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THE CANCER LETTER
Inside information on cancer research and drug development
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PASKETT: A THREE-TIME CANCER SURVIVOR SHOULD NOT GET COVID-19, BUT I DID

Cancer patients and survivors should not get COVID-19. A three-time cancer survivor should definitely not get COVID. But I did. And it was not good. Here is my story and the lessons I learned that might be of value to others.

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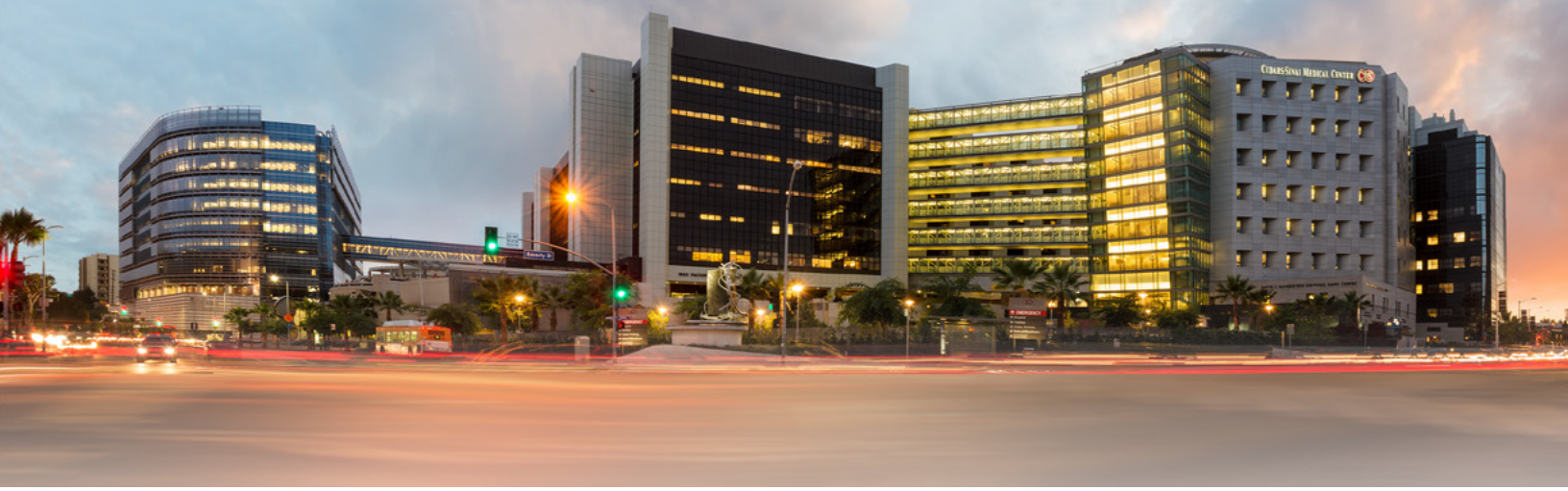

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Chief Financial Officer
Roswell Park Comprehensive Cancer Center

Roswell Park Comprehensive Cancer Center (Roswell Park) is seeking a dynamic, skilled and experienced executive to serve as its Chief Financial Officer. Roswell Park is a Public Benefit Corporation formed by New York State in 1999 that operates a $1 billion nationally ranked NCI-designated Comprehensive Cancer Center located in Buffalo, NY. The Chief Financial Officer will report directly to the President & CEO and will be primarily responsible for all financial aspects of the cancer center.

The Chief Financial Officer is a senior-level executive position responsible for strategic financial planning, executive financial leadership, daily financial operations and financial performance of Roswell Park and its subsidiaries. The CFO also plays a significant role in strategic and operational planning for the organization, participates actively as a primary advisor to the President & Chief Executive Officer and has substantial and consistent interaction with the organization's Board of Directors. The CFO is the primary executive administering and interacting with the Finance Committee of the Board, which has oversight of financial matters for Roswell Park. The CFO is responsible for ensuring that effective financial controls are in place, that finance and accounting activities are comprehensive and accurate and that data-driven information is available and supports strategic and operational planning for the organization. Roswell Park's operating budget has grown to over $1 billion and includes operating 133 inpatient beds and over 278,000 outpatient visits annually, along with a large and wide-ranging research operation.

Roswell Park is the only National Cancer Institute (NCI)-designated Comprehensive Cancer Center in Upstate New York, consistently ranks among the NCI's top recipients of research funding and has been recognized by *U.S. News & World Report – Best Hospitals for Cancer* for many years, ranking #14 on the list in both 2019 and 2020. Over the last decade, Roswell Park has undergone significant growth, adding over 1,500 new jobs, initiating one of the nation's first hospital facilities dedicated to Phase I cancer research studies and setting itself apart as a leader in surgical robotics, vitamin D research, immunotherapy and vaccine therapy, personalized medicine, studies targeting tumor microenvironment and cancer prevention and the development and testing of new agents and technology. Committing the infrastructure, intellectual capital and necessary resources to convert its scientific discoveries into products and applications to help cancer patients, Roswell Park has established several biotech spin-off companies and formed strategic partnerships with investigators and centers throughout the world.

Roswell Park's main campus spans 29 acres in downtown Buffalo and consists of 15 buildings housing a large surgical, inpatient and outpatient operation operated by an employed faculty of nationally known oncology physicians, leading-edge research facilities manned by a science faculty of over 150 members and academic facilities for its accomplished education mission. In addition, the organization built a new medical research complex and renovated existing education and research space to support its future growth and expansion. The latest addition to the campus is the new 150,000-square-foot Clinical Sciences Center, opened in 2019. Roswell Park maintains suburban locations both north and south of the downtown campus and has developed a significant network of hospital system affiliates across Western and Central New York State.

The ideal candidate will have the ability to provide the analytic framework and business judgment for evaluating new initiatives and priorities, and have the capability of operating and providing leadership in a complex organization. Candidates should possess outstanding communication and relationship building skills. Candidates should have a minimum of 10 years of health care management experience, including at least 3+ years of senior management experience. Ideal candidates will possess the following:

- Certified Public Accountant (CPA) designation
- Bachelor's degree in Accounting and or Finance; Master's a plus
- A minimum of ten (10) years of full-time experience in healthcare financial management with increasing responsibilities for multi-faceted direction and planning.
- Extensive experience with core financial systems, an advanced level of experience with long-range financial planning and decision support and excellent analytical, organizational and supervisory skills, with substantial experience in these areas in the health care field
- In-depth knowledge and experience with the business aspects of cancer research and treatment are preferred

Roswell Park offers a competitive salary and performance-based incentives as well as a comprehensive benefits package. Candidates should email their CV and three references to:

Angela K. Gunther, MBA, AASPR
Senior Faculty Recruitment Administrator
Roswell Park Comprehensive Cancer Center
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ROSWELL PARK
COMPREHENSIVE CANCER CENTER

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THE CLINICAL CANCER LETTER

CLINICAL ROUNDUP

DRUGS & TARGETS

NCI TRIALS

LETTER FROM THE EDITOR & PUBLISHER

Presenting the

CANCER HISTORY PROJECT

by THE CANCER LETTER

Historical documents have a way of vanishing. Manuscripts, letters, and photographs end up in city dumps. Memories become less granular, insight is lost. The documents that do get preserved often require a trip to the archives.

Cancer research, a field of science that half-a-century ago was assigned top priority under the National Cancer Act of 1971, must not be allowed to lose connection with history.

We have spent the past couple of years inventing a way to tell the enormous story of cancer research and place a cache of documents within easy reach of researchers, students, and patients.

This groundwork has produced the Cancer History Project, which we have the honor of presenting to you today.

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.

Edited by Otis Brawley and Paul Goldberg, this resource draws on the expertise of an editorial board of physicians, scientists, advocates, historians, and communicators.

We encourage you to participate as a contributor and sponsor.

Contributors: Eligible organizations include cancer hospitals, research organizations, advocacy groups, professional societies, industry, and other healthcare institutions. Participation is free.

Contributor content must be of historical relevance, and will be reviewed by the Cancer History Project team. A list of suggested content is available here.

Contributors are free to publish according to their own calendar, but are also welcome to coordinate on monthly topics to shape dialogue.

Our initial list of contributors is available here.

To become a contributor and access the project's editorial calendar, email admin@cancerhistoryproject.com.

Sponsors: The Cancer History Project is funded through sponsorships.

Sponsors receive an advertising package commensurate with the sponsorship level, and a year-long logo placement on the Cancer History Project.

The goal of the Cancer History Project is to create a starting point for a broader discussion of history and community—and enable finding answers to fundamental questions and deep scholarly research.

The Cancer Letter is uniquely positioned to offer its vast historical resources and—through curation informed by decades of institutional knowledge—to build a central repository for documents from other organizations.

The Cancer Letter was founded in 1973, two years after the signing of the National Cancer Act, and has come out every week for over 46 years, creating a real-time, detailed record.

We are placing the first 30 years of coverage—from 1973 to 2003—onto the website, making this material publicly available and searchable. This archive is available here.

The Cancer History Project begins with the publication of historical materials and is designed to expand beyond the celebration of the 50th anniversary of the National Cancer Act. The project is organized according to monthly topics, with content published both in *The Cancer Letter* and on CancerHistoryProject.com.

In addition to the 30-year archive of *The Cancer Letter*, the Cancer History Project includes contemporary coverage, all obituaries, and select special reports.

This is a massive project, and it will take shape before your eyes.

We have created an editorial calendar for 2021, but we will remain flexible as the project evolves—and we are eager to hear your creative ideas.

The Cancer History Project is a participant in NCI's 50th Anniversary "Nothing Will Stop Us" campaign that celebrates progress in cancer research (*The Cancer Letter*, Oct. 16, 2020).

This announcement is the beginning of a process of storytelling. In the coming weeks, we will add the archives of *The Clinical Cancer Letter*, publish manuscripts we have uncovered, catalogue oral histories, and post historical documents and primary source materials we have in our possession and those provided by academic institutions and scholars.

We need your guidance, the participation of your institution, and sponsorship.

We are confident that, together, we will be able to tell this epic story of small steps and big leaps upon the path of discovery.

***Otis Brawley** is the Bloomberg Distinguished Professor of Oncology and Epidemiology at Johns Hopkins University.*

***Paul Goldberg** is the editor and publisher of The Cancer Letter.*

To request further information, please contact admin@cancerhistoryproject.com.

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GUEST EDITORIAL

Paskett: A three-time cancer survivor should not get COVID-19, but I did

Cancer patients and survivors should not get COVID-19. A three-time cancer survivor should definitely not get COVID. But I did. And it was not good. Here is my story and the lessons I learned that might be of value to others.

Electra D. Paskett, PhD
Marion N. Rowley Professor of Cancer Research,
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I had been sequestered at home—working and supervising my staff of about 40—since March 16, wearing a mask on the rare occasion I ventured out of the house, washing my hands when packages arrived and when returning from trips out of the house.

I declined invitations to attend church events, and I only went to campus for medical appointments. I even participated in our cancer center's core grant site visit preparation and actual site visit remotely via Zoom. My husband got COVID at the end of August, but with attention to isolation, wearing masks, and handwashing, none of the rest of us in the house got it.

At the end of October, I was contacted about participating in a COVID vaccine trial at OSU. I passed the initial eligibility screen and had an appointment scheduled in mid-November to finalize eligibility and then participate in the trial, if eligible. Then, a friend, who had been coming to my house regularly, came to my house on Nov. 2 with symptoms, which she didn't recognize as COVID.

Neither of us wore a mask, but we were socially distant the entire time.

Lesson 1: Never let down your guard with this virus.

My symptoms started with a very mild sore throat and cough on the evening of Nov. 6, when I received a text from my friend, saying she tested positive and that her symptoms had actually started on Oct. 29.

I knew then that I had COVID. The next day, my symptoms persisted, so I contacted my PCP through MyChart and asked to be tested.

I thought I would have a mild case, like my husband and many others, and could wait till Monday to hear back from my PCP. But that night I experienced my first "COVID night"—waking up at 2 a.m., with a headache in the middle of my forehead, coughing, insomnia and alone.

I knew, then, I was in trouble. But, I thought, how does one get tested on the weekend?

Fortunately, I thought to email my oncologist and asked if I could call her. She promptly replied, and I called.

She heard something in my voice that I was not aware of and told me to go to the Emergency Department—the only place a COVID-positive person could seek care other than the hospital. She called ahead and told them to put me in a room.

I got in my car, thinking I would get tested and come back home, as my husband had in August, and drove to the medical center. After checking in with the reception person, saying "no way do you have a room already," and vitals taken, I was indeed taken to a room. Immediately, four staff came in the room, in full PPE gear, and assisted me in changing into a gown, got me hooked up to monitors, and started an IV.

They then started asking me questions, and as I was answering, I noticed that I was out of breath as I spoke. They did a rapid COVID test and left the room for 69 minutes until the results came back. Of course, the results came back positive—then the action really started.

Lesson 2: Listen to the small cues your body gives you and act promptly. Listen to what your patients are not saying.

A hospitalist peeked in and said he would be right in. He came back in full PPE gear and said, "You don't look sick, but the ED personnel told me you have an elevated heart rate and are out of breath when you speak." Key symptoms I had not recognized myself.

We discussed the possible effects of COVID on my body—a body that had a history of three breast cancer diagnoses and treatments, asthma, cardiomyopathy from past chemotherapy (now under control), heterozygous for Factor V Leiden mutation, and pre-diabetic.

Then what I was not prepared for—the discussion of a DNR. That brought the seriousness of this upfront and personal.

The Infectious Disease attending came in for a consult. I had a chest x-ray and a nebulizer treatment. I was started on anticoagulants and steroids and was told I was to stay the night for observation. There were no open beds in the hospital, so I stayed in the ED all night.

I talked to my family who came and got my car, and then I texted my colleagues and staff with the preface "Don't freak out, but…" Of course, everyone freaked out.

Lesson 3: Good friends and colleagues are priceless.

I felt better in the morning, and was discharged with instructions and prescriptions.

I sat on a Zoom meeting and turned in early—all the time isolating from my two boys, who had not been diagnosed with COVID—my husband was immune from his diagnosis in August.

I enjoyed a delicious meal and called it a night. From about 2 a.m. to 4 a.m., I had another COVID night—coughing, headache, insomnia, helpless and alone in the dark waiting for daylight and hoping sleep would come.

In the morning, my oncologist texted to check on me, and I told her I was worse, with coughing and a headache, and she decided to admit me. The troops were called in and mobilized to get me admitted and started on remdesivir.

It was not until 4:30 p.m. that I got a text saying to go to the hospital as a bed had opened up.

My son drove me, and my husband met me at the hospital.

As instructed, I went to Admitting and sat away from others until called into an office for the admission process to begin. Once the staff realized I was COVID-positive, I was isolated in the office—the second time I realized that COVID patients have a big Red "C" on their back and everyone runs away from us.

As I sat in the office, waiting for a room to be ready, I was called by a colleague

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about joining a monoclonal antibody trial. I agreed, and then the clinical trial staff called, and we completed the informed consent process over the phone and by email.

Finally, by about 7 p.m., I was shown to my room, settled in and hooked up to monitors.

Unfortunately, it took six sticks to get my IV started (finally by the IV team) and blood drawn (10 tubes) for the study. I had another chest x-ray, and I got the study drug first, then at 9 p.m. the remdesivir.

An antibiotic was added to my medications to address the pneumonia. I realized I hadn't eaten dinner, but by then it was too late. So started my five-day hospital stay.

I settled into sleep, but at 1 a.m. I was awakened by shaking in my legs, which then proceeded to the rest of my body. I called for the nurse and she gave me a blanket, but for two hours this "COVD night" was marked with shaking, coughing, and insomnia. And I was alone, in the dark, not knowing what was going on.

> "I knew whom to call and how to get help. I wonder about others who are not as connected and educated as I am and how they deal with all these symptoms and side effects."

Lesson 4: The comment I heard from a CBS news anchor is correct—"COVID patients are sick, afraid, and alone."

The next morning, I decided that I was going to sit up in the chair during the daytime, and follow instructions to walk 15 minutes, blow into the spirometry device, and drink water each hour.

After hearing me describe my night, the day nurse decided to do a simple nursing intervention and get me an airbed—what a difference! I received superb care from all the physicians and staff—and all patients—even with the risk of exposure to a COVID patient.

Even the housekeeping staff—there was only one young man who would come into my room—was considerate and brightened my day. Now, the food was not good—HOWEVER, that was because I lost my sense of taste and smell (and did not realize it)—so, I really can't totally blame it on the hospital food.

Lesson 5: Health care workers are superheroes.

I managed to work by Zoom and on my iPad, with most people not knowing that I was talking from a hospital room.

However, those I told were very gracious and understood my delays in completing work. My colleagues and staff checked on me daily, and I Zoomed with my family and a close friend. This all helped pass the time without visitors. I even participated in administering a Master's exam via Zoom one afternoon—the nurse told all the rest of the staff not to bother me for an hour, because I was giving an exam.

Lesson 6: Contact with friends and family provide distractions to help pass the time, even without visitors.

On Nov. 15, I was discharged, with instructions as to what symptoms to look for and came home.

First thing I did was have a nice, hot shower. I set up my bedroom to isolate in and settled in for the end of isolation. That did not come soon, however.

My cough continued, COVID nights continued, and I developed POTS—positional orthostatic tachycardia syndrome, which is reported in COVID patients. This was diagnosed after I blacked out for a second and fell after bending over.

Additional testing found inflammation around my heart—but fortunately, no effect on my ejection fraction. My lungs still had residual damage from pneumonia, and I still had no taste or smell through Thanksgiving and Christmas, missing the taste of the amazing baked goods my husband prepared.

Lesson 7: COVID is evil, no joke, and very dangerous—it can affect every organ system.

The worst part of COVID is the fatigue made worse by COVID insomnia.

I knew I was at the end of my daily ration of energy when the "wall" would descend after five or so hours of Zoom meetings.

COVID brain fog would come and go. Bedtime was usually before 8 p.m., after a routine of checking vitals and a nightly nebulizer treatment. I had to drink at least 84 oz. of water each day for the POTS symptoms and continue using the spirometry device twice a day.

Melatonin has been reported to help with COVID insomnia and inflammation—good thing I was already taking it.

Lesson 8: Rest is essential but sometimes hard to get.

Since I was still coughing, the usual rule for being allowed out of isolation 10 days after diagnosis did not apply—so it was three weeks before I was out of isolation.

When I heard that, I was elated! No more masking in the house among my family, and I could go out of the house—with a mask and social distancing.

When my son heard the news, the first thing he did was give me a BIG hug. Freedom was just in time to do some Christmas shopping! It felt so good to be able to drive my car and leave my house, not to mention being able to be around my family.

Lesson 9: Enjoy the small gains and victories.

I write this on Dec. 30—eight weeks since I was exposed. I am still coughing. I still have COVID nights, but not every night. My heart rate is still elevated some of the time when I stand. My taste and smell are slowly returning. My COVID brain fog is lifting. And I am able to stay awake later and later each day. Progress is very slow for someone who usually goes a mile a minute.

Lesson 10: Patience is a hard lesson to learn.

Overall, I have been very fortunate. I was in the "system." I knew whom to call and how to get help. I wonder about others who are not as connected and educated as I am and how they deal with all these symptoms and side effects.

Once you are diagnosed with COVID, you can only go to the hospital or ED for care—no wonder so many people are dying. No wonder the hospitals and the health care workers are overwhelmed.

This experience has left me with many questions that are not addressed for usual citizens: How do non-medical persons and cancer patients/survivors know when to seek care? How do they know when symptoms are progressing? Where can COVID-positive patients seek care outside the hospital? How is information conveyed to disadvantaged populations or those who do not have access to adequate and equal care? How will the isolation caused by COVID affect all of us going forward?

It is very interesting to talk with other COVID survivors. Each of us has a different experience but each of us: 1) needs to talk about it; and 2) feels overwhelmed by the impact this virus has had on our bodies and on our life.

If you are not a COVID survivor and get in the middle of other survivors sharing their experiences, be ready to listen for a while—and please let us vent. And all of us talk about the COVID nights—being isolated, alone, sick, and not knowing what to do.

My experience as a breast cancer survivor has helped me mold my intervention research to address breast cancer disparities. This experience with COVID likewise is already shaping my current research on COVID behaviors, testing and vaccination behaviors.

I am grateful to my family, friends, colleagues and health care providers for helping me survive COVID. Like the COVID nights turned in to daylight each day, I will recover and will be back full force. A new year, lots to look forward to, but always remembering the lessons learned in 2020.

Lesson 11: I am still here.

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Cancer groups urge CDC to prioritize cancer patients for COVID-19 vaccination

By Matthew Bin Han Ong

The American Cancer Society and the Association of Clinical Oncology are calling on the Centers for Disease Control and Prevention to give cancer patients a higher priority amid the rollout of vaccines against SARS-CoV-2.

In a Dec. 18 letter to the CDC's Advisory Council on Immunization Practices, leaders at ACS and ACO cite "compelling data that shows worse COVID-19 outcomes" in patients with cancer and people with a history of cancer.

"We urge the Committee to frequently review the emerging evidence about the impact of COVID-19 on people with cancer and to place these patients in the appropriate tier of allocation based on their risk. Our organizations stand ready to work with you toward a fair and equitable distribution plan during the coming months," Monica Bertagnolli, chair of the Board Association for Clinical Oncology, and William Cance, chief medical and scientific officer of ACS, wrote in the letter.

Two mRNA COVID-19 vaccines have received emergency use authorization from FDA—the Pfizer-BioNTech vaccine, for people 16 years of age and older, and the Moderna vaccine, for people 18 years of age and older. Both vaccines have been found to be more than 90% effective at preventing COVID-19 infection in people who receive two doses.

States and other authorities rely on CDC guidelines to inform their own priorities for vaccine distribution, but do not have to comply with those guidelines.

"Individual states have varying plans regarding prioritization of these high-risk patient populations for vaccination, with some states recommending cancer patients be vaccinated early while other states place these patients farther down the priority list," members of the COVID Lung Cancer Consortium wrote in a Dec. 29 letter to the CDC advisory council.

"Currently, the CLCC recommends specific attention to this vulnerable population(s) and close follow-up of these individuals to ensure the vaccine is effective and there are no unexpected adverse events."

In a statement Dec. 15, the Association of American Cancer Institutes commended FDA for swiftly granting an EUA to Pfizer for its vaccine.

"Now more than ever, it is critical to ensure that public health recommendations are founded on strong scientific evidence. AACI applauds the rigor with which the current vaccines were evaluated, and its members are thankful for the potential to save lives," said AACI President Karen E. Knudsen, enterprise director at Sidney Kimmel Cancer Center at Jefferson Health.

"In the coming months, AACI cancer centers will be charged with the important task of boosting public trust in clinical research and educating community members on the importance of vaccination. We stand ready to embrace this challenge and help bring an end to the pandemic."

The statements from ACS, ACO, CLCC, and AACI follow:

American Cancer Society and Association for Clinical Oncology

Dear Advisory Council Members:

On behalf of the American Cancer Society and the Association for Clinical Oncology, we write to thank you for your dedication to developing carefully considered and data-driven recommendations on how to distribute the COVID-19 vaccines, and to share data on the impact of COVID-19 on cancer patients and survivors.

Together we represent millions of cancer patients and survivors, and the cancer care teams that treat them. As you make recommendations about the distribution of the vaccination, our hope is that you will consider prioritizing cancer patients because of the compelling data that shows worse COVID-19 outcomes for people in active treatment for, or with a history of, cancer.

While evidence is still emerging about the nature and severity of illness caused by this novel virus, there have been numerous studies examining the risk of severe COVID-19 disease or death from COVID-19 infection in individuals with a history of cancer.

One meta-analysis reported that individuals with a history of cancer had 1.35-times higher odds of COVID-related death compared to individuals without cancer (OR=1.35, 95% CI 1.17-1.55) and another meta-analysis reported 2.31-times higher risk of death in those with a cancer history (95% CI 1.80-2.91). Mounting evidence also demonstrates that individuals with any history of cancer are at a higher risk of severe disease compared to the general population. In a recent retrospective analysis of patients in Massachusetts, those with a history of cancer were twice as likely to develop severe COVID-19 disease compared to the general population.

We appreciate the challenge facing the Committee in recommending priorities for COVID-19 vaccination, and respect the thoughtful and transparent way in which you have approached this unprecedented situation.

We urge the Committee to frequently review the emerging evidence about the impact of COVID-19 on people with cancer and to place these patients in the appropriate tier of allocation based on their risk. Our organizations stand ready to work with you toward a fair and equitable distribution plan during the coming months.

Sincerely,
Monica Bertagnolli, MD, FACS, FASCO
Chair of the Board Association for Clinical Oncology

William G. Cance, MD FACS
Chief Medical and Scientific Officer American Cancer Society

COVID-Lung Cancer Consortium

Dear Advisory Council Members:

Individuals with cancer are at increased risk of severe COVID-19 disease and severe manifestations of the disease including death. Of particular concern, patients with lung cancer have increased mortality rates of ~32% from COVID-19 infection, which calls for specific prevention measures.

Currently, individual states have varying plans regarding prioritization of these high-risk patient populations for vaccination, with some states recommending cancer patients be vaccinated early while other states place these patients farther down the priority list.

The COVID- Lung Cancer Consortium meets on a regular basis to monitor ongoing impacts of the pandemic on patients with lung cancer and is comprised of a global assembly of thought leaders in thoracic oncology, virology, immunology, vaccines and patient advocacy. CLCC recommends that national and state level policies for vaccine administration should strongly consider a high priority for vaccination of all cancer patients and especially lung cancer patients.

Thus, as more vaccine doses are made available, these patients will have early access should they choose to be vaccinated after discussion with their healthcare providers of the associated risks and benefits.

Clearly, we still do not yet have enough information about the effectiveness and any additional side effects of such vaccines in cancer patients depending on their cancer type, stage, treatments, and other medical conditions. As such key information becomes available, such as that from current NCI sponsored research, including SeroNet studies, adjusted recommendations based on scientific knowledge can be made.

Currently, the CLCC recommends specific attention to this vulnerable population(s) and close follow-up of these individuals to ensure the vaccine is effective and there are no unexpected adverse events.

Sincerely,
Fred R. Hirsch, MD, PhD
Executive Director,
Center for Thoracic Oncology.
Mount Sinai Cancer, Mount Sinai Health System

> As you make recommendations about the distribution of the vaccination, our hope is that you will consider prioritizing cancer patients because of the compelling data that shows worse COVID-19 outcomes for people in active treatment for, or with a history of, cancer.
>
> *– American Cancer Society and Association for Clinical Oncology*

Professor of Medicine and Pathology, Icahn School of Medicine.
Joe Lowe and Louis Price Professor of Medicine.
Associate Director, Tisch Cancer Institute

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John Minna, MD
Professor and Director
Max L. Thomas Chair in Molecular Pulmonary Oncology
Sarah M. and Charles E. Seay Distinguished Chair in Cancer Research
UT Southwestern Medical Center

Association of American Cancer Institutes

The Association of American Cancer Institutes commends the U.S. Food and Drug Administration for its swift action to grant Emergency Use Authorization to Pfizer's COVID-19 vaccine.

As an association representing 102 leading academic and freestanding cancer centers in North America, AACI thanks the scientists, researchers, and clinical trial participants who contributed to the development of a safe, effective vaccine for people 16 and older.

We also commend the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices for its efforts to ensure equitable distribution of the vaccine, particularly to underserved communities that have been disproportionately affected by the coronavirus pandemic.

Health care providers at AACI cancer centers care for a particularly vulnerable patient population: many patients with cancer are immunosuppressed, and most have serious co-morbidities that increase their risk of contracting COVID-19.

Cancer patients also experience poor outcomes after infection with the virus. This vaccine—and others that may receive EUA from the FDA—represents a major step forward in protecting these patients from another devastating illness.

"Though the approval of the first COVID-19 vaccine represents a 'light at the end of the tunnel' of the coronavirus pandemic, AACI leadership recognizes that challenges still lie ahead. Widespread, equitable uptake of vaccines is imperative to the success of any COVID-19 vaccination effort," said AACI Executive Director Jennifer W. Pegher.

"Now more than ever, it is critical to ensure that public health recommendations are founded on strong scientific evidence. AACI applauds the rigor with which the current vaccines were evaluated, and its members are thankful for the potential to save lives," added AACI President Karen E. Knudsen, MBA, PhD, enterprise director at Sidney Kimmel Cancer Center at Jefferson Health in Philadelphia.

"In the coming months, AACI cancer centers will be charged with the important task of boosting public trust in clinical research and educating community members on the importance of vaccination. We stand ready to embrace this challenge and help bring an end to the pandemic."

Top 25 stories of 2020

By Matthew Bin Han Ong

The year 2020 was, by any reckoning, one that most of us would prefer to relegate to history books—fun to read about, and hopefully not condemned to repeat.

As if the product of the mind of a dystopian novelist, this *annus horribilis* had it all: A pandemic, an economic recession, a divisive and isolationist presidency, unprecedented threats to American democracy, disinformation campaigns, social unrest, political chaos, lackadaisical public health messaging, and many, many unwarranted deaths.

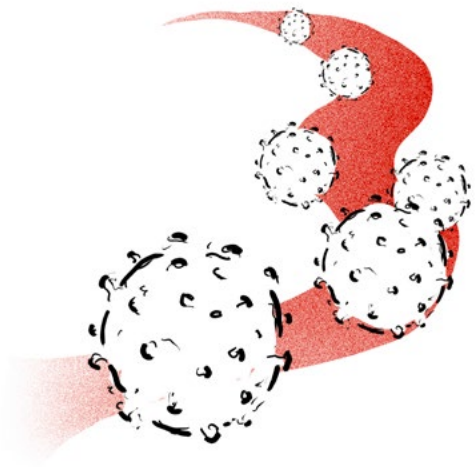
But, 2020 was also a year of survival and resilience—the heroism of first-line responders and a mobilization in health care on a scale reminiscent of war economies, the unmatched global acceleration of COVID-19 research and vaccine development, the sparking of one of the largest movements for racial justice in history amid a long-overdue conversation about police brutality, and a firing-up of the American electorate, which turned out in record numbers to recalibrate the political compass of a nation under siege.

Many of these events put oncology and cancer research in the national spotlight, fundamentally changing the business of cancer care and research funding. At *The Cancer Letter*, we not only covered each development with renewed conviction, but also charted a course for leadership and action:

- To rapidly disseminate information on **best practices and strategies for coping with COVID-19**, we invited leaders in oncology to share their insights as the pandemic overwhelmed hospitals across the country (*The Cancer Letter*, Aug. 7, 2020);
- In partnership with the Association of American Cancer Institutes—and in response to the national dialogue on racial equity and health disparities—we designed a study of cancer centers to assess **representation of women and racial minorities in the oncology leadership pipeline** (*The Cancer Letter*, Oct. 9, 2020);
- In line with growing scholarship on the treatment of women in oncology, we set out to survey the experiences of women who encounter **gender bias and sexual harassment in the top tiers of academic medicine** (*The Cancer Letter*, Oct. 2, 2020).

We also set up a coronavirus landing page to collate our coverage of the pandemic, and asked our audience to share their 2020 reading list—both received significant web traffic.

These stories, conversations, and editorials drove the bulk of *The Cancer Letter*'s readership in 2020.



Despite the eclipsing effect of COVID-19, noteworthy gains were made in oncology:

- A broad collaboration of healthcare research organizations demonstrated that **real-world endpoints** can be used to describe patient outcomes that are analogous to results generated through conventional endpoints in clinical trials (*The Cancer Letter*, Sept. 25, 2020);
- States with **Medicaid expansion** have lower overall cancer mortality, researchers at Memorial Sloan Kettering Cancer Center found. However, no additional decrease was observed in Black populations because of a worse baseline (*The Cancer Letter*, June 5, 2020);
- Sharp declines in **mortality rates for non-small cell lung cancer** in recent years are driven primarily by advances in treatment, NCI researchers concluded in a study published Aug. 12 in the *New England Journal of Medicine* (*The Cancer Letter*, Sept. 4, 2020);
- An artificial intelligence model by Owkin, a company headquartered in New York City and Paris, has provided proof of concept that **machine learning can predict gene expression across cancer types** (*The Cancer Letter*, Oct. 30, 2020);
- NCI produced its master plan for the **Childhood Cancer Data Initiative**, an ambitious data federation for pediatric cancers—which, if done right, is anticipated to become the gold standard for a new generation of comprehensive cancer databases (*The Cancer Letter*, Dec. 4, 2020).

As the United States deploys a novel vaccine for COVID-19 and prepares for a Biden presidency, and as oncology celebrates the 50th anniversary of the National Cancer Act, *The Cancer Letter* stands ready to drive conversations in a new era.

This top-25 list is compiled based on *The Cancer Letter*'s web analytics:

1

Trump et al. are wrong: Biden Cancer Initiative is not to be confused with the Beau Biden Cancer Moonshot

On Nov. 15, shortly after midnight, President Donald J. Trump tweeted a link to a *New York Post* headline:

"Tax filings reveal Biden cancer charity spent millions on salaries, zero on research"

Waking up later that morning, Fox News host Laura Ingraham and former Trump campaign manager Corey Lewandowski, gleefully lent their voices to the now-familiar cacophony of disinformation. A day later, Fox News host Sean Hannity joined their chorus.

For those just tuning in, the president was retweeting a story about the Biden Cancer Initiative, a small organization that is not to be confused with the Beau Biden Cancer Moonshot, a bipartisan effort to increase funding for cancer research.

Read more

2

What to expect: Oncology's response to coronavirus in Italy; "It's like being in a war"

To get a sense of how COVID-19 will affect oncology in the U.S., *The Cancer Letter* called Giuseppe Curigliano, associate professor of Medical Oncology at University of Milano and the head of the Division of Early Drug Development at European Institute of Oncology, Italy, who is based in the Lombardy region—the epicenter of the outbreak.

"So this is actually the perception that I have—it's like being in a war or under a terrorist attack when usually 10% of people go in intensive care," Curigliano said to *The Cancer Letter.*

Read more

3

Coronavirus vs. oncology: Meeting cancellations, travel restrictions, fears about drug supply chain

Forecasts of the inevitable spread of coronavirus can be difficult to ignore, especially at a time when many of us are making travel plans for this spring's big cancer meetings.

The decision was made all the more difficult earlier this week, as cancer centers and at least one biotechnology company—Amgen—implemented travel bans that are expected to last through the end of March and beyond. *The Cancer Letter* was able to confirm such travel bans at Fred Hutchinson Cancer Research Center, MD Anderson Cancer Center, and Dana-Farber Cancer Institute.

Read more

4

Joe Biden has an unparalleled grasp of the science and politics of cancer

For the first time in U.S. history, the White House will soon be occupied by a president who has demonstrated a deep understanding of cancer research.

In January 2016, seven months after his 42-year-old son, Beau, died from brain cancer, then Vice President Joseph Robinette Biden Jr. became the catalyzing force behind the Moonshot, an effort to understand the intricacies of cancer, and find cures.

Read more

5

COVID-19 vs. community oncology: Flatiron's data provides first damage assessment

Community oncology practices in the United States are reeling from a sharp decrease in business—whether you look at new patients, chemotherapy visits, or non-chemo visits—the result of reduced activity and stay-at-home orders across the country to mitigate the spread of SARS-CoV-2.

Early data compiled by Flatiron Health and made available exclusively to *The Cancer Letter* make it possible to visualize the severe impact of the COVID-19 pandemic on community oncologists.

Read more

6

Otis Brawley: I could have been George Floyd, too

The past ten days have seen an outpouring of emotions as American society, devastated by the tragic murder of George Floyd by four Minneapolis police officers, plunges into a crisis of conscience.

Floyd's death may be a pivotal point in America, similar to the televised beating of peaceful civil rights marchers by police on the Edmund Pettus Bridge in 1965. It has led to a number of protests and, unfortunately, some violence, including an attack by federal law enforcement as they beat and pepper-sprayed peaceful protesters in front of the White House.

The use of force against demonstrators in front of the White House is particularly ironic, considering that this entire series of events stems from an act of police brutality.

The police brutality is the tip of the iceberg. The fact is, it is the most obvious and dangerous aspect of systemic racism. There are a number of social injustices that collectively make blacks feel that their lives are not valued, and these issues are not being addressed by American society as a whole. Many Americans simply do not care, or aren't aware.

Read more

7

Pamela Kunz: "In any other industry, if someone had behavior like that, they would be fired."

Pamela Kunz said she left Stanford School of Medicine because of years of gender-related microaggressions and verbal abuse she experienced there.

She wasn't holding back on letting the institution know what was going on every step of the way, she said.

"I let them know, for actually quite a while, that I was unhappy and that I felt that I was being discriminated against for my gender. I gave them examples of what I described as, pervasive microaggressions and verbal harassment," Kunz said.

Read more

8

COVID-19 and Cancer Consortium

We are living in unprecedented times. There remains a great deal of uncertainty about COVID-19 and its effects on individuals, especially the elderly and the immunocompromised. Cancer patients form a unique subset of individuals who are often both elderly and immunocompromised, may have significant comorbidities, and may be actively receiving treatment.

In order to better understand the scope and severity of infection in cancer patients, we are soliciting information under the auspices of a multi-institutional collaboration, the **COVID-19 and Cancer Consortium (CCC19)**.

Read more

9

American Cancer Society announces a wave of furloughs and layoffs as COVID-19 constricts fundraising

The American Cancer Society earlier this week announced immediate furloughs and layoffs of its staff citing "a significant financial hardship" triggered by the novel coronavirus.

"The American Cancer Society has never faced a threat to our mission like the coronavirus," the charity said in a statement. "The COVID-19 pandemic has severely impeded the American Cancer Society's annual fundraising activity. Regrettably, this has created a significant financial hardship and is forcing several cost saving measures.

"While we are pulling back in every area, there is no way to close the gap between current revenue and expenses without immediate furloughs and a reduction in workforce over the next several weeks. It is an aggressive timeline with painful outcomes, but it is the only path forward for ACS to conserve the most resources to fund our life-saving mission."

Read more

Related:

- **ACS faces precipitous drop in fund-raising; Uncertainty surrounds fall round of grants** (*The Cancer Letter,* June 19, 2020)
- **American Cancer Society staff given seven days to vacate the National Home Office** (*The Cancer Letter,* July 24, 2020)

10

Class of drugs used to treat CAR T-cell toxicity may reduce COVID-19 deaths; Two randomized trials announced

A class of drugs that has been used to treat adverse events associated with CAR T-cell therapy is emerging as a potential treatment for COVID-19.

The available drugs, both interleukin-6 receptor antagonists, have the capacity to treat the cytokine release syndrome, sometimes also known as the cytokine storm syndrome, a large, rapid release of cytokines into the blood as a result of viral infections or immunotherapy.

The drugs—two of which are now being rushed into late-stage clinical trials—are approved by FDA for rheumatology indications

Read more

11

What cancer immunologists are doing about COVID-19

It's hard to fathom the number of scientific discoveries that are exploding from the COVID-19 disaster. Though there may be tumbleweeds on every street around the globe and impotent silence in the shuttered stores of every town, the scientists at the frontline of this epidemic are busier and more energized than they've been in a long time.

The tragedy and confusion of our current reality will linger for a very long time to come, but the history of medicine is likely to look back on these months with humbled reverence and gratitude.

Read more

12

Robert Winn: I could have been George Floyd—many times; Reflecting on the cancer of racism

I am almost certain that no other director of an NCI-designated cancer center can claim the distinction of having had a gun pulled on them by police.

I've had that experience not once, but twice.

I struggled a great deal in deciding whether to put something together this week in response to the senseless killing of Mr. George Floyd. His untimely death has stirred up a number of complex issues, which I thought I had wrestled under control.

Read more

13

COVID-Lung Cancer Consortium: An example of how the lung cancer community came together in challenging times

The COVID-19 pandemic has created a host of diagnostic, treatment, and follow-up problems for patients with cancer of all types, and this is particularly true for patients with lung cancer, their families, and health care providers.

Everyone wanted to know and was worried—would patients with lung cancer be more or less likely to contract COVID-19, and if they did so, would they have more serious disease?

Would their susceptibility to and course with COVID-19 be influenced by the type of treatment they received, such as checkpoint inhibitor blockade, chemotherapy, radiotherapy, or surgery? How would COVID-19 in lung cancer patients respond to COVID-19-targeted therapy?

Read more

14

Otis Brawley: Immunotherapy, precision medicine in lung cancer drive sharp decline in cancer mortality overall

As I look through just-published tables of age-adjusted cancer mortality, I recognize an unprecedented development:

Immunotherapy is showing such a dramatic impact in the treatment of locally advanced and advanced non-small cell lung cancer that this effect elevates the statistics for all lung cancer and—this I find astonishing—you can even see its effect in age-adjusted cancer mortality overall.

I am a cautious observer. I resist the common oncologic groupthink that declares any small advance a tremendous breakthrough. In cancer, dribs, drabs and fluky observations have often triggered dancing in the streets, but this is none of the above. It's big, real, undeniable, and it's an honor to write these words:

Today, 49 years after the signing of the National Cancer Act, we look at the 2017 cancer data and see validation of its small-c catholic approach to cancer. Rigorous research, visionary drug regulation, and relentless public health measures have brought about tangible change.

Read more

Related:

- **Are drugs really driving the latest drop in lung cancer mortality? Looks like treatment is playing a role, experts say** (*The Cancer Letter*, Feb. 7, 2020)

15

Moffitt CEO Alan List, director Thomas Sellers resign over conflicts of interests involving China

Thomas Sellers, director of Moffitt Cancer Center, and Alan List, president and CEO of the center, stepped down Dec. 18 after an internal review revealed that they violated "conflict of interest rules

through their work in China," cancer center officials said.

The details of their alleged COIs are not publicly available at this time, and if Sellers and List were directly involved with China's "Thousand Talents" Program, which recruits researchers and academics globally, their exact roles are not known. The internal review at Moffitt also prompted "separation" of another four researchers who were also found to not be in compliance with the center's policies, officials said.

"We found evidence that people were compensated through the Thousand Talents Program and failed to disclose that," the cancer center said in a statement to *The Cancer Letter.*

Read more

Related:

- **Report describes offshore accounts held by Moffitt scientists involved in China's Thousand Talents program** (*The Cancer Letter,* Jan. 24, 2020)
- **Attorney: Moffitt has made a "very irresponsible decision"—Thomas Sellers "never was a participant" in China's Thousand Talents Program** (*The Cancer Letter,* Jan. 24, 2020)
- **Moffitt execs were made aware of Howard McLeod's China activities, ousted researcher's attorney says** (*The Cancer Letter,* March 6, 2020)
- **John Cleveland: How Moffitt will heal from conflict of interest trauma—and from COVID-19** (*The Cancer Letter,* May 29, 2020)
- **Patrick Hwu on the challenge of making Moffitt the "cell therapy capital of the universe"** (*The Cancer Letter,* Dec. 11, 2020)

16

Seeing COVID-19 through a cloud of cigarette smoke

The unprecedented COVID-19 pandemic makes it possible to compare and contrast the public health and political responses to previous health crises.

The most obvious comparison is to the influenza epidemic of 1918-19, which took the lives of 675,000 Americans in less than two years.

Yet a comparison with cigarette smoking, which has killed untold millions of Americans in the 20th century and continues to take the lives of 500,000 a year, is arguably more illuminating. At first glance, comparing COVID-19 to cigarettes seems illogical. Yes, people who take up smoking do so willingly, although most do so before they reach adulthood. And yes, those who contract COVID-19 do not willingly seek out the virus.

Read more

17

CCC19 bridging the knowledge gap for patients with COVID-19 and cancer; First results to be heard at 2020 ASCO Annual Meeting

As the healthcare system faces the onslaught of the novel coronavirus SARS-CoV-2, clinicians caring for individuals with cancer face the challenge of a wide gap in knowledge needed to guide decision-making.

While initial reports suggest that individuals with cancer are at greater risk of COVID-19-related sequelae, available data are limited in volume and granularity. As a field that is driven by evidence-based practice, we are hungry for better data to inform clinical decisions and guideline measures to protect our patients and community.

Read more

18

Sharpless: COVID-19 expected to increase mortality by at least 10,000 deaths from breast and colorectal cancers over 10 years

The COVID-19 pandemic will likely cause at least 10,000 excess deaths from breast cancer and colorectal cancer over the next 10 years in the United States.

Scenarios run by NCI and affiliated modeling groups predict that delays in screening for and diagnosis of breast and colorectal cancers will lead to a 1% increase in deaths through 2030. This translates into 10,000 additional deaths, on top of the expected one million deaths resulting from these two cancers.

"For both these cancer types, we believe the pandemic will influence cancer deaths for at least a decade," NCI Director Ned Sharpless said in a virtual joint meeting of the Board of Scientific Advisors and the National Cancer Advisory Board June 15. "I find this worrisome as cancer mortality is common. Even a 1% increase every decade is a lot of cancer suffering."

Read more

19

HOLA COVID-19 study focuses on disruption of cancer care in Latin America

As of September, more than 270,000 deaths have been confirmed in Latin American countries due to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.

Brazil and Mexico are among the top four countries with the highest death toll due to COVID-19, along with the United States and India. It is believed that Latin American countries are especially vulnerable due to high levels of inequality and poverty, crowded living conditions in urban areas, lack of sanitation, slow and uneven governmental response, and strained healthcare systems.

The rapid outbreak of SARS-CoV-2 has changed how health care is delivered in first-world countries—cancer care is no exception, and is a subject of high concern, given the importance of timeliness of interventions in outcomes. The HOLA (Hematology Oncology in Latin America) COVID-19 study was born out of concern for how the ongoing pandemic has affected cancer care in our home countries.

Read more

20

COVID-19 and the cancer patient: A call to action for balancing cancer care and viral risk

As COVID-19 has now officially been declared a source of the pandemic, with increasing incidence across the nation, it is without question that the needs of patients with particular vulnerabilities should garner particular attention.

Given the specialized needs of cancer patients, it is imperative to consider how we, as the major cancer centers, may address and communicate how the impact of COVID-19 could impact the timing and delivery of cancer care, and to communicate this information to cancer patients.

Read more

21

Lowy: "Our patients are counting on us, and we must not let them down"; NCI Frederick Lab takes aim at COVID-19

NCI's Frederick National Laboratory for Cancer Research has launched three initiatives focused on SARS-CoV-2:

- Identifying genetic determinants of SARS-CoV-2 susceptibility and outcomes at the Cancer Genomics Research Laboratory,
- Testing and validating serologic assays for SARS-CoV-2 in the Serology laboratory of the Vaccine, Immunity, and Cancer Program, and
- High-throughput screening for small molecule inhibitors of SARS-CoV-2 proteins, with technology developed by the RAS Initiative.

"We think that it was built for a situation like this, where speed, flexibility, and expertise are critical to addressing such a deadly public health threat," Douglas Lowy, NCI principal deputy director, said April 9 in an emergency virtual meeting of the NCI Board of Scientific Advisors and the National Cancer Advisory Board.

Read more

22

Is your cancer center ready for COVID-19?

The Cancer Letter spoke with leaders at Seattle Cancer Care Alliance/Fred Hutchinson Cancer Research Center MD Anderson Cancer Center, University of California, Los Angeles, and Robert H. Lurie Comprehensive Cancer Center of Northwestern University to gauge the impact of coronavirus.

"We don't want to be alarmist, but we do want to be truthful. The truth is that all cancer patients should be concerned about COVID-19 because they are at higher risk," said Steve Pergam, medical director of Infection Prevention at Seattle Cancer Care Alliance and clinical and infectious disease researcher at Fred Hutch, which does not provide patient care on its campus. "We are taking numerous precautions, such as screening all patients, staff and providers for respiratory symptoms (including runny nose, congestion, fever or shortness of breath) upon arrival at the clinic."

Read more

23

Raymond DuBois discusses his plans to navigate past the pandemic and take Hollings to comprehensive designation

Raymond N. DuBois was named director of MUSC Hollings Cancer Center effective Aug. 17.

This is an additional role for DuBois, who will continue his other job as the dean of the MUSC College of Medicine. He has held that position since March 2016.

"Our cancer center was established in 1993, and it has evolved over time. It was established to help support the vision of Sen. Fritz Hollings and his legacy of public service, serving our culturally and socio-economically diverse state," DuBois said to *The Cancer Letter*. "My vision for the next five to ten years is to take our enterprise to a higher level and to try to integrate our activities more across the state, interfacing better with our statewide clinical enterprise.

"We have several underserved populations in this state. We really want to have a major impact in approaching and solving many of our health disparity issues."

Read more

24

What are you reading?

A reading list is a glimpse into the soul of a community. A reading list is also a reflection of a time. And a projection of visions of the future.

We asked our readers: "What have you read this year that has made an impression on you?"
There was nothing scientific about our sample. There were no guidelines, no boundaries for genre, topic, or contemporary relevance.

We wanted a reading list and we got one: 67 recommendations, the books your colleagues—clinicians, basic scientists, drug developers, regulators, advocates, senior scientists, early-career researchers—have turned to as the pandemic exposed America's deepest flaws.

Read more

25

Northwell Health reopens cancer services after COVID-19 deluge; New York health system explores NCI designation in affiliation with Cold Spring Harbor Laboratory

Any way you look at it, Northwell Health, New York's largest health system, took a massive hit from COVID-19.

Northwell has treated over 50,000 COVID patients, admitting over 15,000 of them to its hospitals—more than any such system in the U.S.

The financial hit will end up somewhere between $500 million and $1.6 billion, depending in part on how much the U.S. government will kick in, said Richard Barakat, physician-in-chief and director of cancer at Northwell Health Cancer Institute.

Read more

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Mace Rothenberg steps down as Pfizer CMO, replaced by Stanford's Aida Habtezion

By Paul Goldberg

Mace Rothenberg has stepped down as chief medical officer at Pfizer. His successor is Aida Habtezion, a Stanford researcher whose work is focused on leukocyte recruitment and immune responses in diseases affecting the digestive organs.

Rothenberg, who served as the Pfizer CMO for two years, announced his move on social media Jan. 4. "Today is my last day as Chief Medical Officer @pfizer. It has been an honor and privilege to serve in this role. I look forward to spending the next few months helping @aida_habtezion transition into the CMO role," Rothenberg announced on Twitter.

"Aida is an extremely accomplished physician-scientist as well as an inspirational leader. I have every confidence in her continued success in this new role. Welcome to Pfizer."

In an email, Rothenberg said he would stay at Pfizer through the end of March helping transition Habetzion into her role.

"The decision and timing was my choice, and planning has been underway since last summer," Rothenberg said to *The Cancer Letter*. "I plan on staying involved in medicine, science, and drug development after my retirement from Pfizer,

working with innovative pharma and biotech companies in an advisory or board capacity."

Rothenberg, who was trained at NCI, spent 25 years in academic oncology before joining Pfizer 12 years ago.

Prior to becoming CMO, Rothenberg was senior vice president and head of clinical development & medical affairs in Pfizer's newly created Oncology Business Unit from 2008 to 2016, and chief development officer for oncology from 2016 to 2018.

During that period, Rothenberg's organization developed and obtained regulatory approval for 11 new cancer medicines, including Ibrance (palbociclib) the first CDK 4/6 inhibitor for patients with HR+/HER2- advanced breast cancer, and Xalkori (crizotinib) the first targeted medicine developed for patients with ALK+ non-small cell lung cancer.

Rothenberg is a member of the editorial board of the Cancer History Project, CancerHistoryProject.com.

Stanford's website provides the following description of Habtezion's work:

"The Habtezion lab aims to understand immune mechanisms and identify potential immune-based therapeutic targets for pancreatitis and inflammatory bowel disease. Researchers in the lab study leukocyte trafficking and immune responses pertaining to the intestinal tract in states of both health and disease.

"The lab demonstrated a beneficial role and mechanism for heme-oxygenase 1 (HO-1) and its downstream effectors in acute pancreatitis. In chronic pancreatitis the lab characterized macrophage-pancreas stellate cell crosstalk that contributes to disease progression and fibrosis. The significance of this crosstalk is further demonstrated by targeting macrophage polarization and function, as well as altering disease course in established experimental disease. The lab is currently working to elucidate targetable immune pathways that alter and/or reverse the course of disease progression.

"A second major project in the lab pertains to understanding immune responses in the intestine and in inflammatory bowel disease (IBD). Multiple projects on intestinal inflammation pertain to understanding the heterogeneity and immune profiles of IBD patients, host immune-microbiome interaction, immune-enteric nervous system interaction, as well as intestine-specific leukocyte recruitment and therapeutic targets using experimental models of inflammation."

"Aida is an extremely accomplished physician-scientist as well as an inspirational leader. I have every confidence in her continued success in this new role. Welcome to Pfizer."

– Mace Rothenberg

IN BRIEF

Welela Tereffe named chief medical executive at MD Anderson

Welela Tereffe was named chief medical executive of MD Anderson Cancer Center.

Tereffe began the position and joined the institution's Executive Leadership Team Jan. 1. Previously, Tereffe served as the institution's chief medical officer, a position she held for two years.

In this role, Tereffe will engage physicians and advanced practice providers in the delivery of research-driven clinical care that includes the Texas Medical Center campus, community and academic settings in Texas and MD Anderson Cancer Network. She will work closely with leadership to recruit faculty, promote research excellence and enhance the wellness and development of providers.

"Welela is a servant leader with strong emotional intelligence and drive. She has intimate knowledge of medical practice, extensive understanding of academic health care, and is known for partnering and engaging others," Peter WT Pisters, president of MD Anderson, said in a statement. "Her commitment to MD Anderson, to our providers and—most importantly—to our patients is undeniable. She is passionate about improving equity in access to safe, quality care, and to reducing disparities in cancer care and outcomes. We welcome her to our Executive Leadership Team."

Since joining MD Anderson in 2005, Tereffe has earned a Master of Public Health in 2009, and currently she is working toward a Master of Health Care Management at the Harvard School of Public Health.

Adam Marcus named interim executive director of Winship Cancer Institute of Emory University

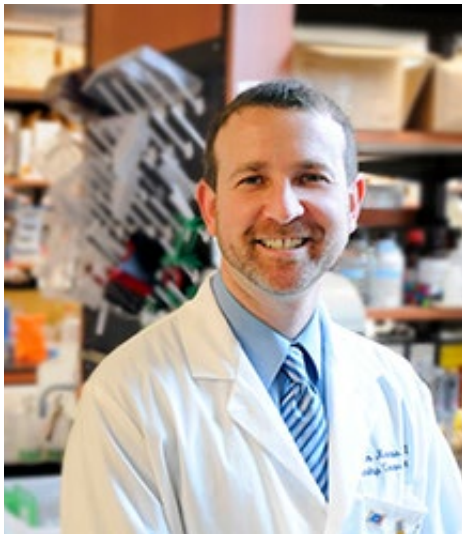
Adam Marcus was named interim executive director of Winship Cancer Institute of Emory University.

Marcus will assume the role from Walter J. Curran, Jr., while Emory University conducts a national search for Winship's next executive director.

"We are very fortunate that Dr. Curran will support Dr. Marcus from now until his departure in late January," Jonathan S. Lewin, executive vice president for health affairs at Emory University and CEO and chair of the board for Emory Healthcare, said in a statement. "They will work together over the next five weeks to ensure a smooth transition in Winship leadership in its research, educational, and clinical missions."

An advisory committee, with representation from across the Woodruff Health Sciences Center, including Winship leaders, will oversee the executive director search.

Curran, who is also the Lawrence W. Davis Professor and chair of the Department of Radiation Oncology, announced in October that he would be stepping down from his Emory leadership roles to serve as the global chief medical officer of GenesisCare, an international health care provider. He was the first and only radiation oncologist to direct an NCI-designated cancer center.



Marcus, a member of Winship's executive leadership team and a fellow of the Woodruff Leadership Academy, serves as the associate director for basic research and shared resources at Winship. He is a professor of hematology and medical oncology and holds the

Winship 5K Professorship. Marcus is also the scientific director of the Emory Integrated Cellular Imaging Core, one of the Emory Integrated Core Facilities.

Marcus' research focuses on cancer metastasis, drug development, and image-guided genomics, and he has been continuously funded by NIH since joining the Emory faculty in 2006. He is a principal investigator of five active NIH grants, including a multi-PI R25 Science Education Partnership Award that supports Citizen Science HD. Marcus co-leads Citizen Science HD, an outreach program that provides opportunities for underrepresented learners in STEM.

Angela L. Talton named first chief diversity, equity and inclusion officer at City of Hope

Angela L. Talton was named senior vice president and chief diversity, equity and inclusion officer at City of Hope.

Talton will begin the role Jan. 11. Her expertise in diversity, equity and inclusion encompasses leadership development, recruitment and retention of talent, communication strategy, philanthropic giving, supplier diversity and analytics.

Most recently, Talton successfully advised national clients through her firm, ALTalton Consulting. Prior to that, she served in senior executive roles at Nielson for nearly 12 years, including chief diversity officer, senior vice president of global diversity and inclusion, and senior vice president of global call center operations.

Kashyap Patel elected president of COA

Kashyap Patel was elected president of the Community Oncology Alliance.

Patel, a long-time COA board member, is a full-time practicing medical oncologist and CEO of Carolina Blood and Cancer Care in Rock Hill, South Carolina. He began his one year term Jan. 1.

Patel is board certified in hematology, oncology, and internal medicine. In addition to his work with COA and its committees, he volunteers with other national cancer and quality organizations.

Patel has extensive expertise in value-based care, including having successfully led multiple oncology payment pilots. He has a special interest in health care policy, racial and ethnic disparities, and end of life care.

Miriam Atkins, a practicing medical oncologist at Augusta Oncology in Georgia, was named vice president of the COA board. Debra Patt, a practicing medical oncologist and executive vice president, policy and strategic initiatives at Texas Oncology in Austin, was named secretary of the board.

Emily Touloukian, a practicing medical oncologist and president-elect at Coastal Cancer Center, was also named to the board.

The nominations were completed during a regularly scheduled board meeting on Monday, Dec. 14, 2020. All board of director positions are three-year terms. These new elections became effective Jan. 1, and will end Dec. 31, 2023.

Steven Lemery named acting associate director of Tissue Agnostic Drug Development at FDA's OCE

Steven Lemery was named acting associate director of Tissue Agnostic Drug Development within FDA's Oncology Center of Excellence.

Lemery will continue as division director for the Division of Oncology 3.

Lemery joined FDA in 2006 as a clinical reviewer in the Division of Biological Oncology Products, which ultimately re-organized into the Division of Oncology Products 2. He served as team lead on the Gastrointestinal Malignancies team in the Division of Oncology Products 2 where he supervised the review of multiple original and supplemental applications.

Subsequently, he assumed the role of the supervisory associate division director in DOP2, primarily leading activities for the melanoma/sarcoma and pediatrics/rare malignancies teams.

More recently, he has assumed the role of acting director of DO3 and is a member of the Medical Policy and Program Review Council. In various roles, he has contributed to Office- and OCE-led regulatory or policy initiatives. These have included both biosimilar development and tissue agnostic development.

In his new role in the OCE, Lemery will focus on scientific and policy efforts related to tissue agnostic drug development and lead outreach and education in this topic.

Roy Herbst, Worta McCaskill-Stevens, and Lawrence Shulman receives 2020 ACCC awards

Roy S. Herbst, Worta McCaskill-Stevens, and Lawrence N. Shulman received awards from the Association of Community Cancer Centers.

Herbst received the 2020 Clinical Research Award. Herbst is Ensign Professor of Medicine, professor of pharmacology, chief of medical oncology and associate director for translational research at the Yale Cancer Center and Smilow Cancer Hospital.

Herbst's work focuses on the identification of biomarkers and bringing novel targeted treatments and immunotherapies to patients. He has served as principal investigator for clinical trials testing these agents in advanced stage lung cancers. His work has led to the approval of several therapies.

Herbst's work on "umbrella" trials prompted FDA approvals of targeted therapies and new cancer drugs. Nationally, he works closely with public-private partnerships to develop large master protocol clinical studies, such as Lung-MAP.

ACCC's Clinical Research Award recognizes individuals whose research has significantly and positively impacted oncology patients, their families, caregivers and communities. Herbst was selected for his distinguished career in lung cancer research and track record of successfully integrating clinical, laboratory and research programs to bring new treatments to cancer therapy.

McCaskill-Stevens has received the 2020 David King Community Clinical Scientist Award.

McCaskill-Stevens is a medical oncologist and chief of the Community Oncology and Prevention Trials Research Group at NCI, Division of Cancer Prevention, NCI Community Oncology Research Program.

McCaskill-Stevens's work focuses on cancer disparities, management of comorbidities within clinical trials, and molecular research to identify individuals who will benefit most from cancer prevention interventions.

The ACCC David King Community Clinical Scientist Award recognizes active community clinical research leaders who have demonstrated leadership in the development, participation and evaluation of clinical studies, and who are active in the development of new screening, risk assessment, treatment or supportive care programs for cancer patients.

Shulman received the 2020 Annual Achievement Award. Shulman is professor of Medicine at the Perelman School of Medicine, deputy director for Clinical Services and director of the Center for Global Cancer Medicine at the Abramson Cancer Center, University of Pennsylvania.

Shulman was recognized for not only his esteemed work as a breast oncologist and oncology-practice thought leader, teacher and mentor, but for his generous approach that drives others in the oncology profession from around the world to seek his counsel.

Shulman has a long history of work in low-resourced areas throughout the United States and internationally, including the promotion of early detection and establishment and maintenance of cancer treatment programs.

Since 1980, the ACCC Annual Achievement Award has recognized distinguished individuals or organizations that reflect the values of community cancer care through their outstanding contributions.

Kristin Ferguson named senior director of ACCC

Kristin Ferguson was named senior director of cancer care delivery and health policy at the Association of Community Cancer Centers.

Ferguson will lead the organization's initiatives to improve cancer care delivery across rural, urban, and under-resourced settings, and will also provide support and resources to members of the oncology workforce, working to reshape reimbursement to better meet the needs of patients and providers.

Ferguson most recently served as clinical operations manager for the Lombardi Comprehensive Cancer Center at Medstar Georgetown University Hospital. There, Ferguson oversaw the daily operations of the clinic, ensured services met hospital and ONS standards, and monitored patient data collection, quality of care, and trends in clinical growth.

Ferguson has served as a voice for nursing and oncology in many policy-making forums, including the ONS Millennial Advisory Panel, the Oncology Nursing Society Congress Planning Team, AACN/GNSA Policy Committee, Cancer Moonshot Summit and the Biden Cancer Summit town Hall. She has also advised and participated on research teams and is a member of an NINR Funded Research Team at Georgetown University on a grant to research symptom clusters in oncology patients.

Melissa Johnson named program director of lung cancer research at Sarah Cannon

Melissa Johnson was named program director of lung cancer research at Sarah Cannon.

In this role, Johnson will lead the lung cancer clinical trial portfolio across the Sarah Cannon network.

Since joining Sarah Cannon in 2014, Johnson has served as the associate director of lung cancer research at Sarah Cannon Research Institute, supporting the growth of early phase compounds in thoracic malignancies.

Johnson will continue to work in early phase drug development as well as lead the Solid Tumor Immune Effector Cellular Therapy Program at Sarah Cannon. She is also the chair of the Cancer Committee at TriStar Centennial Medical Center in Nashville.

Johnson begins her position in January at Sarah Cannon headquarters in Nashville. She will continue to care for patients as a partner with Tennessee Oncology, PLLC.

John Ryan named senior vice president and general counsel at Dana-Farber

John Ryan was named senior vice president, general counsel and chief governance officer of Dana-Farber Cancer Institute.

Ryan began these roles Dec.1, 2020. Ryan has expertise representing health care and life sciences organizations in public company and non-profit settings. He has managed a range of legal matters, including medical research and technology, clinical care, IP protection and international expansion.

Ryan joins Dana-Farber from The Jackson Laboratory, where he was general counsel and corporate secretary. He previously held similar roles at Unilife Corp. and Aramark Corp., and was a partner at the Philadelphia-based law firm Duane Morris LLP.

Rutgers Cancer Institute of New Jersey receives $25 million for Cancer Immunology and Metabolism Center of Excellence

A $25 million anonymous philanthropic gift to Rutgers Cancer Institute of New Jersey will provide groundbreaking support for the Cancer Immunology and Metabolism Center of Excellence.

This donation will support faculty recruitment, shared resource development, and cancer research to help scientists better understand the human immune response to cancer and develop the foundation for new treatments, or make existing therapies more effective.

With the support of this gift, investigators will accelerate laboratory discoveries pertaining to these disciplines into clinical treatments through more effective and efficiently designed clinical trials. These trials would be offered in conjunction with other cancer centers and collaborators such as the Big Ten Cancer Research Consortium, and made accessible to patients at RWJBarnabas Health facilities across the state.

In collaboration with its research consortium partner Princeton University, Rutgers Cancer Institute is considered an authority in the study of metabolism.

The gift also supports the recruitment of a co-director to lead the center along with Eileen White, deputy director of Rutgers Cancer Institute and chief scientific officer. Following a nationwide search, Christian Hinrichs, an expert in cancer immunology and immunotherapy, was recruited from NCI. He will begin his new role in January.

Additional new faculty to the center also will be supported through this gift.

The gift is part of an overall $50 million fundraising campaign, for which the aim is to secure an additional $25 million to fuel the work of the Cancer Immunology and Metabolism Center of Excellence.

SU2C receives $10 million Exact Sciences grant for colorectal cancer screening and prevention initiative

Stand Up To Cancer received a $10 million grant from Exact Sciences to improve colorectal cancer screening, early detection and prevention.

The grant will fund a colorectal cancer Dream Team of researchers, as well as a comprehensive public awareness campaign to increase screenings.

The new Dream Team will be awarded in early 2021 and will identify communities near anchor institutions that serve minority and medically underserved communities, pinpoint the unique local needs of those areas and turn participating at-risk communities into Stand Up To Cancer Zones with high rates of colorectal cancer screening.

The Dream Team will provide free colorectal cancer testing in the identified zones and will study samples collected via approved tests for colorectal cancer, including colonoscopy, CT colonography, flexible sigmoidoscopy, and at-home stool tests that analyze fecal DNA and/or blood. The research will aim to develop better approaches to colorectal cancer interception.

Fellowships for early-career investigators committed to studying health equity and disparities in colorectal cancer will also be funded. Public awareness campaigns will focus on medically underserved communities to increase awareness of the importance of colorectal cancer screening and early detection, and the availability of multiple effective screening options, such as traditional colonoscopy as well as options used at home.

"This funding allows us to bring together institutions, clinicians and communities to address the challenges we face in colorectal cancer screening," said Nobel laureate Phillip A. Sharp, chair of Stand Up To Cancer's Scientific Advisory Committee and an institute professor at the David H. Koch Institute for Integrative Cancer Research at Massachusetts Institute of Technology. "Due to the COVID-19 pandemic, it's more important than ever to make sure people are informed about both the benefits of colorectal cancer screening and their options."

Colorectal cancer is treatable in 90% of cases when detected early, yet one in three adults over age 50 are not up-to-date on recommended colorectal cancer screening. The COVID-19 pandemic has further compounded the problem with screening rates dropping significantly due to stay-at-home orders.

The number of colonoscopies and biopsies performed declined by nearly 90% by mid-April 2020 compared to April 2019. Concurrently, new cases of colorectal cancer are occurring at a growing rate among young and middle-aged adults in the U.S., with the number of cases of colorectal cancer in people under 50 expected to almost double by 2030.

The disease disproportionately impacts people of color; Black people have the highest rates of colorectal cancer of any racial or ethnic group in the US. In October 2020, the U.S. Preventive Services Task Force released a draft recommendation to lower the colorectal cancer screening age from 50 to 45, but educating the public about the benefits of screening, as well as screening options, remains vital.

Research has shown that colorectal cancer screening rates are the lowest in Hispanic communities, with 59% of Hispanics getting screened, compared to 66% of Black people and 69% of white people getting screened.

Black and Hispanic people are typically diagnosed at a later stage in the disease when it is more difficult to treat. These disparities could be driven by financial barriers, lack of insurance, existing health inequities and insufficient information about colorectal cancer and colorectal cancer screening options.

SU2C, along with Exact Sciences, plans to engage with other collaborators to help reach the underserved communities, foster scientific research and guide public participation.

Northwell opens $6.2 million cancer center in Riverhead NY

Northwell Health has opened a $6.2 million, 11,300-square-foot cancer center in Riverhead, on the East End of Long Island.

The center will provide East End residents access to integrated cancer services in an outpatient facility.

The Northwell Health Cancer Institute at Riverhead offers medical oncology/hematology, an infusion/chemotherapy unit with eight individual bays, immunotherapy, hormone therapy, targeted therapy, nutritional counseling and social work.

Cancer surgery consultations are offered in the following subspecialties: breast surgery, colorectal surgery, surgical oncology, plastic and reconstructive surgery and thoracic surgery. The facility also houses a pharmacy and lab.

As part of Northwell's 23-hospital network, the Cancer Institute at Riverhead is seamlessly connected to care in the community, including inpatient cancer care, emergency care, screening and diagnostic imaging, primary care, specialty care and support services through Peconic Bay Medical Center and other Suffolk County facilities.

"Joining other institutional members of the health system's cancer institutes, the Riverhead facility will offer novel clinical trials to patients, some of which are in partnership with the renowned Cold Spring Harbor Laboratory, as well as cancer genetic testing. This is what makes Northwell's cancer institutes unique in delivering cancer care," Richard Barakat, physician-in-chief and director of the Northwell Health Cancer Institute, said in a statement.

Patients treated at the Cancer Institute at Riverhead receive care from a team of cancer specialists with expertise in diagnosing and treating cancer. Each care team meets weekly by teleconference in tumor board meetings to discuss prospective diagnostic tests and treatment options for select cases—allowing for second opinions from a diverse team.

The Northwell Health Cancer Institute at Riverhead becomes the ninth cancer institute or cancer center established by the health system across Long Island, New York City and Westchester.

Northwell treats approximately 16,000 new cancer patients annually.

Mark Foundation awards five grants to accelerate a new class of cancer drugs based on induced proximity

The Mark Foundation for Cancer Research has awarded five grants to support research of induced proximity, which involves controlling the physical distance between proteins to regulate or perturb biological processes in the cancer cell.

The following ASPIRE awards were selected in a competitive request for proposals that followed the January MFCR meeting:

- Amit Choudhary and his team from Harvard Medical School are exploring whether small molecules called phosphorylation-inducing chimeric small molecules, which bring kinases into close proximity with target proteins, can enhance phosphorylation in cancer targets. The ultimate goal is to use aberrant phosphorylation to evoke an immune response.
- Arvin Dar and his lab at the Icahn School of Medicine at Mount Sinai have developed a compound dubbed trametiglue, a version of the FDA-approved MEK inhibitor trametinib, that has enhanced interfacial binding properties. These improved properties show promise in overcoming the resistance that's commonly seen with trametinib. Trametiglue and its analogs are being used as research tools and studied as potential leads for new therapeutics.
- H. Courtney Hodges of the Baylor College of Medicine, and Nate Hathaway, of the University of North Carolina, are collaborating to develop bifunctional small molecules that can activate SWI/SNF-dependent transcriptional enhancers. SWI/SNF is an important chromatin remodeling complex that can lead to cancer when inactivated.
- Benjamin Stanton of Nationwide Children's Hospital and The Ohio State University College of Medicine, and his collaborator Jun Qi, of Dana-Farber Cancer Institute, are developing induced proximity-based precision therapeutics for rhabdomyosarcoma that result in the degradation of the drivers of oncogenic transcriptional programs in this rare pediatric solid tumor.

An additional induced proximity project was selected for MFCR's new Drug Discovery Partnership program, which is designed to accelerate the trajectory of promising scientific discoveries towards becoming therapeutics that will benefit cancer patients.

- Craig Crews is leading a team at Yale School of Medicine to continue developing a TPD approach for treating chordoma. The foundation for this work in the Crews lab originated in a successfully completed study funded by a Therapeutic Innovation Award jointly granted by MFCR and the Chordoma Foundation in 2018.

National Association for Proton Therapy establishes Physician Advisory Committee

To guide the National Association for Proton Therapy, the organization has created a Physician Advisory Committee.

The committee will advise NAPT on critical issues including advancing clinical research collaboration, patient education and equitable insurance reimbursement practices.

Chaired by J. Isabelle Choi, clinical director and research director of the New York Proton Center and Assistant Member at Memorial Sloan Kettering Cancer Center, the committee is comprised of national leaders in radiation oncology and proton therapy including:

- Gopal Bajaj, Inova Schar Cancer Institute Proton Therapy Center,
- Brian Baumann, S. Lee Kling Center for Proton Therapy at the Siteman Cancer Center,
- Jeff Bradley, Emory Proton Therapy Center,
- Andrew Chang, California Protons Cancer Therapy Center,
- Steve Frank, MD Anderson Cancer Center Proton Therapy Center,
- James Gray, Provision CARES Proton Therapy Center,
- Brandon Gunn, MD Anderson Cancer Center Proton Therapy Center,
- Nancy Mendenhall, University of Florida Health Proton Therapy Institute,
- Minesh Mehta, Miami Cancer Institute Proton Therapy Center at Baptist Health South Florida,
- Charles Simone, New York Proton Center,
- Christina Tsien, The Johns Hopkins National Proton Center,
- Torunn Yock, Francis Burr Proton Therapy Center at Massachusetts General Hospital,
- Jing Zeng, Seattle Cancer Care Alliance Proton Therapy Center.

Under Choi's leadership, the NAPT Physician Advisory Committee will promote the benefits of proton therapy. The committee will attend advocacy meetings with federal and state government agencies and members of Congress,

collaborate with other cancer-related stakeholders, and support proton therapy research.

Previously, Choi was an assistant professor at the University of Maryland School of Medicine and served as a clinical lead of the Maryland Proton Treatment Center.

U.S. government passes law honoring legacy of Henrietta Lacks by increasing access to clinical trials

Congress passed legislation aimed at improving access to clinical trials for communities of color and decreasing health disparities. The bill was signed by the president Jan. 5.

The Henrietta Lacks Enhancing Cancer Research Act works to increase access and remove barriers to participation in federally sponsored cancer clinical trials among communities that are traditionally underrepresented.

The bill is named after a Black woman who died from cervical cancer and whose cells, taken without her knowledge or consent during her treatment, have been used to develop some of modern medicine's most important breakthroughs, including the development of the polio vaccine and treatments for cancer, HIV/AIDS and Parkinson's disease.

"ACS CAN is pleased to see this important bill, which is aimed at doing just that, pass in the Senate. Henrietta Lacks' cells have saved countless lives and with this bill, her legacy will continue to improve health outcomes and reduce health disparities for countless more," American Cancer Society Cancer Action Network President Lisa Lacasse said in a statement.

The law directs the federal government to study policies that impact diverse participation in federally sponsored cancer clinical trials nationwide and recommend potential policy changes that would reduce barriers and make it easier for patients from diverse backgrounds to enroll in clinical trials.

Massachusetts health care law expected to improve access to clinical trials

Massachusetts Governor Charlie Baker signed into law a compromise healthcare bill that calls for reimbursing cancer patients for the out-of-pocket expenses associated with clinical trial participation and creating across the board reimbursement programs in the state.

The anticipated result is that thousands of cancer patients in Massachusetts will gain access to advanced treatments offered in clinical trials. The goal is to improve participation and retention in cancer clinical trials, especially among underserved populations.

The legislative action is the result of an effort by Lazarex Cancer Foundation and members of the state legislature, including Representative Hannah Kane, the author and lead on the cancer trial language, Leader Ronald Mariano, former Senator Richard Ross, and others, to bring attention to the issue. Co-authored by Lazarex, the legislation clarifies that reimbursing patients for the out-of-pocket expenses necessary to travel to a clinical trial site are not to be considered inducements or coercion.

Similar legislation is being considered in Florida, and New Mexico, and is already law in California, Pennsylvania, Texas, Illinois and Wisconsin.

THE CLINICAL CANCER LETTER

CLINICAL ROUNDUP

Study: Striking differences seen in COVID-19 responses in cancer patients

A study funded by Cancer Research UK shows that the immune response to COVID-19 is the same in people with solid tumors compared to those without cancer.

However, blood cancer patients varied in their ability to respond to the virus, with many unable to shake off the virus for up to 90 days after the first signs of infection—around five times longer than the average.

Due to the importance of sharing findings related to the pandemic, the publication has been fast-tracked online as a preprint in *Cancer Cell*. The study gives reassurance to many people with cancer, but also highlights that patients cannot be grouped together when it comes to delivering cancer care during the pandemic.

The COVID-19 pandemic has led to many challenges for people with cancer, including decisions around shielding and delaying treatment. There is also conflicting evidence around COVID-19 having a more detrimental effect on those with cancer, and there is little insight into how cancer patients' immune systems respond to the virus.

Researchers led by Sheeba Irshad, a Cancer Research UK clinician scientist based at King's College London, in collaboration with Professor Adrian Hayday and Piers Patten (consultant hematologist) wanted to address two key questions: 1) Does the immune response to COVID-19 in cancer patients differ to those without cancer; and 2) What is the long-term impact of COVID-19 on the immune system in people with cancer.

The study analysed the blood of 76 cancer patients: 41 of them had COVID-19, and 35 had not been exposed to the virus. The samples were compared to the blood of people who didn't have cancer, and who had already been recruited to the previously published COVID-IP study led by Professor Adrian Hayday*. Of the 41 people with cancer, 23 had solid tumors, and 18 had blood cancer.

Immune responses to the virus in people with solid tumors were like those of people without cancer. This was the case even where patients were in the advanced stages of cancer and were undergoing active anti-cancer treatments. Both groups were able to mount a strong immune response to the initial COVID-19 infection, and subsequently developed high levels of antibodies to clear the virus from their systems.

This study was the first to show that high levels of COVID-19 antibodies are sustained long-term in patients with solid tumors—up to 78 days after exposure to the virus. The study also found that once patients had recovered from COVID-19, their immune systems returned to normal, pre-COVID functioning.

The immune response to COVID-19 in people with certain types of blood cancer was similar but milder in the active/early phases of the disease and became stronger over time resembling immune changes often seen in chronic infections. This was especially true for cancers affecting B cells: a type of immune cell that plays an important role in immune memory.

In patients with B cell-related blood cancers, the antibody response to the virus was more diverse compared to people with solid tumors and presented as three distinct groups: 1) those who developed antibodies and cleared the virus like the solid cancer patients and people without cancer; 2) those who never developed antibodies even >75 days after virus exposure and continued to fail to clear the virus; and finally, 3) those who despite having developed antibodies against the virus were unable to clear it.

The next phase of the SOAP study will monitor the immune responses of cancer patients to the COVID-19 vaccine.

American College of Surgeons study reports drop in lung cancer screening, rise in malignancy rates during spring COVID-19 surge

Researchers from the University of Cincinnati have identified a framework that could help people with serious health conditions keep up their lung cancer screening appointments during the current surge.

The study was selected for the 2020 Southern Surgical Association Program and published as an "article in press" on the Journal of the American College of Surgeons website in advance of print.

The researchers compared monthly visits for low-dose computed tomography screening for lung cancer during the three months in which COVID-19 restrictions were in place with the number of monthly visits from the three years before that. LDCT is an imaging modality known to reduce mortality from lung cancer by at least 20% in high-risk patients. The institution suspended LDCT on March 13 and began a phased reopening on May 5 with a full opening on June 1.

"We had 800 scans cancelled during that time and even during the resumed period, we had a decreased total volume of patients scanned and also noted a decreased number of new patients who were scanned for their lung cancer screening," lead author Robert M. Van Haren, an assistant professor and thoracic surgeon at the University of Cincinnati College of Medicine and a member of Cincinnati Research in Outcomes and Safety in Surgery within the Department of Surgery, said in a statement.

The institution averaged 146 LDCT tests a month before COVID-19 compared with 39 in March to June this year ($p<0.01$), with new patient monthly averages falling from 56 to 15 ($p<0.01$).

"Also when we resumed our operations, we found that new patients were less likely to come back to our screening program," he said. They reported that new patient monthly LDCT rates have remained low despite resuming full operations.

"We also found that patients were more likely not to show up for their CT appointments, and this rate was again significantly increased compared with baseline," he said. The no-show rate went from 15% before the COVID-19 restrictions to 40% afterward ($p<0.04$).

When full operations resumed in June, 29% of patients were found to have lung nodules suspicious for malignancy compared with 8% in the pre-COVID-19 period ($p<0.01$). That meant more patients were referred to a specialist for either biopsy or surgery as their suspected cancer entered a more critical phase.

These poor rates of screening probably reflect patient fears about coming into the hospital during the pandemic, although the study did not look at that concern specifically, Van Haren said.

"We've done two things to try to deal with that situation," he said. "One was that we made operational changes to ensure that screening is safe, and we made a big emphasis within our program and with our nurses and coordinators to educate patients about those changes and to really get the message out that screening is safe."

The key operational change was shifting the setting for the LDCT from the hospital to an outpatient center, but other changes included enforcing social distancing in the waiting rooms and in the scanning areas, and spacing appointments farther apart to allow for appropriate cleaning of those areas.

"Our results are important and suggest that it's critical to continue cancer screening operations, such as our lung cancer screening, during this pandemic," he said. "It's maybe more important now as we continue to undergo another surge of COVID-19 cases throughout the country."

In an invited commentary, William B. Weir, and Andrew C. Chang, of Michigan Surgery, Ann Arbor, wrote, "We must find a way to continue routine oncologic care or the true COVID-19 mortality rate will begin to include advanced stages of lung cancer."

Largest, most diverse ever study of prostate cancer genetics brings disparities into focus

Scientists at the USC Center for Genetic Epidemiology and the Institute for Cancer Research, London, led a study that brings together data from the majority of genomic prostate cancer studies globally.

Including more than 200,000 men of European, African, Asian and Hispanic ancestry from around the world, the study is the largest, most diverse genetic analysis ever conducted for prostate cancer. The study was published in *Nature Genetics*.

Risk for the disease is about 75% higher, and prostate cancer is more than twice as deadly, in Blacks compared to whites. Yet whites are often overrepresented as research participants, making these differences difficult to understand and, ultimately, address.

The study's authors identified 86 new genetic variations that increase risk for prostate cancer, not previously discovered, bringing the total number of risk loci for prostate cancer to 269.

Applying a model for assessing prostate cancer risk based on the interplay of these genetic factors, the researchers showed that men of African ancestry inherit about twice the prostate cancer risk on average compared to men of European ancestry, while men of Asian ancestry inherit about three-quarter the risk of their white counterparts—evidence that genetics play some part in the differences in how often cancer occurs in different racial groups.

This research is also a step toward applying precision medicine to early detection.

"Our long-term objective is to develop a genetic risk score that can be used to determine a man's risk of developing prostate cancer," corresponding author Christopher Haiman, professor of preventive medicine at the Keck School of Medicine of USC and director of the USC Center for Genetic Epidemiology, said in a statement. "Men at higher risk may benefit from earlier and more frequent screening, so the disease can be identified when it's more treatable."

"[The Prostate Cancer Foundation] believes that Dr. Haiman's research findings will lead to more effective prostate cancer precision screening strategies for men of West African ancestry," Jonathan W. Simons, president and chief executive officer of the Prostate Cancer Foundation, said in a statement.

The foundation funds Haiman's other work leading the RESPOND initiative exploring the disease among African American men.

Haiman and his colleagues used genomic datasets from the U.S., the UK, Sweden, Japan, and Ghana, to compare 107,247 men with prostate cancer to a control group comprising 127,006 men. By examining a spectrum of races and ethnicities, the study's authors aim to make the genetic risk score more useful for more people.

"We not only found new markers of risk, but also demonstrated that, by combining genetic information across populations, we were able to identify a risk profile that can be applied across populations," Haiman said. "This emphasizes the value of adding multiple racial and ethnic populations into genetic studies."

Today's screening guidelines for prostate cancer suggest that those 55 and older with average risk can choose to take the prostate-specific antigen test in consultation with their physicians. High PSA levels are associated with prostate cancer, but the PSA test tends to detect slow-growing tumors. With widespread use, it too often leads to unnecessary treatment.

The PSA test's value as a screening tool would grow if it were deployed selectively to monitor people found to be at high risk for prostate cancer, which is where the genetic risk score could come into play. Those at particularly high risk might even begin screening before age 55.

In order to translate the current research findings into better early detection, a large-scale clinical trial would be needed.

New NCCN resource for survivors helps guide life after cancer diagnosis and treatment

The National Comprehensive Cancer Network published two new Guidelines for Patients on healthy living and managing late and long-term side effects, and include appropriate ongoing screening for recurrence.

The books are available for free to view and print, or via the NCCN Patient Guides for Cancer App. The guidelines are *Survivorship Care for Healthy Living and Survivorship Care for Cancer-Related Late* and *Long-Term Effects*.

"These guidelines are applicable for survivors who are disease free as well as those living with cancer. They are far reaching across all cancer types, genders, and ages," Crystal Denlinger, of Fox Chase Cancer Center, and chair of the NCCN Guidelines Panel for Survivorship, said in a statement.

"These guidelines include information on healthy living after a health crisis; which are good recommendations even for people who've never been diagnosed with cancer," Tara Sanft, of Yale Cancer Center/Smilow Cancer Hospital, and vice-chair of the NCCN Guidelines Panel for Survivorship, said in a statement. "We want everyone to make a realistic plan to start moving more. It sounds simple, but we have really good data that exercise can reduce recurrence, even in people who didn't exercise before diagnosis."

The guidelines pay heightened attention to mitigating risks of cardiovascular disease. There is also information for primary care providers to appropriately advise survivors, in collaboration with oncologists, to help them stay up-to-date on evolving screening recommendations.

NCCN recognizes that the population of cancer survivors is growing rapidly, due to both an increase in diagnoses, and improving care methods that keep more people alive for longer.

This is resulting in a greater need for research into long-term effects from traditional and emerging therapies, with the latter including immune checkpoint

inhibitors and chimeric antigen receptor T-cell therapy (side-effects from both immunotherapy types are covered in recently-published NCCN Guidelines for Patients).

Triple chemotherapy combination improves metastatic colorectal cancer outcomes

Researchers from SWOG Cancer Research Network have demonstrated that a triple drug combination—of irinotecan, cetuximab, and vemurafenib—is a more powerful tumor fighter and keeps people with metastatic colon cancer disease free for a significantly longer period of time compared with patients treated with irinotecan and cetuximab.

Results of the SWOG study, led by Scott Kopetz, of MD Anderson Cancer Center, are published in the *Journal of Clinical Oncology*.

The findings are expected to change the standard of care for patients with colorectal cancer that is metastatic and includes a mutation in the BRAF gene called V600E. This mutation is found in about 10% of metastatic colorectal cancers and tumors with the mutation rarely respond to treatment, resulting in a poor prognosis for patients.

Kopetz is an expert in the science of BRAF-mutated colorectal cancer and has tested a variety of combination therapies to treat it, including leading the BEACON trial. This phase III trial found that two targeted drugs, cetuximab and encorafenib, significantly shrank tumors and helped patients live longer compared with those who received standard treatment.

In his SWOG study, S1406, Kopetz and his team also pursued combination therapies to see what might work best.

In this trial, they tested 106 patients whose metastatic colorectal cancer includes the deadly V600E mutation. All the patients had been previously treated with chemotherapy, and their cancer didn't respond. The team randomly assigned study participants to one of two treatment groups – those who received irinotecan and cetuximab and those who received that combination with a third drug, vemurafenib.

The SWOG team found that patients who received the triple combination had better tumor response rates to the drugs, 17% compared to 4%, and stayed cancer-free longer.

On a molecular level, Kopetz said, here's how the triplet works: Irinotecan, a traditional chemotherapy drug, kills cancer cells. Cetuximab, a monoclonal antibody, is a targeted drug that blocks cancer growth by blocking the action of a protein called epidermal growth factor receptor, or EGFR. Kopetz says vemurafenib, a BRAF inhibitor and another targeted therapy, attacks the BRAF protein directly, further slowing tumor growth.

"That 1-2-3 action, that triple threat, shuts off a powerful growth pathway in these cancers," Kopetz said in a statement. "In this trial, unlike in BEACON, we added chemo and found that it makes for a more effective way to treat this aggressive form of colorectal cancer."

Another intriguing finding: An 87% decline in circulating tumor DNA (ctDNA) of the BRAFV600E variant allele frequency in patients receiving all three drugs, compared with no ctDNA drop in patients receiving the two-drug combination.

Kopetz said this is strong evidence that measuring the presence of ctDNA can be an effective way to measure short-term response to treatment. And it could be as easy as drawing blood using liquid biopsy.

Miami Cancer Institute launches new and expanded clinical trials for COVID-19 treatments

Miami Cancer Institute, part of Baptist Health South Florida, has initiated several clinical trials based on treatments from initial emergency and experimental COVID-19 therapies.

The institute is leading a trial using mesenchymal stem cells for critically ill patients with SARS-CoV-2 induced respiratory failure. It is also the location of the phase II, BLAZE-4 trial, which continues work on bamlanivimab, a monoclonal antibody recently awarded Emergency Use Authorization status by FDA for those with mild COVID-19 symptoms.

Early in the pandemic, Miami Cancer Institute received single-use emergency approval from the FDA to give mesenchymal stem cells to several COVID-19 patients who were critically ill. The patients recovered. The stem cells aid in healing by regenerating damaged lung tissue. The formal, phase I/IIa trial opening now is for hospitalized patients who are receiving oxygen therapy or who are on ventilation support and are not showing improvement with other therapies.

The Florida Department of Health is allocating bamlanivimab for EUA use and Baptist Health has a limited supply. Miami Cancer Institute participated in the monoclonal antibody's phase I study, BLAZE-1, which led to the EUA. Now the Institute is enrolling patients in the phase II study, BLAZE-4.

Bamlanivimab can be given as an IV infusion to COVID-19-positive patients who are not hospitalized and have mild symptoms. It must be administered within 72 hours of a positive test result.

It works by prohibiting the virus from anchoring to ACE2 receptors, which are proteins on the surface of many cells that allow the SARS-CoV-2 virus to enter and infect cells. In the initial study, it showed a subsequent hospitalization rate of 1.7% among those who received the drug versus a 6% hospitalization rate among those who received a placebo.

The BLAZE-4 trial is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of bamlanivimab (also known as LY3819253) both on its own and in combination with another monoclonal antibody specific to target the spike protein of SARS-CoV-2 to prevent the virus from entering into the epithelial cells (LY3832479). There are five arms to the trial. Arm 1 is a placebo. Arms 2, 3 and 4 consist of bamlanivimab plus a second monoclonal antibody (both given in different dosages). Arm 5 is bamlanivimab alone.

The first trial showed that bamlanivimab may reduce viral load, symptoms and risk of hospitalizations and emergency room visits associated with COVID-19 and this trial may further improve the outcomes.

Phase III Keytruda + Lenvima study shows improved OS, PFS in advanced endometrial cancer

A combination of Keytruda (pembrolizumab) and Lenvima (lenvatinib) demonstrated statistically significant improvement in overall survival, progression-free survival and objective response rate versus chemotherapy in patients with advanced endometrial cancer.

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

The phase III KEYNOTE-775/Study 309 trial evaluating the investigational use of Keytruda, an anti-PD-1 therapy, plus Lenvima, the orally available multiple receptor tyrosine kinase inhibitor, met its dual primary endpoints of OS and PFS, and its secondary efficacy endpoint of ORR in patients with advanced endometrial cancer following at least one prior platinum-based regimen.

These positive results were observed in the mismatch repair proficient subgroup and the intention-to-treat study population, which includes both patients with endometrial carcinoma that is pMMR as well as patients whose disease is microsatellite instability-high (MSI-H)/mismatch repair deficient.

Based on an analysis conducted by an independent data monitoring committee, Keytruda plus Lenvima demonstrated a statistically significant and clinically meaningful improvement in OS, PFS and ORR versus chemotherapy (treatment of physician's choice [TPC] of doxorubicin or paclitaxel).

The safety profile of the Keytruda plus Lenvima combination was consistent with previously reported studies. Merck and Eisai will discuss these data with regulatory authorities worldwide, with the intent to submit marketing authorization applications based on these results, and plan to present these results at an upcoming medical meeting.

KEYNOTE-775/Study 309 is the confirmatory trial for KEYNOTE-146/Study 111, which supported FDA's 2019 accelerated approval of the Keytruda plus Lenvima combination for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation.

This accelerated approval was based on tumor response rate and durability of response and was the first approval granted under Project Orbis. Under Project Orbis, Health Canada and Australia's Therapeutic Goods Administration granted conditional and provisional approvals, respectively, for this indication.

Merck and Eisai are studying the Keytruda plus Lenvima combination through the LEAP (LEnvatinib And Pembrolizumab) clinical program in 13 different tumor types across 20 clinical trials, including a phase III trial evaluating the combination in the first-line setting for patients with advanced endometrial carcinoma (LEAP-001).

Cabometyx significantly improved PFS in phase III trial of previously treated radioiodine-refractory differentiated thyroid cancer

COSMIC-311, the phase III pivotal trial evaluating Cabometyx (cabozantinib) versus placebo in patients with radioiodine-refractory differentiated thyroid cancer who have progressed after up to two prior vascular endothelial growth factor receptor-targeted therapies, met the co-primary endpoint of demonstrating significant improvement in progression-free survival.

Cabometyx is sponsored by Exelixis.

Cabometyx reduced the risk of disease progression or death by 78% with a hazard ratio of 0.22 (96% CI 0.13 – 0.36; p<0.0001) at this planned interim analysis. The safety profile was consistent with that previously observed for Cabometyx.

Given these results, the independent data monitoring committee for the study recommended to stop enrollment and unblind sites and patients. Exelixis intends to discuss the study results, pro-

posed changes to the study conduct, as well as plans for a regulatory filing with FDA in the near term.

COSMIC-311 is a multicenter, randomized, double-blind, placebo-controlled phase III pivotal trial that aimed to enroll approximately 300 patients at 150 sites globally. Patients were randomized in a 2:1 ratio to receive either cabozantinib 60 mg or placebo once daily. Detailed results will be submitted for presentation at a future medical conference.

Ohio State launches statewide study focused on breast cancer in Black women

The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute has launched its fourth statewide cancer research initiative focused on increasing breast cancer education, facilitating access to genetic counseling and ensuring appropriate screening, follow-up for abnormalities and treatment for Black women who are at an increased risk for breast cancer.

The Turning the Page on Breast Cancer in Ohio program was launched with funding support from Pelotonia, the American Cancer Society and Pfizer and is a collaborative effort of experts from the OSUCCC – James, Ohio Association of Community Health Centers, Susan G. Komen and the North Central Region of the American Cancer Society.

Electra Paskett, co-leader of the OSUCCC – James Cancer Control Research Program, Marion N. Rowley Designated Chair in Cancer Research at the Ohio State College of Medicine, and Heather Hampel, a practicing genetic counselor with The James and professor/associate director of the Division of Human Genetics at the Ohio State College Medicine, are principal investigators of the study.

Hampel is also a member of the OSUCCC – James Molecular Carcinogenesis and Chemoprevention Program.

Hampel is a practicing genetic counselor with The James and professor/associate director of the Division of Human Genetics at the Ohio State College Medicine. She also is a member of the OSUCCC – James Molecular Carcinogenesis and Chemoprevention Program.

"Studies confirm that in the United States, Black women are 42% more likely to die of breast cancer than white women – and on average, Black women develop more aggressive breast cancer and die at younger ages than white women. Many factors, including insurance, socioeconomics and more frequent gene mutations, contribute to this disparity," Paskett said in a statement.

"We are working to identify and directly break down those barriers to help women who are at the highest risk of developing breast cancer," Paskett said. "Our goal is to help these women both understand their risk and get the medical guidance they need."

The OSUCCC – James-led collaborative team will use a multi-level approach in 12 Ohio counties to provide breast cancer education and facilitate access to risk assessment, genetic counseling and testing, appropriate screening/surveillance, follow-up for abnormal tests, and prompt and appropriate treatment for Black women.

Researchers will use geographic predictors (county) of aggressive disease to identify and inform women who live in high-risk counties. Participating counties will include Franklin, Fairfield, Clark, Butler, Hamilton, Lake, Cuyahoga, Lorain, Trumbull, Summit, Stark and Mahoning.

Several strategies (e.g., Facebook ads, referral from providers or community organizations) will be used to direct interested women to a website where they can enter information about themselves and their family history of cancer to determine if they are at increased risk for breast cancer.

High-risk women will be referred to genetic counseling, where they can receive a tailored risk assessment and genetic testing when appropriate. Women will then receive a personal prescription for breast health and be connected to experts who can help them navigate next steps.

All participating women will receive information about when to start breast cancer screening and what that screening should entail based on their risk stratification. Women will then be connected to local breast health specialists for their screening and follow-up. Efforts will be made at local health centers to ensure that women seen in those medical clinics have up-to-date screening and that women with abnormal screening tests receive proper and timely follow-up.

Roswell Park researchers: Aggressive breast cancers in Black patients are related to immune factors

A Roswell Park Comprehensive Cancer Center team led by Christine Ambrosone and Song Yao has found a distinct molecular signature in the tumor tissues of Black patients with breast cancer.

The study, published in the *Journal of the National Cancer Institute*, reports that an elevated number of exhausted,"nonfunctional T cells appears to be driving tumors in patients of African descent to

be more aggressive and hard-to-treat — a finding that also opens the door to treatment interventions that could help to eliminate the striking disparities in survival between Black and white patients with breast cancer.

In the United States, rates of death from breast cancer are 40% higher among Black women than white women. Seeking new information about what is driving those unequal outcomes, the Roswell Park team used both pathological and gene-expression profiling to characterize infiltrating immune cells in the breast tumor microenvironments of 1,315 patients included in the Women's Circle of Health Study.

The data the team compiled reveal distinct differences in the tumor immune responses among Black and white patients. While tumors from Black patients exhibited a stronger overall immune cell presence, the immune cells in Black patients appeared to have lower antitumor activities.

"We observed in the tumor microenvironment of breast cancer in patients of African descent a distinct signature of exhausted versus total CD8+ T cells, and noted further that this immune cell profile is associated with poorer breast cancer survival, particularly in the hormone receptor-positive subtype of breast cancer," first author Yao, professor of oncology in the Department of Cancer Prevention and Control at Roswell Park, said in a statement.

The findings suggest that Black patients could have a higher response rate to immune checkpoint inhibitors. The potential of this approach is also supported by the stronger B-cell response in this patient population, a trait recently shown to regulate responses to immunotherapy, the researchers report.

"The activation of the immune system to eliminate and control cancer cells has become a clinical reality with recent breakthroughs in cancer immunotherapy," senior author Ambrosone, chair of cancer prevention and control and senior vice president of population sciences at Roswell Park said in a statement. "We believe these findings may suggest an opportunity to enlist host immunity, part of the fundamental mechanism of human bodies to recognize and defend against the invasion of foreign agents, through immune checkpoint inhibitors in patients whose breast cancers fit this immune profile."

In their new work, which was supported by the Breast Cancer Research Foundation, the Roswell Park team highlighted a lack of clinical trials on immune checkpoint inhibitors that have reported race-specific outcome data, emphasizing the need for enhanced recruitment of racial/ethnic minorities to lessen cancer disparities and to ensure that all patients have the opportunity to benefit from cutting-edge cancer treatment.

UCLA study: More women embracing 'going flat' after mastectomy

A growing number of women forgoing reconstruction after a mastectomy say they're satisfied with their choice, even as some did not feel supported by their physician, according to a study led by researchers at the UCLA Jonsson Comprehensive Cancer Center.

The study, published in *Annals of Surgical Oncology*, surveyed 931 women who had a unilateral or bilateral mastectomy without current breast mound reconstruction to assess the motivating factors for forgoing the procedure and to measure whether surgeons provided adequate information and support for "going flat."

Out of the women surveyed, 74% were satisfied with their outcome and 22% experienced "flat denial," where the procedure was not initially offered, the surgeon did not support the patient decision, or intentionally left additional skin in case the patient changed her mind.

The team also explored reasons given for the choice and found women pointed to a desire for a faster recovery, avoidance of a foreign body placement and the belief that breast mound reconstruction was not important for their body image.

"Undergoing a mastectomy with or without reconstruction is often a very personal choice," senior author Deanna Attai, an assistant clinical professor of surgery at the David Geffen School of Medicine at UCLA, said in a statement. "We found that for a subset of women, 'going flat' is a desired and intentional option, which should be supported by the treatment team and should not imply that women who forgo reconstruction are not concerned with their postoperative appearance."

The results challenge past studies showing that patients who chose not to undergo breast reconstruction tend to have a poorer quality of life compared with those who do have the surgery.

Attai and her team found that a majority of patients who elected to go flat were in fact satisfied with their surgical outcome. The authors believe that the survey tool commonly used for assessing outcomes was biased towards reconstruction. To avoid that bias, Attai partnered with patient advocates to develop a unique survey to assess reasons for going flat, satisfaction with their decision, and factors associated with satisfaction. They also identified concerns unique to these patients not captured by other validated surveys.

While a majority of the women surveyed reported they were satisfied with their surgical outcomes, 27% of patients surveyed reported not being satisfied with the appearance of their chest wall.

"Some patients were told that excess skin was intentionally left—despite a preoperative agreement to perform a flat chest wall closure—for use in future reconstruction, in case the patient changed her mind," said Attai, who is also a member of the UCLA Jonsson Comprehensive Cancer Center. "We were surprised that some women had to struggle to receive the procedure that they desired."

Surgeons may hesitate to recommend mastectomy without reconstruction surgeons due to being less confident that they can provide a cosmetically acceptable result for patients who desire a flat chest wall, she said.

"We hope that the results of this study will serve to inform general and breast surgeons that going flat is a valid option for patients, and one that needs to be offered as an option," said Attai. "We also hope the results may help inform patients that going flat is an option, and to empower them to seek out surgeons who offer this option and respect their decision."

New combination therapy could help fight difficult-to-treat cancers with common mutations

Scientists at the UCLA Jonsson Comprehensive Cancer Center describe a new combination therapy that suppresses the MAPK pathway by holding cancer-driving proteins in a death grip.

This combination of two small molecules has the potential to treat not only BRAF mutated melanoma, but also additional aggressive subtypes of cancers, including melanoma, lung, pancreatic and colon cancers that harbor common mutations in cancer genes called RAS or NF1.

The preclinical study, published in *Cancer Discovery*, a journal of the American Association for Cancer Research, found that a second-generation RAF inhibitor (type II RAFi) in combination with a standard MEK inhibitor could be effective in treating cancers with these mutations and could also help overcome acquired resistance to the current standard-of-care treatment targeting specific BRAF mutations.

"The idea behind this study was to develop a combination treatment that helps people with common lethal cancers by eliciting durable anti-tumor responses," senior author Roger Lo, professor of medicine at the David Geffen School of Medicine at UCLA and member of the UCLA Jonsson Comprehensive Cancer Center, said in a statement. "Right now, MEK inhibitors by themselves provide limited clinical benefits, and the current MAPK pathway-targeted, combination therapy can help only certain patients with cancers harboring specific BRAF mutations."

To test the effectiveness of the experimental combination, researchers used patient-derived models of melanoma, non-small cell lung cancer, pancreatic cancer and colon cancer as well as mouse tumors that mimic these human cancers. The team evaluated how the combination of type II RAFi plus MEKi impacts the MAPK pathway inside the cancer cells and the body's cancer-fighting immune or T-cells over time in order to achieve long-term response by suppressing drug-resistant clones.

The next-generation combination works by two unique mechanisms that can suppress drug-resistant clones. First, the two small molecules lock RAF and MEK proteins in the MAPK signaling pathway into a tight complex, which is unusual. Normally, molecules in this pathway touch and go in order to fire off growth-promoting signals. Keeping these molecules stuck together allows the drugs to effectively and durably block the MAPK pathway.

"It is quite remarkable that two drugs were able to bind to each of two proteins and sequester them from further propagating signals inside the cancer cells," co-senior author Gatien Moriceau, assistant adjunct professor at the David Geffen School of Medicine at UCLA, said in a statement.

The combination prevented an attrition of killer T-cells inside the tumor and promoted T-cell clonal expansion.

"The combination unexpectedly preserves killer T-cells inside the tumors, which allows them to hunt down drug-resistant tumor clones," Moriceau said. "This favorable impact on T-cells paves the way to combine MAPK-targeted therapies with anti-PD-1/L1 immune checkpoint therapy."

The combination of type II RAFi plus MEKi is being tested in clinical trials in both melanoma and other solid cancers such as non-small cell lung cancer.

The work was supported by NIH, the Melanoma Research Alliance and the V Foundation for Cancer Research.

DRUGS & TARGETS

Tagrisso receives FDA approval as adjuvant therapy for NSCLC with EGFR mutations

FDA has approved Tagrisso (osimertinib) for adjuvant therapy after tumor resection in patients with non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

Tagrisso is sponsored by AstraZeneca Pharmaceuticals LP.

Efficacy was demonstrated in a randomized, double-blind, placebo-controlled trial (ADAURA, NCT02511106) in patients with EGFR exon 19 deletions or exon 21 L858R mutation-positive NSCLC who had complete tumor resection, with or without prior adjuvant chemotherapy.

Eligible patients with resectable tumors (stage IB – IIIA) were required to have predominantly non-squamous histology and EGFR exon 19 deletions or exon 21 L858R mutations identified prospectively from tumor tissue in a central laboratory by the cobas EGFR Mutation Test. A total of 682 patients were randomized (1:1) to receive osimertinib 80 mg orally once daily or placebo following recovery from surgery and standard adjuvant chemotherapy, if given.

The major efficacy outcome measure was disease-free survival in patients with stage II – IIIA NSCLC determined by investigator assessment. Median DFS was not reached (38.8, NE) in patients on the osimertinib arm compared with 19.6 months (16.6, 24.5) on the placebo arm (HR 0.17 95% CI: 0.12, 0.23; <0.0001). DFS in the overall study population was a secondary efficacy outcome measure; the median was not reached (NE, NE) in patients on the osimertinib arm compared with 27.5 months (22, 36) on the placebo arm (HR 0.20 95% CI: 0.15, 0.27; <0.0001).

Iclusig receives FDA sNDA approval for adult patients with resistant or intolerant chronic-phase CML

FDA has approved the supplemental New Drug Application for Iclusig (ponatinib) for adult patients with chronic-phase chronic myeloid leukemia with resistance or intolerance to at least two prior kinase inhibitors.

Iclusig is sponsored by Takeda Pharmaceutical Company Ltd.

The updated label includes an optimized, response-based ICLUSIG dosing regimen in CP-CML with a daily starting dose of 45 mg and, upon achieving ≤1% BCR-ABL1IS, dose reduction to 15 mg. This dosing regimen aims to maximize benefit-risk by providing efficacy and decreasing the risk of adverse events, including arterial occlusive events.

The sNDA approval is based on data from the phase II OPTIC (Optimizing Ponatinib Treatment In CML) trial, as well as five-year data from the phase II PACE (Ponatinib Ph+ ALL and CML Evaluation) trial.

The OPTIC trial included patients with CP-CML whose disease was highly-resistant to their immediate prior TKI, the majority of whom (65%) did not achieve a response greater than complete hematological response on immediate prior therapy.

At 12 months, 42% of 88 patients utilizing the newly approved response-based dosing regimen (45 mg to 15 mg) achieved ≤1% BCR-ABL1IS, the primary endpoint of OPTIC, and at a median follow up time of 28.5 months, 73% of these patients maintained their response. In these patients, 13% experienced an AOE of any Grade, 7% experienced Grade 3 or higher. Risk factors such as uncontrolled hypertension or diabetes should be managed, and caution should be exercised when treating patients with active or substantial history of clinically significant, uncontrolled cardiovascular disease.

Xpovio receives FDA approval for refractory or relapsed multiple myeloma

FDA has approved Xpovio (selinexor) in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

Xpovio is sponsored by Karyopharm Therapeutics Inc.

FDA granted Xpovio accelerated approval in 2019 in combination with

dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.

Efficacy of Xpovio in combination with bortezomib and dexamethasone was evaluated in the BOSTON Trial (KCP-330-023, NCT03110562), a randomized (1:1) open-label, multicenter, active comparator-controlled trial in patients with RRMM who had previously received at least one and at most three prior therapies.

Patients received once-weekly selinexor orally in combination with once-weekly bortezomib subcutaneous and low-dose dexamethasone twice-weekly orally compared to the standard twice-weekly bortezomib plus low-dose dexamethasone.

The main efficacy outcome measure was progression free survival assessed by an independent review committee using International Myeloma Working Group response criteria. The estimated median PFS was 13.9 months (95% CI: 11.7, Not Estimable) for the SVd arm and 9.5 months (95% CI: 7.6, 10.8) for the Vd arm (estimated hazard ratio 0.70; 95% CI: 0.53, 0.93).

Orgovyx receives FDA approval for advanced prostate cancer

FDA has approved the first oral gonadotropin-releasing hormone receptor antagonist, Orgovyx (relugolix) for adult patients with advanced prostate cancer.

Orgovyx is sponsored by Myovant Sciences inc.

Efficacy was evaluated in HERO (NCT03085095), a randomized, open label trial in men requiring at least one year of androgen deprivation therapy with either prostate cancer recurrence following radiation or surgery or newly diagnosed castration-sensitive advanced prostate cancer. Patients (N=934) were randomized (2:1) to receive relugolix 360 mg oral loading dose on the first day, followed by daily oral doses of 120 mg, or leuprolide acetate 22.5 mg injection subcutaneously every 3 months for 48 weeks.

The main efficacy outcome measure was medical castration rate defined as achieving and maintaining serum testosterone suppression to castrate levels (< 50 ng/dL) by day 29 through 48 weeks of treatment. The medical castration rate was 96.7% (95% CI: 94.9%, 97.9%) in the relugolix arm.

Margenza receives FDA approval for metastatic HER2-positive breast cancer

FDA has approved Margenza (margetuximab-cmkb) in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.

Margenza is sponsored by MacroGenics.

Efficacy was evaluated in SOPHIA (NCT02492711), a randomized, multicenter, open-label trial of 536 patients with IHC 3+ or ISH-amplified HER2+ metastatic breast cancer who had received prior treatment with other anti-HER2 therapies. Patients were randomized (1:1) to margetuximab plus chemotherapy or trastuzumab plus chemotherapy. Randomization was stratified by chemotherapy choice (capecitabine, eribulin, gemcitabine, or vinorelbine), number of lines of therapy in the metastatic setting (≤ 2, > 2), and number of metastatic sites (≤ 2, > 2).

The main efficacy outcome measures were progression-free survival by blinded independent central review and overall survival. Additional efficacy outcome measures were objective response rate and duration of response assessed by BICR.

Median PFS in the margetuximab arm was 5.8 months (95% CI: 5.5, 7.0) compared with 4.9 months (95% CI: 4.2, 5.6) in the control arm (HR 0.76; 95% CI: 0.59, 0.98; p=0.033). Confirmed ORR was 22% (95% CI: 17, 27) with a median DOR of 6.1 months (95% CI: 4.1, 9.1) in the margetuximab arm compared to an ORR of 16% (95% CI: 12, 20) and median DOR of 6.0 months (95%CI: 4.0, 6.9) in the control arm.

CPI-613 receives FDA Fast Track Designation for treatment of AML

FDA has granted Fast Track designation to CPI-613 (devimistat) for the treatment of acute myeloid leukemia.

CPI-613 is sponsored by Rafael Pharmaceuticals Inc.

Rafael Pharmaceuticals received Fast Track designation for devimistat for the treatment of metastatic pancreatic cancer in November 2020. The company also received Orphan Drug Designation for the treatment of soft tissue sarcoma for devimistat, and the initiation of a phase II clinical trial of devimistat in combination with hydroxychloroquine in patients with clear cell sarcoma of soft tissue.

EU CHMP issues positive opinion for Keytruda as first-line treatment in adult patients in colorectal cancer indication

The Committee for Medicinal Products for Human Use of the European Medicines Agency has adopted a positive opinion recommending approval of Keytruda, Merck's anti-PD-1 therapy, as monotherapy for the first-line treatment of adult patients with metastatic microsatellite instability-high or mismatch repair deficient colorectal cancer.

Keytruda is sponsored by Merck.

This recommendation is based on results from the pivotal phase III KEYNOTE-177 trial, in which Keytruda, as a monotherapy, demonstrated a significant improvement in progression-free survival compared to chemotherapy (investigator's choice: mFOLFOX6 with or without bevacizumab or cetuximab; or FOLFIRI with or without bevacizumab or cetuximab), a current standard of care.

Data from KEYNOTE-177 were presented at the virtual scientific program of the 2020 American Society of Clinical Oncology Annual Meeting and were published in *The New England Journal of Medicine*. The CHMP's recommendation will now be reviewed by the European Commission for marketing authorization in the European Union, and a final decision is expected in the first quarter of 2021.Servier and Celsius Therapeutics collaborate on colorectal cancer research

Servier and Celsius Therapeutics have formed a strategic collaboration focused on the identification and validation of novel colorectal cancer drug targets.

"Through this collaboration, we will leverage Celsius' single-cell genomics platform, machine learning capabilities, and target validation expertise to refine our understanding of the different subtypes of CRC and discover new drug targets with the goal of developing novel precision therapies for specific patient subsets," Hugues Dolgos, global head of oncology research and development at Servier, said in a statement. "Servier will discover and develop candidate drugs leveraging our end-to-end small molecule and large molecule capabilities."

Under the terms of collaboration, Celsius will analyze hundreds of samples from defined CRC patient populations using its proprietary single-cell genomics platform and will work to identify and validate new drug targets during the three-year research period. Servier will receive an exclusive option to research, develop, and commercialize products directed to up to three of the targets.

Celsius would receive an upfront payment and research funding, and would be eligible to receive over $700 million in potential discovery, development, and commercialization milestone payments, along with tiered royalties.

Bayer and Veracyte collaborate on precision oncology in thyroid cancer

Bayer and Veracyte have entered a collaboration to advance the Precision Oncology Patient Identification Program in thyroid cancer.

Through the program, Bayer will offer testing with Veracyte's Afirma Xpression Atlas to identify underlying genomic drivers, including NTRK gene fusions, within patients' tumors. The program will focus on patients with advanced or metastatic thyroid cancer that is radioactive iodine refractory who may potentially benefit from biomarker-driven therapies.

"Patients whose thyroid cancer contains actionable alterations and no longer responds to traditional radioactive iodine therapy now have targeted treatment options available to them. Our goal is to identify such patients so physicians can make more informed treatment decisions for their patients," Bhavesh Ashar, senior vice president and head of U.S. Oncology at Bayer, said in a statement. "With its comprehensive ability to identify broad genomic alterations through its Afirma XA test and its widespread reach among physicians who diagnose thyroid cancer, Veracyte is an ideal collaborator for this program."

The Afirma XA uses RNA whole-transcriptome sequencing to identify 905 DNA variants and 235 RNA fusions in 593 genes, including novel NTRK fusions, on fine needle aspirates taken from thyroid nodules or lymph nodes.

Through this collaboration, Bayer will provide Afirma XA testing at no cost to all eligible patients when ordered by the physician, regardless of the final results and treatment decision. Additionally, physicians of patients found to harbor NTRK gene fusions as an underlying driver in their thyroid cancer will be alerted of the results. The companies anticipate the program to launch in the first quarter of next year.

Servier to acquire Agios Pharmaceuticals' oncology business

Servier has entered into an agreement for the acquisition of Agios Pharmaceuticals' oncology business including its commercial, clinical and research-stage

oncology portfolio for up to $2 billion, including an upfront payment of $1.8 Billion and a potential $200 million in regulatory milestone, plus royalties.

The transaction has been approved by both companies' respective boards of directors. Subject to receipt of regulatory clearances and approval by Agios' shareholders, the acquisition is expected to close in Q2 2021.

Servier has made oncology one of its strategic priorities, allocating 50% of its overall research and development budget to this therapeutic area. The acquisition will reinforce Servier's presence in the U.S., where the group has been operating since 2018.

The transaction includes the transfer of Agios' oncology portfolio and associated employees, including its marketed medicine Tibsovo, which is approved in the U.S. as monotherapy for the treatment of adults with IDH1-mutant relapsed or refractory acute myeloid leukemia and for adults with newly diagnosed IDH1-mutant AML who are ≥75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy.

Tibsovo is also under investigation in two phase III combination trials in newly diagnosed AML, and as a potential treatment for previously treated IDH1-mutant cholangiocarcinoma and IDH1-mutant myelodysplastic syndrome. Servier will also acquire Agios' co-commercialization responsibilities for Bristol Myers Squibb's Idhifa (enasidenib) and conduct certain clinical development activities within the Idhifa development program.

In addition, the transaction includes Agios' oncology pipeline and clinical programs, including vorasidenib, an investigational, brain-penetrant, dual inhibitor of mutant IDH1 and IDH2 which is currently being studied in the registration-enabling phase III INDIGO study in patients with IDH-mutant low-grade glioma; AG-270, an investigational first-in-class methionine adenosyltransferase 2a inhibitor being evaluated in combination with taxanes in patients with methylthioadenosine phosphorylase-deleted non-small cell lung cancer and pancreatic cancer; AG-636, a novel inhibitor of dihydroorotate dehydrogenase; and Agios' oncology research programs.

All of Agios' U.S.-based employees who primarily support the oncology business will receive a comparable offer at Servier.

Kite and Oxford BioTherapeutics establish cell therapy research collaboration in blood cancers and solid tumors

Kite, a Gilead Company, and Oxford BioTherapeutics Ltd. have entered into a research collaboration to evaluate five novel targets for a number of hematologic and solid tumor indications.

Through this collaboration, OBT will validate five novel oncology drug targets, previously identified using OBT's OGAP discovery platform, and generate antibodies against these targets. Kite and Gilead will have the exclusive right to develop and commercialize therapies based on these targets or antibodies.

Under the terms of the agreement, OBT will receive an upfront payment and will be eligible to receive additional payments based on achievement of certain discovery, clinical and regulatory milestones, as well as royalties on future potential sales.

NCI TRIALS

NCI Trials for Jan. 2021

The National Cancer Institute approved the following clinical research studies last month.

For further information, contact the principal investigator listed.

Phase I - NRG-HN008
Phase I Trial with Expansion Cohort of DNA-PK Inhibition and IMRT in Cisplatin-Ineligible Patients with Stage 3-4 Local-Regionally Advanced Head and Neck Squamous Cell Carcinoma (HNSCC)

NRG Oncology
Gillison, Maura Lianne
(713) 792-6363

Phase I/II - 10384
A Phase 1b/2 Study of Hu5F9-G4 (Magrolimab) in Combination with Mogamulizumab in Relapsed/Refractory Treated T-Cell Lymphoma

City of Hope Comprehensive Cancer Center LAO
Khodadoust, Michael Siavash
(650) 725-6451

Phase II - 10371
A Pharmacodynamics-Driven Trial of Talazoparib, an Oral PARP Inhibitor, in Patients with Advanced Solid Tumors and Aberrations in Genes Involved in DNA Damage Response

National Cancer Institute LAO
Chen, A P
(240) 781-3320

Phase II - A222001
A Randomized, Double-Blind, Placebo-Controlled Phase II Study of Oxybutynin versus Placebo for Treatment of Hot Flashes in Men Receiving Androgen Deprivation Therapy

Alliance for Clinical Trials in Oncology
Stish, Bradley J.
(507) 538-6120

Phase II - S2007
A Phase II Trial of Sacituzumab Govitecan (IMMU-132) (NSC #820016) for Patients with HER2-Negative Breast Cancer and Brain Metastases

SWOG
Brenner, Andrew Jacob
(210) 450-5936

Phase III - A031901
Duration of Immune Checkpoint Therapy in Locally Advanced or Metastatic Urothelial Carcinoma: A Randomized Phase 3 Non-Inferiority Trial

Alliance for Clinical Trials in Oncology
Wei, Xiao X.
(617) 632-4524

Phase III - URCC-19185
Multicenter Randomized Controlled Trial Comparing Brief Behavioral Therapy for Cancer Related Insomnia (BBT-CI) and Healthy Eating Education Learning (HEAL)

University of Rochester NCORP Research Base
Palesh, Oxana
(650) 725-7011