

S2302 PRAGMATICA-LUNG TRIAL: REACHING MORE REPRESENTATIVE GROUPS OF PATIENTS WITH EXCITING CLINICAL TRIALS

S2302 Pragmatica-Lung is a federally-funded, streamlined clinical trial examining a new combination of agents in patients with advanced non-small cell lung cancer (NSCLC).

NCI'S CANCER PREVENTION-INTERCEPTION TARGETED AGENT DISCOVERY (CAP-IT) PROGRAM, A MILESTONE IN CANCER PREVENTION RESEARCH

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The Cancer Letter is taking a publication break. We will return on Jan. 6.

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GUEST EDITORIAL

S2302 Pragmatica-Lung Trial: Reaching more representative groups of patients with exciting clinical trials



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S 2302 Pragmatica-Lung is a federally-funded, streamlined clinical trial examining a new combination of agents in patients with advanced non-small cell lung cancer (NSCLC). Like most studies, it is focused on improving outcomes for patients with cancer—but it is also poised to simplify and transform the entire clinical trials model as we know it.

S2302 Pragmatica-Lung is an inclusive real-world clinical trial for patients whose NSCLC has advanced after immunotherapy and chemotherapy. The phase III trial will evaluate the effectiveness of ramucirumab and pembrolizumab compared to standard of care treatments.

It starts with a "pragmatic trial" design, which means it is planned to inform decision-makers about the comparative balance of the benefits, burdens, and risks of a health intervention. Rather than solely determining efficacy, which may overestimate benefits and underestimate harm, pragmatic trials pivot to measure the real-world effectiveness of treatments in more diverse patient populations, highly representative of patients seen in oncology clinics.

The design of the S2302 Pragmatica-Lung trial looks to the pragmatic end of the spectrum across each of the key elements below:

- Eligibility: will enroll patients like those seen in most community oncology clinics, with minimal exclusion criteria
- Recruitment: will recruit a representative group of patients with NSCLC
- Setting: trial sites will cover the full gamut of clinical settings, including the NCI National Clinical Trials Network's (NCTN's) more than 2,000 academic and community sites

- Organization: minimal changes to clinical delivery and resources
- Follow-up: follow-up requires minimal data collection
- Primary outcome: primary outcome is simple, easy to measure and important to patients with lung cancer (overall survival)

[adapted from PRECIS-2 tool, Loudon et al. 2015]

S2302 Pragmatica-Lung has a simple design, aimed at rapid enrollment and easing the burden of data collection and monitoring on research sites. Its eligibility criteria have been cut to a minimum to make enrollment more inclusive. The more representative the patient population in the study, the more generalizable the study results.

SWOG Cancer Research Network and the NCI's NCTN have conducted practical studies in the past. But one of the groundbreaking differences of this trial is it is a Food and Drug Administration (FDA) registration trial—the agency has agreed to consider data from a simplified pragmatic trial for registration intent in considering a new indication, despite the more limited information collected.

In addition to being a product of Lung-MAP, a unique public—private partnership across SWOG, the NCI, the Foundation for the NIH, and Friends of Cancer Research, the phase II S1800A study that gave us the signal being tested in S2302 Pragmatica-Lung evaluated two drugs that were previously FDA-approved and commonly used across multiple tumor types.

We already had a full set of outcomes and safety data across various malignancies, making investigators and sites more comfortable conducting a follow-on study with a single trial objective and minimal adverse event collection. This allowed us to forego the collection of specific data for RECIST, a modestly cumbersome system of response assessment, and to focus on overall survival as the endpoint that matters most to patients.

Right time, right protocol, right team

Lung cancer is, by far, the leading cause of cancer deaths. Yet, there are limited FDA-approved regimens in the second-line setting following first-line immune checkpoint blockade plus or minus chemotherapy. S2302 Pragmatica-Lung represents an area of unmet need and will help us address a key question in a timely way. It is a way to innovate, reduce barriers and be intentional in addressing key meaningful questions—in this case, can we improve overall survival?

Previous work has demonstrated the role of vascular endothelial growth factor (VEGF) and its receptor in promoting an immunosuppressive tumor microenvironment. The combination of Eli Lilly's ramucirumab (Cyramza) and Merck's pembrolizumab (Keytruda) was safe and had provided a signal of efficacy in a phase I trial across tumor types, including lung cancer, that was led by Roy Herbst, MD, PhD, and colleagues.

The premise that ramucirumab as a VEGFR2 antibody could overcome immune modulation and restore benefit to anti-programmed death 1 (PD1) therapy, such as pembrolizumab, was the hypothesis of our phase II S1800A trial.

Given the promising results of this phase II trial, which showed improved overall survival with ramucirumab and pembrolizumab in the acquired resistance setting, with a hazard ratio of 0.69 (80% Cl: 0.51-0.92), we moved to bring the combination to a pragmatic phase ISSUE 46 | VOL 48 | DECEMBER 23, 2022 | THE CRNCER LETTER

III study as S2302 Pragmatica-Lung to confirm this result.

Although the protocol has not yet received ultimate approval, it is very close to final form. The condensed, simplified format requires minimal data reporting compared to a typical phase III trial:

- No tissue specimens
- No protocol-required laboratory tests
- No protocol-required disease assessments (no imaging requirements or use of RECIST)
- No reporting of other medications being taken (concomitant medications)
- No patient-reported outcome instruments to complete
- Very limited adverse event reporting
- No cycle-specific treatment reporting

The data collection requirements for the trial have been trimmed to the bare minimum, compared to those in a standard NCTN clinical trial, particularly relative to other trials with registrational intent. This includes reductions in the time points at which data must be submitted, the number of data forms to be submitted, and the number of data elements.

Eligibility criteria are extremely broad, to ensure the trial population represents the full population of patients with NS-CLC. They mimic the package inserts as closely as possible:

- Histologically or cytologically confirmed stage 4 or recurrent NSCLC
- Simple restrictions on prior therapy:

- Acquired resistance to prior immunotherapy
- Prior receipt of platinum-based chemotherapy
- Fewer clinical/laboratory criteria:
 - ► Age 18 or older
 - Zubrod Performance Status of 0-2 (most studies do not allow PS=2)
 - Ability to safely take the investigational drugs per FDA instructions and institutional guidelines

The control arm is non-restrictive, allowing physicians to use any accepted treatment for these disease conditions.

Although SWOG is the NCTN group coordinating the study, no large NCTN trial succeeds without extensive crossgroup collaboration, and S2302 Pragmatica-Lung is no exception. The trial is co-chaired by an Alliance investigator (Dr. Konstantin Dragnev, who also co-chaired the S1800A Lung-MAP substudy), and Dr. Wade lams is ECOG-ACRIN study champion.

Condensing requirements, protocol, and timeline

It took a massive effort from many groups to simplify the protocol and informed consent document while answering key questions and remaining compliant with good clinical practice and regulations. After discussions with the NCI, the SWOG operations team moved the purely administrative and instructional parts of the protocol to an appendix. This allowed reviewers from the NCI, FDA, and the Central Institutional Review Board (CIRB)—and will allow site reviewers—to focus on the scientific content and practical application of the study in the main document. Data collection will be done using the Medidata RAVE system, as is standard for all trials conducted within the NCTN. Using a subset of the standard SWOG trial forms, the study team modified the content to include only those data elements needed to address the study objectives. The information collected at baseline was reduced to only that needed to adequately describe the study population.

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The study's informed consent document is now 11 pages, written at a seventh-grade reading level. Lung cancer study consent forms are typically twice as long.

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While a patient is on treatment, sites' only regular submission requirement is vital status information and information on adverse events that are Grade 5 or that are Grade 3 or 4 if they are treatment-related, serious, and unexpected. To address the primary objective, if a patient dies, sites need to report only the date and primary cause of death.

In addition to limiting data collection and adverse event reporting, other regulatory components were also streamlined for Pragmatica-Lung, given the outcome and safety data already available on the two drugs. Most trials developed for a registration intent include significant monitoring with extensive verification of data, often performed on-site on a frequent basis. For S2302 Pragmatica-Lung, with its simplified pragmatic design, the NCTN's standard site auditing program will be used for review and verification of collected data in addition to SWOG's standard QA/QC methods for trial conduct. This approach will significantly lessen operational burdens on the sites participating in this clinical trial.

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S2302 Pragmatica-Lung should ease the burden on sites wishing to conduct clinical research in NSCLC. As we look to continually optimize the design of other pragmatic trials, we remain steadfast in improving outcomes for patients with lung cancer and ushering in new treatment paradigms.

The rigor of executing major trials in the modern era has increased in intensity to the point where we frequently require tissue submission, measurable disease, and collection of data on all adverse events, concomitant medications, and more.

While this may be appropriate for some trials, with this trial, we aim to reduce the burden associated with conducting a study and to answer the key clinical question of overall survival. A significant fraction of "standard" requirements have been intentionally removed from the protocol to make it more practical, which, in turn, allows it by design to open at more sites and reach more patients.

We anticipate opening the trial in mid-January, which is one of the quickest-ever NCTN activations. This took a tremendous amount of communication to integrate feedback from all stakeholders into the protocol and informed consent. The collective desire to reduce the burden on sites and reach more patients was a huge motivator.

The study's informed consent document is now 11 pages, written at a seventh-grade reading level. Lung cancer study consent forms are typically twice as long. The consent form for S1800A, the phase II study that led to S2302 Pragmatica-Lung, was 24 pages.

Many clinical sites, and clinical researchers as a whole, have struggled post-COVID. There have been multiple challenges for both academic and community sites. In an era of significant research staff turnover, as well as training and onboarding challenges, the simplicity of S2302 Pragmatica-Lung makes it the ideal NCTN trial for onboarding new staff.

Recruiting more diverse trial participants

The NCI has charged cancer centers with creating diversity, equity and inclusion (DEI) plans to enhance health equity. S2302 Pragmatica-Lung will improve access to clinical trials for patients with lung cancer while maintaining scientific rigor and clinical relevance and significance within the field. Whether the trial is positive or negative, the findings will have an impact.

Pragmatic trials by nature lend themselves to enrolling a representative population, but this study contains many extra elements to ensure vigorous recruitment and a participant sample that reflects the full diversity of the population of patients with advanced NSCLC—a more diverse patient population than we have historically seen on randomized phase III trials in lung cancer.

Enrollment goals by race, ethnicity, gender, and age categories are based on real-world national data from patients with NSCLC, as drawn from NCI's Surveillance, Epidemiology and End Results (SEER) program.

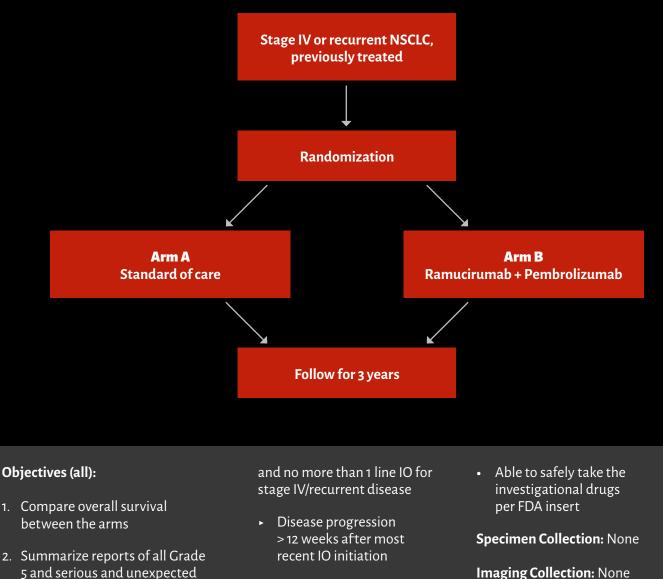
Incorporating both the NCTN and NCORP networks, S2302 Pragmatica-Lung will use validated data from geographical information systems and the U.S. Census Bureau for purposeful outreach to a diverse set of sites that serve a high percentage of patients from underrepresented groups. Site enrollment rates will be monitored monthly. SWOG Operations will communicate regularly with sites, providing start-up and accrual or additional support as needed.

We are developing a community engagement package for sites, that includes outreach strategies, advertising materials, a patient-friendly PowerPoint targeting underrepresented populations and evaluation tools. We aim to provide support to selected sites for local advertising and to host community engagement educational events in underserved communities. All patient education material will also be made available in Spanish.

SWOG's Lung Committee already has a dedicated DEI champion (Lucy Gansau-

S2302 PRAGMATICA—LUNG

A Prospective Randomized Study of Ramucirumab plus Pembrolizumab versus Standard of Care for Participants Previously Treated with Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer



- Best response of at least stable disease on IO for stage IV/recurrent
- Disease progression within 1 year if the only line of IO was for neoadjuvant/ adjuvant therapy

disease (if received)

Grade 3 or 4 treatment-

within each arm

Eligibility Criteria (all):

>18 years old

related adverse events (AEs)

Stage IV or recurrent NSCLC

At least 1 line of prior anti-PD1/

PDL1 therapy (IO), for any stage,

- Prior platinum-based chemo
- Zubrod Performance Status 0-2

Imaging Collection: None

Patient-Reported Outcomes Instruments: None

AE Reporting:

- Per package inserts
- For Medidata Rave, only serious AEs that meet the criteria for expedited reporting

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or visit: http://cancerletter. com/subscribe/ er) and a community engagement subcommittee (represented by Drs. Paul Hesketh and Dan Carrizosa) working with the group's patient advocate (Judy Johnson) and SWOG's community advocates, to direct community outreach.

SWOG also has a dedicated DEI monitoring committee that tracks the diversity of trial enrollment. These efforts are augmented by a custom training program in improving trial diversity that all SWOG leadership and study teams complete, and all of these efforts will be directed toward ensuring representative enrollment for S2302 Pragmatica-Lung.

Patient needs are paramount in S2302. In addition to disseminating patient education materials via advocacy organizations and social media outreach, targeted search result ads will direct visitors looking for a clinical trial in NS-CLC to CIRB-reviewed patient education content.

SWOG is also working to secure funding to help cover some of the costs of participation that patients face, such as travel costs for trial-related clinic visits. A recent report found that the average patient on a clinical trial travels 67 miles for each visit. At standard IRS-allowed mileage reimbursement rates, this comes out to about \$84 per clinic visit.

S2302 Pragmatica-Lung should ease the burden on sites wishing to conduct clinical research in NSCLC. As we look to continually optimize the design of other pragmatic trials, we remain steadfast in improving outcomes for patients with lung cancer and ushering in new treatment paradigms.

Following are *The Cancer Letter*'s recent stories on changes in the NCI's and FDA's approaches to the conduct of clinical trials.

• FDA's Singh and Rivera describe the "new normal"—and the future—in cancer pragmatic trials

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- FDA, NCI align to simplify clinical research, producing a model "pragmatic" registration trial in NSCLC
- Roy Herbst: I hope Pragmatica-Lung will become the norm
- Ellen Sigal: Pragmatica-Lung may be a model for other trials that are unnecessarily complex
- <u>A "new normal" for</u> <u>NCI-sponsored clinical</u> trials is long overdue
- <u>A brief report sets forth a</u> <u>"new normal," lets NCI start</u> <u>to streamline clinical trials</u>
- Bertagnolli sets out eight "core principles" for NCI: "We've got to be nimbler, faster"
- ODAC considers the first application based wholly on RWE methodology—and nixes it unanimously

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GUEST EDITORIAL

NCI's Cancer Prevention-Interception Targeted Agent Discovery (CAP-IT) Program, a milestone in cancer prevention research



Margie Clapper, PhD

Principal investigator, Fox Chase Cancer Center CAP-IT Award; Samuel M.V. Hamilton Endowed Chair in Cancer Prevention, Professor and co-leader, Cancer Prevention and Control Program, Fox Chase Cancer Center; Adjunct faculty, Lewis Katz School of Medicine, Temple University

Steady advancements in cancer treatments over the past century have led to significant improvements in the expected lifespan of cancer patients. However, to this day, cancer is very rarely cured.

For more than 50 years, NCI has invested heavily in elucidating the fundamental biology underlying the formation of tumors in order to reduce the burden of cancer across the population. This support has equipped the cancer research community with a rich understanding of the fine distinction between normal and neoplastic cell growth, and an armamentarium of robust "omics" approaches. Greater knowledge of the earliest events that precede the formation of invasive tumors is emerging and transforming the field of cancer prevention research, which is now well poised to capitalize on decades of investment. Excitingly, several cancer prevention trials in highrisk subjects are yielding very promising results.

Recognizing the vast need for rational preventive agent development, NCI recently established the new <u>Cancer Prevention-Interception Targeted Agent</u> <u>Discovery (CAP-IT)</u> Program. Fox Chase Cancer Center is one of two founding members of the CAP-IT Program, along with Weill-Cornell Medicine. This initiative represents a significant milestone in the history of cancer prevention research, as it is the first national consortium dedicated to the preclinical development of molecularly and immunologically targeted agents for precision cancer prevention and early interception in populations at high risk for cancer.

Importantly, this basic research initiative underscores the feasibility of not only preventing cancer by attenuating the detrimental effects of known extrinsic risk factors, but of also performing precision cancer "interception" by effectively targeting those biological processes known to be essential for the growth of precancerous lesions. The vision for establishing a formal and robust pipeline for the preclinical development of novel cancer preventive agents has been provided by Shizuko Sei, MD, director of the NCI CAP-IT Program, and her colleagues in the Division of Cancer Prevention, NCI. This initiative is deeply rooted in the pioneering work of many others in the field of prevention over decades.

Among these is the discovery of the preventive properties of tamoxifen and other Selective Estrogen Receptor Modulators (SERMS) by V. Craig Jordan, PhD, DSc, at the University of Leeds in the 1970s. This work provided the first definitive evidence of the feasibility of using therapeutic strategies to impact cancer development in high-risk subjects. Dramatic reductions in the incidence of breast cancer followed, paving the way for the repurposing of agents as cancer preventives.

The late Michael Sporn, MD, of NCI and later the Dartmouth Cancer Center, was unwavering in his commitment to establish chemoprevention—a term that he coined—as a discrete discipline within the broader field of cancer research at a time when his view of cancer as a chronic disease that could be impacted by early drug intervention was not widely accepted.

This concept gained momentum as natural and synthetic compounds were identified that were able to disrupt the initial phases of carcinogenesis and the transition of premalignant cells to invasive cancer. His early vision served as a strong foundation for the establishment of the NIH Chemodietary Study Section and has come to full fruition with the new NCI CAP-IT Program.

Importantly, the CAP-IT Program expands the cancer prevention field's focus beyond chemoprevention to include immunoprevention and emphasizes the discovery of vaccines and novel immunotherapeutics that can bolster the host immune system to enhance tumor immune surveillance.

This approach is firmly anchored in the Nobel Prize-winning discovery of the hepatitis B virus by Baruch Blumberg, MD, PhD, at Fox Chase and the neoplastic potential of HPV infection by Harald zur Hausen, MD, of Germany, both of which have broadly impacted global health.

Routine immunization of healthy subjects with cancer-preventive vaccines continues to lead to extraordinary reductions in the incidence of cervical and liver cancer, saving millions of lives worldwide.

The CAP-IT Program addresses the challenge of adapting these successes to populations at increased genetic risk for cancer by taking advantage of recent technological advances in harnessing the immune system. Exciting clinical research has begun with the study of cancer vaccines in individuals with heritable cancer syndromes, including those with Lynch syndrome.

Entering the field in the early 1990s, as one of the first basic research labs dedicated to the development of cancer-preventive agents and later as a founding member of the Chemodietary Study Section, I was inspired by the work of Sporn and others.

My research interests quickly evolved from an early focus on the use of detoxification enzyme inducers to confer protection from carcinogens and environmental exposures, to establishing biomarkers of cancer risk and developing novel strategies for therapeutic intervention, including targeted disruption of estrogen metabolism and inflammation-associated pathways.

My work, as well as the prevention field, continues to be driven by the insights of

Alfred Knudson, my close colleague and collaborator at Fox Chase, who, in the 1970s, established the "two-hit theory" of cancer development.

This theory first recognized that germline alleles inactivating potent tumor suppressors increase the likelihood of some forms of cancer by requiring only a single additional "hit" to initiate tumor growth.

In later work, Knudson, in collaboration with Fox Chase investigators and the NCI, demonstrated that mutant tumor suppressor genes in a heterozygous state can alter the expression profile of phenotypically normal epithelial cells in a gene-specific manner.

These findings suggest that detectable effects of "one-hit" represent early molecular changes in tumorigenesis that may serve as novel targets for preventive intervention. The field is now wellequipped to identify and validate these targets for cancer prevention/interception in an unprecedented way.

For three decades, my colleagues in the Department of Clinical Genetics at Fox Chase have been intently focused on providing genetic counseling, cancer surveillance, and optimal care to cancer prone families, with over 15,000 highrisk individuals now enrolled in the Fox Chase Risk Assessment Program.

Cancer prevention and interception are key goals of this program. For many, prophylactic risk-reducing surgery remains the best option; a drastic approach that is often associated with life-altering side effects.

While this option is not feasible for patients with Lynch syndrome who are predisposed to colon cancer, high-dose aspirin is emerging as an efficacious preventive regimen. However, the risk of gastrointestinal bleeding sometimes outweighs the known benefit. Thus, a critical need exists to identify non-toxic, targeted agents and vaccines that can reduce cancer risk.

As a basic prevention researcher, the thought of potentially providing this large cohort of primarily younger men and women with an efficacious regimen to attenuate their high chance of developing cancer has always been extraordinarily motivating. With support from the NCI, this goal now moves a step closer to becoming a reality.

The focus of the new NCI CAP-IT Program on cancer interception, as well as prevention, reflects its ultimate goal of intervening very early in the carcinogenesis process to inhibit tumor development and/or the progression of precursor lesions to invasive cancers. Interception is essential in high-risk individuals who have already inherited a genetic predisposition—the population being targeted by the CAP-IT Program.

The number of individuals known to carry germline mutations that confer increased susceptibility to cancer, approximately 5-10%, is expected to rise in the future, as additional genetic variants of functional significance emerge from the application of state-of-the-art genomic technologies.

The NCI CAP-IT Program provides a long-awaited infrastructure to support the rational development of preventive agents and vaccines, from *in silico* drug design to *in vivo* testing.

Omics technologies will be employed to elucidate the complex cellular interactions required to support the growth of precancerous lesions, and provide fuel for the systematic identification and validation of critical molecular targets for interception, as well as potential biomarkers of cancer risk. These studies will benefit greatly from discoveries that emerge from other NCI initiatives, including the Precancer Atlas project. The bar for approval of cancer preventives has always been much higher than for chemotherapeutics, as agents will most likely need to be taken by asymptomatic individuals for decades.

The NCI CAP-IT's systematic approach of "checks and balances" is expected to increase the chances for success by proactively circumventing some of the speed bumps encountered in past decades that derailed the development of initially promising cancer preventive drugs (e.g., cyclooxygenase 2 inhibitors).

Agents and vaccines will be characterized comprehensively, and only those with advantageous profiles will enter in vivo efficacy testing in the PREVENT component of the NCI drug discovery pipeline, of which Fox Chase has been a Prime Contractor for more than two decades.

I anticipate that discoveries from the CAP-IT Program will accelerate the translation of novel cancer preventive and interceptive agents from the "bench to the bedside" and impact the high cancer risk faced by asymptomatic individuals with heritable cancer syndromes.

Furthermore, since many of these predisposing genes are also somatically mutated in sporadic disease, it seems plausible that the novel preventive/interceptive regimens developed under the CAP-IT Program may also be effective in inhibiting sporadic cancers in the general population.

Half a century after the introduction of chemoprevention, the field is now better poised than ever to meet these challenges and prevail.

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Top 25 stories of 2022

By Alexandria Carolan and Katie Goldberg

2022 was the year to try to return to normal or at least an approximation thereof.

The oncology field rallied back from isolation imposed by COVID-19, returning to in-person events. #MyFirstASCO, an initiative of the Cancer History Project, showed how much in-person events mean to us, documenting the experiences of people who have been attending the annual meeting of the American Society of Clinical Oncology as early as 1965 (*The Cancer Letter*, June 3, 2022).

Our reactions to historic calamities revealed who we are. As bombs fell on Ukraine, international groups worked together to help cancer patients, doctors, and refugees in that country (*The Cancer Letter*, <u>March 4</u>, 2022).

When the Supreme Court overturned Roe v. Wade in June, oncologists told *The Cancer Letter* about the dangers the decision posed (*The Cancer Letter*, July 1, 2022).

There were many firsts. President Biden's appointee Monica Bertagnolli became the first woman and the first cooperative group chair to run NCI (*The Cancer Letter*, <u>April 4</u>, July 21, 2022).

Some stories are mainstays at *The Cancer Letter*, among them award-winning investigations, practice-shaping editorials, the yearly reading issue—and, of course, the occasional scandal.

Other stories take us by surprise: The second most-read story of the year is a brief historical article about Betty Ford and a 1974 NCI press conference that erupted with tabloid coverage after her mastectomy (*The Cancer Letter*, June 25, 2021). The Emmy-nominated series <u>The First Lady</u> is the most likely reason this story climbed to the top of the list.

As we ring in the New Year, we invite you to revisit some of our most-read stories of 2022. This top-25 list is compiled based on *The Cancer Letter*'s web analytics:

14

1

Wake Forest's entire EAB resigns in protest as director Boris Pasche is fired



All 15 members of the External Advisory Board of the Wake Forest Baptist Comprehensive Cancer Center resigned, stating that they are also withdrawing their "endorsement for submission of the competitive renewal of the Cancer Center Support Grant."

The Feb. 18 letter of resignation was signed by the EAB Chair Gerold Bepler, president of the Barbara Ann Karmanos Cancer Institute, on his own behalf and on behalf of all members of the committee.

The letter of resignation, which was obtained by *The Cancer Letter*, states that during the competitive renewal process, Wake Forest leadership gave an endorsement of the center's director Boris Pasche.

Read more

2

Betty Ford and the press conference that changed oncology



An NCI press conference is rarely a tabloid affair—except on Sept. 30, 1974. What was anticipated to be a dry occasion shifted when Betty Ford, wife of President Gerald Ford, underwent a radical mastectomy Sept. 28.

The Cancer Letter was there: "Breast Cancer Report To The Profession Suddenly Is a Report To The Nation; Treatment Progress Noted," was the Oct. 7, 1974 issue's lead story.

Nathaniel Berlin, then director of NCI's Division of Biology & Diagnosis and chairman of the Breast Cancer Task Force, had been concerned the breast cancer report would receive limited public attention. Instead, he got a media circus—leading to fears of publishing the findings prematurely.

Read more

3

Did Vinay Prasad need to mention the Nazis to make a point on the U.S. pandemic response?



Vinay Prasad might well have made his contrarian points without invoking the specter of the Third Reich. He didn't have to go there—but he did. Voluntarily.

Prasad, an oncologist and associate professor in the Department of Epidemiology and Biostatistics at UCSF, likes a good Twitter fight. He has incited brawls over FDA's accelerated approval of cancer drugs, efficacy of checkpoint inhibitors, usefulness of next-gen sequencing, and—in recent months—the restrictions aimed at curbing the spread of COVID-19.

In an Oct. 2 Substack <u>blog post</u>, Prasad argues that public health measures may have laid the groundwork for the onset of fascism in the U.S.

The comparison set off a deluge of Twitter controversy, including accusations of anti-Semitism and ignorance of the circumstances that led to the rise of German fascism.

Read more

4

Prominent GI oncologist Axel Grothey was forced out of Mayo Clinic for unethical sexual relationships with women he mentored



The aftermath of sexual misconduct at premier medical institutions rarely leaves visible traces: HR is brought in, confidentiality invoked, deals made. The case of Axel Grothey's exit from Mayo Clinic is a notable exception.

Last year, the prominent gastrointestinal oncologist was reprimanded by medical licensure boards in three states for engaging in unethical sexual relationships with an oncology fellow and a faculty colleague at Mayo Clinic Rochester, his longtime place of employment.

Three reprimands notwithstanding, Grothey has kept his appointment as co-chair of the NCI National Clinical Trials Network's Gastrointestinal Steering Committee, an influential group that reviews ideas for clinical trials and helps determine the priorities in federally funded clinical research in GI oncology. **Editor's note:** Additional articles in this award-winning series are available <u>here</u>.

5

UChicago oncologist settles SEC charges, pleads not guilty to criminal insider trading



In the morning of Nov. 10, 2020, Daniel V.T. Catenacci, director of the GI oncology program at the University of Chicago, did some trading, court documents say.

Catenacci bought 8,743 shares of Five Prime Therapeutics Inc., knowing that the company was about to release positive results from a phase II study of bemarituzumab, a monoclonal antibody for gastric cancer, civil and criminal complaints say.

A day later, Catenacci, who was the lead clinical investigator on the study, sold those shares for a profit of more than \$134,000, court documents say.

Read more

6

Monica Bertagnolli, first woman and first clinical trials group chair to direct the National Cancer Institute



Monica M. Bertagnolli, a professor of surgery at Harvard Medical School, stands poised to become the first woman and the first chair of a clinical trials cooperative group to be named director of the National Cancer Institute.

President Joe Biden is expected to name Bertagnolli, who is now chief of the Division of Surgical Oncology at Brigham and Women's Hospital and Dana-Farber Cancer Institute, to the position of institute director.

The rollout of Bertagnolli's appointment didn't go smoothly, as news leaked out on Twitter and in the press, first appearing in STAT, in the morning of July 21, shortly after the White House announced that the president had contracted COVID-19.

Bertagnolli, 63, will be the <u>16th</u> NCI director since the institute's founding in 1937 and the tenth since the National Cancer Act elevated the job to the status of a presidential appointment. The NCI director is presidentially appointed but is not subject to approval by the Senate.

Read more



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 <u>tweeted</u> 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

8

"This is not about protecting life": Supreme Court overturn of Roe v. Wade threatens lives of cancer patients, doctors



When Jill Hawkins realized that she was six weeks pregnant this March, her oncologist gave her two options.

One was to continue with the pregnancy and switch to interferon, a treatment that would be safer for the fetus, but more toxic to her. Alternatively, she could get an abortion.

Hawkins was diagnosed with chronic myeloid leukemia in August 2021 and

was taking the drug Bosulif (bosutinib), a tyrosine kinase inhibitor not recommended for use during any part of pregnancy.

"At the end of the day, for me, I can handle the risk to me, or the birth defect. I don't think I can handle both. I don't think I can handle the uncertainty and the fear around all of it. I need to feel good about one thing. In this situation, I didn't feel good about any of it," Hawkins, a clinical social worker and therapist based in New York City, said to *The Cancer Letter.* "It's not a good idea for my health. Do I want to let go of this pregnancy and be sad and grieve, or do I want to keep it and feel anxious and fearful of losing my life?"

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Related:

- Oncology and healthcare groups respond to the end of Roe v. Wade (The Cancer Letter, July 1, 2022)
- Virginia gynecologic oncologists:
 "Pro-life" is not pro-life at all (The Cancer Letter, July 1, 2022)
- Cancer care must remain in the hands of doctors and their patients (The Cancer Letter, July 1, 2022)
- Harvard Law's I. Glenn Cohen: To provide good care, doctors will run afoul of criminal law in some states as Roe v. Wade ends (The Cancer Letter, July 1, 2022)
- Cancer patients and their families will feel the impact of SCOTUS abortion ruling (The Cancer Letter, July 1, 2022)

9

Ned Sharpless steps down as NCI director



After nearly five years in the federal government—at both NCI and FDA— Ned Sharpless is stepping down from his position as NCI director.

"I feel like it's a good time from a government calendar point of view to step aside and let someone else help lead the president's new initiatives in this area," Sharpless said to *The Cancer Letter.* "And I feel like it's a good time for me personally, so it just felt like the right time."

Sharpless was sworn in as the 15th director of NCI on Oct. 17, 2017, before becoming acting FDA commissioner for seven months in 2019. Prior to coming to NCI, he was director of UNC Lineberger Comprehensive Cancer Center for four years (*The Cancer Letter*, June 16, 2017).

Sharpless is one of two directors to have served as NCI director and head of FDA, and the only one to resume NCI directorship after leaving FDA (*The Cancer Letter*, Dec. 6, 2019; Nov. 8, 2019).

Read more

10

As bombs fall, international efforts are ramping up to help Ukraine's cancer patients, doctors, and refugees



On March 2, a bus filled with Ukrainian children was getting ready to leave Odesa for the border of Moldova, Ukraine's closest neighbor.

As the port city on the Black Sea braced for an onslaught from Russian tanks and artillery, St. Jude Children's Research Hospital was working with allies on the ground to secure transportation and evacuate children with cancer. The kids were ready to go.

Then bombs rained down on Odesa.

"They could not move," Carlos Rodriguez-Galindo, director of St. Jude Global, chair of the Department of Global Pediatric Medicine, and executive vice president at St. Jude Children's Research Hospital, said to *The Cancer Letter*.

"These kids will probably never be able to get out of Odesa."

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Related:

- Three weeks in Mariupol; How Dr. Hanych kept his cancer patients alive amid Russia's attack (The Cancer Letter, <u>Aug. 5</u>, 2022)
- To help Ukraine's cancer patients, a coalition of U.S., European cancer groups aims to provide a coordinated response (The Cancer Letter, March, 11, 2022)

11

The unKOOL, unfiltered history of menthol cigarettes



Quick, what color is menthol?

No, it's not green. That's the color of the KOOL, Newport, or Salem cigarette pack. Get it? Green is cool. Red is hot.

Menthol, a component of peppermint oil, is a colorless topical pain reliever like Novocain that the dentist uses to numb a tooth.

The idea of adding menthol to reduce smoking's harshness on the throat came to Lloyd "Spud" Hughes in the 1920s, after he'd stored his cigarettes in an old tin of menthol crystals that his mother insisted that he inhale for his asthma. He patented the process in 1924, and three years later, the Axton-Fisher Tobacco Company acquired the patent and began manufacturing "Spud Menthol Cooled Cigarettes."

Today, as the Biden administration targets mentholated cigarettes, it behooves us to review the history of the tobacco industry's marketing campaigns that target Black Americans.

Read more

12

Chernobyl: a 35 year follow up on longterm health effects



In the early morning of April 30, 35 years ago, I was awakened by a call from Anatoly Dobrynin, a long-time Soviet Ambassador to the United States.

He said General Secretary Mikhail Gorbachev wanted me to come to the Soviet Union to help treat victims of the Chernobyl nuclear power facility accident. I had cabled Gorbachev a few days earlier, offering my assistance.

Read more

13

What are you reading in 2022?



Is 2022 the year of thrillers? Statistics? Thrillers about statistics?

For the third year in a row, *The Cancer Letter* has asked a diverse panel of clinicians, basic scientists, early-career faculty, and regulators to tell us what they are reading.

Read more

14

#MyFirstASCO: Memories from 57 years of annual meetings



The ASCO annual meeting began in 1964 as a group of 51 physicians finalizing the bylaws of the organization and has since turned into a much-anticipated global event that brings together 35,000 to 40,000 people across all areas of oncology.

"Big trees begin as tiny acorns," said John Laszlo, an early childhood leukemia researcher, professor emeritus at Duke University Medical Center, and a retired national vice president for research at the American Cancer Society.

Laszlo attended one of the first ASCO annual meetings in the 1960s. The first scientific meeting was in 1965, and according to <u>ASCO Connection</u>, that gathering included a 1.5 hour-long program with three presentations on leukemia and multiple myeloma.

"No one predicted that a small group of oncologists could spark a movement the size of the current membership of ASCO," Laszlo said.

The Cancer History Project asked people who have played a role in oncology—fellows, cancer center directors, lawyers, pharmaceutical executives, CEOs, past ASCO presidents, and one journalist—to share their memories from their first ever annual meeting experience.

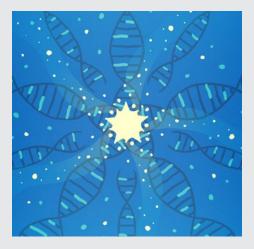
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Related:

• ASCO annual meetings through the years: A timeline of *The Cancer Letter's* coverage (*The Cancer Letter*, <u>June 3</u>, 2022)

15

All colorectal cancer patients require germline testing at diagnosis and somatic testing at advanced disease diagnosis



Technological advances are transforming our understanding of cancer, accelerating the evolution of new treatment approaches. In the past decades, researchers deploying new techniques for analyzing DNA have extended our knowledge of inherited genetic abnormalities that can predispose a person to develop colorectal and other cancers.

Those insights have led to specific strategies to manage and minimize risk for affected individuals and their family members. Today, these insights permit us to decipher the heterogeneity of colorectal and other cancers based upon the identification of the genetic abnormalities that drive the development and progression of an individual patient's cancer.

<u>Read more</u>

16

Wafik El-Deiry: Cancer research beset by a Gordian Knot of problems



It's been a hot summer all over the world, but our work doesn't stop as our problems need solutions.

There's a war in <u>Ukraine</u>, we are continuing this summer to work with colleagues in the U.S. from Ukraine to help Ukrainian physicians and scientists find opportunities, and we're emerging out of a COVID pandemic that may always be with us, according to some sources.

Academic oncology forges ahead with numerous challenges, but a new day lies ahead.

There are champions for the importance of cancer research and care in the White House in President Joe Biden and First Lady Dr. Jill Biden, a respected new leader Dr. Monica Bertagnolli on the way to direct the NCI, a re-energized ACS with Dr. Karen Knudsen, important cancer research and advocacy initiatives by AACR through amazing leadership by Drs. Margaret Foti, David Tuveson, Lisa Coussens, Phil Greenberg, and others, and ASCO's role in education, invigorating the oncology workforce, and bringing forward practice-changing advances.

I'll get right to the point, as what I'm going to say won't surprise many, but the problems just aren't going away. This makes me ask whether the problems are bigger than all of us combined?

Read more



Biden's FY23 proposal cuts NCI funds by \$199M, while boosting ARPA-H by \$4B



In a move that appears to prioritize biomedical engineering over cancer research, President Joe Biden's proposal for fiscal year 2023 cuts NCI funding by \$199 million, a 2.9% cut from the current year's level.

At the same time, the White House proposes adding \$4 billion to the Advanced Research Projects Agency for Health (ARPA-H), Biden's agency for high-risk, high-reward biomedical research which he touts as a key element of his goal to "end cancer as we know it."

This boost in funding for ARPA-H would create a tradeoff, potentially

jeopardizing progress within NIH and its institutes, said Ellie Dehoney, vice president of policy and advocacy at Research!America.

Read more

18

Flatiron CEO Carolyn Starrett: We're reimagining the infrastructure of cancer care, and we're going global



As real-world evidence becomes ever more essential, a cancer health technology company that played a key role in modernizing 21st-century health data is capitalizing on its accomplishments in the U.S.—and moving into international markets to meet the growing demand for actionable data.

Founded in 2012, Flatiron Health, now in its 10th year, is entering the third phase of its evolution as a pioneer of real-world data and machine learning applications in cancer informatics.

Carolyn Starrett, a long-time business operations and strategic development executive at the company, was named CEO in April 2021, after Flatiron co-founders Nat Turner and Zach Weinberg stepped down from management.

"We had our startup phase and days early on. We then had an acquisition and a period of learning what it meant to exist post-acquisition," Starrett said to *The Cancer Letter.* "Now, we're internally talking about Flatiron 3.0. And I think 3.0 is an opportunity to really think about how we further advance and realize the mission that we set out to achieve 10 years ago."

Read more

19

John Mark Cleland, first man to be cured of metastatic testicular cancer, dies at 71



John Mark Cleland died peacefully on Feb. 7, 2022, in Indianapolis.

Some people reading this headline will have little or no idea who John Cleland was. However, if you are a medical or urological oncologist, you should. John Cleland was the first man whose metastatic testicular cancer was cured with combination chemotherapy containing cisplatin. His survival, 47 years ago, which occurred soon after the breakthrough reports of impressive cure rates of certain leukemias and Hodgkins and non-Hodgkins lymphomas, ushered in an age of great excitement in the treatment of cancer.

Read more



Gynecology's deadly surprise: Cancers are frequently missed prior to routine procedures



As they reach for surgical tools, gynecologists vastly underestimate the probability that their patients have undiagnosed uterine cancers, a study by Yale University researchers found.

Their paper, published in *Obstetrics & Gynecology* last month, is immediately relevant in the clinic, because a suspicion that cancer may be present dictates the choice of surgical techniques employed in gynecological procedures that are performed in about 650,000 women every year in the U.S.

Read more

Northwell's Barakat on the omicron wave: Hospitalizations spike, but not as many need ICU



After having treated over 200,000 COVID cases over two years—more than any health system in the U.S.— Northwell Health once again finds itself in the center of the storm as cases of the omicron variant escalate in New York State.

How does omicron differ from previous variants? How has preparation for its onslaught been informed by the past two years of the pandemic? How will cancer services be affected? *The Cancer Letter* posed these questions to Richard Barakat, physician-in-chief and director of Northwell Health Cancer Institute and the Edward and Carol Miller Distinguished Chair in Cancer.

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22

Robert Stone: How City of Hope will go national through acquisition of Cancer Treatment Centers of America



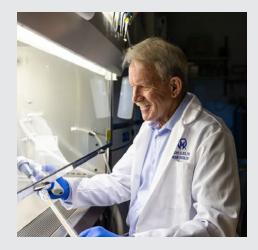
The acquisition of Cancer Treatment Centers of America will allow City of Hope to build a national network of cancer centers that is fundamentally different from those of other cancer centers.

"This will create a one-of-a-kind national cancer-focused system. I'm not aware of anybody else doing that," Robert Stone, president and CEO of City of Hope, said to The Cancer Letter.

The two organizations are very different. City of Hope is an NCI-designated comprehensive cancer center based in Southern California and has founded a subsidiary, AccessHope, to provide remote cancer expertise to employers and their health care affiliates. CTCA has been a for-profit, family-owned business that operates cancer centers in Chicago, Atlanta, and Phoenix.

23

Moffitt's Robert Gillies, "father of radiomics," dies at 69



Moffitt Cancer Center and the global research community have lost a great leader, scientist, and collaborator. Dr. Robert J. Gillies died June 7 after an extended illness. His recruitment in 2008, and the contributions to science he made over the ensuing 14 years, elevated Moffitt's scientific stature. He was 69.

"It is indeed rare for a single investigator to have major impacts on such a broad swath of disciplines. Bob did just that, where he was the Father of Radiomics, a leader in cancer metabolism and evolution, and an innovator in drug development and radiopharmaceuticals. He was indeed a jack-of-all-cancer-trades, and we are unlikely to find his like again. We were blessed by his presence and are inspired by his legacy," said Moffitt Center Director Dr. John Cleveland.

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24

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

25

White House's Danielle Carnival: I'm moving the Cancer Moonshot forward with an all-ofgovernment approach



Changes at Mission Control notwithstanding, the new Cancer Moonshot is ready for liftoff, says Danielle Carnival, coordinator of the White House cancer initiative.

"I hope that you and your readers are comforted and reassured as to where the president's priorities are," said Carnival, senior advisor to the director of the White House Office of Science and Technology Policy. "And with new leadership to come, I know that they will pick right up and continue to move that forward." Carnival spoke with *The Cancer Letter* Feb. 15, one day before President Joe Biden <u>appointed</u> Alondra Nelson and Francis Collins to step in as leaders of the White House science agenda, replacing Eric Lander, who stepped down after findings that he mistreated his staff members.

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By Alexandria Carolan and Katie Goldberg

The Cancer History Project preserves legacies, stories, and transcripts.

n 2022 the Cancer History Project:

- Published <u>interviews</u> with survivors of cancer to record what it was like to be diagnosed with cancer in the 1960s, 1990s, and the 2010s,
- Collected oral histories, including never-before-published interview transcripts with <u>Donald Pinkel</u>, <u>James and Jimmie</u> Holland, and Lucius Sinks,
- Published <u>foundational texts</u> in oncology, collated <u>edu-</u> <u>cational resources</u>, and
- Hosted a series of panels on oncology's most pressing issues.

The Cancer History Project is making these stories even more accessible with the <u>Cancer History Project podcast</u>—available anywhere you listen to podcasts—an ongoing <u>panel series</u>, and continuing opportunities for experts to lead as <u>guest editors</u>.

The Cancer History Project Podcast

On Feb. 11, the Cancer History Project published its first podcast episode, a conversation with Harold Freeman the father of patient navigation.

This <u>episode</u>, now the podcast's top episode of the year, opens with Freeman's emotional recollection of his early days as a physician:

I'm ready to cut cancer out of Harlem. I'm ready to do it. I'm skilled. I know how to cut cancer out. I want to cut it out of Harlem.

I can't do that. I can't cut it out. It won't yield. It won't yield to the surgeon's knife. Cancer wouldn't yield. So now I'm frustrated. I said, "I got all this skill. I can cut this thing out."

But then I get to the reality, I can't cut it out.

Why? Because the people were coming in too late with cancer for me to be able to cut it out.

Now with 787 minutes of new content on the history of oncology, the Cancer History Project podcast is ranked in the top 25% most followed podcasts and the top 30% most shared globally, according to Spotify wrapped.

Recent episode highlights:

- <u>Craig Jordan on discovering</u> tamoxifen's role in breast cancer and a lifetime of innovation
- <u>Robin Scheffler on viral on-</u> cology's complicated path
- Dwight Tosh, the 17th patient at St. Jude, on surviving lymphoma in 1962
- <u>Susan Love: Breast can-</u> cer activism in the 1990s



Contributors

The Cancer History Project, with its 56 institutional contributors who are dedicated to preserving oncology's history, continues to be a valuable resource.

The most prolific contributors of 2022 have published oral histories, profiles, videos, podcasts, and obituaries as part of this continued project. If you would like your institution to become a contributor of the Cancer History Project, contact <u>admin@cancerhisto-</u> <u>ryproject.com</u>.

Interested in learning more and following this project?

Sign up here to hear from us about the latest articles and events, as well as editorial, advertising, and sponsorship opportunities.

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Top 25 most-read articles in 2022:



Remembering Jane Cooke Wright, a Black woman, who was among seven founders of ASCO

By Edith P. Mitchell, MD | Feb. 19, 2021



Edith Mitchell: It is a great privilege and honor to have the opportunity to represent the National Medical Association in this tribute to Dr. Jane Cooke Wright. I first met Dr. Wright during an ASCO meeting and maintained subsequent contact. She is affectionately known in the cancer research community as the Mother of Chemotherapy. She is not only known as the Mother of Chemotherapy, but Dr. Wright is listed in the Women Pioneers of Medical Research and among the top Medical Researchers.

As a researcher, physician, administrator, teacher, mentor, educator, her many discoveries have brought continued health into the lives of millions of people. Across the board, doctors and research scientists dedicated themselves to find cures and treatment for some of the most severe and significant diseases that have challenged mankind for many ages.

Read more

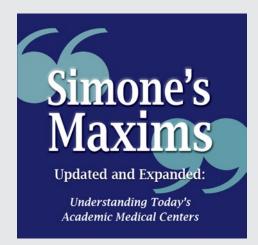
Related:

• Jane Cooke Wright: Personal photographs, Feb. 19, 2021

2

Book: Simone's Maxims: Understanding Today's Academic Medical Centers

By Joseph V. Simone, made available through his estate | Jan. 29, 2021



Joseph V. Simone, a visionary physician-scientist and writer of guidelines and maxims, died on Jan. 21. He was 85.

To celebrate Joe's life, his family is allowing *The Cancer Letter* and the Cancer History Project to make Simone's Maxims available in electronic form. The book continues to be available in paperback from Editorial Rx Press.

"Simone's Maxims" is a book so fundamental to academic oncology that we don't know when we are stealing Joe's lines.

Read more

3

Video: Padmanee Sharma on coming to America and falling in love with science

By Jim Allison: Breakthrough | April 1, 2021



Dr. Padmanee Sharma discusses her childhood, immigration to the United States, and how she found her path into science.

Archival footage from filming <u>Jim Allison: Breakthrough</u>.

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4

Panel: Black History Month panel: "We need to talk about justice"

By Cancer History Project | Feb. 25, 2022



A panel convened by the Cancer History Project for Black History Month started with a discussion of mentorship, and concluded with a big underlying concept—justice.

The panel, which met Feb. 23 at 7 p.m., included:

Robert A. Winn, MD Guest editor, Cancer History Project; Director and Lipman Chair in Oncology, VCU Massey Cancer Center; Senior associate dean for cancer innovation and professor of pulmonary disease and critical care medicine, VCU School of Medicine

Otis W. Brawley, MD Co-editor, Cancer History Project; Bloomberg Distinguished Professor of Oncology and Epidemiology, Johns Hopkins University

• Edith P. Mitchell, MD

Member, President's Cancer Panel; Clinical professor of medicine and medical oncology, Department of Medical Oncology; Director, Center to Eliminate Cancer Disparities; Associate director, diversity affairs; Sidney Kimmel Cancer Center at Jefferson, Thomas Jefferson University

John H. Stewart, MD, MBA

Professor of surgery, Section of Surgical Oncology; Founding director, LSU Health/ LCMC Health Cancer Center

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Lucius Sinks: 2013-2015 interview transcripts

By Tim Wendel | June 10, 2022



The following interview notes were created by Tim Wendel, lecturer at Johns Hopkins University, in the process of writing his book, "Cancer Crossings: A Brother, His Doctors, and the Quest for a Cure to Childhood Leukemia." Wendel is a member of the Cancer History Project editorial board. Wendel's brother sought treatment for acute lymphoblastic leukemia at <u>Ros-</u> well Park Comprehensive Cancer Center in the late 1960s and early 1970s. Sinks was his doctor.

Wendel conducted several interviews with members of the ALGB, or Acute Leukemia Group B, including Donald Pinkel, James and Jimmie Holland, Jerry Yates, James Holland, Emil "Tom" Frei, and Emil J. Freireich. Considered "cancer cowboys" of the time, this group of doctors sought to treat and cure childhood leukemia, which Wendel's brother died of in 1973, at a time when the survival rate was about 10%.

Read more

6

Remembering the "Murderers' Row" at Fox Chase's Institute for Cancer Research

By Jonathan Chernoff, MD, PhD | May 20, 2022



The Institute for Cancer Research (ICR) was and is a hotbed for basic and translational discovery. Initially a standalone institute, the ICR is currently the main science engine for the Fox Chase Cancer Center.

Despite its modest size and budget, ICR, which thrives on small-scale, old-school science in the best sense of those terms, has historically punched well above its weight. This is due largely to its ability to attract top talent. Starting in the late 1960s, Tim Talbot, the longtime scientific director, had the wit and the means to assemble a veritable "Murderers' Row" of cutting-edge cancer researchers that set the tone for the ICR for decades to come.

What he offered these scientists wasn't so much better money, more modern equipment, or roomier space, though he did offer some of that. No, the real draw was the chance for these advanced thinkers to realize their dreams, unfettered by other institutional responsibilities, and to work alongside an absolutely stellar group of creative people who, over time, have had an outsized impact on our understanding of the genetic and cellular bases of tumorigenesis.

Read more

Related:

• Photo archive: Fox Chase Cancer Center's "Murderers' Row", by Fox Chase Cancer Center, May 20, 2022

7

Podcast: Edith Mitchell on her path from Tennessee farm to becoming a cancer doctor and brigadier general

By Cancer History Project | Feb. 18, 2022



Edith Mitchell came a long way from growing up on a Tennessee farm, to becoming a brigadier general and serving on the President's Cancer Panel.

"It was making a plan, having a plan, and all of us had similar type plans that we needed to leave the farm—yes I grew up on a farm—and get out of town," Mitchell, member of the President's Cancer Panel, clinical professor of medicine and medical oncology, director of the Center to Eliminate Cancer Disparities, and associate director of diversity affairs at Sidney Kimmel Cancer Center at Jefferson, Thomas Jefferson University. "Yes, you have success, but look back and pull somebody behind you, pull them up."

Mitchell spoke with Robert Winn, director of VCU Massey Cancer Center, and John Stewart, founding director of LSU Health/LCMC Health Cancer Center.

Read more



Coal Miner's Son: Dr. Dennis Slamon

By UCLA Jonsson Comprehensive Cancer Center | Feb. 17, 2021



It is roughly 2,500 miles from New Castle, Pennsylvania, to Los Angeles, California, but distance alone doesn't define how far the two communities are apart. New Castle is a mill town that was known as the tinplate capital of the world in the early 1900s. L.A. is ... L.A. Yet, UCLA's Dennis J. Slamon, MD (FEL '82), PhD, the 2019 recipient of the Lasker-DeBakey Clinical Medical Research Award—widely regarded as America's top biomedical research honor-really hasn't strayed far from his roots. His father, uncle, and grandfather all were coal miners in West Virginia before Dr. Slamon's parents moved to New Castle, where Dr. Slamon was born. Dr. Slamon choose to mine a different vein: data.

It is his belief in data and a dogged perseverance that led Dr. Slamon, professor and chief of hematology/oncology at the David Geffen School of Medicine at UCLA, to the groundbreaking development of the breast cancer drug Herceptin, a lifesaving monoclonal antibody for women with HER2-positive breast cancer, a particularly aggressive form of the disease. Monoclonal antibodies are proteins created in a lab that, when injected into humans, bind to and destroy specific invader organisms like cancer cells. He shares the award with H. Michael Shepard, PhD, an American cancer researcher then working at the biotechnology company Genentech, and Axel Ullrich, PhD, a German cancer researcher also formerly of Genentech and now at the Max Planck Institute of Biochemistry outside of Munich, Germany.

Read more



Podcast: Harold Freeman, father of patient navigation, on cutting the cancer out of Harlem

By Cancer History Project | Feb. 11, 2022



Harold Freeman had big plans after he finished his residency at Memorial Sloan Kettering Cancer Center in 1968. He planned to cut cancer out of Harlem.

"I'm ready to do it. I'm skilled. I know how to cut cancer out. I want to cut it out of Harlem. I can't do that. I can't cut it out. It won't yield. It won't yield to the surgeon's knife. It won't yield to what we call the Bard-Parker, which was the name of the surgeon's knife. Cancer wouldn't yield," Freeman said to *The Cancer Letter* in an interview with Robert A. Winn, director of VCU Massey Cancer Center, and John Stewart, founding director of LSU Health/LCMC Health Cancer Center. "Then I get to the reality, I can't cut it out. Why? Because the people were coming in too late with cancer for me to be able to cut it out."

Freeman made his career out of asking why it was that his patients, who were poor and Black, sought treatment too late. As president of the American Cancer Society in 1988-89, he published a study, "Cancer in the socioeconomically disadvantaged," and made an unprecedented conclusion—"that the principal reason that Black people were dying from cancer was because they were poor."

Read more

10

Panel: Odunsi, Pisters, Platanias, and Ulrich: How immigrating to the U.S. shaped their perspectives on oncology

By Cancer History Project | April 22, 2022



In a panel discussion this week, four cancer centers directors described how their experiences as immigrants have shaped their approach to oncology and the U.S. healthcare system. The "International perspectives in U.S. cancer center leadership" panel, hosted by the Cancer History Project April 20, included:

- Narjust Duma, MD, moderator Associate director, The Cancer Care Equity Program, Thoracic oncologist, Lowe Center For Thoracic Oncology, Dana-Farber Cancer Institute, Assistant professor of medicine at Harvard Medical School,
- Kunle Odunsi, MD, PhD,
 Director, University of Chicago Medicine Comprehensive
 Cancer Center,
 Dean for oncology, University of Chicago Biological Sciences Division,
 AbbVie Foundation Distinguished Service Professor of
 Obstetrics & Gynecology,
- Peter WT Pisters, MD, President, MD Anderson Cancer Center,
- Leonidas Platanias, MD, PhD, Director, Robert H. Lurie Comprehensive Cancer Center of Northwestern University Jesse, Sara, Andrew, Abigail, Benjamin and Elizabeth Lurie Professor of Oncology, Departments of Medicine and Biochemistry and Molecular Genetics,
- Cornelia Ulrich, PhD, MS, Executive director, Comprehensive Cancer Center at Huntsman Cancer Institute, Jon M. and Karen Huntsman Presidential Professor in Cancer Research, Professor, Department of Population Health Sciences, University of Utah.

Read more

11

Sarah Cannon: The Name & The Story

By Sarah Cannon Research Institute | April 28, 2022



Sarah Cannon was the real name of the television and radio personality, Minnie Pearl. Sarah Cannon received treatment for breast cancer at the founding center in Nashville. Afterwards, she offered the use of her name to promote cancer research and patient education with a vision of offering patients convenient access to early detection, clinical trials, and a team approach to cancer care.

Since its inception in 1993, Sarah Cannon has taken many first steps in the fight against cancer, beginning with clinical research. With the focus of offering patients greater access to clinical trials at the earliest phases, Sarah Cannon's founders established the first community-based cancer research program and, four years later, formed the first drug development program outside of an academic setting.

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Podcast: Wayne Frederick on the legacy of LaSalle Leffall, Jr.

By Cancer History Project | Feb. 4, 2022



The Cancer History Project Guest Editor Robert Winn focused on the legacy of LaSalle Leffall, a Howard University surgical oncologist.

Winn is the director of VCU Massey Cancer Center. He and John H. Stewart, director of Louisiana State University-Louisiana Children's Medical Center Health Cancer Center spoke with Wayne A.I. Frederick, president of Howard University.

Stewart and Frederick were mentored by Leffall.

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Related:

• LaSalle D. Leffall, Jr., a pioneering surgeon, dies at 89, by Edith P. Mitchell, MD (*The Cancer Letter*, <u>May 31</u>, 2019)

13

Podcast: Dave Boule confronted polycythemia vera with an accountant's consistency

By Cancer History Project | June 17, 2022



Soon after Dave Boule was diagnosed with polycythemia vera in 2006, he had a hunch that there were better treatment options out there.

"Not too long into my course of treatment with phlebotomy only, my platelets started to rise along with my red count, which is not unusual with the disease, and the doctor wanted to treat me with the anagrelide," he said to Doroshow.

Boule did his research.

He had found studies by Richard T. Silver, professor of medicine at Weill Cornell Medical College, who is now director emeritus of the Richard T. Silver MD Myeloproliferative Neoplasms Center, and Jerry Le Pow Spivak, professor emeritus of medicine at Johns Hopkins University School of Medicine and director of the Center for the Chronic Myeloproliferative Disorders.

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Panel: The three comprehensive cancer centers that set the model for a nation

By Cancer History Project | Aug. 6, 2021



Directors of the first three NCI-designated Comprehensive Cancer Centers are learning from the past, starting with the National Cancer Act, and mapping an equitable future for oncology.

On July 29, 2021, the Cancer History Project convened panelists Candace S. Johnson, president and CEO of Roswell Park Comprehensive Cancer Center, Craig B. Thompson, president and CEO of Memorial Sloan Kettering Cancer Center, and Peter WT Pisters, president of MD Anderson Cancer Center, for a two hour Zoom session moderated by co-editor Otis W. Brawley.

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Related:

The history—and future—of oncology, according to directors of the first three NCI-designated Comprehensive Cancer Centers (The Cancer Letter, Aug. 6, 2021)

15

Podcast: In 1998, a CML patient was out of options. Then she chanced into a treatment–Gleevec

By Cancer History Project | June 3, 2022



When Judy Orem learned of her chronic myeloid leukemia diagnosis in 1995, she chose interferon over a treatment that seemed more risky—a bone marrow transplant.

"I don't think I had any decision to make. I was simply told I was going to do that... It was that or nothing," Orem said to Deborah Doroshow, assistant professor of medicine, hematology, and medical oncology at the Tisch Cancer Institute, Icahn School of Medicine at Mount Sinai, who is guest editor of the Cancer History Project during the month of June.

Orem ruled out bone marrow transplantation from the outset. Doctors at Stanford told her that she would have a 50% chance of survival during her first year of that treatment. With interferon, she could get three to five years, she was told. What did it take—and what did it mean—to survive with the disease and treatment at that time?

"We walked out of there, talked about it, and said, 'You know? I'd rather spend the year feeling OK than to go through all that and 50% chance of dying from the treatment," she said. "And so I chose not to do anything other than the interferon."

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Panel: Knudsen, Hudis, Hughes-Halbert, Leader, Willman propose action plan on health equity

By Cancer History Project | May 13, 2022



In a panel discussion this week, five leaders in oncology proposed an action plan for tackling cancer health disparities and enhancing health equity.

The panel, "Health Equity: Advocacy and access," hosted by the Cancer History Project May 9, 2022, included:

- Karen Knudsen, MBA, PhD, CEO, American Cancer Society and the American Cancer Society Cancer Action Network, who moderated the event
- Clifford A. Hudis, MD, CEO, American Society of Clinical Oncology; Executive vice chair, Conquer Cancer Foundation; Chair, CancerLinQ
- Chanita Hughes Halbert, PhD, Vice chair for research, professor, Department of Population and Public Health Sciences; Associate director for cancer equity, Norris Comprehensive Cancer Center, University of Southern California
- Amy E. Leader, DrPH, MPH, Associate professor of population science and medical oncology, associate director of community integration, Sidney Kimmel Cancer Center; Public health teaching faculty, College of Population Health, Thomas Jefferson University
- Cheryl Willman, MD, Executive director, Mayo Clinic Cancer Programs (nationally and globally); Director, Mayo Clinic Comprehensive Cancer Center

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Helen Coley Nauts: The Woman Who Resurrected Cancer Immunotherapy

By Cancer Research Institute | April 1, 2021



Helen Coley Nauts, the founder of the Cancer Research Institute (CRI), was a high school-educated housewife and mother who, from the time of her father's death in 1936 until her own passing in 2001, would go on to fundamentally change the fields of cancer research and immunology.

Her determination and perseverance in the face of constant resistance from the medical establishment of her day laid the foundation for cancer immunotherapy as it is known today. For her contributions, Helen was named Commandeur de l'Ordre National du Merite by French president Valéry Giscard d'Estaing in 1981, and received the Gold Medal for "distinguished service to humanity" from The National Institute of Social Sciences in 1997—the first woman in the medical field to do so since the honor was bestowed upon Marie Curie in 1921.

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The Story of City of Hope

By City of Hope Comprehensive Cancer Center | Feb. 23, 2021



In 1913, tuberculosis would kill nearly 150,000 people, more than twice the toll taken by cancer. A group of committed volunteers refused to accept this tragedy and established the Jewish Consumptive Relief Association (JCRA), a free, nonsectarian tuberculosis sanatorium.

After hosting several fundraisers, the JCRA placed a down payment on 10 acres of sun-soaked land in Duarte, California, where they would establish the Los Angeles Sanatorium a year later. The original sanatorium consisted of two canvas cottages and ultimately launched a century-long journey that would place City of Hope at the forefront of the nation's leading medical and research institutions.

Their visionary efforts were rewarded when, by the mid-1940s, the discovery of antibiotics pushed tuberculosis into a decline across the United States. But there was no time for celebration. The pioneering thinkers at City of Hope had already trained their focus on humanity's next great medical challenge: tackling the catastrophic disease of cancer. Later, they mounted a fight against diabetes and HIV/AIDS. In accepting each new medical challenge, however daunting, City of Hope continually reaffirms its humanitarian vision that "health is a human right."

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Paul Calabresi: A Founder and Giant in the Field of Medical Oncology

By Fred Schiffman, MD and Wafik El-Deiry, MD, PhD | May 12, 2021



The story of modern cancer therapy would not be complete without the inclusion of the work of Paul Calabresi and some insights about the challenges he faced, along with his accomplishments.

For this chapter in the "Cancer History Project", I revised and extended a Memorial I wrote for Paul in 2006. I also had the pleasure of interviewing many who knew him well including his children: Steven Calabresi, Janice Calabresi Maggs, and Peter A. Calabresi, MD. Others gave generously of their time to speak with me and share stories and experiences which I hope will add some richness to Paul's contributions as an oncologist.

They included Dr. Roy Herbst, Ensign Professor of Medicine (Medical Oncology), Professor of Pharmacology, Chief of Medical Oncology, Yale Cancer Center and Smilow Cancer Hospital and Associate Cancer Center Director, Translational Science, Dr. Edward Chu, Director of the National Cancer Institute-designated Albert Einstein Cancer Center, Vice President for Cancer Medicine at Montefiore Medicine, Professor of Medicine and of Molecular Pharmacology and Roger Einiger Professorship of Cancer Medicine at Einstein, Dr. Vincent De-Vita, Amy and Joseph Perella Professor of Medicine at the Yale Cancer Center, Professor of Epidemiology and Public Health at Yale and Former Director of the Yale Cancer Center and Dr. Thomas DeNucci, Medical Director, Rhode Island Hospital Endoscopy, Gastroenterologist at Lifespan Physician Group and a Clinical Associate Professor of Medicine at The Warren Alpert Medical School of Brown University.

Paul Calabresi was born in Milan, Italy on April 5, 1930. He was the son of Dr. Massimo Calabresi and Bianca Maria Finzi-Contini Calabresi. In Europe, his family was active in the anti-fascist resistance but in 1939 fled to the United States.

Paul's parents told the story of Paul's arrival to America. He was literally the first one off the boat and ran down the gangway. He spread his arms wide and shouted, "I am an American boy now!" The family moved to New Haven where his father joined the faculty of Yale University School of Medicine as a cardiologist at the Veterans' Administration Hospital. Paul's mother was a scholar of European literature, earned a Ph.D. in French at Yale and was Professor of French and Italian at Connecticut College and for many years Professor and Chair of the Italian Department at Albertus Magnus College.

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Dr. John Ultmann (1925-2000), a pioneer in the treatment of lymphoma

By University of Chicago Medicine Comprehensive Cancer Center | July 14, 2022



John E. Ultmann, MD, (1925-2000) was an internationally recognized expert on the diagnosis, staging and treatment of Hodgkin's disease and non-Hodgkin's lymphoma as well as on the development of cancer chemotherapy. He was a professor in the department of medicine and the founding director of the University of Chicago Cancer Research Center (now known as the University of Chicago Medicine Comprehensive Cancer Center).

Ultmann was a pioneer in efforts to distinguish between the many different types of lymphomas. He was particularly well known for his work on precise staging of Hodgkin's disease and the uses of staging as a guide for treatment.

"John Ultmann was an early proponent of the multi-disciplinary approach to treatment of lymphoma, which is associated with a tremendous improvement in the curability of the disease," said Samuel Hellman, MD, the A.N. Pritzker Distinguished Service Professor in the department of radiation and cellular oncology and former dean of the biological sciences at the University. "He was known within the University as an outstanding teacher who trained many of the current leaders in the field, as a key player in assembling the world-renowned medical oncology group here, and as a compassionate physician who took excellent care of his patients until just a few weeks before his own death."

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Duke Celebrates 50 Years of Cancer Care — and Looks Toward the Next 50

By Duke Cancer Institute | July 7, 2022



When Joseph O. Moore, MD, came to Duke as a fellow in 1975, he and his mentors treated chronic myeloid leukemia (CML) with a chemotherapy regimen that was like a "wet blanket." It suppressed the cancer for a few years. "But it didn't change the trajectory of the disease," Moore said. Patients developed acute leukemia, which was almost always fatal. By the early 1990s, younger patients could achieve a cure with a bone marrow transplant, though complications were common. By 1999, Moore was the Duke investigator for a national study of a targeted drug, imatinib, which stops leukemia cells from growing by shutting down a key protein. When imatinib was approved by the Food and Drug Administration (FDA) in 2001, it transformed CML into a disease easily treated by taking a pill.

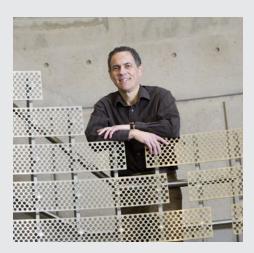
When Moore retired from clinical practice in 2019, he was involved in a study following people with CML who had been taking imatinib long term, which showed they could safely stop therapy.

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Gone Too Soon: Dr. Neil Spector Passes Away (1956-2020)

By Duke Cancer Institute | April 15, 2022



Flags were lowered to half-staff today (June 17, 2020) across Duke for Neil Spector, MD, a nationally recognized physician-scientist, translational research leader, and oncology mentor, who passed away on Sunday, June 14, 2020. He was 63. Dr. Spector was the Sandra Coates Associate Professor in the Department of Medicine, an associate Professor of Pharmacology and Cancer Biology, and a member of the Duke Cancer Institute.

He joined Duke Cancer Institute and the faculty at Duke University School of Medicine in September 2006 after serving for eight years as director of Exploratory Medical Sciences-Oncology at GlaxoSmithKline and as adjunct associate professor of Medicine, Division of Hematology/Oncology, University of North Carolina at Chapel Hill.

Dr. Spector's appointments at DCI include having served as associate director for Translational Research, director of the Developmental Therapeutics Program, and associate co-director of Clinical Research with the Breast Cancer disease group.

His laboratory research focused on elucidating molecular mechanisms of therapeutic resistance to targeted therapies and strategies to prevent and overcome resistance. He is credited with leading two molecularly targeted therapies to FDA approval, one for the treatment of pediatric T-cell acute lymphoblastic leukemia (nelarabine) and another for the treatment of HER2 overexpressing breast cancers (lapatinib).

A medical oncologist, Dr. Spector most recently served as an attending physician and supervised medical oncology fellows at the Durham VA Healthcare System.

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Carol Fabian on breast cancer prevention and tissue sampling using fine needle aspiration



Carol Fabian recalls the emotional hardship that came with treating women for breast cancer in the 1970s and eighties.

"This was prior to adjuvant trastuzumab, and despite aggressive cytotoxic adjuvant treatment, too many of these young women relapsed and died," said <u>Carol Fabian</u>, director of the Breast Cancer Prevention and Survivorship Research Center, holder of the Medical Oncology Mark and Bette Morris Family Professorship in Cancer Prevention, Mark and Bette Morris Foundation, and University Distinguished Professor at the University of Kansas Medical Center.

"These women often had young children and/or were at the height of their careers," Fabian said to *The Cancer Letter.* "This was a tragedy over, and over, and over again. It was becoming emotionally very difficult to handle."

Fabian's husband recognized the toll this took on her, and suggested another field of medicine.

"I did not want to give up oncology, but for balance wanted to switch to a research focus, with a little more light at the end of the tunnel. That research focus was cancer prevention," Fabian said.

While Fabian still treated breast cancer patients, she pivoted to prevention work and developed a minimally invasive technique to collect healthy breast tissue in women called fine needle aspiration.

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How Utah's Unique Resources Spearheaded Cancer Genetic Discoveries at Huntsman Cancer Institute

By Huntsman Cancer Institute | Feb. 17, 2022



Utah is a veritable wellspring of genetic discoveries. Researchers at the University of Utah (U of U) can claim the discovery of 50 genes involved in inherited disease risk.

The foundation of that wellspring was a singular resource: an abundance of detailed family trees. But it took the foresight of several Utah researchers to understand the potential of this data and determine how to harness its power for genetic discovery.

This focus on a genetic approach to understanding disease came to the attention of Jon M. and Karen Huntsman. Jon Huntsman lost his mother to cancer. After his own experience with the disease, he and Karen became committed to the cancer cause. When they learned of the genetics work occurring at the U of U—in their own backyard—they felt their financial support would have the greatest impact there.

In 1995, the Huntsman family made a major gift that enabled the establishment of a state-of-the-art research, education, and cancer care facility on the U of U campus, becoming critical investors in the cancer genetics work that has had a significant impact across the world. Today, Huntsman Cancer Institute has grown into more than one million square feet of research and clinical space.

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Podcast: Tim Wendel on the "Cancer Cowboys" and getting to know the ALGB

By Cancer History Project | March 18, 2022



A band of "Cancer Cowboys" once known as the ALGB—Acute Leukemia Group B—are, in large part, responsible for flipping the mortality rate of childhood leukemia from 90% to 10%, where it stands today. "The Cancer Cowboys arguably better utilized many of the newer meds becoming available—6-MP, methotrexate, daunomycin, Cytoxan," Tim Wendel, member of the Cancer History Project editorial board, lecturer at Johns Hopkins University, and author of "Cancer Crossings: A Brother, His Doctors, and the Quest for a Cure to Childhood Leukemia," said to *The Cancer Letter*. "Most of the old guard...were giving them to the patients one at a time. What the ALGB group did was, 'Screw this. We don't have time. We're going to do it in combination two, three, even four at a time.""

While researching his book from 2013 to 2017, Wendel spoke with the doctors of ALGB, among them longtime St. Jude Children's Research Hospital CEO Donald Pinkel, who died March 9, Jerry Yates, Lucius Sinks, James and Jimmie Holland, Emil "Tom" Frei, and Emil J Freireich. Wendel's brother Eric was treated at Roswell Park Comprehensive Cancer Center beginning when he was diagnosed in 1966, until he died in 1973.

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Related:

- The Donald Pinkel Archive
- Donald Pinkel, St. Jude founding medical director who brought the word "cure" to cancer, dies at 95, by Tim Wendel, March 18, 2022
- Reflecting on Donald Pinkel's legacy as a physician, scientist, and humanitarian, by Mary Pinkel, March 18, 2022
- <u>Children First: Dr. Donald</u> <u>Pinkel and the Quest to Cure</u> <u>Childhood Leukemia</u>, by Ros- well Park Comprehensive Can-cer Center, March 16, 2022
- St. Jude's founding medical director Donald Pinkel set the scientific trajectory for curing childhood cancer, by St. Jude, March 17, 2022