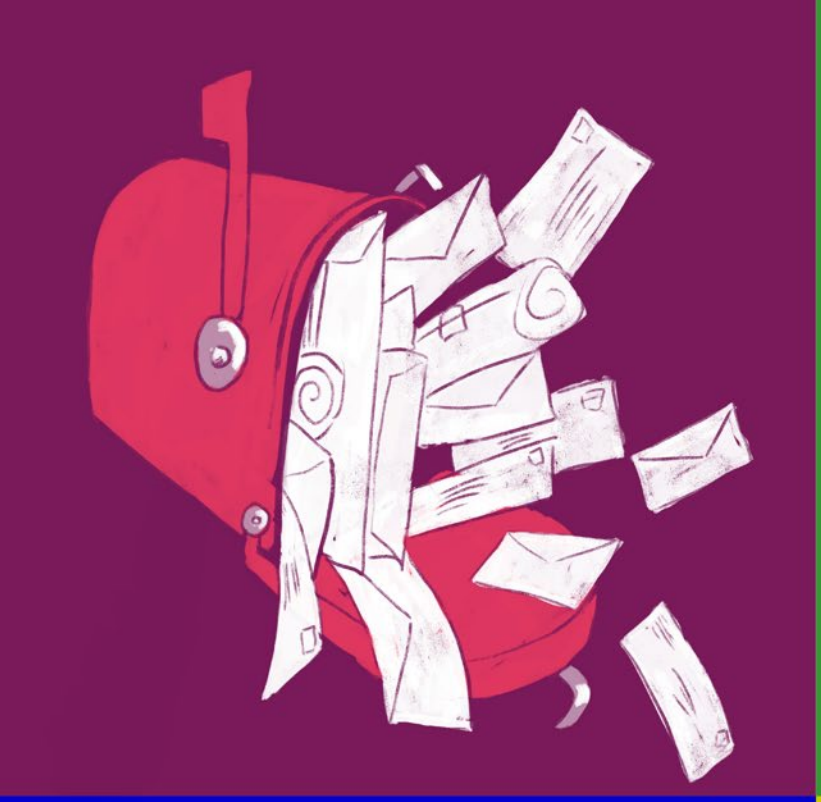

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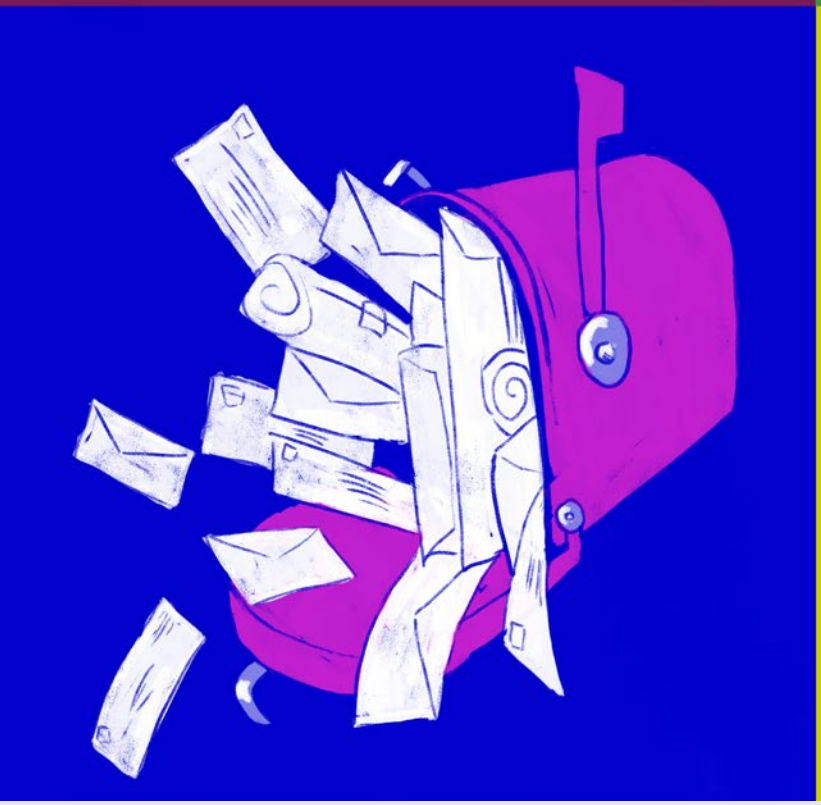

INSTITUTIONS WILL BE REQUIRED TO REPORT SEXUAL MISCONDUCT TO NIH IF HOUSE COMMITTEE BILL BECOMES LAW

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University of New Mexico Comprehensive Cancer Center

The University of New Mexico Comprehensive Cancer Center is the Official Cancer Center of New Mexico and the only National Cancer Institute-designated Cancer Center in a 500-mile radius. Its 146 board-certified oncology specialty physicians include cancer surgeons in every specialty (abdominal, thoracic, bone and soft tissue, neurosurgery, genitourinary, gynecology, and head and neck cancers), adult and pediatric hematologists/medical oncologists, gynecologic oncologists, and radiation oncologists. They, along with more than 600 other cancer healthcare professionals (nurses, pharmacists, nutritionists, navigators, psychologists and social workers), provide treatment to 65% of New Mexico's cancer patients from all across the state and partner with community health systems statewide to provide cancer care closer to home. They treated approximately 13,000 patients in more than 100,000 ambulatory clinic visits in addition to in-patient hospitalizations at UNM Hospital. A total of nearly 1300 patients participated in cancer clinical trials, 40% of whom participated in clinical trials testing new cancer treatments that include tests of novel cancer prevention strategies and cancer genome sequencing. The more than 100 cancer research scientists affiliated with the UNMCCC were awarded $36.2 million in federal and private grants and contracts for cancer research projects. Since 2015, they have published nearly 1000 manuscripts, and promoting economic development, they filed 136 new patents and launched 10 new biotechnology start-up companies. Finally, the physicians, scientists and staff have provided education and training experiences to more than 500 high school, undergraduate, graduate, and postdoctoral fellowship students in cancer research and cancer health care delivery. Learn more at cancer.unm.edu.

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INSTITUTIONS WILL BE REQUIRED TO REPORT SEXUAL MISCONDUCT TO NIH IF HOUSE COMMITTEE BILL BECOMES LAW

By Matthew Bin Han Ong

Institutions receiving NIH funds through grants or cooperative agreements would be required—by federal law—to notify the NIH director when a principal investigator or other key personnel are removed or disciplined for "harassment, bullying, retaliation, or hostile working conditions."

In a committee report that accompanies the appropriations bill, lawmakers used unusually strong language to allege inaction on the part of NIH's leaders:

"The Committee is deeply frustrated by NIH's failure to implement its direction to address harassment in extramural research settings," House appropriators wrote on page 151 of the bill report.

By directly requiring NIH-funded institutions to report rogue behavior, the new provision goes one step further, compared to past efforts by Congress to address harassment in academia:

"Both the Statement of managers accompanying the Further Consolidated Appropriations Act, 2020 (Public Law 116–94) and the Consolidated Appropriations Act, 2021 (Public Law 116–260) directed NIH to revise its guidance to make clear that grantees must identify any changes to key personnel on an award that are related to concerns about harassment," House appropriators wrote in the report. "The Committee has included a new general provision to require institutions that receive NIH funding to notify the agency when key personnel are removed from their position for harassment."

The requirement, approved by the House Appropriations Committee in the July 15 markup of the FY2022 Labor-HHS funding bill, is expected to be considered in the full House of Representatives in the coming week.

The provision represents a cultural shift toward striving for gender equity in academic medicine and is in line with a renewed commitment in government and academia to address racial injustice and health disparities.

The disclosure requirement would make it more difficult for researchers accused of harassment and sexual misconduct to move from institution to institution without anyone being the wiser. A recent investigation by The Cancer Letter presented the case of oncologist Axel Grothey, who was allowed to resign from a position at Mayo Clinic but was able to shift to another job and maintain his position on an NCI steering committee (*The Cancer Letter*, May 28, 2021).

The Grothey case came to light only because a medical licensure board in Minnesota got involved. State licensure boards and hospital credentialing bodies play no role in cases that involve basic scientists and other non-clinical faculty, in effect allowing perpetrators to escape public scrutiny.

The House committee bill would apply to clinicians and non-clinicians alike.

If the disclosure provision contained in the committee bill is signed into law, NIH would have the authority to "issue regulations" that would delineate reporting requirements for institutions.

It's unclear whether the reported information would become public record. Also, it's too early to tell whether non-academic entities that receive NIH funding—such as government contractors or companies involved in Cooperative Research and Development Agreements or the Small Business Innovation Research program—would be subject to the requirement.

The proposed statutory language directs NIH to take immediate action:

> SEC. 247. The Director of the National Institutes of Health shall hereafter require institutions that receive funds through a grant or cooperative agreement during fiscal year 2022 and in future years to notify the Director when individuals identified as a principal investigator or as key personnel in an NIH notice of award are removed from their position or are otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions. The Director may issue regulations consistent with this section.

"NIH does not comment on pending legislation," NIH officials said in a statement to *The Cancer Letter.*

"Necessary steps"

The Grothey reportage by *The Cancer Letter* prompted NCI Director Ned Sharpless to remove Grothey from the NCI National Clinical Trials Network's Gastrointestinal Steering Committee, which Grothey co-chaired. More than 10 cancer organizations and institutions have censured or barred Grothey (*The Cancer Letter*, June 4, 2021).

Responding to questions about the House provision on harassment, NIH officials said "necessary steps" were taken when they were informed of Grothey's misconduct.

"As we have shared with The Cancer Letter before, while Axel Grothey was not an NCI employee or grantee, NIH does not tolerate pervasive or severe harassment of any kind, including sexual harassment, whether it is within the agency, at research organizations that receive NIH funding, or anywhere else NIH-funded activities are conducted," NIH said in a statement to *The Cancer Letter.* "Once we were made aware of the issue, we took the necessary steps in the swiftest and most direct way possible."

In April and May 2019, two women reported Grothey's misdeeds to NIH and NCI, documents obtained by *The Cancer Letter* show. NIH wasn't exactly helpful—the Office of Extramural Research sent an automated response and never followed up, one of the women said.

A survey conducted by *The Cancer Letter* in 2020 found that that women who experienced gender bias and sexual harassment in academic medicine unanimously rated their institutions' response as inadequate (*The Cancer Letter*, Oct. 2, 2020).

Nearly 60% of women in academia have experienced sexual harassment on the job, according to a June 2018 report from the National Academies of Sciences, Engineering, and Medicine.

The NASEM study found no evidence that current policies, procedures, and approaches—which often focus on symbolic compliance with the law and on avoiding liability—have resulted in a significant reduction in sexual harassment (*The Cancer Letter*, June 15, 2018).

"Statutory assistance"

It may have been necessary for Congress to legislate reporting requirements into existence.

In a May 26 hearing before the Senate appropriations subcommittee on Labor, Health and Human Services, Education and Related Agencies, NIH Director Francis Collins said NIH has asked institutions to report harassment and sexual misconduct, but lacked authority to require such reporting.

"I wish we were able to simply require—at the present time, legally, we are told we don't have that authority," Collins said to Sen. Patty Murray (D-WA), chair of the Senate appropriations subcommittee. "We would have to go through a two-year rulemaking effort, or we would need statutory assistance."

The House bill would provide that statutory assistance, said Heather Pierce, senior director of science policy and regulatory counsel at the Association of American Medical Colleges.

"We believe the language included in the House Appropriations Committee's spending bill is intended both to grant NIH the authority and direct NIH to require notification to NIH if an investigator or personnel are removed from their position or disciplined for harassment or related reasons, in a policy that would be closer to the approach taken by the National Science Foundation," Pierce said to *The Cancer Letter.*

"Eliminating harassment will require a multipronged approach, and the AAMC continues to urge leaders in academic medicine to make this goal a top priority."

The new provision in the House bill is a "positive first step," said Jennifer Pegher, executive director of the Association of American Cancer Institutes.

"However, it is concerning that a reporting mechanism isn't outlined in detail," Pegher said to *The Cancer Letter.* "AACI encourages open dialogue among its members about important issues—including diversifying the oncology leadership pipeline and addressing disparities in cancer research and care—and stands against harassment and intimidation in all forms."

The American Society of Clinical Oncology is working to address harassment issues more directly in professional development programs, said Julie Gralow, ASCO chief medical officer.

"ASCO hasn't weighed in on the legislative provision with regard to the NIH at this point," Gralow said to *The Cancer Letter.* "However, we're watching it closely, and generally support accountability on this front."

As it stands, the House provision is unlikely to encounter opposition from Senate appropriators, given Murray's commitment to eliminate harassment in biomedical research. President Joe Biden is likely to support the requirement.

"Whatever we need to do," Murray said at the May 26 hearing. "We cannot afford to have this agency's potential limited or its success threatened by bias, discrimination, harassment, or assault in the workplace.

"Unfortunately, we know that in the biomedical research community, the prevalence of researchers of color is too low and the prevalence of sexual harassment is too high. These are real problems with real consequences for biomedical research and the people who do the lifesaving work we're all benefiting from today.

"I commend NIH for the efforts it has taken on both of these fronts so far, NIH has done work to examine barriers to diversity among its researcher ranks and how its own practices have reinforced structural biases that allow discrimination to persist, but more work remains to tear down barriers and create lasting change," Murray said. "And when it comes to sexual assault… NIH must do more to use its enormous influence with the research community to enforce change in the nation's universities and research institutions.

"I expect NIH to continue building on its efforts so far to remove racism, discrimination, and harassment from research. And I will continue to follow up on that progress."

Unabridged statements from AAMC, ASCO, and AACI follow:

Heather H. Pierce, JD, MPH
Senior director,
Science policy and regulatory counsel,
Association of American
Medical Colleges

Sexual, gender, or any other form of harassment has no place in biomedical research. NIH has undertaken a number of initiatives in recent years to help deter harassment, including directing awardee institutions to notify the agency if changes in investigators or key personnel on NIH awards are related to concerns about harassment, bullying, retaliation, or hostile working conditions.

Through written policy and also the explicit commitment from Dr. Francis Collins to address harassment in intramural research and for NIH funded research at grantee institutions, these actions have sent an important message to the community that such conduct will not be tolerated and that NIH is committed to ensuring a safe and equitable environment for all researchers, including trainees.

One issue that NIH has raised repeatedly as a barrier to taking additional actions with respect to harassment in the extramural research is the lack of statutory authority to require institutions to report findings or disciplinary actions taken as a result of harassment in the absence of changes to the grant.

> “Eliminating harassment will require a multipronged approach, and the AAMC continues to urge leaders in academic medicine to make this goal a top priority.”
>
> *– Heather Pierce*

We believe the language included in the House Appropriations Committee's spending bill is intended both to grant NIH the authority and direct NIH to require notification to NIH if an investigator or personnel are removed from their position or disciplined for harassment or related reasons, in a policy that would be closer to the approach taken by the National Science Foundation.

This expectation is one of several parallel actions being taken at the federal and organizational levels to promote a culture of inclusiveness and respect, and we are committed to working with NIH and our members to ensure such an expectation is fulfilled appropriately.

Eliminating harassment will require a multipronged approach, and the AAMC continues to urge leaders in academic medicine to make this goal a top priority. We continue to convene discussions on the topic among our constituency groups and have developed a number of resources to help guide their work.

Julie R. Gralow, MD, FACP, FASCO
Chief medical officer,
American Society of Clinical Oncology

ASCO hasn't weighed in on the legislative provision with regard to the NIH at this point. However, we're watching it closely, and generally support accountability on this front.

ASCO is committed to providing information, resources, and programs that promote inclusion, professionalism, and professional opportunity across the oncology community. At all ASCO events we require that participants show respect in their speech and actions and refrain from harassing speech or behavior, including sexual harassment.

Our meetings and journals offer important platforms, as well as safe and supportive environments, where research on this issue can be

presented and published to not only shine a light on sexual harassment, but also to help bring about needed change. ASCO is also actively working to address harassment issues more directly in our professional development programs including developing ideas for more focused resources to offer ASCO members who experience harassment.

“

ASCO is also actively working to address harassment issues more directly in our professional development programs including developing ideas for more focused resources to offer ASCO members who experience harassment.

”

– Julie Gralow

We have multiple policies and processes to respond to a complaint of harassment. If the issue arises during an ASCO event, we have an online tool for any participant to report unacceptable conduct. ASCO's immediate response will focus on maintaining a safe and respectful educational environment at the event. If ASCO becomes aware of allegations of harassment concerning a member of the Society, we follow our member discipline procedures and determine if there are grounds to sanction the member.

As an employer, ASCO does not tolerate sexual harassment or any conduct that violates the rights, privacy, safety, or dignity of individuals on the basis of personal characteristics, including gender. We have a number of organizational policies and HR procedures in place to enforce these standards and expectations in our workplace, including mandatory sexual harassment training for every employee and an anonymous hotline to report concerns.

Jennifer W. Pegher, MA
Executive director, Association of American Cancer Institutes

AACI supports efforts to eliminate harassment and believes these new provisions serve as a positive first step toward addressing hostile workplace conditions in the research setting. However, it is concerning that a reporting mechanism isn't outlined in detail.

In its role as an association representing 103 leading cancer centers in the United States and Canada, AACI

“

AACI encourages open dialogue among its members about important issues—including diversifying the oncology leadership pipeline and addressing disparities in cancer research and care—and stands against harassment and intimidation in all forms.

”

– Jennifer Pegher

provides a platform for cancer centers to share challenges and develop best practices. AACI encourages open dialogue among its members about important issues—including diversifying the oncology leadership pipeline and addressing disparities in cancer research and care—and stands against harassment and intimidation in all forms. However, specific policies to protect clinical trainees and mentees are established by individual cancer centers.

As a membership organization, AACI does not work directly with clinical research personnel. Individual cancer centers develop their own policies regarding harassment complaints, or follow the policies established by their parent institutions, such as hospitals and universities.

HEALTH EQUITY

To combat health disparities in communities of color, City of Hope recruits its most diverse class for leadership training in 2021

By Matthew Bin Han Ong

As a comprehensive cancer center in Los Angeles, City of Hope serves one of the most diverse—and vulnerable—patient populations in the U.S.

In this series, *The Cancer Letter* invites conversations about diversity, equity, and inclusion in recruitment and mentorship at academic cancer centers.

The objective is to help disseminate best practices employed to diversify the oncology workforce of the future.

If you'd like to take part, reach out to Matthew Ong (matthew@cancerletter.com), associate editor of *The Cancer Letter.*

Located in Duarte, approximately half an hour northeast of downtown Los Angeles, City of Hope serves more than 90,000 patients each year, many of whom are residents in underserved communities that surround the city.

In many communities immediately east and south of Duarte, 25% or more of residents lack a high school education, and 30% or more of residents live in poverty.

"Despite remarkable advances in cancer treatments and cures, many patients lack access to specialty care, which is even more pronounced among vulnerable and disadvantaged communities," Angela Talton, senior vice president and chief diversity, equity, and inclusion officer at City of Hope, said to *The Cancer Letter.*

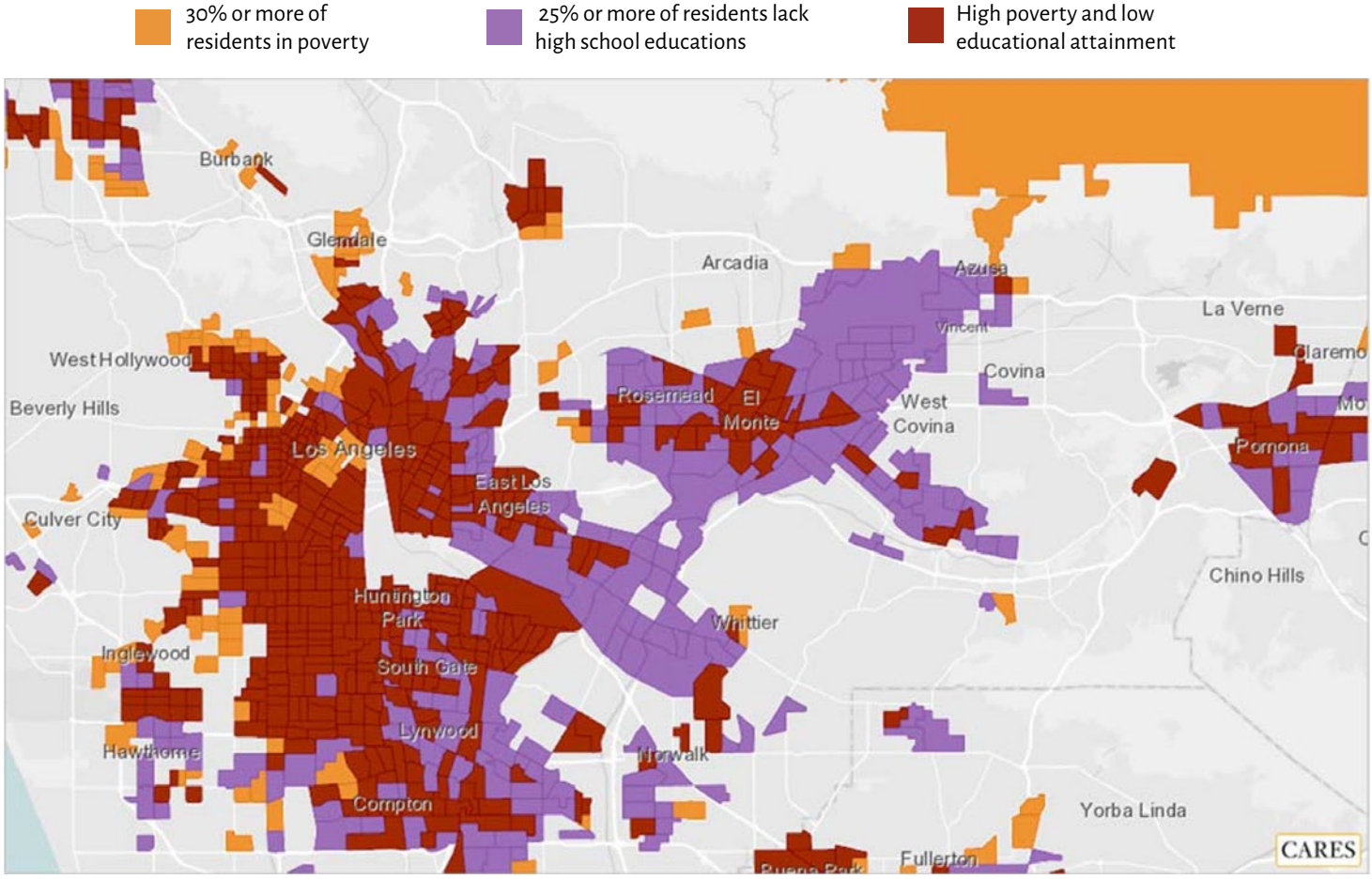
Talton was recruited to City of Hope on Jan. 11 as the cancer center's inaugural chief DEI officer.

The hospital's primary service area, which spans the northern length of greater LA from Sun Valley to Riverside and extends into four other counties, including Orange, Riverside, and San Bernardino, and Ventura, is 46% Latino.

According to City of Hope, cancer is the leading cause of death among Latinos in California.

The majority of City of Hope's patients come from Los Angeles County, specifically communities within Service Planning Area 3 in San Gabriel Valley,

MAP OF CITY OF HOPE SERVICE AREA HIGHLIGHTING VULNERABLE POPULATIONS



Source: American Community Survey 5-Year Estimates, 2013-2017

the third largest of the county's 8 geographic regions. With 1.8 million people spanning 34 cities, SPA 3's population is 44.7% Latino, 29.9% Asian, 19.3% white, and 3.6% Black or African American.

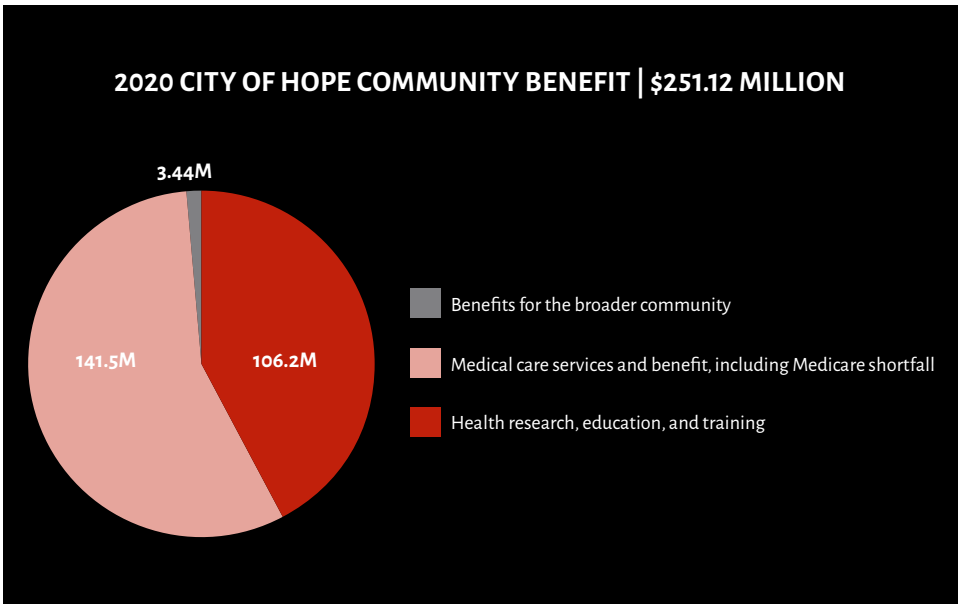
Earlier this year, City of Hope announced its 2021-2023 Implementation Strategy, which sets forth a plan to address the needs of the hospital's communities. The report identifies "access to care" as the hospital's first priority—to formulate a policy and systems-focused approach that addresses social determinants of health and responds to implicit bias and structural racism.

To address systemic underrepresentation of Black and Hispanic scientists and physicians in oncology and in academic medicine (*The Cancer Letter*, July 2, June 25, 2021; Oct 9, 2020), the cancer center created a suite of programs that has increased recruitment and training of diverse leaders in recent years.

"City of Hope has established a Diversity, Equity & Inclusion Governance Council and recruited the most diverse class for our leadership training program this year," Talton said. "We have unconscious bias training for all our employees, as well as situational inclusivity training for managers."

City of Hope's 2016 Community Health Needs Assessment identified stark disparities in its service areas:

- Black women and men in all five counties are diagnosed later and more likely to die from cancer than adults of other races.
- The rate of cancer diagnosis is highest among whites.
- Cancer rates and mortality tend to be lowest among Asians. The rate of death from cancer tends to be highest among Blacks.
- Cancer deaths are highest in San Bernardino County, driven mostly by lung, breast, prostate and colorectal cancers.
- Los Angeles County has the highest rates of cancer deaths due to liver, bile duct and stomach cancers.
- In Riverside County, 39.2% of teenagers (ages 12-17 years) are overweight.
- In San Bernardino County, 34% of all adults are obese.
- In Los Angeles County, Asian Pacific Islander women have the lowest rate of receiving a Pap test in the last three years (65.9%), as compared with whites (83.9%), Latinas (86.3%) and Blacks (89.3%).
- All five counties in the service area exceed the Healthy People 2020 objective for colorectal cancer screening. However, only 67.4% get the exam at the recommended age.



"Our most recent Community Benefit Implementation Strategy focuses on access to care, economic and housing insecurity, healthy living, mental health and cancer prevention," Talton said. "Programming for these strategies is delivered through our Healthy Living and Community Capacity Building Grants, which funds ideas presented by organizations to support their communities. The food security programs include cooking, nutrition, community garden programs and subsidized farmers markets in local elementary schools."

City of Hope invested more than $251 million in 2020 through its community benefit program, which is the hospital's response to a legislative mandate (SB697) from the State of California requiring nonprofit hospitals to address the needs of their communities through programs designed to help prevent diseases and improve public health.

Of that amount, City of Hope spent:

- $106.2 million on health research, education, and training,
- $141.5 million on medical care services and benefit, including Medicare shortfall, and
- $3.44 million on benefits for the broader community.

DEI is an executive priority at City of Hope, Talton said.

"I am working on a strategic approach to infuse diversity, equity, and inclusion into all levels of our institution," Talton

Q & A

Talton spoke with Matthew Ong, associate editor of The Cancer Letter.

CONVERSATION WITH THE CANCER LETTER

said. "Our strategy includes tactics such as diverse slates, diverse interview panels, inclusive interview training, and the identification of alternative recruitment sources.

"Our catchment area is extremely diverse and we want all communities to see themselves reflected, and thus welcomed at City of Hope."

Talton spoke with Matthew Ong, associate editor of *The Cancer Letter.*

Matthew Ong: What best practices in hiring and recruitment—or in pipeline programs—do you use at your institution to elevate diverse leaders? How effective are these strategies?

Angela Talton: City of Hope is striving to create generational change by increasing interest in STEM among students from the elementary to the graduate

> "City of Hope has established a Diversity, Equity & Inclusion Governance Council and recruited the most diverse class for our leadership training program this year."

Angela L. Talton
Senior vice president;
Chief diversity, equity, and inclusion officer,
City of Hope

level in an effort to cultivate future health care leaders and research scientists of color.

For instance, we have partnerships with several local school districts that create a pipeline of diverse students who are interested, engaged and prepared for biomedical research as a possible college and career choice.

At the high school and undergraduate level, the Arthur Riggs Diabetes and Metabolism Research Institute Summer Research Program provides students research exposure in the field of diabetes and metabolism. Our summer mentorship program provides students throughout the Los Angeles area with experience learning and working at City of Hope, exposing them to careers in research, patient care and technology.

As part of the Eugene and Ruth Roberts Summer Student Academy, college students and exceptional high school students conduct hands-on research experience. Participants choose their own biomedical research project based on their interests, work closely with mentors and peers, and gain invaluable skills that help prepare them for graduate and postdoctoral research.

In addition, City of Hope's Irell & Manella Graduate School of Biological Sciences equips graduate students to become professionally trained scientists prepared for academia, medicine, or industry.

City of Hope's graduate school also has two postdoctoral fellow programs funded by the National Cancer Institute (known as T32 programs) that strongly encourage members of underrepresented minority groups to apply.

One program focuses on cancer metabolism and the other on DNA damage response and oncogenic signaling in cancer biology. Both programs are for exceptionally motivated postdoctoral fellows and equip them with scientific knowledge, research training, professional skills and mentorship.

As part of our employee recruitment efforts, City of Hope emphasizes that diversity is an integral part of City of Hope's mission—to provide leading-edge cancer care with compassion and transform the future of health care. City of Hope has been a welcoming place for people of all backgrounds since its inception.

Our commitment to inclusiveness hasn't stopped. For instance, City of Hope has established a Diversity, Equity & Inclusion Governance Council and recruited the most diverse class for our leadership training program this year. We have unconscious bias training for all our employees, as well as situational inclusivity training for managers.

As senior vice president and chief officer of diversity, equity and inclusion, I am working on a strategic approach to infuse diversity, equity, and inclusion into all levels of our institution. Our strategy includes tactics such as diverse slates, diverse interview panels, inclusive interview training, and the identification of alternative recruitment sources.

How has increased diversity among your faculty improved patient outcomes, as well as your ability to reach and engage underserved communities in your catchment area? Could you provide a few examples?

AT: Diversity makes City of Hope a better place for our patients and employees.

We strive to build an inclusive workplace that engages the voices and insights of all of our employees. Our catchment area is extremely diverse and we want all communities to see themselves reflected, and thus welcomed at City of Hope.

One great example of this is: City of Hope has increased its recruitment of scientists, doctors and leaders of color in recent years.

These faculty members engage in diverse communities, lending their voices to share the importance of cancer screening as well as sharing the need for participation in clinical trials. These clinical and research scientists are leading research on health disparities within communities of color and helping us find the best way to address complex health issues in these communities.

City of Hope's Diversity, Equity & Inclusion Governance Council is tasked with providing guidance and alignment on initiative recommendations regarding advancing contributions to health equity and community outreach, increasing the diversity of its workforce and suppliers, and ensuring an inclusive experience with supporting systems, policies and procedures.

The council has been instrumental in providing forums or listening sessions to hear the voice of City of Hope staff and use that input to ideate multiple programs, initiatives and best practices to further City of Hope's diversity, equity and inclusion efforts.

City of Hope has also brought greater diversity, representation and accountability, and a broader range of perspectives and ideas, to its executive leadership. The institution is working to build awareness, ownership and accountability for infusing diversity, equity and inclusion into our daily operations. This cultural transformation is tracked by inclusive behavior training and other performance indicators.

Additionally, City of Hope is focused on extending its leadership development programs, employee resource groups and cross-cultural mentoring throughout the enterprise to increase opportunities for growth and career advancement.

What programs have you led that are or have directly contributed to greater equity i.e. a reduction in disparity of outcomes or disparity of access in your catchment area? What was the nature of those disparities and what have you learned?

AT: City of Hope and key partners are leading Cancer Care Is Different in California.

The campaign's goal is to raise awareness about the adverse impact for patients that restricted access to leading cancer treatment centers causes and to urge passage and adoption of a Cancer Patients' Bill of Rights in the California legislature. (The California Senate passed the resolution and is now awaiting review by the California Assembly.)

Despite remarkable advances in cancer treatments and cures, many patients lack access to specialty care, which is even more pronounced among vulnerable and disadvantaged communities. The Cancer Patients' Bill of Rights recognizes that cancer patients should receive appropriate, timely and equitable access to expert cancer care.

City of Hope also strives to decrease health disparities in its service area by creating an institution-wide emphasis on community benefit to organize thoughtful collaborations with local stakeholders that address root causes of health inequities and aim to improve health outcomes.

Our most recent Community Benefit Implementation Strategy focuses on access to care, economic and housing insecurity, healthy living, mental health and cancer prevention.

Programming for these strategies is delivered through our Healthy Living and Community Capacity Building Grants, which funds ideas presented by organizations to support their communities. The food security programs include cooking, nutrition, community garden programs and subsidized farmers markets in local elementary schools.

City of Hope's new Prescription for Produce program will provide food-insecure patients with fresh produce on a regular basis. The Conrad N. Hilton Foundation has also funded a five-year community nutrition education and research initiative.

What are your next steps?

AT: City of Hope's diversity, equity and inclusion strategy focuses on our staff, the patient experience and our engagement in the community at large.

Training will continue to be an integral part of our program to build awareness and actively participate in conscious inclusion as a northstar for our interactions throughout the enterprise.

We will also leverage scorecarding and regular review of programs and initiatives to increase diverse representation and engagement.

Partnering with universities with high diverse student enrollment is another key component to our strategy to increase recruitment. Community engagement is also important and we will look to increase partnerships and community outreach in an effort to reduce health disparities.

One such initiative is Genentech's Advancing Inclusive Research® Site Alliance.

This coalition of clinical research sites, which includes City of Hope, will partner with Genentech to advance the representation of diverse patient populations in the company's oncology clinical trials, test recruitment and retention approaches, and establish best practices that can be leveraged across the industry to help achieve health equity for people with cancer.

This story is part of a reporting fellowship on health care performance sponsored by the Association of Health Care Journalists and supported by The Commonwealth Fund.

“Partnering with universities with high diverse student enrollment is another key component to our strategy to increase recruitment.”

Q & A

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

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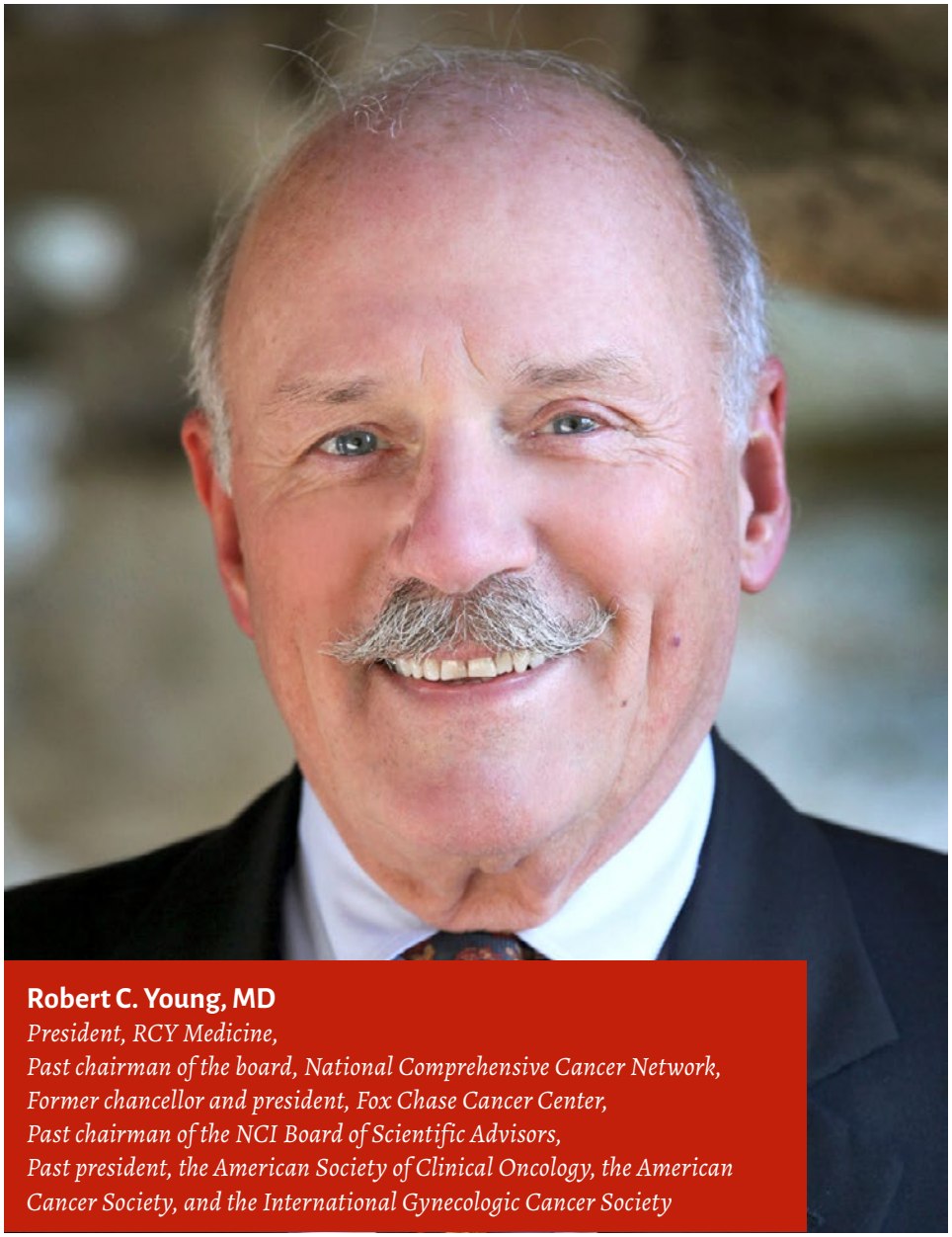
CANCER HISTORY PROJECT

Bob Young tells us about the evolution of consortium cancer centers since the signing of the National Cancer Act



Robert C. Young, MD
President, RCY Medicine,
Past chairman of the board, National Comprehensive Cancer Network,
Former chancellor and president, Fox Chase Cancer Center,
Past chairman of the NCI Board of Scientific Advisors,
Past president, the American Society of Clinical Oncology, the American Cancer Society, and the International Gynecologic Cancer Society

> There were a lot of people in universities who didn't like the idea that there were cancer centers, that they had independent leadership roles at the level of the chairmans of departments and so forth. There was not a widespread acceptance of cancer centers as a mainstream part of academic medicine.

Consortium cancer centers have been around for 50 years—since the signing of the National Cancer Act of 1971.

The consortium model has generated a lot of interest in recent years , in part because technology is making it easier to do science and run institutions across long distances (*The Cancer Letter*, April 19, 2013; May 10, July 12, 2019; July 2, 2020).

NCI's attitude toward consortia has varied over the years, with changes largely following the contours of development of the science of cancer control, said Robert C. Young, who has observed consortium cancer centers from multiple vantage points: as associate director of the NCI Centers and Community Oncology Program, as president and CEO of Fox Chase Cancer Center (which started out as a consortium), as chairman of the External Advisory Board of Dana Farber/Harvard Cancer Center, and as chairman of the NCI Board of Scientific Advisors.

After NCA was enacted, several institutions formed consortia, leveraging their resources.

"Most of the small cancer centers at the time were basic science-oriented, and they really didn't have cancer control programs," Young said to *The Cancer Letter*. "And so, there was a lot of discussion about, well, how could you create these outreach cancer control programs? And so, a lot of squirreling around was done to try to create mechanisms by which you could bring in community-based activities and community-based, so-called cancer control.

"Actually, what happened is that cancer control and prevention became a real science, and scientists based in cancer centers became the drivers of cancer control.

"But that was 20 years after the fact. Early on, there weren't such people in the centers. So, there was a great deal of interest in creating these things, like the Northern California Cancer Center, and the Illinois Cancer Control group, bringing together consortiums of people to facilitate the cancer control research effort," Young said.

Consortia were controversial from the start, and by mid-1980s, several had either dissolved because of the lack of resources or lost NCI designations after failing to withstand peer review by NCI.

The NCI designation rules were tightened at that time, and institutions that were considering the consortium cancer center model were being discouraged from doing so by NCI officials.

This changed in the late 1990s, when NCI came out in opposition to creating multiple cancer centers in Boston. At the same time, in Seattle, Robert Day, director of the Hutch from 1981 to 1997, was waging local political battles to create a consortium cancer center in Seattle.

A package of stories on the Seattle consortium was published in last week's issue (*The Cancer Letter*, July 16, 2021).

A video of their conversation appears here.

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

Paul Goldberg: Thank you for agreeing to talk with me. I was working on a story about that 20th anniversary of the Seattle Cancer Care Alliance, and I realized that there were so many changes of thought about consortium cancer centers through NCI history, really 50 years' worth of that, that it would be really interesting to reconstruct how all of that worked. And there's really only one person who can do this.

Robert Young: Well, I don't know about that. There're probably a number.

You totally can, because you were in the center of it all from the beginning, really. How do you want to start? Start in 1971?

RY: Yes. It's interesting to go back and look at some of the documents. I had an occasion a while ago to look at Benno Schmidt's, June 12, 1974, President's Cancer Panel report. I got it online, so I'm sure you can.

It's interesting, because he really does spell out what Mary Lasker and the framers of the [National] Cancer Act really had in mind in terms of what they wanted to accomplish. And a lot of it was basic science oriented. It's amazing reading Benno Schmidt's words, how much it's focused on basic science and how the delivery of cancer care is not specifically the role of cancer centers.

And so, you can see how the system developed as a result of the messages that were received.

Now, at the time, people were trying to follow the National Cancer Act. It's an interesting document, because it basically says, [Frank] Rauscher ought be able to do whatever he wants to do. And, of course, as soon as that happened, the OMB said, "Well, not so fast. We don't have the money to do that. Furthermore, we're not going to give you the money to do it."

So, there was a lot of back and forth about the number of cancer centers, the number of comprehensive cancer centers and all this sort of stuff.

And superimposed upon that, there were the issues of money. Surprise, surprise!

But in fact, in the early days, the cancer grants were a major source of funding for cancer centers. And it didn't take long before it became just holy water. Nowadays, it's such a small part of the cancer center's budget as to be almost not measurable.

It's basically a license to use the NCI's blessing to go out and raise money, and it's been successful that way. There was all this talk about, "Well, we got to be much more comprehensive. We got to be like some of the comprehensive cancer centers."

And, of course, most of the small cancer centers at the time were basic science-oriented, and they really didn't have cancer control programs.

And so, there was a lot of discussion about, well, how could you create these outreach cancer control programs? And so, a lot of squirreling around was done to try to create mechanisms by which you could bring in community-based activities and community-based, so-called cancer control.

Actually, what happened is that cancer control and prevention became a real science, and scientists based in cancer centers became the drivers of cancer control.

But that was 20 years after the fact. Early on, there weren't such people in the centers. So, there was a great deal of interest in creating these things, like the Northern California Cancer Center, and the Illinois Cancer Control group, bringing together consortiums of people to facilitate the cancer control research effort.

Also Fox Chase; right?

RY: Yes. For the most part, it really didn't work very much. It really didn't work very much, because, in fact, it was not science-driven, it was organizationally driven. And they set up all these things, and people were saying, "Well, I'm going to talk to the American Cancer Society, and I'm going to the Public Health Service, the local health control officers and so forth."

And those groups were not really interested in doing the kind of cancer control that the cancer centers were talking about.

They were talking about, how do we get a real science-based cancer control effort in place? And what happened is, it had to slowly grow up on its own. That is, we had to have groups of people who entered the cancer center structure: epidemiologists, cancer control research people, cancer prevention scientists, and they went out and actually created the science-based relationships with the community that actually, ultimately, proved successful.

So we are really not talking about money here, we're talking about cancer control.

RY: Except in the very early years, where there was some serious money relative to the needs of the cancer center, money has never been the driving force of expanding this. That's a myth. Even in the days when Fox Chase had a big cancer center grant, it was 5% of our budget, and now, I'm on still on two cancer advisory boards, and their percent of the budget is less than 1%.

I was thinking more about starting, getting started, that kind of money—seed money.

RY: Well, I mean, there was seed money early on, and it was used in a whole variety of ways to produce consortium cancer centers. For the most part, it didn't work very well. I mean, if you look at the consortium cancer centers like, Colorado, like Northern California, like the Illinois one, they ultimately just imploded, or they evolved in a different way. They became more cancer center-focused and science-driven.

So, we're talking about the first generation now. So, then comes a time when you were actually running the program during the rewrite of the designation criteria in 1985. Can you walk me through the politics?

I'm looking at the old *Cancer Letters.* I was still a general assignment reporter in 1985—elsewhere.

RY: It became a problem of, again, money for getting these things started. That is, there weren't a lot of scientists already in these cancer centers and the cancer centers said, "Well, we would be happy to stimulate this, to work on it, to expand the research in this area, but we don't have any money to do that."

The cancer centers program said, "Well, we don't have any new money, and we don't want to shrink your grant to shunt money from one place to another." And so they said, "Well, you can't just keep asking us for more and more unfunded mandates."

And, of course, that's been one of the siren calls of the cancer centers program since it was founded, just because the Cancer Institute is always coming up with great new ideas that they wish cancer centers to do without funding.

But that was when they phased out a lot of the consortium centers, or did they just die on their own?

RY: I think for the most part, they died on their own. I think that there was a general lack of great satisfaction with what they'd been able to accomplish scientifically. There was a lot of people setting up meetings with community-based institutions and so forth, but you couldn't really measure very much in terms of what real impact occurred as a result of that.

So, it was happening on its own.

RY: Yeah, I think so. The other thing, of course, is that these programs, at least early on, fared very poorly in peer review. Scientists came into review them and said, "Well, there isn't any science here. There's lots of meetings, people are doing all sorts of things, and they are talking to people in the community and so forth, and all that's laudable, but it's not science." And so it really didn't fare very well when it got reviewed in peer review.

And again, what the problem was the lack of science-based cancer control in the cancer centers, because there just weren't that kind of science being done. Now it is, and now you can get peer review groups that are really very knowledgeable and say, "Look, I can give you examples of how to do this. Here's a cancer center that's doing it." But that wasn't the case back in 1985. There just weren't a lot of actual science-based cancer control programs out there. The strongest cancer control stuff was epidemiology at that point.

So then, 1985, the new guidelines emerge... Would it be helpful to go through the list of the consortia that we know of, that we can still remember? There's the Illinois Cancer Council. They died because they ran out of state money. Right?

RY: Well, yeah. I mean that's what was said, and that's a problem. The problem with state money, in general, until recently, has been that it depended upon the attitude of the governor of the state at the time. At that time, this was all fledgling stuff.

Now, most of the major cancer centers in states have essentially a line-item, a multi-million dollar line-item in state budgets. And these are very well-defended within the state legislatures, because these are bragging rights. But that wasn't the case when these things were fledgling programs. States didn't see that they were doing very much.

> "Actually, what happened is that cancer control and prevention became a real science, and scientists based in cancer centers became the drivers of cancer control."

The other thing is that cancer centers back early on were fighting their way up into the academic ladder within their universities.

There were a lot of people in universities who didn't like the idea that there were cancer centers, that they had independent leadership roles at the level of the chairmans of departments and so forth. There was not a widespread acceptance of cancer centers as a mainstream part of academic medicine.

We've talked about the Illinois Cancer Council. Northern California fell apart, too, but I think there were two different organizations involved, and one was academic, and the other was more of a business organization.

RY: Well, that's the problem. And again, I don't want to be super critical of what was done back then, simply because people were experimenting with different models to see whether or not they could get something that would actually accomplish the goal, which was to link in some productive way, cancer centers with the communities in which they existed.

Now, if you go back and look at the original intent of the Cancer Act, it was primarily to create cancer research.

Any community relationship was deemed to be fine, but it was just gravy, in the sense that that wasn't the central mission.

That changed, as well it should. I think that there's much more, now, focus on what impact does the presence of the cancer center now make in the disease, cancer, within your catchment area or within your state, or whatever. You really need to make a difference. And it can't just be from the publications in *Cell* or *New England Journal*. You have to make an impact in your community, and that's a healthy evolution as far as I'm concerned.

Oh, we can get to outreach and engagement, too, in a little bit, but that's later. Let's stay in that mid-'80s for a few more moments. So, you're really saying that what you're dealing with there in the first phase is more of a dying out of the herd of natural causes, as opposed to being culled by NCI.

RY: Yeah, I think that's true. I mean, I think for the most part, they just weren't very successful on the ground, in the places where they tried them. At the same time, there was not very much classic peer review support for those kinds of mechanisms.

They did not fare very well in review. So, that was an additional issue that they faced. And the Cancer Institute was, in a sense, agnostic about whether or not any particular experiment would work or not work. They tried things and they worked, they continued to use them. If they didn't work, they just let them go.

Okay, so 1985, there's not much going on after that, I guess?

There is an attempt made by Louis Sullivan to create a cancer center consortium of Meharry, Howard and Drew. That just didn't get off the ground, right?

RY: Yes, I think that's right. I mean, obviously, I think that there was a great deal of interest in trying to expand cancer research related to minorities.

And so, that there was a good deal of initial enthusiasm for this idea, "Let's see if we can invest something here and make it evolve into something important."

I think that the desire was justifiable, but in the long run, I just don't think there was enough science-based activities at the time, and enough interaction within the scientists at that particular time to make it work.

And then, of course, Fox Chase, what happened there? Because I know that the original Fox Chase was a consortium with Penn, I believe.

RY: Well, yeah, it's interesting. I mean, at the time that was created, both institutions had about $5 million in grant funding. They were equal size, and the director of the Fox Chase Cancer Center was Tim Talbot, the director of the Penn Cancer Center was Peter Nowell, and Peter Nowell worked with [David] Hungerford in identifying the Philadelphia chromosome.

So, there was a scientific interaction between the two institutions. They knew each other well, they had worked together in scientific issues, and so they said, "Well, we'll just do it that way."

And there was a good deal of flexibility at the time about what was acceptable and what isn't as a collaboration. And it worked reasonably well, but the two institutions grew. And when I went to Fox Chase, the first grant I put in, we applied for comprehensive cancer center status and got it.

There wasn't any real big, ongoing relationship. Penn loved the idea of being able to call Barry Blumberg, the Nobel laureate, a member of their faculty and things like that. But it never was a big institutional collaboration in a major scientific way.

There were individual collaborations. Still are, for that matter, but it was more a practical way of responding to the Cancer Institute's desire to have comprehensiveness at the time.

They've gone back and forth about how much they want to have comprehensiveness, which is funny, because there's no money in it. You don't get money for being a comprehensive cancer center.

And so, you can use that again for bragging rights, and you can go in and raise money from your community and from your state and from things like that. I mean, cancer center directors will die to get comprehensiveness, but there's no money in it.

There's external money, and bragging rights, and all sorts of things, but there's no money from the Cancer Institute for it.

It's a good use of government money, because you're leveraging resources.

RY: Oh, absolutely. Oh, absolutely.

Fantastic.

RY: Yes.

And the political support for research, that's also great. So back in 1985-ish, from that point on, as these consortia are dying out, NCI is telling people, "Hey, don't bother submitting for a consortium grant, because won't approve it." I think that's what Paul Calabresi must have told me around 1990-something, [maybe] 1995. He was told not to bother.

RY: As I say, whenever somebody proposed a consortium cancer center, it had to get peer review. And peer review, just really, they fared very poorly in peer review. Lots of things fare poorly in peer review. Peer review is a very narrow microscope in many ways, and it is not par-

ticularly flexible. And as a result, they just fared very badly whenever they were reviewed by peer review groups.

So, nothing happens for 15 years or so, right? They just strangling all attempts to set up the [consortia]...

RY: Well, at least from my vantage point, a lot happened in those 15 years, which had nothing to do with this. It had to do with the emergence of serious cancer prevention and control research, not just in a few institutions, but in a lot of them. And they were churning out people who could then compete effectively in the NCI peer review system for serious grant money.

I mean one of the amazing things early on, if you had scientists who were skilled in peer review, or skilled in cancer control, you did extremely well. Paul Engstrom's program at Fox Chase, almost all of his investigators had peer reviewed funding, and a lot of their salaries on peer reviewed funding.

Much better than the basic science group or the clinical investigations groups, just simply because there weren't that many people out there competing for these grants.

But that changed dramatically in those 15 years.

Indeed, a lot happens. We're now around year 2000, really, no, about 1998-ish, right when the Harvard is trying to set up, Dana-Farber actually is trying to its own cancer center.

And so is Seattle, Washington, and so forth. And as you were saying, Bob Day is a cancer prevention control guy. And then Rick Klausner says... Well, you go... You understand this better than I do...

RY: My impression at the time, because I talked to Rick about it, was that he just said, "We could have 17 cancer centers in Boston if we tried, and we're not going to have it." And so, he just said, "It's not going to happen. You guys are going to have to get together and work together," which was a miracle.

It was a good move, actually, because it turned out that it worked, despite the fact that those guys compete rigorously with each other scientifically, they actually managed to come together and build a very, very strong cancer research program that was reasonably well-integrated.

And it's become a very impressive cancer center with serious participation with scientists in the institutions that wouldn't ordinarily not work together at all. It was a good move on his part. I think it was just his own strong feeling that he wasn't going to have to stand up and defend seven cancer centers in Boston.

Also, when you think back to this, there was another previous consortium cancer center in Boston, the Harvard Dana-Farber that, I think, just either died on its own or fell apart in some other ways. Is that correct?

RY: There've always been a significant number of Harvard faculty that have been a part of that cancer center. It's not just MGH guys and Dana-Farber guys. There've always been a lot of classical Harvard University investigators interested in cancer research.

I'm talking about consortia, formally organized consortium. There was one before that didn't make it. Is that correct or am I...

RY: I don't actually know whether there was. It wouldn't surprise me if there was that it didn't work. The way it basically works now, and the way it's worked since they founded it, is that everybody who happens to be interested scientifically in it, and wants to participate, can do that, but it's on a scientific basis, not on a institutional basis. The institutions up there don't play well together.

What about Seattle? Bob Day told me the story, many times, I think he's sworn me to secrecy about his battles to get [a consortium] going. And you know the stuff, you haven't been sworn to secrecy by Bob Day, so maybe you could tell me what happened in Seattle.

RY: In many ways, Bob was ahead of his time, because he was somebody who really was deeply interested in the science of cancer prevention and control, and he wanted to see that be amalgamated into these cancer centers.

And so, what he wanted to do, was to try to build an example of that in Seattle by bringing in a number of institutions, to have more in the way of cancer control outreach. But he was swimming against the current at the time.

He actually got there. He got it done.

RY: Well, he did. Yeah, yeah.

So, 15 years after the massacre of 1985, he brings back this whole thing of, and well, with Rick Klausner's support-

RY: Yes.

Well, what was Rick's thinking about Seattle? Do you know?

RY: That I don't know. I don't know. I never talked to him about that specifically, so I don't know whether he had a... I knew about his very specific attitude toward the Dana-Farber program, but I never talked to him specifically about the Seattle one.

So, what happens next? There are a few consortia, there aren't that many, really. So, it's 20 years go by, well, really, about 10 to 15, and then there's the consortium model changes a little bit. Science changes, too. How does that work now? I'm thinking Georgetown-Hackensack, for example.

RY: Well, I don't know. One of the things that's happened is that the consortiums that are being proposed now, for the most part, are between established institutions that have real science and have real research investigations ongoing.

They're not paper relationships that build in a hope that, if we get together, something good will come of it. And so, I think that's one of the big differences, that, to my knowledge, at least, no one is proposing a consortium relationship in which you don't have real science going on in the two institutions, and they don't see ways that they can leverage each other's scientific expertise in productive ways. So, I just think we've grown into a different situation than we were in in the early days.

And then, also, it's fascinating to see how the catchment area also changes with that, when you can actually combine areas from a few states apart, if you wanted to. You can, or you can even probably go across oceans if you wanted to.

RY: Again, I think what would happen in all those situations now, is that they would end up being subjected to peer review, and the peer review investigators would say, "Okay, show me the science, show me what real research is going on in this relationship. I'm not just interested in having two institutions add up their grants and put them together and say we're bigger and better."

One of the things that peer reviewers look for, as soon as they get into one of these situations, is show me evidence that there's really a collaboration that's producing significant science.

And you have to live up to the five and seven rule, right?

RY: Yes.

Which certainly weeds out a lot of players, potentially. It's really fascinating. So, what is the future of the consortium model now? What do you think?

RY: Well, I think we'll always have unique situations where collaborations with two institutions will be real and successful. I think that they are always more difficult than either the two participants think they are going to be.

Institutions have different cultures, and even though they think there are good reasons on paper to get together, getting together is not simple. And in my view, most of the time, the ones that work are the ones where the relationship comes together from the bottom up, not from the top down, and where collaborations developed between scientists at the two institutions, and that's what actually produces the collaboration.

Give you an example. One of the cancer centers that I followed with great interest is the University of Oklahoma. And Oklahoma has one of the biggest Indian populations of any state in the country.

And, of course, one of the things that the cancer center has always tried to stimulate is programs that are unique and represent an inroad into trying to produce cancer-related science relevant to unique populations in the country, minority populations, Indian populations... well, whatever. They have done it in a very interesting way. They have done it through scientists, some of whom were actually Indians, MDs, there are PhDs who happen to be part of Indian tribes.

And the relationship between the Indian tribes and the cancer center have developed as a result of scientific interactions. And so they have started that way and grown up into institutional relationships. They now have institutional relationships with most of the big Indian populations across the state.

But that was done not first, it was done after the scientific interactions, and after people began to know each other on a first-name basis before the institutions got together. And I think the bottom-up relationships that are science driven are the ones that work.

I think this is also getting us away from the subject of consortium cancer centers, but one of the things that I don't think Doug Lowy is getting enough credit for is, that he did require outreach and engagement component on the cancer center grant.

RY: No, I think that's true. I think that's true. You could push, to a certain extent. And, of course, I think institutions, mostly cancer centers, are now in a much better position to be able to respond to the Cancer Institute's push than they were in the past. They've got manpower, they've got scientists interested in outreach programs, and they have more of the capacity.

I mean, in the early days, responding to unfunded mandates was really hard, because you just didn't have any money. And now, cancer centers have got a lot of money coming from a lot of different non-NCI sources, that they can actually put their own money into some of these outreach programs, and build them, significantly, in a way that they couldn't 20 years ago.

So, it all comes down to science, that's what I'm hearing you say-

RY: That's my own personal belief. I think that's what's caused the ones that work, to work, and it's what causes the ones that didn't work, to fail. At least that's my view. Rick Klausner just forced Dana-Farber and MGH to work together, and said, "Look, there's not going to be but one cancer center, so you guys work it out. I don't care, but there's only going to be one." Well, they worked it out, and it works. And there's scientific interaction as well as scientific competition, but it works.

One in Seattle.

RY: Yeah, yeah. Exactly.

Bob Day did win.

RY: Yes, he did. And it's a good thing. Because it's been hard, I think, to reach a critical mass of understanding about the importance of cancer prevention and control in cancer centers. It just wasn't that simple early on.

Is there anything we forgot?

RY: I don't think so. Not that I know of. I mean, there all sorts of interesting things about the evolution of cancer centers, and we can talk about a whole host of things. I think the issues you were interested in getting at...

And in a simple sense, the Cancer Institute, I think, would take the position that it has peer reviewed any concept that's developed out of the Cancer Centers Program. And if it passes peer review, then it gets funded, and if it doesn't, it fades away.

That's fascinating. This was really panoramic, Bob. Thank you so much.

RY: Well, it's quite all right. I hope it was helpful and shed a little light on the issue. But go back and look at Benno Schmidt's first report. One of the things that disappeared very rapidly after the National Cancer Act was this idea that the President's Cancer Panel, this three-person panel, that was supposed to directly report to the President about what was going on.

That may still exist, but in fact, it never worked past Benno Schmidt. But at the time of Benno Schmidt, he did have access to the president, and he was a very, very smart man who had a very clear vision about what he wanted to accomplish and what he wanted the cancer centers new program to accomplish.

And it succeeded.

"I think institutions, mostly cancer centers, are now in a much better position to be able to respond to the Cancer Institute's push than they were in the past. They've got manpower, they've got scientists interested in outreach programs, and they have more of the capacity."

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Peter WT Pisters, MD, MHCM
President, MD Anderson Cancer Center

Peter WT Pisters, MD, MHCM, has served as president of The University of Texas MD Anderson Cancer Center in Houston, Texas since December 2017. A renowned cancer surgeon, researcher, professor and administrator, Dr. Pisters established his career at MD Anderson, serving over 20 years in faculty and senior leadership positions. He left MD Anderson to serve as president and CEO of the University Health Network in Toronto, Canada's largest research hospital, before returning to MD Anderson. Dr. Pisters earned his medical degree at Schulich School of Medicine and Dentistry at the University of Western Ontario in Canada before completing his postgraduate work at Memorial Sloan Kettering Cancer Center in New York. In 2014, he received a master's degree in health care administration at the Harvard T.H. Chan School of Public Health in Boston. He earned designation as a Certified Physician Executive in 2014 and was named a fellow of both the American College of Healthcare Executives and the American College of Surgeons.

Craig B. Thompson, MD
President and CEO, Memorial Sloan Kettering Cancer Center

Craig B. Thompson, MD, is the president and CEO of Memorial Sloan Kettering Cancer Center (MSK). Dr. Thompson received his BS from Dartmouth and MD from the University of Pennsylvania, followed by clinical training in internal medicine at Harvard Medical School and in medical oncology at the Fred Hutchinson Cancer Research Institute. Dr. Thompson has extensive research experience in cancer, immunology, and translational medicine. His current research focuses on the regulation of cellular metabolism during cell growth/differentiation and on the role that metabolic changes play in the origin and progression of cancer. Dr. Thompson is a member of the Institute of Medicine, the National Academy of Sciences, and the American Academy of Arts and Sciences. He is also a fellow of the AACR Academy.

IN THE ARCHIVES

CANCER HISTORY PROJECT

The National Cancer Act of 1971 and the birth of NCI-Designated Cancer Centers

Letter to the Editor: *Who was first?*

To the Editor:

We read with great interest the July 9, 2021, article in *The Cancer Letter*, titled, "Which cancer center was first? The answer depends on what you mean by 'cancer center'" (*The Cancer Letter*, July 9, 2021)—especially since this discussion is central to our book, *Centers of the Cancer Universe: A Half-Century of Progress Against Cancer*, to be released this October by Rowman & Littlefield.

We agree with Katie Goldberg that the answer is complex, revolving around subsidiary questions such as what is a cancer center, what is a cancer hospital, or even what is considered cancer research.

Also, we found that the definition depends on who you ask, what institution they consider to be first, and how legitimate was their source of information.

Ms. Goldberg was careful to point out that the timeline provided by the NCI notes that in "1963: The first Cancer Center Support Grant or 'core grant' was awarded to the ICR [Institute for Cancer Research] in Philadelphia. This was followed by another core grant awarded to support Dr. Henry Kaplan's Radiotherapy Research Program at Stanford University."

This apparently is the first core grant but hardly qualifies as support for a comprehensive cancer center, as the example of the second core grant illustrates.

Examination of the history of the core grant funding mechanism suggests that it was originally envisioned to simplify the grant review and accounting process rather than to support multiple complex and interrelated research projects, as it does now.

Ms. Goldberg also recounts the founding history of what we agree are very likely the first "cancer centers," defined as treatment facilities where some research is conducted (Memorial Sloan Kettering, MD Anderson, and Roswell Park Memorial Institute).

Reflection also reminds one that there were several other early, often government-sponsored facilities for the treatment of cancer patients that very likely conducted some research, although that part of their history remains largely unelucidated, e.g., Pondville State Hospital[1], Norfolk MA – founded in 1927; Francis Delafield Hospital[2], NY, NY – founded in 1951; Ellis Fischell State Cancer Hospital[3], Columbia, MO – founded in 1940.

Our research showed that these institutions were among the very first cancer research institutes,[4] but for a variety of reasons, mostly clouded in the mists of time, they never received the NCI designation one might have anticipated in their early years.

In 2019 we began work on our book dealing with the establishment of NCI-designated cancer centers and their impact on the evolution of cancer research and treatment since the signing of the National Cancer Act (NCA) of 1971 by President Richard Nixon[5].

Among the many questions we sought to address was: "What was the first NCI designated center?" Following two years of research and interviews with more than 75 past and present cancer center directors and leaders in the cancer community, we learned that the answer is less than clear and cancer centers claiming that distinction should probably qualify their assertions.

The National Cancer Act signed December 23, 1971, provided for the establishment of "15 National Research & Demonstration Centers," which initially were all defined as Comprehensive Cancer Centers. These centers, in the minds of the supporters[6] of increased national investment in cancer research, would conduct basic, clinical and what we now call translational research, and were exemplified by the existing "multifaceted programs" at Memorial Sloan Kettering Cancer Center, Roswell Park Memorial Institute, and MD Anderson.

When we began our research, we anticipated that thorough investigation and interviews would provide an answer to the fundamental question: Which was the first NCI-designated cancer center in the United States?

However, what we found was that the individuals with whom we spoke and institutions whose records we reviewed, including many from the NCI, were often uncertain or imprecise about significant parts of their histories; further confounding a look back is the fact that many records at the National Cancer Institute are destroyed every seven years

due to a federal records management mandate, which left even high-ranking officials unable to answer questions that may have predated their tenures.

We asked Linda Weiss, PhD, former director of the NCI Office of Cancer Centers (2002-2015), about the specific chronology of NCI designation, and she replied via email: "The definitive start dates for these first cancer centers have always been a bit fuzzy and when we were asked about it in the past, we tended to hedge a bit; even the initial number of centers was not entirely clear.

Information from different sources seemed to vary a bit as I recall, and it is probably in part due to the fact that several centers had precursor grants of varying kinds (some clinical infrastructure, some research project based, etc.) prior to the official implementation of the program."

She went on to explain that she seemed to recall "some lack of standardization historically" regarding how various grants were numbered, citing that she remembered "some evidence indicating that Fox Chase was the first center, under its old name, and that eight others followed." Weiss's recounting of the murky history was entirely consistent with the views of Henry P. Ciolono, PhD, current director of the NCI OCC.

The answer to the question "who was first?" is primarily of historical importance 50 years later and would accomplish nothing more than providing one center with the bragging rights to the claim of first NCI-designated cancer center.

That said, as we neared the end of our research, we did find an NCI document "...that comes close to addressing that question, albeit with an imprecision that is regrettable[7].

In August 1974 the NCI published its Operational Plan, FY1976-1980 that noted: 'During 1973 and 1974, the NCI recognized that the following institutions were *proceeding rapidly toward meeting* [italics added] the criteria for becoming Comprehensive Centers: Fred Hutchinson Cancer Research Center affiliated with the University of Washington, Seattle; University of Southern California, Los Angeles; University of Alabama, Birmingham; University of Wisconsin, Madison; University of Miami, Florida; Duke University, Durham, North Carolina; The Johns Hopkins University, Baltimore, Maryland; Dana Cancer Center, Boston, Massachusetts; The Mayo Clinic, Rochester, Minnesota.'"

"In addition, *three institutions were judged to be comprehensive at the time of the National Cancer Act of 1971* [italics added]: Roswell Park Memorial Institute, Buffalo, New York; Memorial Sloan Kettering Cancer Center, New York City; University of Texas MD Anderson Hospital and Tumor Institute, Houston, Texas.

"The plan further notes: 'By the end of 1974 these nine' [referring to those listed as 'proceeding rapidly toward meeting the criteria for becoming Comprehensive Centers'],'plus six others' "[which are not named][8]" are expected to be recognized by the NCI as Comprehensive Centers. With the three that were Comprehensive Centers at the time of the Act, together with the 15 centers authorized by the Act, the planned 18 centers will have been designated.'"

"This information had been noted in a discussion of the estimated number of centers that would be necessary to execute the National Cancer Plan and the budgetary requirements for funding this number.[5]"

The above information is consistent with the information noted by Ms. Goldberg, which was drawn from a document authored by Frank J. Rauscher Jr., PhD, director of the NCI from 1971 to 1976.[9]

This document appears also to have been drawn from the National Cancer Plan 1976-1980 and contains a similar, albeit somewhat circumspect statement: "Three other institutions were recognized as having Comprehensive Cancer Centers at the time of enactment of the National Cancer Act of 1971: MD Anderson Hospital and Tumor Institute, Houston; Memorial Sloan Kettering Cancer Center, New York; and Roswell Park Memorial Institute Buffalo."

Ms. Goldberg noted that in: "1971: The National Cancer Act of 1971 formally establishes the definition of a "cancer center," with Roswell Park, MD Anderson, and MSK as the first three to achieve comprehensive designation in 1972. No document has been located so far identifying which received this designation first."

We wholeheartedly agree with the last sentence; there appears to be no document that defined which was the first NCI-designated cancer center. In fact, in the available data there is no document or date formally designating any of the first several centers as NCI-designated.

It seems reasonable to assume that Memorial Sloan Kettering, MD Anderson, and Roswell Park began to think of themselves as NCI-designated centers in 1972, and we agree that it seems a stretch (as we have seen some centers contend) that any center received designation in 1971, since there were only eight days (including the Christmas holidays) following the actual signing of the NCA during which this could have been possible.

This discussion and our work to delineate the history and accomplishments of NCI-designated cancer centers emphasize the importance of contemporaneous recording and retention of important historical information to retain the accuracy of history that could otherwise be lost or distorted.

With regards,
Donald L. "Skip" Trump, MD, and
Eric T. Rosenthal
Coauthors of *Centers of the Cancer Universe: A Half-Century of Progress Against Cancer*

References

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2. *Accessed 7/17/21 https://www.nytimes.com/1950/08/31/archives/new-cancer-unit-dedicated-by-city-francis-dela-field-hospital-is.html*
3. *Accessed 5/18/21 https://www.muhealth.org/locations/ellis-fischel-cancer-center/ellis-fischel-history*
4. *In 1959 Pondville State Hospital was a founding member of the Association of Cancer Institute Directors (ACID), whose name was changed to the Association of American Cancer Institutes (AACI) at an ACID meeting in Oklahoma City in 1967.*
5. *Trump, DL and Rosenthal, ET Centers of the Cancer Universe: A Half Century of Progress Against Cancer (in press) Publication date 10/1/2021.*
6. *Mary Lasker, Benno Schmidt, and Sidney Farber, MD were among the prime movers behind the campaign which led to the NCA.*
7. *National Cancer Program Operational Plan FY1976–1980, DHEW Publication No. (NIH) 75-777 August 1974 V3-V5*
8. *Presumably these 6 included American Oncologic Hospital/Institute for Cancer Research which became Fox Chase Cancer Center.*
9. *Frank J. Rauscher Jr, Cancer Program is Well Under Way January 15, 1975. https://cdn.cancerhistoryproject.com/media/2021/03/25104335/18146.1.pdf*

Upcoming event

Fifty years after the National Cancer Act of 1971 became law, establishing the effort to tackle cancer as a national priority, Cancer History Project co-editor **Otis Brawley, MD,** sits down with the directors of America's first three comprehensive cancer centers to discuss the history, achievements, goals, and future directions of NCI-designated Comprehensive Cancer Centers.

Join Brawley in discussion with directors from the three centers that shaped the NCI Cancer Centers Program as model comprehensive centers:

- **Candace S. Johnson, PhD**
  Roswell Park Comprehensive Cancer Center
- **Peter WT Pisters, MD, MHCM**
  MD Anderson Cancer Center
- **Craig B. Thompson, MD**
  Memorial Sloan Kettering Cancer Center

A free virtual panel discussion will take place on July 29 at 5:30 P.M., EDT. Register to attend.

Recent contributions to the Cancer History Project

Children's Mercy Among Those at the Forefront of Historic Pediatric Cancer Treatment
By The University of Kansas Cancer Center | July 20, 2021

This column features the latest posts to the Cancer History Project by our growing list of contributors.

The Cancer History Project is a free, web-based, collaborative resource intended to mark the 50th anniversary of the National Cancer Act and designed to continue in perpetuity. The objective is to assemble a robust collection of historical documents and make them freely available.

Access to the Cancer History Project is open to the public at CancerHistoryProject.com. You can also follow us on Twitter at @CancerHistProj.

Is your institution a contributor to the Cancer History Project? Eligible institutions include cancer centers, advocacy groups, professional societies, pharmaceutical companies, and key organizations in oncology.

To apply to become a contributor, please contact admin@cancerhistoryproject.com.

IN BRIEF

VCU's Robert Winn voted president-elect of AACI

Robert A. Winn was elected president-elect of the Association of American Cancer Institutes.

A statement by Caryn Lerman, the association's new president and director of USC Norris Comprehensive Cancer Center, H. Leslie Hoffman and Elaine S. Hoffman Chair in Cancer Research, and associate dean for cancer programs, follows:

First, I hope you will join me in congratulating AACI's new board members. Robert A. Winn, MD, director of VCU Massey Cancer Center, was selected by AACI members as vice president/president-elect of the AACI Board of Directors. University of Arizona Cancer Center Director Joann Sweasy, PhD, was appointed to join the board, completing the remainder of Dr. Winn's term as a regular board member. Their new positions are effective immediately.

In October during the 2021 AACI/CCAF Annual Meeting, three additional cancer center directors will begin their terms on the AACI board: Marcia Cruz-Correa, MD, PhD, University of Puerto Rico Comprehensive Cancer Center; Ruben Mesa, MD, FACP, Mays Cancer Center, UT San Antonio Health MD Anderson Cancer Center; and Robert H. Vonderheide, MD, DPhil, Abramson Cancer Center. Drs. Cruz-Correa, Mesa, and Vonderheide will replace outgoing board members Leon Platanias, MD; Randall Holcombe, MD, MBA; and Tom Loughran, MD.

AACI also welcomed the Sandra and Edward Meyer Cancer Center at Weill Cornell Medicine to its roster. Located in New York City, the Meyer Cancer Center is a matrix cancer center that includes four research focus areas: Cancer Biology; Cancer Genetics & Epigenetics; Experimental Therapeutics; and Cancer Prevention & Control. The center, directed by Lewis C. Cantley, PhD, brings AACI's membership number to 103.

AACI's Corporate Roundtable is also growing. Fulgent Genetics is the newest addition to the Corporate Roundtable, which provides a forum for AACI cancer centers to address topics of mutual interest with their industry colleagues. Established in 2011, Fulgent develops a wide range of flexible, effective, and affordable genetic testing and develops biomarkers and therapeutics for cancer and other diseases.

I look forward to seeing you all virtually at the 2021 AACI/CCAF Annual Meeting in October, and to continue working with you toward our shared mission of accelerating progress against cancer.

Jeff Michalski voted president-elect of ASTRO

Jeff Michalski was elected president-elect of the American Society for Radiation Oncology.

ASTRO members also elected Catheryn Yashar as health policy council vice chair and John Buatti as science council vice chair. The officers will begin their terms in October during ASTRO's annual meeting in Chicago.

Michalski, the Carlos Perez Distinguished Professor and vice chair of radiation oncology at the Washington University School of Medicine in St. Louis, will serve a one-year term as president-elect, followed by single-year terms as president, chair and immediate

past chair of the ASTRO board. Yashar and Buatti will serve two-year terms as vice-chairs, followed by two-year terms as chairs of their respective councils.

In his tenure as president-elect and eventual chair of ASTRO, Michalski plans to focus on the society's priority issues including safeguarding equitable patient access to life-saving cancer treatment; building a pipeline of diverse radiation oncology clinicians and researchers; and developing programs and policies that will prepare the future workforce to meet the evolving cancer care landscape.

An expert in genitourinary cancers, pediatric cancers and cancer survivorship care, Michalski has experience leading and supporting clinical trials and developing clinical guidelines with ASTRO and NCI. He also co-chairs the radiation oncology section of the NRG Oncology national clinical trials group.

Additionally, Catheryn Yashar (Health Policy Council vice chair) is a professor of radiation oncology at the University of California, San Diego, and the current chair of ASTRO's Health Policy Committee.

An expert in gynecologic oncology, Yashar is the senior editor of gynecology for *Practical Radiation Oncology* and vice chair of the cervical/uterine panel for the National Comprehensive Cancer Network. In her board role, Yashar will work with policy stakeholders including the Centers for Medicare and Medicaid Services on key health policy issues, such as establishing an alternative payment model for radiation oncology that will protect patient access to value-based, guideline-concordant cancer care; reducing the burden of prior authorization hurdles that can unnecessarily delay cancer treatment; and reversing excessive payment cuts that undermine access to care and disproportionately impact rural and community-based practices.

John Buatti (Science Council vice chair) is the founding chair and a professor in the Department of Radiation Oncology at the University of Iowa's Carver College of Medicine, where he also holds secondary faculty appointments in neurosurgery and otolaryngology.

Buatti is a scholar and an expert on the treatment of cranial malignancies, as well as efforts to improve the quality of cancer imaging in therapy. He previously served on ASTRO's Science Council Steering Committee and currently chairs the ASTRO task force on radiopharmaceuticals—an emerging approach of combining radiation particles to targeted therapies, such as the use of radiation drugs to both find and treat tumors—and he recently led the development of ASTRO's framework for patient-centered care in radiopharmaceutical therapy.

In his role, Buatti will continue to support innovations in radiation biology, medical physics and clinical research that advance modern and multidisciplinary cancer care.

The ASTRO membership also elected three new members to the Society's Nominating Committee. Helen Shih, of Massachusetts General Hospital, Join Y. Luh, of St. Joseph Hospital, and Kristy Brock, of the University of Texas MD Anderson Cancer Center, will serve three-year terms beginning in October.

Michael Birrer named Kent C. Westbrook, M.D. Director's Chair at Winthrop P. Rockefeller Cancer Institute

Michael Birrer, vice chancellor and director of the Winthrop P. Rockefeller Cancer Institute at the University of Arkansas for Medical Sciences, was invested July 15 in the Kent C. Westbrook, M.D. Director's Chair for the Winthrop P. Rockefeller Cancer Institute.

The chair, established with the help of a $500,000 challenge gift, honors Kent C. Westbrook, the founding director of what is now the Winthrop P. Rockefeller Cancer Institute, and a distinguished professor in the Department of Surgery in the UAMS College of Medicine. He received the college's Distinguished Faculty Award in 1978 and the Distinguished Faculty Service Award in 2013.

Birrer was named vice chancellor and director of the Cancer Institute in 2019 and leads all cancer-related activities for UAMS, whose cancer clinics report more than 150,000 patient visits each year. There are about 150 UAMS faculty members engaged in cancer-related research and clinical activities. He was selected to lead the cancer institute toward achieving its goal of receiving NCI Designation.

A native of Clarksville, Arkansas, Westbrook graduated first in his class from UAMS in 1965. Following his general surgery residency at UAMS, he completed a surgical oncology fellowship at MD Anderson Cancer Center in Houston.

He returned to Arkansas determined to establish a cancer program with friend and fellow cancer surgeon James Y. Suen, so Arkansans would not have to leave the state for treatment. Westbrook worked with colleagues throughout much of the 1970s and early 1980s to develop comprehensive cancer programs at UAMS, culminating in the 1984 formation of the Arkansas Cancer Research Center, the Cancer Institute's predecessor. Westbrook served as its founding director for 14 years.

Rachel Katzenellenbogen named co-leader of CPC research program at IU Simon Comprehensive Cancer Center

Rachel Katzenellenbogen was named a co-leader of the Cancer Prevention and Control research program at the Indiana University Melvin and Bren Simon Comprehensive Cancer Center.

She serves along with Susan Rawl and Todd Skaar.

A member of the program since 2018, Katzenellenbogen is the chief of the Division of Adolescent Medicine in the Department of Pediatrics, associate professor of pediatrics and of microbiology and immunology, and the Richard E. and Pauline P. Klingler Scholar in Pediatrics at IU School of Medicine. She is also the Chuck and Tina Pagano Scholar at the cancer center.

Katzenellenbogen's cancer research focuses on the fundamental way human papillomavirus drives cancer development and progression, how that drive is common to all cancers or is unique to this infection-associated cancer, and identifying ways to detect and disrupt these pathways to intervene early in treatment.

Before joining IU, Katzenellenbogen was an associate professor of pediatrics at the University of Washington and Seattle Children's Research Institute.

Georgetown Lombardi establishes Institute for Cancer and Aging

Georgetown Lombardi Comprehensive Cancer Center has established the Georgetown Lombardi Institute for Cancer and Aging.

The mission of GLICA is to apply knowledge about aging across the life span to improve the lives of cancer patients and their families and achieve equity in cancer outcomes.

Jeanne Mandelblatt, a pioneer of gero-oncology, was the inaugural GLICA director.

Zachary Frosch named assistant professor at Fox Chase

Zachary Frosch was named assistant professor within the Department of Hematology/Oncology at Fox Chase Cancer Center.

Frosch is a graduate of the Perelman School of Medicine at the University of Pennsylvania and completed his residency in internal medicine at Brigham and Women's Hospital.

Following his residency, he served from 2017 to 2018 as associate director of the Scholars in Medical Education Pathway, as an instructor in medicine at Harvard Medical School, and as a physician in the Dana-Farber Cancer Institute's Division of Oncology Hospital Medicine. He was also named a scholar in the Harvard Macy Program for Educators in the Health Professions at Harvard Medical School.

Frosch will begin work at Fox Chase on Aug. 1.

ASCO, ACCC invite 75 research sites in the U.S. participate in pilot project of site self-assessment tool, implicit bias training program

The American Society of Clinical Oncology and the Association of Community Cancer Centers have invited 75 research sites to participate in a pilot project testing a research site self-assessment tool and an implicit bias training program focused on increasing racial and ethnic diversity among clinical trial participants.

Originally planned as a pilot project involving approximately 40-50 research sites, the program has expanded in response to interest from the oncology community.

The launch of this next phase of the oncology organizations' collaboration will help ensure racial and ethnic diversity among clinical trial participants and support for clinicians so they are able to routinely offer clinical trials to all eligible patients.

The invited sites represent a diverse mix of small and large research sites at community- and academic-based oncology programs, which will allow ASCO and ACCC to draw actionable conclusions about effectiveness of the tool and training in a variety of research and clinical settings.

Each site has been assigned to participate in the site self-assessment tool pilot study, the implicit bias training program pilot study, or both pilot studies.

The site self-assessment tool is intended to help research sites conduct an internal assessment of their policies, procedures, and programs that may impact which patients are screened for and offered a clinical trial, as well as factors impacting subsequent enrollment and retention.

Once the sites enter their responses, they will receive recommendations for specific strategies to implement and improve their performance. After completing their assessments, participants will provide feedback and suggested revisions to enhance the tool.

The implicit bias training program is designed to help research sites acknowledge and mitigate implicit bias across research and care teams related to which patients are offered clinical trials and which choose to participate. It is a virtual, curriculum-based program and includes self-directed and interventional components. Participants' feedback will be used to enhance the training program.

ASCO and ACCC will work with each of the invited sites to confirm and facilitate participation in the pilot project, which will officially begin this summer.

This work is part of an ASCO-ACCC initiative to establish evidence-based practical strategies and solutions to advance a vision where every patient with cancer has the opportunity to participate in research, focusing initially on patients who are Black and/or Hispanic/Latinx. The collaboration launched in July 2020 with a RFI to the oncology community seeking novel innovations to remedy participation barriers.

If the tool and training prove useful across a variety of research sites, the organizations plan to explore a longitudinal intervention study to evaluate their effectiveness in diversifying participation of people from all racial and ethnic minority populations historically underrepresented in cancer treatment trials.

THE CLINICAL CANCER LETTER

CLINICAL ROUNDUP

Oncology leaders recommend continuation of some pandemic-related changes to cancer clinical trials

Oncology leaders published an article in *Cancer Discovery*, a journal of the American Association for Cancer Research, on positive changes to cancer clinical trials brought about by the COVID-19 pandemic and recommendations for continuing these changes after the pandemic.

The authors of the article are Keith Flaherty, director of clinical research at Massachusetts General Hospital, a professor at Harvard Medical School, and member of the AACR Board of Directors; James Doroshow, a senior investigator at NCI; Susan Galbraith, executive vice president of oncology research and development at AstraZeneca and member of the AACR Board of Directors; Antoni Ribas, a professor at the University of California Los Angeles and the immediate past president of the AACR; Paul Kluetz, deputy director of the Oncology Center of Excellence at FDA; Richard Pazdur, director of the OCE; and Marc Theoret, a deputy director of the OCE.

The authors outline adaptations to clinical trial procedures implemented during the pandemic in four key sectors: academic centers, industry sponsors, government-sponsored clinical trials, and regulatory agencies such as the FDA.

Some of the highlighted adaptations include:

- Uptake of remote consenting and telemedicine to avoid in-person appointments,
- Permitting the use of alternative laboratories and imaging centers,
- Delivery of investigational drugs to the patient's home or local clinic,
- Administration of intravenous investigational drugs at the patient's home or at a local clinic; and
- Commercial attainment of study drugs already approved for other indications.

"The restrictions during the pandemic have highlighted that cancer clinical trials should be patient-centered, as opposed to centered on the study sites," Ribas said in a statement.

Changes implemented during the pandemic could help increase access to patients living in underserved communities that are underrepresented in clinical trials, he said.

"The ability to distribute oral investigational drugs by mail to patients at their home has probably been the single most impactful change to clinical trial conduct, linked with virtual visits with patients to assess side effects and symptoms," Flaherty said in a statement. "This has made it more feasible for patients for whom participation in clinical trials poses a disruption of their ability to work or provide care for family members to participate in trials."

In the article, the authors recommend that these changes continue beyond the pandemic.

In addition, they recommend the following adaptations to enhance efficiency and further expand access to clinical trials:

- Incorporation of patient-reported outcomes and alternative endpoints in efficacy assessments
- Goal of 100% remote drug infusions and monitoring
- Increased funding for clinical trials conducted in underserved communities
- Expansion of clinical trial eligibility to include patients with a wide range of comorbidities
- Reduced collection of low-grade adverse events and allowing minor protocol deviations

This manuscript reflects discussions that originated in the AACR COVID-19 and Cancer Task Force, from which this

subgroup of co-authors was self-selected to define the scope of the manuscript and contribute to the generation of first and subsequent drafts, as well as the final version.

All AACR journal content related to COVID-19 is freely available in the COVID-19 and Cancer Resource Center.

Fox Chase researchers assess racial disparities in prostate cancer treatment during COVID-19

Researchers at Fox Chase Cancer Center found that the odds of a patient undergoing prostate cancer surgery were lower among Black patients compared with white patients during the initial wave of the COVID-19 pandemic.

The results were published in *JAMA Oncology*.

"If you look at the prostate cancer literature there is an unfortunate signal that Black patients do worse than white patients when it comes to prostate cancer outcomes," Andres F. Correa, author on the study and assistant professor for the Department of Surgical Oncology at Fox Chase, said in a statement.

"Historically there has been interest in exploring possible genetic links that may explain the difference in outcomes between Black and white patients. Recent reports, however, have demonstrated that when you provide equal care, those differences go away," he said.

The study was prompted by early reports showing that minority populations were disproportionately adversely affected by the COVID-19 pandemic. Correa said they sought to assess how a significant stressor, such as the lockdown, affected the delivery of routine cancer care within a certain region.

The study compared prostatectomy rates between Black and white patients with untreated, non-metastatic prostate cancer during the COVID-19 pandemic and was based on numbers from the Pennsylvania Urologic Regional Collaborative database.

"Prior to the pandemic, there was no difference in the rate of surgery for Black and white patients diagnosed with prostate cancer," said Adrien Bernstein, lead author on the study and second year urologic oncology fellow at Fox Chase. "During the pandemic, however, Black men were 97% less likely than white men to undergo a prostatectomy."

The study further demonstrated that these changes in care were not secondary to difference in prostate cancer severity or the risk of severe COVID-19 infections. Rather, the disparity in surgical treatment was driven by clear systemic variations—institutions that cared for a greater proportion of black patients experience a greater decline in operative volume.

The researchers note that this study highlights the potential frailty of the healthcare system and caution that patterns such as those reported in the study are likely unfolding across medicine.

"Healthcare disparities are often multifactorial in origin and represent a key determinant of health. Only by bringing these inequities to light are we able to begin the work to rectify them," said Bernstein. "Different policies were enacted for different communities. While prostate cancer surgery can be safely delayed up to a year, balanced mitigation strategies are needed as we continue to navigate the COVID-19 pandemic."

Study: COVID-19 created significant disruptions in breast, colorectal and cervical cancer screenings among federally qualified health centers

The COVID-19 pandemic contributed to significant disruptions in breast, colorectal and cervical cancer screenings among federally qualified health systems spanning 15 states across the U.S.

The postponed screenings have created backlogs that systems will need to address as health facilities re-open for preventive care, according to the study. The study was published in the *Journal of Preventive Medicine*. Data were collected August-September 2020.

Of the 22 systems in the study, 11 (50%) reported stopping cancer screening completely for the cancer type specified in their application since the start of COVID-19 disruptions. One center reported never stopping screening entirely for their specified cancer types. Over half of all systems reported enforced screening service disruptions/cancellations as a result of state or local COVID-19 restrictions.

The Cancer Screening during COVID-19 projects aim to help FQHCs resume cancer prevention services and catch up on missed cancer screenings to mitigate the impact of disruptions in care related to COVID-19 on cancer morbidity and mortality.

The study shows that when clinics were asked about service disruption, there was not one unified picture, and different clinics even within the same state

described different times when experiencing peaks in disruption of screening.

Half of the systems were able to maintain home-based stool sampling testing for colorectal cancer without any disruptions. The study also found that 100% of the clinics switched to telehealth visits, and 100% implemented structural changes in the office, including waiting room protocols.

Studies find combination chemotherapy beneficial, cost-effective in sub-Saharan Africa

Researchers at the UNC Lineberger Comprehensive Cancer Center demonstrated in a clinical trial in Malawi that a five-drug combination chemotherapy provided curative benefit compared to current standard-of care-therapy in people diagnosed with lymphoma, and now they have determined this option is also cost-effective.

The economic finding appeared July 22, 2021, in *Lancet Global Health*.

The clinical trial results, reported May 19, 2021, in *Lancet Global Health* involved 37 people with diffuse large B-cell lymphoma. The majority of patients were also HIV-positive, which greatly increased their risk of DLBCL; all HIV-positive patients were treated with anti-viral drugs.

The trial participants received a standard four-drug chemotherapy of cyclophosphamide, doxorubicin, vincristine and prednisone (CHOP) along with rituximab, an antibody therapy. After two years of follow-up, 55% of the patients were still alive, an outcome that is higher than CHOP alone based on earlier studies.

With the trial results in hand, the researchers wanted to know if either CHOP or CHOP plus rituximab were cost-effective treatments in a resource-limited setting. Demographically, Malawi is a sub-Saharan country in Africa with roughly 19 million residents.

The healthcare resources available in the 2017-2018 government budget for Malawi were $170 million dollars (about $9 per person); external donors contribute approximately another $350 million annually to health expenditures.

UNC Lineberger's Matthew Painschab, MD, lead author of the economic analysis and co-lead author of the treatment efficacy study, said cost-effectiveness analyses allow comparisons across diverse diseases so that limited resources can be optimally allocated.

"Without such analyses, relatively expensive upfront costs for cancer medicines will often seem prohibitively costly for a relatively small number of patients compared to other available public health interventions," Painschab, assistant professor in the Division of Hematology at UNC School of Medicine and a member of UNC-Project Malawi, said in a statement. "We demonstrated that an upfront, time-limited expense followed by decades of healthy life may be a prudent investment, relative to other accepted interventions such as daily, lifelong antiretroviral treatment for HIV."

On a per-patient basis, comparing supportive care to chemotherapy with CHOP, chemotherapy prevented more than seven disability-adjusted life years (DALYs) at a cost of $193 per DALY prevented. One DALY is a year of life lived in perfect health and therefore losses represent both years lost from dying early as well as quality life-years lost to disability. Adding rituximab to CHOP prevented about three DALYs at a cost of $1,145 per DALY.

"Though precise estimates of cancer incidence are lacking, we estimate it would cost about one million dollars annually to treat all cases of DLBCL in Malawi with CHOP, saving an estimated 252 lives," Painschab said. "For two million dollars more annually, we could add rituximab, which costs about $500 a dose in Malawi, and the five-drug regimen could save an additional 100 lives."

In addition to the recently published studies, the researchers are conducting some of the first molecular profiling studies for HIV-associated lymphoma. They hope that greater biologic understanding of DLBCL in Malawi may lead to more targeted, safe and effective treatment strategies. They note there is still much work to be done in this area, both in the U.S. and Malawi.

Dana-Farber researchers find signs of worsening pain management for terminal cancer patients

In a sign that pain management for patients dying of cancer is worsening, a new study by Dana-Farber Cancer Institute investigators has found a sharp decline in opioid access among these patients over a recent 10-year period, even as many more of them turned to hospital emergency rooms for pain treatment.

The findings, in a paper published online today by the *Journal of Clinical Oncology*, suggest that efforts to counter the ongoing epidemic of opioid abuse may have had the unintended effect of reducing terminally ill cancer patients' access to these critically needed pain medications.

The study drew on data for 270,632 Medicare patients with poor prognosis cancers who died between 2007 and 2017. Investigators analyzed the data for trends in opioid prescriptions written within 30 days of patients' death or enrollment in hospice care.

Over the study period the researchers found a 34% reduction in the number of opioid prescriptions filled per patient and a 38% reduction in the total dose of opioids filled per patient near the end of their lives. The researchers found a particularly steep decline in use of long-acting opioids, which provide more predictable, steady pain relief and are important for managing severe cancer pain. Between 2007-2017, the number of long-acting opioid prescriptions filled per patient fell by 50%.

At the same time that patients dying of cancer were filling fewer opioid prescriptions, the proportion of these patients who visited hospital emergency departments for pain rose 50.8%. These findings suggest that many patients may be forced to seek care in emergency departments because they lack access to necessary opioid pain medications at home, the study authors say.

"The opioid crisis in the United States prompted regulators, healthcare providers, and insurers to enact a variety of measures to curb the inappropriate prescribing of these medications," said first author Andrea Enzinger, a medical oncologist specializing in gastrointestinal cancers and a member of the Population Sciences Department at Dana-Farber Cancer Institute. "While these efforts have had their intended effect of reducing overall rates of opioid prescribing in the past decade, our findings indicate that the restrictions may be inadvertently depriving patients with advanced cancers of medicines they need to control their pain near the end of life.

"Opioids are the cornerstone of managing moderate to severe cancer pain," she said. "Yet we know that undertreatment of cancer pain is a major problem in the U.S., and many patients with advanced-stage cancers only receive mild analgesics, which are completely inadequate for the very severe pain that they experience. Opioid regulations may exacerbate the heartbreaking problem of undertreatment of cancer pain at the end of life."

"Policies have focused largely on reducing inappropriate prescribing, which is useful, but they are a blunt instrument. New regulations have made it very cumbersome and time-consuming to prescribe opioids, even for patients with cancer. Pharmacies and insurance companies have also added further barriers that make it difficult for patients to fill these prescriptions," Enzinger said. "The safety aspect is important, but these additional barriers interfere with patients' ability to access critical pain medication."

Cultural biases and preconceptions also may be deterring patients with end-stage cancers from requesting and using opioids.

"Many patients dying of cancer are living with high levels of pain that interfere with their ability to spend valuable time with their family because they're afraid of becoming addicted. Some patients worry that using pain medications means they're weak, are doing something immoral or wrong, or are disappointing their families—instead of simply getting adequate pain relief," said senior author Alexi Wright, medical oncologist and director of gynecologic oncology outcomes research at Dana-Farber.

Although patients with end-stage cancer are exempt from many of the restrictions on opioid prescriptions, the challenges of obtaining and filling a prescription remain an obstacle for those whom the exemptions are intended to protect, she said.

Mount Sinai researchers develop engineered molecule that may disrupt enzyme in many cancers

Mount Sinai researchers have developed a therapeutic agent that shows high effectiveness in vitro at disrupting a biological pathway that helps cancer survive, according to a paper published in *Cancer Discovery*, a journal of the American Association for Cancer Research, in July.

The therapy is an engineered molecule, named MS21, that causes the degradation of AKT, an enzyme that is overly active in many cancers. This study laid out evidence that pharmacological degradation of AKT is a viable treatment for cancers with mutations in certain genes.

"Our study lays a solid foundation for the clinical development of an AKT degrader for the treatment of human cancers with certain gene mutations," Ramon Parsons, director of The Tisch Cancer Institute and Ward-Coleman Chair in Cancer Research and chair of oncological sciences at the Icahn School of Medicine at Mount Sinai, said in a statement. "Examination of 44,000 human cancers identified that 19 percent of tumors have at least one of these mutations, suggesting that a large population of cancer patients could benefit from therapy with an AKT degrader such as MS21."

MS21 was tested in human cancer-derived cell lines, which are models used in laboratories to study the efficacy of cancer therapies. Mount Sinai is looking to develop MS21 with an industry partner to open clinical trials for patients.

DRUGS & TARGETS

Keytruda + Lenvima receive FDA approval for advanced endometrial carcinoma

Keytruda (pembrolizumab) in combination with (Lenvima) lenvatinib (Lenvima, Eisai) has received FDA approval for patients with advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.

Keytruda is sponsored by Merck and Lenvima is sponsored by Eisai.

FDA granted accelerated approval on Sept. 17, 2019 to pembrolizumab with lenvatinib for advanced endometrial carcinoma. Study 309/KEYNOTE-775 (NCT03517449) was a multicenter, open-label, randomized, active-controlled trial required to confirm the clinical benefit of this accelerated approval.

Study 309/KEYNOTE-775 enrolled 827 patients with advanced endometrial carcinoma previously treated with at least one prior platinum-based chemotherapy regimen in any setting, including neoadjuvant and adjuvant treatments. Patients were randomized (1:1) to either pembrolizumab 200 mg intravenously every 3 weeks with lenvatinib 20 mg orally once daily or investigator's choice of doxorubicin or paclitaxel.

For patients with advanced endometrial cancer that is not MSI-H or dMMR, the median PFS was 6.6 months (95% CI: 5.6, 7.4) for patients in the pembrolizumab and lenvatinib group and 3.8 months (95% CI: 3.6, 5.0) for those receiving investigator's choice chemotherapy (HR 0.60; 95% CI: 0.50, 0.72; p<0.0001). Median OS was 17.4 months (95% CI: 14.2, 19.9) and 12.0 months (95% CI: 10.8, 13.3), respectively (HR 0.68; 95% CI: 0.56, 0.84; p=0.0001). ORR was 30% (95% CI: 26, 36) and 15% (95% CI: 12, 19), respectively (p<0.0001). Median DOR was 9.2 months (1.6+, 23.7+) and 5.7 months (0.0+, 24.2+).

Rezurock receives FDA approval for chronic graft-versus-host disease

Rezurock (belumosudil), a kinase inhibitor, has received FDA approval for adult and pediatric patients 12 years and older with chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy.

Rezurock is sponsored by Kadmon Pharmaceuticals, LLC.

Efficacy was evaluated in KD025-213 (NCT03640481), a randomized, open-label, multicenter dose-ranging trial that included 65 patients with chronic GVHD who were treated with belumosudil 200 mg taken orally once daily.

The main efficacy outcome measure was overall response rate through Cycle 7 Day 1 where overall response included complete response or partial response according to the 2014 criteria of the NIH Consensus Development Project on Clinical Trials in Chronic Graft-versus-Host Disease.

The ORR was 75% (95% CI: 63, 85); 6% of patients achieved a CR, and 69% achieved a PR. The median time to first response was 1.8 months (95% CI: 1.0, 1.9). The median duration of response, calculated from first response to progression, death, or new systemic therapies for chronic GVHD, was 1.9 months (95% CI: 1.2, 2.9). In patients who achieved response, no death or new systemic therapy initiation occurred in 62% (95% CI: 46, 74) of patients for at least 12 months since response.

Venclexta + azacitidine receive breakthrough therapy designation from FDA for myelodysplastic syndromes

Venclexta (venetoclax) in combination with azacitidine was granted Breakthrough Therapy Designation from FDA for the treatment of adult patients with previously untreated intermediate, high- and very high-risk myelodysplastic syndromes based on the revised International Prognostic Scoring System.

This designation was granted based on interim results from the phase Ib M15-531 study investigating Venclexta plus azacitidine in people with previously untreated, higher-risk MDS.

This is the 38th BTD for Genentech's portfolio of medicines, and the 11th designation for its hematology portfolio.

Venclexta is being developed by AbbVie and Genentech, a member of the Roche Group.