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MARKEY CANCER CENTER

In a region where cancer is at its worst, it takes bold action to make a difference. That's why the University of Kentucky Markey Cancer Center has set an ambitious goal: significantly reduce cancer incidence and mortality in our state, and the Appalachian region, by 2020. With the momentum we're building, we believe **MARKEY CAN** do it.

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THE CANCER LETTER | JANUARY 6, 2017 | VOL 43 | ISSUE 01

Paul Goldberg
Editor & Publisher,
The Cancer Letter

Introducing a redesign of The Cancer Letter

Dear Reader,

The Cancer Letter is starting 2017 with something we haven't done in … well, ever.

We've redesigned our "print" edition. I hesitate to say PDF, because, there was no such thing on Dec. 21, 1973, when our newsletter layout was first executed.

Ours was a practical design: two "galleys" per page. The galleys were typeset on a super-duper, iconic IBM Selectric typewriter—the sort that could actually justify lines! Thus typeset, the galleys were placed on a light table and attached with rubber cement to the mockup pages. The mockup was then taken, by car, to the printer and mailer.

The Cancer Letter had to be strictly at eight pages per issue so it could be folded, and placed in envelopes. Twelve pages could be done, but expensive to produce and mail. The process was digitized in 1989, but the layout lived on.

We've been getting away from our spartan design heritage over the past three years: first, by launching our new website in January 2014, to enable you to read and share individual articles online. Then, we added videos and weekly art features.

For a while, we thought the PDF would go the way of the Betamax, eight-track tapes, and, for that matter, the IBM Selectric. These predictions notwithstanding, the PDF remains popular, even as our web readership doubles annually. This sleek, colorful redesign is our recognition that many of you like to print and read.

Now, take a look at the issue in your hands (or on your electronic device). It's just as newsy, but less severe, and easier to navigate. We put in more white space, abandoned the primeval Times New Roman font, and, to reduce visual fatigue, moved the body copy into three columns. The bite-sized version of our logo also acknowledges that many of you have been referring to The Cancer Letter simply as TCL.

Also, we listened to our advertisers. We introduced web ads three years ago, but due to popular demand, we are bringing back full-page PDF ads. Cancer centers, universities, pharmaceutical companies, and government agencies continue to widely circulate the PDF, from desk to desk, or via email. Your institution can now place premium PDF ads that will reach our growing list of over 120 site license subscribers—pretty much everyone who matters in oncology.

Over the years, many a design consultant has told us to update our logo, which they described as "too retro." A bit of history: an art student whose name we no longer remember created the logo in 1973. Jerry Boyd, the founder of The Cancer Letter, paid him a princely sum of $60 for his excellent work. We like it, and we are keeping it.

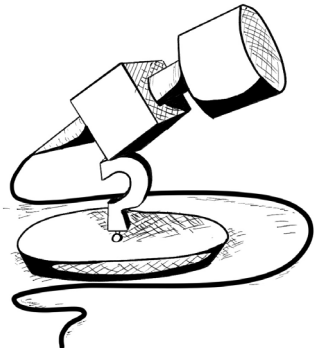
However, this time, we allowed a designer, Jacqueline Ong, to clean up the logo, while maintaining the look and feel that has been a part of the cancer world since the launch of Richard Nixon's National Cancer Program.

With the beginning of the Trump administration two weeks—and one issue—away, we look forward to continuing the in-depth, cutting-edge reporting that defines The Cancer Letter.

DOUG LOWY ON THE MOONSHOT, NCI'S INVIGORATED AGENDA

As administrations change, cancer research stands in an unusually strong position, NCI Acting Director Douglas Lowy said in an interview with The Cancer Letter.

CONVERSATION WITH THE CANCER LETTER



> I'm the acting director of the NCI, so I am not a presidential appointee; therefore, I am simply staying on. I would be very happy to continue as acting director or to become the permanent director, but those decisions are above my pay grade.

Watch the interview with NCI Acting Director Douglas Lowy here.

"We're very fortunate that both Republicans and Democrats strongly support biomedical research in general, and cancer research in particular," Lowy said in a wide-ranging interview. "The leadership of the House and Senate appropriations subcommittees was responsible for the increase in FY16 for the NIH appropriation."

With the importance of cancer research catapulted to a new level of visibility by Vice President Joe Biden's Cancer Moonshot, the White House Precision Medicine Initiative, and the 21st Century Cures Act, Congress is likely to continue investing in biomedical research during the Trump administration, Lowy said.

"[House and Senate leaders] have both said they don't want to be one-year wonders," he said. "They both strongly support increasing the NIH budget, including increases for NCI, and I look forward to that being a very important aspect of an accomplishment for the incoming Congress."

In the past, NCI directors moved on when administrations changed, but not immediately. Richard Klausner, for example, started his job as institute director 31 months into the Clinton administration (The Cancer Letter, Dec. 9, 2016).

Lowy's case is unique because he is an acting director, and therefore not a presidential appointee. While other appointees were expected to submit their letters of resignation, Lowy wasn't.

"I'm the acting director of the NCI, so I am not a presidential appointee; therefore, I am simply staying on," Lowy said. "I would be very happy to continue as acting director or to become the permanent director, but those decisions are above my pay grade."

Lowy, who is known for his decades of research into HPV and cancer, became acting director of NCI on April 1, 2015, when Harold Varmus, the institute's 14th director, left for Weill Cornell Medical College's faculty as the Lewis Thomas University Professor of Medicine, and teamed up with the New York Genome Center as a senior associate core member to promote the use of cancer genomics (The Cancer Letter, March 6, 2015).

NCI is working with Big Data leaders and cancer centers to aggregate and share molecular and clinical information in a federated, interoperable system, Lowy said.

"NCI can be a leader, but this is a problem that goes far beyond NCI, and we need to work with many entities in order to accomplish this goal," he said. "In the long run, I suspect that this will be an international system that will include data from other countries as well as data from different sources in the United States.

"For the NCI, we have the Genomic Data Commons, which is one of the signature achievements of this past year." (The Cancer Letter, June 10, 2016).

On Lowy's watch, NCI increased funding for investigator-initiated research and the cancer centers. Though NCI is slated to receive new money for its moonshot activities, these funds will flow to NIH (The Cancer Letter, Dec. 2, 2016).

"I can safely say that we are working very closely with [NIH Director] Francis Collins to make sure that the quality of the research and its scope are very much in keeping with the Beau Biden Cancer Moonshot initiative and the recommendations of the [NCI Blue Ribbon Panel]," Lowy said (The Cancer Letter, Sept. 9, 2016).

Lowy spoke with Paul Goldberg, editor and publisher of The Cancer Letter, and Matthew Ong, a reporter with The Cancer Letter.

Paul Goldberg:

Dr. Lowy, you've been the acting director for almost two years. How do you like the job?

Douglas Lowy:
It's really a terrific job. It is a great opportunity for me to lead the cancer research effort here in the U.S.

PG:

What's the best part of the job? What's the most difficult?

DL:
The best part of the job, really, I would say there are two aspects:

The first is seeing the tangible benefits that come from research that we are supporting, and those benefits include increased understanding of cancer, and then tangible benefits to our patients.

The second part is being able to work with a large number of fantastic people at the NCI and cancer researchers throughout the country and the world, and also the cancer advocacy community.

Matthew Ong:

What are NCI's most notable accomplishments during your time as acting director?

DL:
This has been a really active time for cancer research, and so there really are quite a few accomplishments that have occurred. First, we have increased the funding for investigator-initiated research and, second, we have increased the funding for the NCI cancer centers, which is where the majority of our extramural funding actually goes.

In addition, we have given renewed emphasis to cancer health disparities with new initiatives in that area, and we have been extraordinarily fortunate in having not one, but two initiatives from the White House that shine a light on the importance of cancer research: the Precision Medicine Initiative in oncology, which was in 2015 for the FY16, and most recently the Beau Biden Cancer Moonshot, which was very recently funded.

This is enabling us to make substantial progress and more strongly support precision medicine and a broad area of research that we have been supporting up to now, but can do so in a much more effective and efficient way.

PG:

You've been able to do this without overpromising too, which—just noting it—that must have been difficult.

DL:
I feel that cancer is a problem that has been with us since, really, men have walked the Earth, and there are Egyptian mummies that have evidence of cancer.

And even though I look forward to us making tremendous strides, we are going to continue to be faced with people being at risk of developing cancer, and for the foreseeable future, developing cancer, because we all understand that, while, cancer, when it develops in children is a terrible thing, in terms of overall incidence and mortality, it really is a disease of older people, and because we are living longer, cancer, of necessity, is going to affect a lot of us.

PG:

We know that you've saved lives through your work on the HPV vaccine, but we don't know much, actually, we don't know anything about your politics. How do you see politics coming into play in terms of your staying or going?

DL:
Fortunately, cancer and cancer research transcend politics. I think that this is a disease that people of all different persuasions are affected by and everyone understands that in order to make progress, there needs to be research and we're extremely fortunate that there is bipartisan support that is very strong for cancer research.

PG:

But in terms of your predecessors staying or going and when administrations change ...

DL:
Well, I'm the acting director of the NCI, so I am not a presidential appointee; therefore, I am simply staying on. I would be very happy to continue as acting director or to become the permanent director, but those decisions are above my pay grade.

PG:

But the science is in a different place than it was with your predecessors. Does that argue for your staying, in a sense, because of continuity, for example?

DL:
I would very much like to be able to continue to pursue the cancer research efforts that we are initiating, but I certainly also appreciate that there are other people who are capable of doing this, and whatever the new administration decides, that's what will happen.

MO:

And if you do not become a permanent director, will you be continuing your work at NCI?

DL:
Yes. I certainly will look forward to doing that, having an opportunity to spend more time in the laboratory would be a little bit like Br'er Rabbit being thrown back in the briar patch.

MO:

Right. What would you work on?

DL:
My research involves mainly papilloma viruses and also some growth regulatory genes, and I would look forward to being able to continue to do that research. As a matter of fact, my laboratory has its site visit this coming November, and I'm looking forward to our getting a positive review, but, as with all other research endeavors, peer review is critically important.

PG:

What do you expect from the incoming administration and Congress? What will they do about biomedical research, based on what you are seeing now?

DL:
As I said earlier, we're very fortunate that both Republicans and Democrats strongly support biomedical research in general, and cancer research in particular. The leadership of the House and Senate appropriations subcommittees was responsible for the increase in FY16 for the NIH appropriation.

They have both said they don't want to be one-year wonders. They both strongly support increasing the NIH budget, including increases for NCI, and I look forward to that being a very important aspect of an accomplishment for the incoming Congress.

MO:

And now that the Cancer Moonshot has actually received funding in the [21st Century] Cures bill and the continuing resolution, has that money come to NCI?

DL:
We are working very closely with NIH leadership to make sure that the money from the Cancer Moonshot is spent wisely on meritorious research that is aligned with the recommendations of the Blue Ribbon Panel.

MO:

Do you have an estimate of when that might occur in fiscal 2017?

DL:
Probably in the near future we'll have a clearer idea, but right now I can safely say that we are working very closely with [NIH Director] Francis Collins to make sure that the quality of the research and its scope are very much in keeping with the Beau Biden Cancer Moonshot initiative and the recommendations of the BRP.

PG:

How will you be prioritizing the implementation of the Blue Ribbon Panel recommendations, and which of the recommendations do you see NCI acting on right away?

DL:
All of the recommendations are important, but there are aspects of the recommendations which are easier to implement than others, and so we will be prioritizing according to ease of implementation, in terms of what we do right now, but we are setting up implementation teams and will continue to get input from our advisory groups, as well as from others, to prioritize how the research is done.

I should also point out that we can't do this alone, and we're really looking forward to working collaboratively with the private sector, with private philanthropy, as well as with other countries and funders in other countries to help to accomplish the ambitious goals of the Cancer Moonshot.

MO:

As a public entity, NCI seems to have been designated as the de facto leader for data sharing in oncology as part of the moonshot. Do you foresee NCI playing a larger role in terms of facilitating and developing standards for aggregating health data?

DL:
Yes. Data-sharing clearly has been front and center especially for Vice President [Joe] Biden and we have already had a number of meetings with the NCI cancer centers as well as with leaders from different platforms for large data, and we, I think, all agree that we are working towards the goal of being able to aggregate and share data much more efficiently and comprehensively than has been possible—in the future. Again, NCI can be a leader, but this is a problem that goes far beyond NCI, and we need to work with many entities in order to accomplish this goal.

MO:

Right. And you think at some point those standards may actually become a reality?

DL:
I think that we will end up with a federated, interoperable system, but, importantly, we will try to have data that's not only molecular information about cancer, not only clinical information about how people have been treated and the outcome, but putting the two together with a large number of patients, so that we can use that aggregated data to make as much progress as possible through the analysis of large data.

PG:

How large a federated, interoperable system will it be? What will it cover?

DL:
In the long run, I suspect that this will be an international system that will include data from other countries as well as data from different sources in the United States.

For the NCI, we have the Genomic Data Commons, which is one of the signature achievements of this past year, which was opened and housed at the University of Chicago, and all of the data that's supported by the NCI, really, is going to be housed in the GDC, and we are offering to other groups, if they wish to put their data into the GDC, to seriously consider it, and we would like to help incentivize that by providing resources to help make it easier for that to happen.

MO:

Do you think ... is there anyone else in the system that also has as large a role as NCI—an individual entity—is anyone else capable of doing this and leading this work?

DL:
To the extent that this is going to be an international effort, we want to work closely with colleagues outside of the United States, because the information that is generated in other countries can be usefully applied to the United States, because cancer has many similarities in other countries to cancer here, and, in fact, for example, we have signed memorandums of understanding to do cancer proteogenomics with a number of different countries, but focusing on the cancers that are of most importance to them.

PG:

How do the Big Data players in the industry fit into this?

DL:
We have been trying to work closely with Project Data Sphere, which is an activity of the CEO Roundtable on Cancer, and they have been aggregating and de-identifying data from completed clinical trials, and we look forward to being able to make use of those data, not just for standard chemotherapy, but also for more contemporary and newer forms of treatment, such as immunotherapy and targeted treatment.

MO:

How do you see the political continuity of the moonshot? I know it's been approved by the 21st Century Cures and authorized for funding. How do you see it panning out over the next, say, four years?

DL:
I think that we have a great start. We are committed to supporting some signature initiatives, utilizing the funds from the Cancer Moonshot, and we think that there will be really compelling evidence, and easy for people to see that this investment is going to pay off, and so we look forward to Congress renewing the funding for the moonshot for its duration.

PG:

What's the most important lesson you've learned on this job?

DL:
It's to be decisive, but making decisions only after you have gotten input from different perspectives.

That, really, is by far, I think, the most important lesson that I have learned.

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MD Anderson lays off 900 staff members

By Paul Goldberg

The year got off to a bad start for some employees of MD Anderson Cancer Center.

As part of a cost-cutting measure announced Jan. 5, about 900 of them received layoff notices.

Television crews crowded the parking garages of the Houston hospital, capturing images of teary-eyed people carrying boxes to their cars.

Almost 5 percent of MD Anderson's workforce of over 20,000 is being let go as the institution struggles to eliminate operating losses. During the first three months of the fiscal year that started Sept. 1, 2016, the cancer center lost $110 million on its operations.

MD Anderson President Ronald DePinho announced the layoffs in an email blast and a video.

"For months, we've been working to improve our financial performance," DePinho said in the email. "Despite great effort from everyone, we must take additional measures to protect our mission to end cancer. Today, I accepted a recommendation from the Shared Governance Committee, and I wanted you to hear this news directly from me.

"Since it isn't feasible to gather at one time as a community, I have recorded a video message you can watch by clicking on this image."

The video was available exclusively through MD Anderson, but a copy is posted here. DePinho also faced the press at a news conference later that day.

> "Despite great effort from everyone, we must take additional measures to protect our mission to end cancer. Today, I accepted a recommendation from the Shared Governance Committee, and I wanted you to hear this news directly from me."

The reduction in the workforce doesn't affect faculty positions. Most of those losing their jobs are classified staff: secretaries, administrative assistants, lab technicians, and administrators. Layoffs will continue through the end of the week, cancer center officials said.

On Jan. 4, the day before the staff cuts were announced, the Houston Chronicle reported that DePinho received a $208,000 annual performance bonus. DePinho's was the largest such bonus given to any president of a UT System institution in 2016.

However, DePinho told the Chronicle that he would donate the bonus to MD Anderson, a contribution that he described as "consistent with his annual charitable giving practices."

His total compensation, with the bonus included, is just above $2 million.

After watching the day's news coverage of the layoffs, Leonard Zwelling, a former physician and administrator at the hospital, had more questions than answers.

"It is safe to say that the leadership of Anderson was forced into this decision and took it reluctantly," Zwelling wrote on his blog. "But do the leaders take responsibility for the mismanagement that got the institution to this point? Is the layoff a good move?

"If they have a $2.8 billion war chest of cash reserves as they claim and if the 'balance sheet is strong,' is this layoff a statement of managerial neglect up to now on the part of these leaders? When they should have been running lean, were they running fat?

"Did the electronic medical record's slowing of the pace of care really account for the majority of this budget shortfall or are there other factors to blame like poor operations, a bloated workforce, and over-investment in drug development?"

Other large cancer centers in the black

MD Anderson lost $267.1 million in fiscal 2016.

Despite these operating losses, officials at the cancer center said repeatedly that they project ending fiscal 2017 in the black (The Cancer Letter, Dec. 9, Dec. 2, Nov. 4, 2016).

Explaining the losses last year, DePinho and other top MD Anderson officials said in a recent email that other institutions are similarly suffering from "decreasing clinical reimbursement from government and insurance companies, a shrinking pool of potential patients as insurance providers restrict coverage, and record rates of automatic denials by insurance companies contributing to bad debt."

Other large freestanding cancer centers aren't reporting operating losses:

Memorial Sloan Kettering Cancer Center reported $164 million in operating income through the first nine months of 2016, a 14.6% increase from the same period last year. Growth in the volume of outpatient visits and overall surgical visits resulted in an 8.9% growth in operating revenue to $2.9 billion. Operating expenses grew 8.6% to $2.8 billion.

Fred Hutchinson Cancer Research Center reported total revenues of $126.4 million and operating expenses of $117.1 million, giving it a $9.3 million operating surplus for the first quarter, which ended Sept. 30, 2016. For the fiscal year ended June 30, Fred Hutchinson reported total revenues of $615.5 million and expenses of $484.6 million, creating a $130.9 million surplus.

Speaking points for managers

To keep the message consistent, MD Anderson officials produced the following "speaking points" for managers to use to describe the layoffs and the financial problems that triggered them.

The document, which was obtained by The Cancer Letter, appears below:

- MD Anderson has had several months when our expenses have been higher than our revenue.
- A convergence of many internal and external factors contributed to our financial situation.
- Like other health care institutions, we're facing decreasing reimbursement from payors, regulatory changes that negatively impact reimbursement, the narrowing of insurance networks and an increase in denials.
- We've also made the necessary culture changes and adopted new ways of working as a result of our electronic health record. We have not yet realized our forecasted productivity and efficiency levels. We're seeing a recovery trend but more time is needed.
- Areas like personnel, overtime, purchased services and travel have driven up our expenses over time.
- For months, we've focused our efforts on controlling or eliminating expenses, increasing clinical activity and better using our people in critical positions or shared services. Many of you have been involved in these efforts and we thank you for your contributions.
- While we appreciate the skills and dedication of all our employees, personnel costs are our largest expense—nearly 60% of our overall expenses.
- We've implemented a less than 5% reduction in force. This percentage is less than originally planned due to the extraordinary productivity and efficiency efforts of everyone in the MD Anderson community.
- This reduction in force is a difficult step to take, but it will allow our organization to adapt to health care's current environment by lowering our expenses so we can continue providing high quality cancer prevention, diagnoses, treatment, education, research and survivorship.
- The decision to eliminate positions is a financial necessity. It means separating with staff who have supported MD Anderson patients and our mission. We appreciate their service.
- These reductions are only one part of the overall strategy to align expenses to revenue. We must continue to watch all expenses and increase revenue to ensure these changes are sustainable.
- We remain dedicated to our mission of eliminating cancer and, through collaboration and mission-driven decision-making, we'll find more efficient and cost-effective ways of delivering on this promise.
- Our patients remain our highest priority. We will continue to provide safe and effective care to those counting on us to save their lives.

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Biden plans to create moonshot nonprofit, may focus on drug prices

By Matthew Bin Han Ong

After leaving the White House, Vice President Joe Biden plans to consolidate his work on the Cancer Moonshot into an independent, nonprofit organization, while juggling non-cancer programs at two universities.

Biden aims to continue work on the National Cancer Moonshot Initiative through a new nonprofit that will not be connected to any cancer center or university, according to sources familiar with Biden's post-administration goals.

The vice president appears to be finalizing plans for creating a foreign policy institute at the University of Pennsylvania and a domestic policy institute at the University of Delaware—both within driving distance of his home in The First State.

After The Cancer Letter first reported Biden's plans Dec. 22, the vice president said he would create "The Biden Trust, to continue the cancer work." He seems to have revealed these details inadvertently, in a conversation picked up on a C-SPAN hot microphone Jan. 3.

"It's not so much about raising money or philanthropy—though there will be some of that—but it's more about keeping these guys cooperating and changing the culture," Biden said to a woman who came up to greet him after a ceremonial swearing in of Sen. Kamala Harris (D-Calif.). "I'm going to be based out of Penn for foreign policy.

"I'm deliberately not associating with any one medical center."

Biden has said repeatedly that he intends to be involved in cancer advocacy for years to come.

"I'm going to begin a national conversation and get Congress and advocacy groups in to make sure these treatments are accessible for everyone, including these vulnerable underserved populations, and that we have a more rational way of paying for them while promoting innovation," Biden said to The Washington Post.

In 2016, Biden emerged as the principal convener in oncology. As vice president, he aggressively pushed for what he called "breaking down siloes" by removing barriers that prevent researchers and institutions from sharing data (The Cancer Letter, June 3). In one instance, the moonshot announced plans to work with the Association of American Cancer Institutes to match cancer centers with private investment and philanthropy (The Cancer Letter, Sept. 6).

At the moment, the White House is transferring moonshot projects to federal agencies, insiders say.

President-Elect Donald Trump hasn't publicly discussed the moonshot, which was renamed Beau Biden Can-

cer Moonshot in the bipartisan 21st Century Cures Act (The Cancer Letter, Dec. 9).

White House and UPenn officials declined to comment.

In addition to continuing his work on the moonshot, Biden said he will "bring down drug prices" in an interview with Time magazine in December.

"The researchers, the insurers, all of the major cancer centers … want me to pursue it," Biden said to The Washington Post. "They all realize they have a problem."

The moonshot nonprofit will be based in either Wilmington, Del., or Washington, he said. According to the Post, the organization is being referred to as the Biden Cancer Initiative inside the White House, but the final name could be different. More details are expected in early February.

President Barack Obama announced the moonshot at his 2016 State of the Union address in memory of Beau Biden, 46, who died from brain cancer in May 2015. He was treated at MD Anderson Cancer Center.

In November, the Houston hospital created the Beau Biden Chair for Brain Cancer Research.

It's unclear when the vice president will create the moonshot institute or begin his work at UPenn and UD. It is not publicly known who will be joining Biden's staff in these endeavors, and whether Greg Simon, the executive director of the Cancer Moonshot, will be participating in these programs.

As part of the Cures Act, the moonshot received $300 million in the second fiscal 2017 continuing resolution. The Cures Act authorizes $4.3 billion for NIH over the next decade, of which $1.8 billion is slated for NCI over seven years for cancer research.

FDA's Oncology Center of Excellence was slated to receive $75 million in Obama's FY 2017 budget proposal (The Cancer Letter, July 1). The Cures Act authorizes the creation of intercenter institutes at the agency.

With the first year of funding secure, NCI is expected to begin implementing the Blue Ribbon Panel's 10 scientific recommendations for the moonshot (The Cancer Letter, Sept. 9).

The Cancer Letter's coverage of the moonshot is posted here.

IN BRIEF

Chi Van Dang named scientific director of Ludwig Institute

Chi Van Dang was appointed scientific director of the Ludwig Institute for Cancer Research.

He joins Ludwig from the University of Pennsylvania Perelman School of Medicine's Abramson Cancer Center, which he has directed since 2011.

As scientific director, Dang will oversee the execution of Ludwig's scientific strategy to advance the prevention, diagnosis and treatment of cancer, with a special focus on the operations and staffing of the Lausanne, Oxford and San Diego Branches of the Ludwig Institute for Cancer Research.

He will also align these efforts with those of the six independent Ludwig Centers across the U.S. to further cultivate collaboration within Ludwig's global research community.

Dang is best known for his elucidation of the molecular signaling pathways and mechanisms that govern the unusual metabolism of cancer cells, which require vast quantities of energy and molecular supplies to sustain their wild proliferation. His laboratory was the first to show that a master regulator of gene expression named MYC—a gene whose mutation or aberrant expression is associated with many types of cancer—alters the utilization of a key sugar in cancer cells.

This body of work, which explained a hallmark of tumor metabolism known as the "Warburg effect", bolstered the hypothesis that cancer cells can become addicted to their reengineered signaling pathways and dependent on particular nutrients.

Dang and his colleagues also showed that disrupting those pathways could be a powerful approach to treating cancer and identified drug targets to that end. Therapies based on this work are today in various stages of clinical development.

Dang has served as vice dean for research at John Hopkins University and director of the Hopkins Institute for Cell Engineering before joining the Abramson Cancer Center. He was recently appointed to the Blue Ribbon panel that provided strategic guidance to Vice President Joe Biden's Cancer Moonshot initiative. He is a member of the U.S. National Academy of Medicine, fellow of the American Academy of Arts and Sciences, and currently chairs the NCI Board of Scientific Advisors.

"Ludwig has a rich history of discovery in basic and translational cancer research and I am excited and honored by the opportunity to lead its network of accomplished scientists," said Dang.

"We are today at a unique place in the history of this field, in which advances in a variety of biomedical disciplines are converging at an unprecedented rate to revolutionize our understanding of cancer. Ludwig is well positioned to take advantage of this phenomenon, as many of its scientists and research

groups are playing a leading role in driving this convergence.

"I look forward to working with Ludwig researchers across institutions and disciplines, drawing on each group's expertise and interests to forge collaborations aimed at solving specific and significant challenges of cancer research—and to translating their insights into therapies and diagnostics that will benefit patients."

Vacirca elected COA president

Jeffrey Vacirca was elected president of the Community Oncology Alliance for a one year term starting Jan. 1.

Vacirca is the CEO and managing partner/director of clinical research at New York Cancer Specialists in Long Island, NY.

In addition to Vacirca, new executive committee officers and members of the board of directors were elected.

A complete and updated list of Officers and Board members can be viewed here.

Ruckdeschel heads cancer institute at University of Mississippi Medical Center

John Ruckdeschel was named director of the cancer institute of the University of Mississippi Medical Center as well as Ergon Chair in Cancer Research.

Ruckdeschel, who previously served as the director of the Moffitt Cancer Center, led that institution to NCI Comprehensive Cancer Center designation and to become the third largest clinical cancer program in the U.S.

He then moved to the Barbara Ann Karmanos Cancer Center in Detroit where he re-acquired its NCI comprehensive status and completed the process of making Karmanos a freestanding cancer hospital.

His research was originally in basic immunology but gravitated to clinical and translational research in thoracic malignancies. Ruckdeschel's career has focused on lung cancer and other thoracic malignancies. He is credited with more than 150 peer reviewed manuscripts and co-editorship of the Textbook of Thoracic Oncology. He is a North American Editor for the Cochrane Lung Cancer Review Group.

Ruckdeschel and Terrance Albrecht co-developed a means to effectively video record patient-physician interactions and applied this technology to understanding clinical trials accrual and end of life decision-making.

Cassels retires as chief administrator at Winship

Diane Cassels will retire as chief administrator of Winship Cancer Institute of Emory University after 24 years of service, having served in a number roles including including chief department administrator for radiation oncology and administrator for the Emory Clinic's Section of Radiation Oncology and chief operating officer at the Emory Children's Center and Department of Pediatrics.

Cassels was named Winship's executive administrator in 2010, transitioning to Winship's chief administrative officer in January 2016.

During her tenure, Winship doubled its clinical footprint and clinical patient volume, expanded its membership from 268 to 434, and expanded the infrastructure for the conduct of clinical trials and laboratory research.

ACS names three new members to board

The American Cancer Society announced the election of three new members of its board of directors:

Amit Kumar, of San Jose, CA, executive chairman of ITUS Corporation, a cancer diagnostic company;

Joseph Naylor of San Ramon, CA, vice president of policy, government, and public affairs for Chevron Corp., a position he has held since April 2016.

William Novelli of Bethesda, MD, professor in the McDonough School of Business at Georgetown University and former CEO of AARP.

In other developments:

Arnold Baskies, of Cherry Hill, NJ, became chair of the board. Baskies is a medical director at Virtua Health Systems in southern New Jersey, where he specializes in surgical oncology and general surgery.

Kevin Cullen, of Baltimore, became vice chair. Cullen is the director at the University of Maryland Marlene and Stewart Greenebaum Cancer Center

Lewis Foxhall, of Houston, became board scientific officer. Foxhall is the vice president for health policy and professor of clinical cancer prevention at MD Anderson Cancer Center;

John Alfonso, of Bellerose Village, NY, became sctretary/treadurer. Alfonso is a partner in the CohnReznick LLP New York office and leads the efforts of the firm's not-for-profit and education industry practice in New York; and

Scarlott Mueller, of Gainesville, FL, became immediate past chair. Mueller is a former vice president and chief nursing officer at the North Florida Regional Medical Center.

The ACS board consists of 21 members, including five officers and 16 directors. Directors are elected for a two-year term, and officers hold their position for a one-year term. The Board is responsible for setting policy, establishing long-term goals, monitoring general operations, and approving the organizational outcomes and allocation of resources.

Kratzke, O'Regan chosen to leadership roles at Big Ten consortium

Members of the Big Ten Cancer Research Consortium steering committee appointed Robert Kratzke as the committee's first chair and Ruth O'Regan as its vice chair. Each will serve a one-year term, with O'Regan serving as chair in the subsequent year.

Kratzke is a lung cancer researcher at Masonic Cancer Center, University of Minnesota and associate professor in the University of Minnesota Medical School's Department of Medicine. He has served as the University of Minnesota steering committee representative since 2014, and is a member of the BTCRC's Thoracic Clinical Trial Working Group.

O'Regan is division head, hematology/oncology, and associate director of faculty development and education at the University of Wisconsin Carbone Cancer Center. She is a breast cancer researcher and physician, and has served as the University of Wisconsin's representative on the steering committee since 2015. She is a member of the BTCRC's Breast Clinical Trial Working Group.

The BTCRC Steering Committee is composed of one researcher from each member institution. The committee meets on a regular basis to review activities of the consortium and decide matters of policy. The BTCRC opened its first multi-institutional clinical trial in the spring of 2015, and completed enrollment for the study in July 2016, six months ahead of projections. The BTCRC is currently offering clinical trials for patients with breast cancer, esophageal cancer, hepatocellular carcinoma, and urothelial cancer. More studies are in development and are expected to open soon.

The Big Ten Cancer Research Consortium was created in 2013 to transform the conduct of cancer research through collaborative, hypothesis-driven, highly translational oncology trials that leverage the scientific and clinical expertise of Big Ten universities.

PCORI approves $42 million in funding for comparative studies on healthcare approaches

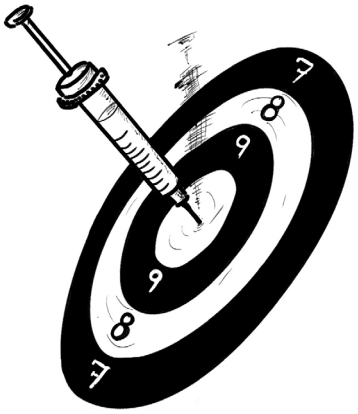
The Patient-Centered Outcomes Research Institute Board of Governors has green-lighted nearly $42 million to fund 19 new studies comparing which healthcare approaches work best.

Thirteen of the projects will support research on which care options work best in treating a range of conditions and problems that impose high burdens on patients, caregivers, and the healthcare system. These include:

- A $6 million study to compare the effectiveness of two types of palliative care, hospital-based versus home-based, in reducing patients' pain, anxiety and depression.
- A $2.7 million study to determine the effect of accupressure on relieving treatment-related symptoms in children with cancer.
- A $2.3 million project to determine whether established treatment or a newer drug is more effective against treatment-resistant cases of Kawasaki disease, which can cause heart problems in children.

Another six projects will study ways to improve methods for conducting patient-centered outcomes research. Among them are projects on assessing the quality of communications between healthcare providers and patients, preserving patient privacy when data sets including medical information are linked, and measuring patients' preferences.

DRUGS & TARGETS



AACR project GENIE releases cancer genomic data set

The American Association for Cancer Research announced the first public release of cancer genomic data aggregated through its initiative known as AACR Project Genomics Evidence Neoplasia Information Exchange (GENIE).

The data set includes nearly 19,000 de-identified genomic records collected from patients who were treated at eight international institutions, making it among the largest fully public cancer genomic data sets released to date.

The release includes data for 59 major cancer types, including data on nearly 3,000 patients with lung cancer, more than 2,000 patients with breast cancer, and more than 2,000 patients with colorectal cancer. The genomic data and a limited amount of linked clinical data for each patient can be accessed via the AACR website or downloaded directly from Sage Bionetworks.

"These data were generated as part of routine patient care and without AACR Project GENIE they would likely never have been shared with the global cancer research community," said Charles Sawyers, AACR Project GENIE Steering Committee chair, chair of the Human Oncology and Pathogenesis Program at Memorial Sloan Kettering Cancer Center, and a Howard Hughes Medical Institute investigator.

"We are committed to sharing not only the real-world data within the AACR Project GENIE registry but also our best practices, from tips about assembling an international consortium to the best variant analysis pipeline, because only by working together will information flow freely and patients benefit rapidly."

The data are fully de-identified in compliance with the Health Insurance Portability and Accountability Act.

They are derived from patients whose tumors were genetically sequenced as part of their care at one of the eight international institutions that participated in the first phase of AACR Project GENIE. Therefore, the genomic data are clinical grade.

The eight institutions participating in AACR Project GENIE phase 1 are:

- Dana-Farber Cancer Institute;
- Gustave Roussy Cancer Campus ;
- The Netherlands Cancer Institute, on behalf of the Center for Personalized Cancer Treatment;
- Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins;
- Memorial Sloan Kettering Cancer Center;
- Princess Margaret Cancer Centre;
- University of Texas MD Anderson Cancer Center; and
- Vanderbilt-Ingram Cancer Center.

To expand the AACR Project GENIE registry, the consortium is accepting applications for new participating centers. Any nonprofit institution that meets a set of criteria can submit an application to become a project participant.

Strata Trial study launched with UNC, Alabama cancer centers

Strata Oncology today announced launch of the Strata Trial, a nationwide observational study providing no-cost tumor sequencing and clinical trial matching for 100,000 advanced cancer patients, to study the impact of tumor sequencing on clinical trial enrollment.

Strata Oncology completed collaboration agreements with its first two cancer center partners, University of North Carolina Lineberger Comprehensive Cancer Center and University of Alabama Comprehensive Cancer Center.

Participation in the Strata Trial enables the centers to offer tumor sequencing to all eligible advanced cancer patients at no cost, and to access Strata Oncology's portfolio of affiliated pharma-sponsored clinical trials. To broaden regional access to the Trial, the agreements also provide for patient participation at the cancer centers' regional affiliate hospitals.

In addition, Strata Oncology announced validation of its Strata next-generation sequencing Test and CLIA certification of its high-throughput cancer sequencing laboratory in Ann Arbor, MI. The company will provide access to the Strata NGS Test, under an IRB-approved screening protocol, to cancer patients at UNC Lineberger and UAB and their affiliate hospitals, with additional clinical partnerships to follow.

Foundation Medicine receives FDA approval as companion diagnostic

FoundationFocus CDxBRCA received FDA approval for use as a companion diagnostic to aid in identifying women with ovarian cancer.

It is a next generation sequencing test for qualitative detection of BRCA1 and BRCA2alterations in formalin-fixed paraffin-embedded ovarian tumor tissue. The FoundationFocus CDxBRCA assay detects sequence alterations in BRCA1 and BRCA2 genes.

Results of the test are used as an aid in identifying ovarian cancer patients for whom treatment with Rubraca (rucaparib) is being considered. If a patient is positive for any of the deleterious alterations specified in the BRCA1/2 classification, the patient may be eligible for treatment with Rubraca. This may help identify more women who could benefit from Rubraca therapy as compared to conventional testing methods that only identify germline BRCA1/2mutations. Germline-only BRCA1/2 testing identifies approximately half of all BRCA1/2 mutations.

Rubraca is a poly polymerase inhibitor indicated as monotherapy for the treatment of patients with deleterious BRCA mutation (germline and/or somatic) associated advanced ovarian cancer who have been treated with two or more chemotherapies, and selected for therapy based on an FDA-approved companion diagnostic for Rubraca.

Foundation Medicine and Clovis Oncology closely collaborated on a regulatory strategy to develop FoundationFocus CDxBRCA in parallel with the development of Rubraca (rucaparib). Tissue samples taken from individuals

with ovarian cancer who enrolled in rucaparib clinical trials were analyzed by Foundation Medicine utilizing comprehensive genomic profiling to identify biomarkers associated with a response to therapy.

These molecular signatures of response informed the development of FoundationFocus CDxBRCA, which was utilized in Clovis' pivotal trial, ARIEL2, to identify patients and accelerate recruitment into the study. The companies filed concurrent pre-market approval and new drug application submissions with the FDA earlier this year.

With this FDA approval, FoundationFocus CDxBRCA is the first validated, tissue-based assay developed from the Quality Systems Regulations-compliant version of Foundation Medicine's CGP assay, providing uniform analysis of all BRCA1/2 coding exons.

"These simultaneous approvals by the FDA represent a step forward for women with advanced ovarian cancer, an area where there is a tremendous need for effective therapeutic approaches and efficient ways to identify those most likely to respond to PARP inhibitor therapy," said Michael Pellini, chief executive officer of Foundation Medicine. "This approval also represents a significant milestone for Foundation Medicine, one that underscores the quality and value of our molecular information solutions to inform patient care and to accelerate and streamline the therapeutic development programs of our biopharmaceutical partners."

Ionis gets $28 million from AstraZeneca for new cancer drug

Ionis Pharmaceuticals Inc. announced that it has earned $28 million from AstraZeneca following AstraZeneca's completion of IND-supporting studies and license of IONIS-KRAS-2.5, or AZD4785. IONIS-KRAS-2.5x is a Generation 2.5 antisense drug discovered by Ionis designed to directly target KRAS, one of the most frequently mutated genes in cancer.

IONIS-KRAS-2.5x will be the first drug to enter clinical development that directly targets KRAS, regardless of mutation type.

AstraZeneca will be responsible for further developing and commercializing IONIS-KRAS-2.5.

Ionis and AstraZeneca are collaborating to discover and develop antisense drugs to treat cancer under a Collaboration, License and Development Agreement entered into in December 2012. The collaboration combines AstraZeneca's experience and expertise in developing anti-cancer agents with Ionis' antisense technology platform to broaden Ionis' cancer franchise.

With the completion of the IND-supporting studies for IONIS-KRAS-2.5Rx, Ionis has received more than $85 million in upfront and milestone payments from its oncology collaboration with AstraZeneca and is eligible to earn additional milestone payments as the drug progresses in development as well as royalties on sales of IONIS-KRAS-2.5x if it is commercialized.

AstraZeneca is also evaluating, as part of the oncology collaboration, another drug to treat cancer, AZD9150 (IONIS-STAT3-2.5Rx), in combination with durvalumab, AstraZeneca's investigational anti-PD-L1 antibody, in patients with head and neck cancer and in patients with diffuse large B-cell lymphoma.

The two companies have also formed a collaboration to discover and develop antisense therapies for treating cardiovascular, metabolic and renal diseases.

MaxCyte, Washington University in St. Louis announce collaboration

MaxCyte Inc. and Washington University in St. Louis announced a collaboration to develop unique immunotherapy drug candidates based on MaxCyte's proprietary cell engineering platform technology, CARMA.

CARMA allows simple and rapid manufacture of advanced cancer treatments that utilize a patient's own immune system and is differentiated from traditional CAR therapy due to its use of mRNA to engineer immune cells delivered back into a patient. By utilizing transient expression via mRNA delivery, CARMA allows control over severe adverse effects, opening the high potency of CAR immunotherapies to a broader range of cancers than traditional CAR approaches.

John DiPersio, chief of the Division of Oncology at Washington University School of Medicine and deputy director of the Siteman Cancer Center, and members of his team will collaborate with MaxCyte to conduct preclinical research with a focus on developing a potential investigational CAR therapy targeting acute myeloid leukemia and other related blood cancers. Financial terms were not disclosed.

MD Anderson, Affimed collaborate on immunotherapy combination

MD Anderson and German-based Affimed N.V., announced an exclusive strategic clinical development and

commercialization collaboration to evaluate Affimed's TandAb technology in combination with MD Anderson's natural killer cell product.

The technology to grow NK-cells from umbilical cord blood was developed at MD Anderson.

Collaborative studies will research, develop, and eventually commercialize novel oncology therapeutics resulting from this combination of products. MD Anderson will be responsible for conducting preclinical research activities aimed at investigating its NK-cells derived from umbilical cord blood in combination with Affimed's lead NK-cell engager, the CD30- and CD16A-targeting TandAb AFM13. These are intended to be followed by a phase I study.

Affimed will fund research and development expenses for this collaboration and the agreement includes a provision for the potential expansion of the partnership. Affimed holds an option to exclusive worldwide rights to develop and commercialize any product developed under the collaboration.
AFM13 is a bispecific NK-cell TandAb simultaneously targeting CD16A on NK-cells and CD30 on tumor cells. AFM13 is designed to treat CD30-positive malignancies including Hodgkin lymphoma and T-cell lymphoma and is currently in phase II development in HL patients. Based on its safety profile, AFM13 is being developed both as monotherapy and in combination with other therapeutics such as Merck's checkpoint inhibitor Keytruda.

Gradalis, Mount Sinai announce research alliance

Gradalis Inc. and the Icahn School of Medicine at Mount Sinai established a research alliance to advance the scientific understanding of the Gradalis Vigil Engineered Autologous Tumor Cell therapy.

Under the agreement, Gradalis will provide funding and clinical samples for studying the immune response to the therapy.

The research collaboration will be jointly headed by Gradalis' Chief Scientific Officer John Nemunaitis and Seunghee Kim-Schulze, assistant professor of medicine and facility director, Human Immune Monitoring Core at The Tisch Cancer Institute at the Icahn School of Medicine at Mount Sinai.

The collaboration will span multiple clinical trials including the recently completed first in human study and ovarian phase 2A study. Additional collaboration efforts may be initiated to support ongoing registrational clinical trials in Ewing's sarcoma and ovarian cancer, as well as trials exploring the combination of Vigil and PD-1/PDL-1 inhibitors in non-small cell lung cancer, melanoma and triple negative breast cancer.

With Vigil, a patient's tumor cells are engineered with a plasmid carrying the gene vector for shRNA Furin and GMCSF to elicit a systemic T-cell directed immune response when administered to the patient through intradermal injections.

Phylogica, Genentech extend agreement

Phylogica Ltd. said Genentech has extended its exclusivity period for the research collaboration and license agreement to discover novel antibiotics utilizing Phylogica's Phylomer drug discovery platform, including its proprietary cell penetrating peptide discovery technology.

A member of the Roche Group, Phylogica is a public Australian drug discovery company. Genentech is a member of the Roche Group.

Senhwa gets FDA orphan drug designation

Senhwa Biosciences Inc. of Taipei and San Diego received the orphan drug designation to CX-4945 for the treatment of cholangiocarcinoma.

CX-4945 is a novel small molecule drug that inhibits protein kinase CK2, the company said.

Orphan drug designation is granted by the FDA to novel drugs or biologics that treat rare diseases or conditions affecting fewer than 200,000 patients in the U.S. In the US, orphan drug status carries with it seven years of marketing exclusivity following FDA approval.

Under the agreement, Phylogica will receive a milestone payment of $2 million. Phylogica is eligible to receive research, development, and commercialization milestone payments totaling up to $142 million.

Oncotype DX included in AJCC staging criteria

The American Joint Committee on Cancer has incorporated the Oncotype DX test in its recently published Eighth Edition AJCC Cancer Staging Manual.

"For the first time, AJCC has added molecular signatures to complement the traditional anatomic features of the disease, transitioning cancer diagnosis and care to truly personalized medi-

cine," said Steven Shak, chief scientific officer, Genomic Health. "We believe this groundbreaking milestone will enhance physicians' ability to deliver the excellent patient outcomes demonstrated across multiple prospective studies of the Oncotype DX test."

Effective January 2018, the new AJCC Prognostic Stage Groups will add the Oncotype DX Breast Recurrence Score, hormonal status, and HER2 status to nodal status, tumor size, and tumor grade for staging breast cancer. For patients with node-negative disease or micrometastases in the nodes, a low Oncotype DX Recurrence Score (RS<11) classifies a patient as having the most favorable Prognostic Stage, regardless of tumor grade or tumor size (up to five centimeters).

As part of the implementation process, all AJCC partners, including the College of American Pathologists and the National Comprehensive Cancer Network, will develop and update protocols and tools to facilitate successful adoption of the required new staging system rules in 2018. The electronic version of the Eighth Edition AJCC Cancer Staging Manual is scheduled to be available the first quarter of 2017.

As stated in the AJCC publication, "Based on the best available evidence at this time, the Expert Panel determined that it was appropriate to incorporate multigene molecular profiling to incorporate the Oncotype DX score into staging for the subgroup of patients defined by Arm A of the TAILORx study. These patients should be staged according to the AJCC Prognostic Stage Groups. The findings for the ODX (Oncotype DX) test are supported by Level I Evidence (large-scale prospective clinical trial data)."

The results of the **T**rial **A**ssigning **I**ndividua**L**ized **O**ptions for Treatment (**Rx**), or TAILORx, led by the ECOG-ACRIN Cancer Research Group were published in The New England Journal of Medicine in 2015. Additionally, the Eighth Edition AJCC Cancer Staging Manual cites clinical outcomes data from tens of thousands of patients in the United States generated by the NCI Surveillance, Epidemiology, and End Results registry, demonstrating that patients with low Recurrence Scores have excellent breast cancer survival at five years.

FUNDING OPPORTUNITIES

Addario foundation, IASLC announce grant

The Bonnie J. Addario Lung Cancer Foundation and the International Association for the Study of Lung Cancer announced the second annual joint fellowship award to support research on the early detection of lung cancer.

The objective of the ALCF-IASLC Fellowship Award for the Early Detection of Lung Cancer is to identify brilliant, young, "out of the box" thinkers/researchers who can deliver meaningful and measurable results for the early detection of lung cancer that have a high probability of near-term benefit to lung cancer patients or individuals at risk, as well as to provide an opportunity for young researchers to learn new cutting-edge technologies and take this expertise back to their home country.

Additional information is posted here.

BONNIE J. ADDARIO LUNG CANCER FOUNDATION

IASLC
International Association for the Study of Lung Cancer

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