

In terms of cuts, which projects do you see staying and which of them might be going away? Which parts of MD Anderson need to be rethought?

SH: The one mistake I am not going to make is making that a top-down decision, and my good friend and colleague Julie Izzo says this all the time, and that has to be a shared governance recommendation to the president.

I think what we have to say is the following: What is sort of sacred that we can't touch? That is delivering high quality care to our patients and our mission to cure cancer. That has to be our relentless focus moving forward.

Everything else that surrounds that, and even some components that go into that from an efficiency point of view, in my opinion is on the table. We ought to have a discussion about what are those things that we need to perform the mission I just described, and what are the things that aren't necessary?

Paul, I'm convinced that over the next couple of months, when we have these discussions, when we uncover more of the processes that we need to change, it's going to become very apparent to us what we need and what we don't need.

My guess is it's going to be extremely non-controversial about what programs need to get to be cut, because I'm seeing people rally around the fact that we can't spend money on things that don't help us with our core mission.

I wouldn't presume to suggest any cuts, but what about something like the Moon Shots, or Institute for Applied Cancer Science—drug discovery?

SH: Again, I think, everything needs to be discussed. You might have seen the chancellor's comments regarding innovation and high-risk/high-reward. I'm not suggesting that that should be the mission.

What I'm suggesting is that there may be areas that we, as shared governance, are going to recommend to Ron that we continue to look at as an investment in our future, so that we can continue our mission of curing cancer.

I think, again, we need total engagement and total transparency around what's being spent where.

We need everyone to have a voice around it and we need to have that discussion and not just I want to be secretive, but we have to be able to have an open discussion behind closed doors as a shared governance. That includes Faculty Senate, administration, and division heads, department heads. We have to have that conversation, and then we have to decide what are our priorities and what are we going to spend money on.

It might be that Program X, we decide that the juice isn't worth the squeeze, that we really shouldn't be putting money into that. But I think it's premature for suddenly me to say that and I don't want to dictate that to the institution.

I want this, again, to be a shared governance approach, and the way that the system's set up that we all agreed upon, is that shared governance will make a recommendation to Ron.

When you say make a recommendation to Ron are you saying just Ron or are you saying also the chancellor? Are there any recommendations that don't go to both of them?

SH: The responsibility for the institution solely resides with Ron.

The chancellor has made that clear. It's the way, I don't know if it's in statute or not, but that's sort of what's in our shared governance compact, and everybody agrees to that. Faculty senate, not that I speak for them, but we've all said this over and over again. Everybody knows those are the rules of the road and the chancellor has not deviated, to my knowledge from that sort of decision making.

But you're keeping him informed? You go to both of them? Right?

SH: Yeah. Of course. That's part of the job, my new job, is to actually keep that information flowing. That's correct, Paul.

Okay. What's the most difficult part of the job?

SH: Seriously? Finding enough time in the day to get it all done.

I'll tell you what, and I mean this. I sound like such a corny, but I'm a Northeast guy, for goodness sake. I love this place, and I'll burn a lot of energy trying to make this place the best it can be--in conjunction with my colleagues.

That's the toughest part, honestly.

I can totally believe it.

SH: My colleagues here have been so great in terms of voicing their support for moving forward, and I want to give those colleagues a voice is the bottom line.

Medicare payment in January helps MD Anderson reduce its operating losses

By Paul Goldberg

MD Anderson Cancer Center reduced its year-to-date operating loss to $77.3 million in January, the fifth month of the fiscal year.

In January, the cumulative operating loss was $169.4 million. The loss shrunk because in January MD Anderson booked about $63.4 million in a settlement from Medicare, which allowed the cancer center to claim a portion of its expenses for implementing the Epic system.

Due to increased clinical activity by about 10 percent from December to January, operating revenues were around $28.7 million. This the first monthly positive margin since Epic's rollout in March 2016.

In an interview with The Cancer Letter, MD Anderson Chief Operating Officer Steve Hahn said the installation, which he described as the largest in the history of Epic, changed over the cancer center's inpatient, outpatient and billing systems at the same time.

Hahn, deputy to the president, said the installation of Epic exposed and exacerbated inefficiencies in the cancer center's operations.

The cancer center's financials are on the next page.

MD ANDERSON CANCER CENTER MONTHLY FINANCIALS, SEPTEMBER 2016 TO JANUARY 2017

	Actual September 2016		Actuals October 2016		Actual November 2016		Actual December 2016		Actual January 2017	
Revenue										
Hospital Gross Patient Revenue	$ 527,053,725		$ 547,141,855		$ 553,162,416		$ 546,740,639		$ 592,978,574	
Professional Fee Gross Patient Revenue	103,957,679		107,838,878		105,339,452		118,409,303		117,028,229	
Total Gross Patient Revenue	631,011,405		654,980,732		658,501,868		665,149,942		710,006,803	
Deductions from Gross Patient Revenue	343,906,711	54.5%	384,418,941	58.7%	371,839,317	56.5%	393,608,817	59.2%	318,551,507	44.9%
Total Net Patient Revenue	287,104,694		270,561,791		286,662,552		271,541,125		391,455,296	
Other Operating Revenue	35,790,604		37,341,656		42,930,870		36,133,733		58,290,074	
Total Operating Revenue	**322,895,298**		**307,903,447**		**329,593,422**		**307,674,858**		**449,745,370**	
Operating Expense										
Personnel Expenses	210,045,936	65.1%	207,714,858	67.5%	209,302,995	63.5%	212,622,998	69.1%	211,643,280	47.1%
Other Operating Expense	154,316,447		161,083,445		129,324,468		153,061,456		146,011,114	
Total Operating Expense	**364,362,383**		**368,798,302**		**338,627,463**		**365,684,454**		**357,654,394**	
Total Operating Income(Loss)	**(41,467,084)**		**(60,894,855)**		**(9,034,041)**		**(58,009,596)**		**92,090,976**	
Non-Operating Operating Revenue(Expense)										
State Appropriations	16,753,839		17,406,957		17,056,518		16,743,918		16,738,771	
Restricted and Designated Gift	4,590,378		8,120,731		9,611,699		25,856,727		15,941,995	
Investment Income	9,188,375		11,791,475		17,342,692		9,961,843		19,723,043	
Adjusted Income / (Loss)	**(10,934,493)**		**(23,575,693)**		**34,976,868**		**(5,447,108)**		**144,494,784**	
Change in Investment Value	362,736		12,919,239		(38,906,609)		(11,847,236)		7,002,222	
Net Income / (Loss)	**$ (10,571,757)**		**$ (10,656,454)**		**$ (3,929,741)**		**$ (17,294,344)**		**$ 151,497,006**	

Cancer groups to Trump: FDA's oncology division is NOT "slow and cumbersome"

By Matthew Bin Han Ong

FDA's approval process for drugs is "slow and cumbersome," President Donald Trump said in his first address to a joint session of Congress on Feb. 28.

In a wide-ranging speech on national security, the economy, foreign policy, and health care, Trump zeroed in on FDA, citing a patient's experience with drug development as evidence for slashing "restraints" at the agency:

"Today is Rare Disease Day, and joining us in the gallery is a rare disease survivor, Megan Crowley," Trump said Tuesday evening, addressing the Senate and House members, and Supreme Court justices. "Megan was diagnosed with Pompe Disease, a rare and serious illness, when she was 15 months old. She was not expected to live past five.

"On receiving this news, Megan's dad, John, fought with everything he had to save the life of his precious child. He founded a company to look for a cure, and helped develop the drug that saved Megan's life. Today she is 20 years old—and a sophomore at Notre Dame. Megan's story is about the unbounded power of a father's love for a daughter.

"But our slow and burdensome approval process at the Food and Drug Administration keeps too many advances, like the one that saved Megan's life, from reaching those in need. If we slash the restraints, not just at the FDA, but across our government, then we will be blessed with far more miracles like Megan.

"In fact, our children will grow up in a nation of miracles."

Trump's comments on FDA come shortly after reports that the White House's FY18 budget request would cut $54 billion from non-defense federal agencies to boost the defense budget. Earlier, on Jan. 30, the president signed an executive order requiring agencies to cut two regulations on businesses for each new regulation introduced.

"We are facing some serious and challenging fiscal headwinds in 2017, especially as we advocate for and seek to secure robust, sustained, and predictable annual funding increases for the NIH and FDA," said Jon Retzlaff, managing director for science policy and government affairs at the American Association for Cancer Research. "These challenges were underscored by President Trump's announcement this week that he plans to propose boosting defense spending by $54 billion in his FY 2018 budget by offsetting it by an equivalent cut from the rest of the government's discretionary budget.

"It's very concerning that the Trump Administration appears to be geared up to use the non-defense, discretionary accounts of the federal government, as, in essence, a bank to pay for the president's proposals to increase military and veterans spending, pay for a massive infrastructure program, build a wall along the southern border, and cut taxes for all income groups," Retzlaff said to The Cancer Letter. "Since the NIH and FDA are both funded from the non-defense, discretionary side of the budget, the Trump administration's FY 2018 budget proposal would very likely slow the rate of progress in our understanding of the hundreds of diseases that afflict millions of people, and reduce the number of safe and effective treatments available to patients.

"It's just paramount that if we are to help build on our nation's prior investments in medical research, ensure that our nation is able to respond to emerging health and research needs, and train the future generation of scientists, the Trump administration, as well as our leaders in Congress, must prioritize funding for the NIH and FDA."

Questions about Trump's remarks on FDA should be directed to the White House, an agency spokesperson said to The Cancer Letter.

In 2016, the FDA Center for Drug Evaluation and Research approved 22 novel drugs, which is less than the average number—30—approved annually during the past decade, but the "number of applications for these drugs that sponsors have submitted over time has remained relatively stable," the agency said in its 2016 Novel Drugs Summary.

As of Dec. 14, 2016, almost all—95 percent—of the novel drugs approved in calendar year 2016 were approved in the first review cycle, and met their PDUFA goal dates for the approval review cycle, according to a 2016 CDER new drug review update.

FDA officials said in the document that the center has granted 141 breakthrough therapy designations since the FDA Safety and Innovation Act was signed in July 2012.

Almost half of these designations were granted for drugs that are indicated for the treatment of cancer and hematologic conditions, which fall under the purview of the Office of Hematology and Oncology Products.

Until recently, OHOP was led by the agency's "cancer czar," Richard Pazdur, who is now director of the FDA Oncology Center of Excellence. An acting director for OHOP is yet to be named.

One of the landmark achievements of then-Vice President Joe Biden's National Cancer Moonshot Initiative, Pazdur's OCE aims to consolidate the agency's cancer portfolio and serve as an incubator for developing new regulatory frameworks for cross-center review of cancer-related products.

Trump's characterization of FDA is disappointing, said AACR CEO Margaret Foti, CEO.

"We were very disappointed when we heard President Trump state during his speech to a joint session of Congress on Tuesday night that the 'slow and burdensome approval process at the U.S. Food and Drug Administration keeps too many advances from reaching those in need,'" Foti said to The Cancer letter. "We strongly disagree with this characterization about the FDA.

"For the past six years, the AACR has had the special opportunity to work even more closely with the oncology team at the FDA, and what we've witnessed is that Dr. Pazdur and his highly qualified colleagues at the FDA's Office of Hematology and Oncology Products are working tirelessly to speed the availability of therapies for cancer patients, especially when the drugs are the first available treatment or have advantages over existing therapies.

"Dr. Pazdur, who has led that FDA Office since 2005, and who was most recently appointed as Director of the FDA Oncology Center of Excellence, has recruited a remarkable team of oncologists and other experts who are extremely committed to gaining a better understanding of the needs of cancer patients, clinical oncologists, physician-scientists, and developers of novel cancer therapies so as to speed the delivery of innovative cancer treatments. Dr. Pazdur and his colleagues are respected in the oncology community for their creative and groundbreaking methods to ensure a flexible, evidence-based regulatory approach to expediting the approval of promising new cancer drugs.

"It's important to also point out that the FDA is significantly underfunded given the scope of the cancer problem and the challenges and complexities surrounding the review and approval of safe and effective cancer therapies. Additional funding for the FDA is sorely needed to incorporate the latest scientific breakthroughs into the approval of cancer therapeutics."

The agency's cancer experts have been able to approve drugs quickly while maintaining quality, said Clifford Hudis, CEO of the American Society of Clinical Oncology.

"ASCO supports efforts to continuously increase efficiencies to ensure the delivery of safe and effective treatments to patients with life-threatening diseases," Hudis said to The Cancer Letter.

"We were very disappointed when we heard President Trump state during his speech to a joint session of Congress on Tuesday night that the 'slow and burdensome approval process at the U.S. Food and Drug Administration keeps too many advances from reaching those in need.' We strongly disagree with this characterization about the FDA."

"A robust and stable commitment to research and regulation that supports drug discovery and development leading to the efficient approval of safe and

Supplementary Table S1 | **Summary of FDA oncology drug approvals in 2016**

Drug	Indication	Type	Comments
Rucapirib	*BRCA1/2*-mutated ovarian cancer after two lines of chemotherapy	NME	AA, BTD, PR, CoDx
Bevacizumab*	Platinum-sensitive ovarian cancer	Supplement	RA
Daratumumab‡	Multiple myeloma after at least one prior therapy	Supplement	RA, PR
Nivolumab	HNSCC after platinum-containing therapy	Supplement	RA, IO, BTD, PR
Pembrolizumab	First-line treatment of metastatic NSCLC with ≥50% of tumour cells expressing PD-L1	Supplement	RA, IO, BTD, PR, CoDx
Pembrolizumab	Second-line treatment of metastatic NSCLC with any level of PD-L1 expression	Supplement	RA, IO, CoDx
Olaratumab§	Soft-tissue sarcoma	NME	AA, BTD, PR
Atezolizumab	Second-line treatment of metastatic NSCLC	Supplement	RA, IO, BTD, CyDx
Pembrolizumab	HNSCC after platinum-containing therapy	Supplement	AA, IO, PR
Atezolizumab	Urothelial carcinoma after platinum-containing therapy	NME	AA, IO, BTD, PR, CyDx
Nivolumab	CHL after HSCT and brentuximab vedotin	Supplement	AA, IO, BTD, PR
Lenvatinib‖	Advanced-stage RCC after antiangiogenic agents	Supplement	RA, BTD, PR
Cabozantinib	Advanced-stage RCC after antiangiogenic agents	Supplement	RA, BTD, PR
Venetoclax	CLL with 17p deletion	NME	AA, BTD, PR, CoDx
Afatinib	Second-line treatment of squamous metastatic NSCLC	Supplement	RA
Defibrotide sodium	Hepatic veno-occlusive disease following HSCT	NME	RA, PR
Crizotinib	*ROS1*-rearranged metastatic NSCLC	Supplement	RA, BTD, PR
Everolimus	Progressive, well-differentiated, nonfunctional gastrointestinal or lung neuroendocrine tumours	Supplement	RA
Obinutuzumab¶	Follicular lymphoma after treatment with a rituximab-containing regimen	Supplement	RA, PR
Palbociclib#	HR-positive, *HER2*-negative metastatic breast cancer after endocrine therapy	Supplement	RA, PR
Eribulin	Metastatic liposarcoma after prior treatment with anthracyclines	Supplement	RA, PR
Ofatumumab	Maintenance therapy for patients with CLL after at least two prior lines of therapy	Supplement	RA, PR

AA, accelerated approval; BTD, breakthrough-therapy designation; BRCA, breast cancer susceptibility protein; CHL, classic Hodgkin lymphoma; CLL, chronic lymphocytic leukaemia; CoDx, companion diagnostic; CyDx, complementary diagnostic; HR, hormone receptor; HNSCC, head-and-neck squamous-cell carcinomas; HSCT, haematopoietic stem-cell transplantation; IO, immunotherapy; NME, new molecular entity; NSCLC, non-small-cell lung cancer; PR, priority review; RA, regular approval; RCC, renal cell carcinoma. *Plus carboplatin and paclitaxel or gemcitabine. Entries are listed by chronological order of approval. A more detailed summary of anticancer drug approvals in 2016 is provided on the FDA website. ‡Plus dexamethasone and lenalidomide or bortezomib. §Plus doxorubicin. ‖Plus everolimus. ¶Plus bendamustine. #Plus fulvestrant.

SUPPLEMENTARY INFORMATION

In format provided by Blumenthal and Pazdur (doi:10.1038/nrclinonc.2017.15)

Source: FDA, Nature Reviews | Clinical Oncology

effective treatments offers the greatest hope to millions of Americans patients and families coping with cancer.

"Within the FDA, the oncology division has demonstrated that it can increase the pace of drug approval and make more treatments available faster while maintaining critical safety and efficacy standards. We look forward to working with the administration to build on these successes while ensuring that the FDA continues to protect the health and well-being of Americans."

The number of cancer drugs approved is a testament to FDA's ability to review and rapidly bring therapies to the U.S. market, said Nancy Davidson, AACR president, executive director of oncology for Fred Hutchinson/University of Washington Cancer Consortium, and president of Seattle Cancer Care Alliance

"We've seen firsthand how the FDA has worked for years to build collaborative partnerships with academia, industry, other government agencies, scientific societies, and patient advocacy organizations to improve both the pace and quality of new cancer drugs reaching patients," Davidson said to The Cancer Letter.

"On an annual basis, approximately 30 percent of all new drugs approved by the FDA are oncology products, and Dr. Pazdur, along with the team at the FDA, has led the approval of many innovative treatments for cancer patients, such as the recent approvals of immune-check point inhibitors, immune modulators, and many of the targeted therapies that have extended the lives of patients and greatly improved their quality of life.

"Additionally, Dr. Pazdur and colleagues have embraced regulatory science to truly inform and improve the way in which new cancer medicines are evaluated for their safety and efficacy. For example, they are effectively employing a variety of regulatory tools such as master clinical trial protocols, expedited approval pathways, including the agency's new breakthrough therapy designation, and clinical trial enrichment strategies for approving targeted therapies in oncology.

"In the case of the breakthrough therapy designation, the FDA received statutory authority in 2012 to designate medical products as a "breakthrough therapy" if the therapy treats a serious or life-threatening disease or condition and if preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies.

"Since that time, the FDA has received over 500 breakthrough therapy designation applications and granted 170, of which more than 60 therapies have received accelerated approval, a majority being oncology products. These successes are a testament to the accomplishments of the FDA in bringing cancer medicines rapidly to patients."

IN BRIEF

Karmanos, Wayne State receive grant to conduct nation's largest study of factors affecting African Americans with cancer

The Karmanos Cancer Institute and Wayne State University School of Medicine will launch the nation's largest study of African American cancer survivors to better understand disproportionately high incidence and mortality from cancer and its impact on this specific patient population.

The study is being funded with a five-year, $9 million grant from the National Cancer Institute.

"This study is uniquely poised to investigate the major factors affecting African-American cancer survivors," Douglas Lowy, acting director of NCI, said in a statement.

"Efforts like this will help us move toward bridging the gap of cancer disparities, ensuring that advances in cancer prevention, diagnosis, and treatment reach all Americans."

Principal Investigators Ann Schwartz, professor and deputy center director, and Terrance Albrecht, professor and associate director for population sciences at Karmanos and Wayne State, will lead the research.

According to Schwartz and Albrecht, the Detroit Research on Cancer Survivors (Detroit ROCS) study will include 5,560 cancer survivors to better understand major factors affecting cancer progression, recurrence, mortality and quality of life in African American cancer survivors.

African Americans continue to experience disproportionately higher cancer incidence rates than other racial/ethnic groups in the United States. They are also diagnosed with more advanced-stage disease and experience higher cancer mortality rates than other groups.

The Detroit ROCS study will focus on lung, breast, prostate and colorectal cancers—the four most common cancers—each of which is marked by poorer survival rates among African Americans than whites.

A unique aspect of this study is the inclusion of 2,780 family members to understand how a cancer diagnosis affects the mental, physical and financial health of those providing care.

The study also brings an added benefit to doctors who treat African American cancer patients.

An earlier pilot study, supported by a $400,000 grant from GM Foundation and additional funds from Karmanos Cancer Institute, made it possible for Karmanos' scientists to collect the data necessary to secure the NCI funding for the larger study.

Feldman named chief of breast surgery & surgical oncology, director of breast cancer services at Montefiore and Einstein

Sheldon M. Feldman was named chief of the division of breast surgery and surgical oncology, and director of Breast Cancer Services at Montefiore Einstein Center for Cancer Care, the clinical arm of the Albert Einstein Cancer Center.

Feldman will also join the faculty of Albert Einstein College of Medicine as a professor of clinical surgery. Feldman has pioneered techniques such as intraoperative radiation. He is also an innovator in reducing risk of lymphedema. Feldman is the president of the American Society of Breast Surgeons.

Feldman is the former chief of the breast surgery division at New York-Presbyterian Hospital/ Columbia University Medical Center and as the Vivian L. Milstein Associate Professor of Clinical Surgery. Feldman will serve

as a principle investigator on multiple breast cancer studies focused on advancing prevention, early diagnosis and patient centered treatment of the disease.

Michael Rosen named chief communications officer at Pancreatic Cancer Action Network

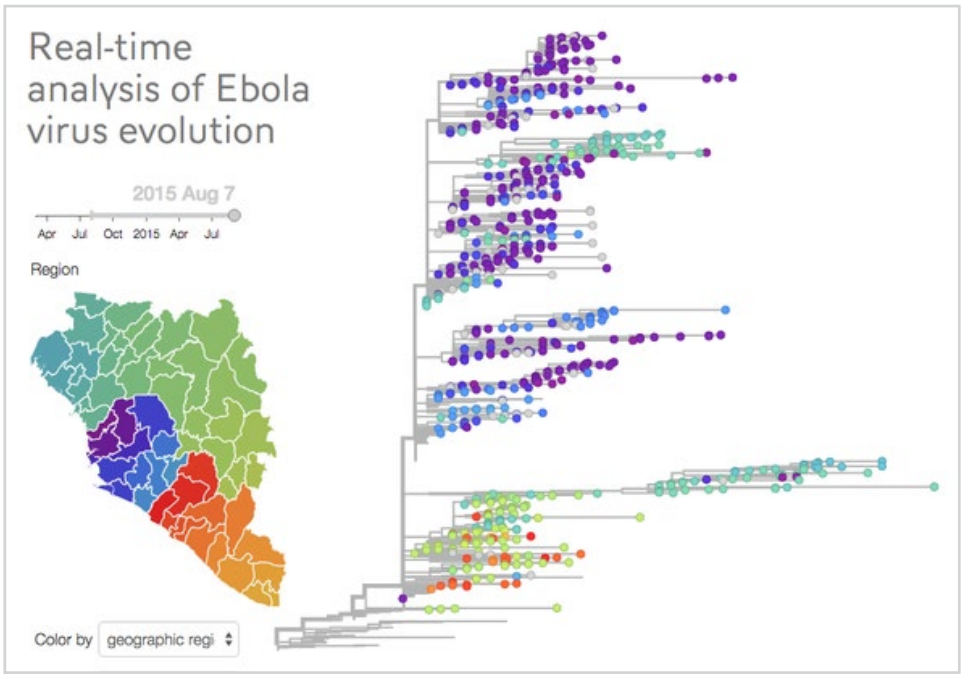
Michael Rosen was named chief communications officer at the Pancreatic Cancer Action Network.

One of Rosen's key roles will be increasing awareness about the organization's ground breaking research and clinical initiatives like Precision Promise, a revolutionary clinical trial that will dramatically accelerate progress and bring promising therapies to patients faster.

Most recently, Rosen served as executive vice president of marketing and communications for the Mental Health Association of New York City, where he managed all marketing, communications strategies and development.

Between 2013 and 2016, Rosen led strategic communications for Autism Speaks, the world's largest autism advocacy organization.

Prior to entering the nonprofit sector, Rosen was the executive producer first of The Saturday Early Show and then CBS This Morning Saturday. At ABC News, Rosen was second in charge for the network's Peabody Award-winning coverage of 9/11, and covered the war in Kosovo on location. Rosen has won three Emmy Awards, two Peabody Awards and four DuPont Awards.



Open Science Prize goes to software tool for tracking viral outbreaks

After three rounds of competition — one of which involved a public vote — a software tool developed by researchers at Fred Hutchinson Cancer Research Center and the University of Basel to track Zika, Ebola and other viral disease outbreaks in real time has won the first-ever international Open Science Prize.

Fred Hutch evolutionary biologist Trevor Bedford and physicist and computational biologist Richard Neher of the Biozentum Center for Molecular Life Studies in Basel, Switzerland, designed a prototype called nextstrain to analyze and track genetic mutations during the Ebola and Zika outbreaks.

Using the platform Bedford and Neher built, anyone can download the source code from the public-access code-sharing site GitHub, run genetic sequencing data for the outbreak they are following through the pipeline and build a web page showing a phylogenetic tree, or genetic history of the outbreak, in a few minutes, Bedford said.

He and Neher envision the tool as adaptable for any virus — a goal to which they will apply the $230,000 prize announced today by its three sponsors, the U.S. National Institutes of Health, the British-based charitable foundation Wellcome Trust and the U.S.-based Howard Hughes Medical Institute.

"Everyone is doing sequencing, but most people aren't able to analyze their sequences as well or as quickly as they might want to," Bedford said. "We're trying to fill in this gap so that the World Health Organization or the U.S. Centers for Disease Control and Prevention — or whoever — can have better analysis tools to do what they do. We're hoping that will get our software in the hands of a lot of people."

For now, the tool is easy to use for Zika and Ebola. (The researchers also built a separate platform called nextflu for influenza.) But adapting the platform for other pathogens still involves a fair amount of work and technical skill, so Bedford is working with a web

developer to "get that bar down so it will be easier to have this built out for other things."

By lowering the technical bar, he and Neher hope to nudge researchers to overcome another obstacle: a long-standing reluctance to share data. That is also a goal of the Open Science Prize. Bedford and Neher were among six teams of finalists chosen in May from 96 entries representing 450 innovators and 45 countries.

Fred Hutchinson announces Harold M. Weintraub Graduate Student Award winners

Fred Hutchinson Cancer Research Center today announced the recipients of the Harold M. Weintraub Graduate Student Award, which recognizes the outstanding achievement of graduate studies in the biological sciences. The thirteen award recipients were chosen by a selection committee of Fred Hutch faculty members and students for the quality, originality and significance of their work, and for representation of a diverse range of research topics.

The 2017 awardees attend universities across the U.S. — from Caltech to the Massachusetts Institute of Technology to Baylor College — and one international recipient who attends the Weizmann Institute of Science in Israel. Their studies explore areas as far ranging as evolvability and order in the nervous system, how microbiome dynamics may control host immunity and metabolism and innovative treatment strategies for mitochondrial disease.

Named for the late Harold Weintraub, the award honors Weintraub's scientific leadership in the field of molecular biology and his legacy as an extraordinary mentor, colleague, collaborator and friend. He was passionate about understanding how a certain protein drives cell development, investigating RNA interference, and applying molecular manipulations pioneered in his lab to other areas of medical research, such as stem cell transplantation.

Weintraub helped found the Basic Sciences Division at Fred Hutch and died of brain cancer in 1995 at age 49.

Weintraub Award recipients will travel to Seattle for an award symposium held May 5 on the Fred Hutch campus. At the symposium, recipients will give scientific presentations and have the opportunity to convene with other students and faculty members.

Each awardee will receive a certificate, travel expenses and honorarium from The Weintraub and Groudine Fund, created to foster intellectual exchange through supporting programs for graduate students, fellows and visiting scholars.

2017 Harold M. Weintraub Graduate Student Award recipients:

- **Thomas Bartlett**
  Molecular Biology
  Princeton University
- **Lynne Chantranupong**
  Biology
  Massachusetts Institute of Technology
- **Raphael Cohn**
  Neurophysiology and Behavior
  Rockefeller University
- **Kelsie Eichel**
  Cellular Biology
  University of California, San Francisco
- **Qing Feng**
  Molecular and Cellular Biology
  Fred Hutch/University of Washington
- **Isha Jain**
  Health Sciences and Technology
  Massachusetts Institute of Technology
- **Daniel Lin**
  Biochemistry and Molecular Biophysics
  Caltech
- **Lucy Liu**
  Neuroscience
  Baylor College of Medicine
- **Siew Cheng Phua**
  Cellular and Molecular Biology
  Johns Hopkins School of Medicine
- **Dheeraj Roy**
  Brain & Cognitive Sciences
  Massachusetts Institute of Technology
- **Sukrit Silas**
  Chemical and Systems Biology
  Stanford University
- **Christoph Thaiss**
  Immunology
  Weizmann Institute of Science
- **Candice Yip**
  Neurobiology
  Harvard Medical School

Boehringer Ingelheim, Vanderbilt expand collaboration to tackle hard-to-treat cancers

Boehringer Ingelheim announced a new multi-year collaboration with Vanderbilt University, complementing an already existing collaboration by focusing on the research and development of small molecule compounds targeting the protein SOS (Son Of Sevenless).

This molecule activates KRAS, a molecular switch that plays a central role in the onset of some of the deadliest can-

cers. The collaboration combines pioneering research in the laboratory of Stephen Fesik, Orrin H. Ingram II professor in cancer research at Vanderbilt, with the unique expertise and strength of Boehringer Ingelheim in drug discovery and clinical development.

The collaboration adds to an ongoing joint project with Vanderbilt initiated in 2015 that achieved two major milestones by identifying lead compounds that bind to KRAS with high affinities. These discoveries raise the prospect of developing novel cancer treatment options based on molecules that are able to block this critical cancer driver.

Mutations in the genes that encode KRAS are among the most powerful and frequent cancer drivers. They contribute to some of the most aggressive and deadly cancers, including up to 25 percent of lung, 35-45 percent of colorectal and about 90 percent of pancreatic tumors.

KRAS has been a particularly difficult protein to target and no effective treatments targeting KRAS have been developed since its discovery in human cancers more than 30 years ago. The development of the first molecules inhibiting KRAS activation promises huge potential for the development of improved cancer therapies, which would offer treating physicians unprecedented options to complement existing treatment regimens.

iKnowMed recognized as No. 1 oncology EHR by Black Book Research

For the sixth year in a row, iKnowMed electronic health record has been named the top-ranked EHR platform for oncologists and hematologists by Black Book Research, an industry-leading source for polling, surveys and market research.

iKnowMed was recognized for its superior focus on meeting the unique needs of community-based oncology practices. Implemented in nearly 650 sites of care nationwide and used by 1,700 providers, iKnowMed was the top-ranked oncology EHR across all practice sizes and delivery sites.

The EHR platform received number one rankings in nine key performance areas – the most in this year's report - including support and customer care, client relationships and cultural fit, reliability, best of breed technology and process improvement, and strategic alignment with client goals.

iKnowMed Generation 2, developed in collaboration with oncologists in The US Oncology Network and supported by McKesson Specialty Health, was the first next generation EHR for oncology and hematology available. This innovative EHR platform seamlessly integrates with McKesson Specialty Health's technology solutions.

CTCA, Allscripts, NantHealth to launch clinical pathways, custom oncology treatment platform

Cancer Treatment Centers of America, in collaboration with NantHealth and Allscripts, is implementing a custom technical solution that, for the first time, enables eviti, a NantHealth clinical decision support solution, access to clinical workflows in the Allscripts Sunrise electronic health record.

With integration of this clinical decision support solution, the Clinical Pathways program helps inform the cancer treatment process, without interrupting the physician's clinical workflow.
The direct interface of the clinical operating system was built with the input of hundreds of oncologists across the nation and holds a comprehensive collection of evolving cancer care data. Clinical Pathways integrates the latest cancer research available, treatment regimens and complementary therapies into the Allscripts Sunrise EHR, giving oncologists the ability to create a curated list of care protocols at the point of care.

When the treatment platform is engaged, it provides:

- Custom treatment regimens specific to the patient, their health and specific disease state
- Comparisons between treatment options, including average market cost of delivery
- Computer order entry with the tap of the screen – safe for the patient and efficient
- Each treatment regimen recommended by eviti is mapped within the EHR to proprietary CTCA order sets that reflect an integrative approach to care delivery, which combines evidence-based clinical approaches with supportive therapies to meet each patient›s unique needs and optimize their quality of life while undergoing cancer treatment
- Access to referenced up-to-date guidelines, response rates, adverse drug reactions and toxicity
- Supporting clinical data
- Real-time functionality

The integration of the eviti solution with Allscripts Sunrise EHR for Clinical Pathways allows physicians to retrieve information from an unbiased Evidence-Based Medical Library, which encompasses over 2,700 treatment regimens covering all cancers and cancer subtypes and all modalities.

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Each regimen incorporates the level of evidence, expected clinical outcomes, treatment costs, toxicities and supporting literature. Once a regimen is selected, providers can launch directly into order entry through Allscripts' open ability to integrate eviti regimens with Sunrise order sets.

Blackfynn and CHOP expand partnership for data integration and analysis in pediatric brain tumors

Blackfynn and Children's Hospital of Philadelphia said they have expanded their relationship. Under the expanded relationship, Blackfynn's Data Platform will be used by CHOP and the Children's Brain Tumor Tissue Consortium to bring together complex non-identifiable patient data for collaboration and analysis, thereby accelerating translational discovery toward treatments for brain cancer in children.

Blackfynn and CHOP began their relationship focused on pathology data one year ago. The expanded relationship will allow ongoing access to the Blackfynn Data Platform for CHOP and CBTTC members to conduct research across non-identifiable patient data, including pathology, imaging, genomics, EEG, clinical and other data. The ability to integrate and conduct analyses across all relevant data together is crucial to identifying meaningful patterns in treatment and disease.

Blackfynn is a privately held life sciences company focused on the development of a data platform to enable integration and analytics of complex, multimodal research and clinical data to enable better therapeutics and clinical care for patients with neurologic disease.

DRUGS & TARGETS

FDA approves Xermelo as first and only treatment for carcinoid syndrome diarrhea

Lexicon Pharmaceuticals Inc. said FDA approved Xermelo (telotristat ethyl) 250 mg as a first and only orally administered therapy for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog therapy in adults inadequately controlled by SSA therapyi.

Carcinoid syndrome is a rare and debilitating condition that affects people with metastatic neuroendocrine tumors (mNETs)ii.

Xermelo targets the overproduction of serotonin inside mNET cellsiii, providing a new treatment option for patients suffering from carcinoid syndrome diarrhea.

Carcinoid syndrome is a rare condition that occurs in patients living with mNETsiv and is characterized by frequent and debilitating diarrhea that often prevents patients from leading active, predictable lives, as well as by facial flushing, abdominal pain, fatigue and, over time, heart valve damage.

"The approval of XERMELO establishes a new treatment option for patients with carcinoid syndrome diarrhea that is inadequately controlled by SSA therapy," said Matthew Kulke, primary investigator of the company trial and director of the Program in Neuroendocrine and Carcinoid Tumors at Dana Farber Cancer Institute. "Inhibition of tumoral serotonin production represents a novel approach for patients with this condition."

Discovered using Lexicon's approach to gene science, Xermelo is the first and only approved oral therapy for carcinoid syndrome diarrhea. Xermelo targets tryptophan hydroxylase, an enzyme that mediates the excess serotonin production within mNET cells.

According to the label, a 12-week double-blind, placebo-controlled, randomized, multicenter trial of Xermelo was conducted in adult patients with a well-differentiated metastatic neuroendocrine tumor and carcinoid syndrome diarrhea who were having between four to 12 daily bowel movements despite the use of SSA therapy at a stable dose for at least three months.

Patients were randomized to placebo or treatment with Xermelo 250 mg three times daily. A total of 90 patients were evaluated for efficacy. The primary efficacy endpoint was the change from baseline in the number of daily bowel movements averaged over the 12-week treatment period.

In the 12-week study, a difference in average weekly reductions in bowel movement frequency between Xermelo and placebo was observed as early as one to three weeks, and persisted for the remaining nine weeks of the study.

FDA Accepts avelumab BLA for Priority Review for urothelial carcinoma

Merck and Pfizer Inc. said FDA accepted for priority review the BLAfor avelumab for patients with locally advanced or metastatic urothelial carcinoma with disease progression on or after platinum-based therapy.

The BLA was submitted by EMD Serono, the biopharmaceutical business of Merck in the US and Canada. The FDA has set a Prescription Drug User Fee Act target action date of Aug. 27.

"Taken together with last year's filing for metastatic Merkel cell carcinoma, this BLA acceptance confirms our rapid and continued progress in the clinical development of avelumab," said Luciano Rossetti, executive vice president, global head of research & development at the biopharma business of Merck. "We continue to evaluate avelumab in cancers that have limited or suboptimal treatment choices, such as metastatic or locally advanced urothelial carcinoma, to hopefully be able to provide patients with new treatment options for fighting their disease."

Despite advances in the treatment of UC, the prognosis for patients remains poor, particularly when the disease has metastasized. Bladder cancer makes up approximately 90% of urothelial cancers and is the sixth most common cancer in the US.

Avelumab is an investigational, fully human anti-PD-L1 antibody. FDA's priority review status reduces the review time from 10 months to a goal of six months from the day of filing acceptance and is given to drugs that may offer major advances in treatment or may provide a treatment where no adequate therapy exists. In November 2016, the FDA accepted, and granted Priority Review status to, the BLA for avelumab for the treatment of patients with metastatic Merkel cell carcinoma.

The international clinical development program for avelumab, known as JAVELIN, involves at least 30 clinical programs, including nine phase III trials, and more than 4,000 patients evaluated across more than 15 tumor types. In December 2015, Merck and Pfizer announced the initiation of a phase III study (JAVELIN Bladder 100) of avelumab in the first-line setting as a maintenance treatment in patients with locally advanced or metastatic UC. This trial is enrolling patients.

BMS expands International Immuno-Oncology Network with addition of Columbia and MacCallum Cancer Centre

Bristol-Myers Squibb announced that Columbia University Medical Center and Peter MacCallum Cancer Centre joined the International Immuno-Oncology Network (II-ON), a global peer-to-peer collaboration between BMS and academia that aims to advance immuno-oncology science and translational medicine to improve patient outcomes.

Launched in 2012 by BMS, the II-ON was one of the first networks to bring academia and industry together to further the scientific understanding of I-O, and has expanded from ten to 15 sites including more than 250 investigators working on over 150 projects across 20 tumor types.

The II-ON has generated cutting-edge I-O data that have informed the development of new I-O agents, yielded publications and produced some of the earliest findings on a variety of biomarkers and target identification and validation.

Through the II-ON, Bristol-Myers Squibb is collaborating with leading cancer research institutions around the world to generate innovative I-O science, launch biology-driven trials and seek out cutting-edge technologies with the goal of translating research findings into clinical trials and, ultimately, clinical practice. Building on the II-ON, BMS has invested in several other models of scientific collaboration with academic partners across the globe, including the Global Expert Centers Initiative and the Immuno-Oncology Integrated Community Oncology Network.

The research in the collaboration is focused on three fundamental scientific pillars: understanding the mechanisms of resistance to immunotherapy; identifying patient populations likely to benefit from immunotherapy; and exploring novel combination therapies that may enhance anti-tumor response through complementary mechanisms of action.

The II-ON facilitates the translation of scientific research findings into drug discovery and development, with the goal of introducing new treatment options into clinical practice.

In addition to Bristol-Myers Squibb, the II-ON comprises 15 cancer research institutions, including: Clinica Universidad Navarra, Dana-Farber Cancer Institute, The Earle A. Chiles Research Institute, Institut Gustave Roussy, Istituto Nazionale per lo Studio e la Cura dei Tumori, Bloomberg-Kimmel Institute for Cancer Immunotherapy at the Johns Hopkins Kimmel Cancer Center, Memorial Sloan Kettering Cancer Center, National Cancer Center Japan, The Netherlands Cancer Institute, The Royal Marsden NHS Foundation Trust and The Institute of Cancer Research, Uni-

versity College London, the University of Chicago, West German Cancer Center/University Hospital Essen, and now Columbia University Medical Center and Peter MacCallum Cancer Centre.

Exelixis, BMS collaborate on late-stage combination trial in first-line RCC

Exelixis Inc. and Bristol-Myers Squibb Co. entered into a clinical development collaboration to evaluate Cabometyx (cabozantinib), Exelixis' small molecule inhibitor of receptor tyrosine kinases, with BMS's Opdivo (nivolumab), either alone or in combination with Yervoy (ipilimumab).

The clinical development program, which will be co-funded by the companies, is expected to include a phase III pivotal trial in first-line renal cell carcinoma, with additional trials planned in bladder cancer, hepatocellular carcinoma, and potentially other tumor types.

Cabometyx and Opdivo have both received approval in the U.S, and E.U. for specific uses in previously treated renal cell carcinoma, and both compounds are the subject of ongoing, global phase III pivotal trials in hepatocellular carcinoma. Opdivo is approved in the United States for previously treated bladder cancer.

Exelixis, Roche to evaluate cabozantinib and atezolizumab in solid tumors

Exelixis Inc. announced a new collaboration with Roche on a phase Ib dose escalation study that will evaluate the safety and tolerability of cabozantinib, Exelixis' tyrosine kinase inhibitor, in combination with atezolizumab, Roche's anti-PD-L1 immunotherapy, in patients with locally advanced or metastatic solid tumors.

Enrollment is scheduled to begin mid-year 2017; Exelixis will be the sponsor of the trial, and Rochewill provide atezolizumab.

Based on the dose-escalation results, the trial has the potential to enroll up to four expansion cohorts, including a cohort of patients with previously untreated advanced clear cell renal cell carcinoma and three cohorts of urothelial carcinoma, namely platinum eligible first-line patients, first- or second-line platinum ineligible patients, and patients previously treated with platinum-containing chemotherapy.

Ipsen, Exelixis' global partner for cabozantinib, except in the United States and Japan, will participate in this study and have access to the results for potential future development in its territories.

Takeda may also participate in these and future studies and have access to the results to support potential future regulatory submissions in their territories, if they opt into their funding obligations under the respective collaboration agreement.

Advaxis, SELLAS announce licensing agreement to develop antigen-targeting immunotherapy

Advaxis Inc. granted SELLAS Life Sciences Group a license to develop a novel cancer immunotherapy agent using Advaxis' proprietary Lm-based antigen delivery technology with SELLAS' patented WT1 targeted heteroclitic peptide antigen mixture (galinpepimut-S).

Advaxis' proprietary technology generates innate immune stimulation, alongside potent and sustained T-cell responses.

When combined with SELLAS' WT1 antigens, this has the potential to precisely direct an immune response, yielding improved clinical activity against many cancer types that express WT1. SELLAS' future clinical studies will investigate this capability in the presence of measurable residual or recurrent disease.

Galinpepimut-S has demonstrated positive phase II clinical results in acute myeloid leukemia and malignant pleural mesothelioma and positive early clinical data in multiple myeloma. It has been shown to induce strong immune responses (CD4+/CD8+) against the WT1 antigen and to access a broad range of HLA types.

Advaxis's Lm-based antigen delivery technology has demonstrated the potential to induce an enhanced innate immune stimulation and generate specific T cells while reducing immune tolerance in the tumor microenvironment.

Advaxis will conduct all pre-clinical activities required for an IND filing.

Thereafter, SELLAS will be responsible for all clinical development and commercial activities. Advaxis will receive future payments of up to $358 million from SELLAS if development, regulatory, and commercial milestones are met.

Following any regulatory approval of the product candidate emanating from this particular program, SELLAS has agreed to pay Advaxis single-digit to low double-digit royalties based on worldwide net sales upon commercialization.