



# TCL

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## **E-CIGARETTE SMOKE ASSOCIATED WITH LUNG CANCER, INFLAMMATION, AS FEDERAL AGENCIES RESPOND TO VAPING DEATHS**

E-cigarette smoke, like tobacco smoke, may, in fact, cause cancer, new studies suggest.

→ PAGE 4

### **GUEST EDITORIAL**

MUSEUM MALIGNANCY: WHAT  
THE SACKLERS AND PHILIP  
MORRIS HAVE IN COMMON

→ PAGE 8

REAL-WORLD DATA, EVIDENCE  
SHOULD BE LEVERAGED IN  
CLINICAL RESEARCH TO BETTER  
INCLUDE AND ULTIMATELY TREAT  
LARGER PATIENT POPULATIONS

→ PAGE 21

### **IN BRIEF**

BROWN NAMED SYAPSE  
CHIEF MEDICAL OFFICER

→ PAGE 16

### **CLINICAL ROUNDUP**

UCLA OPENS CAR T-CELL  
TRIAL FOCUSED ON THE  
MOST COMMON TYPES OF  
LYMPHOMA, LEUKEMIA

→ PAGE 24

# Moving Breast Cancer Treatments Forward

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### COVER STORY

- 4** E-cigarette smoke associated with lung cancer, inflammation, as federal agencies respond to vaping deaths

### GUEST EDITORIAL

- 8** Museum malignancy: What the Sacklers and Philip Morris have in common

### IN BRIEF

- 16** Brown named Syapse chief medical officer
- 16** Barker, Fingert, Hayes-Jordan and Vadaparampil named to NCAB
- 17** Virginia Tech announces cancer research initiative
- 17** Ribas, Jaffee, Eshhar, Samelson, Seed and Weiss share Coley awards for immunology
- 18** Cambridge's Nik-Zainal wins Josef Steiner Cancer Research prize
- 19** Backman named associate director for research technology at Northwestern
- 19** City of Hope provides cancer support services to Amazon employees
- 19** NCI grant UNC to help patients navigate costs of cancer care
- 20** Third Edition of Cancer Atlas highlights patterns and inequities in cancer burden

### THE CLINICAL CANCER LETTER

### REAL-WORLD EVIDENCE

- 21** Real-world data, evidence should be leveraged in clinical research to better include and ultimately treat larger patient populations

### CLINICAL ROUNDUP

- 24** UCLA opens CAR T-cell trial focused on the most common types of lymphoma, leukemia
- 24** Results from STELLAR trial in MPM published in *The Lancet Oncology*
- 25** IASLC invites comments on "Multidisciplinary Recommendations for Pathologic Assessment of Lung Cancer Resection Specimens Following Neoadjuvant Therapy"
- 26** Expert second opinion improves reliability of melanoma diagnoses

### DRUGS & TARGETS

- 27** Xenikos receives Fast Track designation for T-Guard for steroid-refractory SR-aGVHD
- 27** Flatiron announces clinical decision support application through Epic's App Orchard



**E-CIGARETTE SMOKE  
ASSOCIATED WITH LUNG  
CANCER, INFLAMMATION,**

**AS FEDERAL AGENCIES  
RESPOND TO VAPING  
DEATHS**

*By Alex Carolan and Matthew Bin Han Ong*

E-cigarette smoke, like tobacco smoke, may, in fact, cause cancer, new studies suggest.

According to one just-reported study, mice exposed to e-cigarette smoke were five times more likely to develop lung cancer, and 10 times more likely to develop precancerous lesions of the bladder.

Another study found that a specific vaping component led to lung inflammation, a result of short-term e-cigarette use on the lungs. Inflammation often presages medical conditions that include bronchitis, asthma, heart disease, and cancer.

Peter Shields, thoracic oncologist at The Ohio State University Comprehensive Cancer Center and a study author, said this study is the first experimental demonstration of an impact of e-cigarette use on inflammation in the human lung among never-smokers.

Researchers specifically studied e-cigarette users who were healthy, non-smokers. This is an important aspect of the study design as e-cigs were developed originally to be a smoking cessation tool, but have since been widely adopted by non-smokers.

“The rise in electronic cigarette use is quickly becoming a public health crisis that the scientific community is rushing to address so that the FDA has the information it needs to regulate this industry to protect public health,” Shields said in a statement.

The e-cigarette smoke mice study was published [Oct. 7](#) in *Proceedings of the National Academy of Sciences*. The inflammation pilot study was published [Oct. 16](#) in the journal *Cancer Prevention Research*.

“This work and other mouse studies show that e-cigarette aerosols have adverse health effects,” Ron Johnson, program director of the DNA and Chromosome Aberrations Branch in the Division of Cancer Biology at NCI, said to *The Cancer Letter*. “E-cigarette aerosols are known to contain other carcinogens (e.g. heavy metals and formaldehyde) and it is unclear how these carcinogens and other

constituents may contribute to toxicity. A recent [publication](#) has shown that e-cigarette aerosols without nicotine disrupt normal lung function and cause lung tissue damage in exposed mice.”

These new studies are being reported at a time when young adults are smoking more e-cigarettes and when a string of vaping-related deaths often associated with e-cigarettes containing THC has brought national attention to the issue. FDA, NIH, the Centers for Disease Control and Prevention, and state and local departments are investigating a multi-state outbreak of lung injury associated with the use of e-cigarettes.

The new vaping-related illness recently received a name—“e-cigarette, or vaping, product use associated lung injury”—and acronym EVALI. As of Oct. 8, CDC has received reports of 1,299 cases of EVALI, including 26 deaths, which occurred in 21 states.

Recent studies show that while fewer teenagers are using conventional cigarettes, more are using e-cigarettes.

Fewer eighth, 10th, and 12th graders are using conventional cigarettes, according to a study from the National Institute on Drug Abuse. In eighth graders, 13% reported using cigarettes in 2015, compared to about 9.1% in 2018. In 10th graders these rates fell from 19.9% to 16%, and in 12th graders these fell from 31.1% to 23.8%, respectively (*The Cancer Letter*, [Sept. 27](#)).

Though cigarette use fell from 8.1% to 5.5% overall, vaping rates increased from 21% to 27%, according to CDC’s Tobacco Survey published in early 2019.

E-cigarettes contain a lower number of toxic substances than conventional cigarettes, but their long-term health effects are not yet clear, the National Academies of Sciences, Engineering, and Medicine concluded in a [report](#) published Jan. 23, 2018 (*The Cancer Letter*, [Jan. 26](#), 2018).

Tobacco companies are losing customers of products that involve burning tobacco and are increasingly emerging as dominant players in the market for alternative products, which include electronic cigarettes and similar devices. Meanwhile, mainstream tobacco control organizations say that while new products may present safer alternatives, their prevalence and harms must be studied.

The NASEM report does not say, “e-cigarettes are saving lives,” David Eaton, chair of the NASEM committee that authored the report, said at the time (*The Cancer Letter*, [Feb. 9](#), 2018).

Vaping-related illness, where most patients report having used e-cigarettes containing THC, has prompted former FDA Commissioner Scott Gottlieb to examine the impasse on federal regulation of marijuana.

“The Justice Department remains unwilling or unable to enforce existing federal laws, even on matters not specifically mentioned by the congressional budget riders,” Gottlieb wrote in a [commentary](#) for the *Wall Street Journal*. “The feds are also reluctant to regulate this market. Exerting partial oversight over the riskiest products would effectively signal the end of federal marijuana prohibition. Justice officials see such a step as politically controversial, even as it becomes clear that a blanket ban is no longer politically practicable.

“The result is an impasse. Federal agencies exert little oversight, and regulation is left to a patchwork of inadequate state agencies. The weak state bodies sanction the adoption of unsafe practices such as vaping concentrates, while allowing an illegal market in cannabis to flourish.

“Any federal regulation would need to be backed up with oversight and vigorous enforcement to keep a black market from continuing to flourish and causing these lung injuries,” Gottlieb wrote. “Expanding access to marijuana

for legitimate medical research would allow more scientists either to validate or dispel the myriad claims about marijuana's therapeutic usefulness. Whatever medical claims are made should be subject to the same federal standards applied to other drugs.

"The protracted hand-wringing over federal cannabis policy must stop," Gottlieb said. "The tragic spate of fatalities related to vaping of pot concentrates means the time has come for Congress and the White House to stop blowing smoke and clear the air."

At this time, FDA and CDC have not identified the cause or causes of the lung injuries among EVALI cases, and the only commonality among all cases is that patients report the use of e-cigarette, or vaping, products.

## CDC, FDA statements

"CDC recommends that persons should not use e-cigarette, or vaping, products that contain tetrahydrocannabinol," CDC officials said in an Oct. 11 [interim guidance](#) for health care providers. "At present, CDC recommends persons consider refraining from using e-cigarette, or vaping, products that contain nicotine. Irrespective of the ongoing investigation, e-cigarette, or vaping, products should never be used by youths, young adults, or women who are pregnant. Persons who do not currently use tobacco products should not start using e-cigarette, or vaping, products.

"This outbreak might have more than one cause, and many different substances and product sources are still under investigation," the CDC interim guidance states. "To date, national and state data suggest that products containing THC, particularly those obtained off the street or from other informal sources (e.g., friends, family members, or illicit dealers), are linked to most of the cases and play a major role in the outbreak. Therefore, CDC recommends

that persons should not use e-cigarette, or vaping, products that contain THC."

FDA, too, has issued a public health [warning](#) that uses similar language.

"A majority of the samples tested by the states or by the FDA related to this investigation have been identified as vaping products containing THC," the agency states in the Oct. 4 warning. "Through this investigation, we have also found most of the patients impacted by these illnesses reported using THC-containing products, suggesting THC vaping products play a role in the outbreak.

"Do not use vaping products that contain THC. Do not use vaping products—particularly those containing THC—obtained off the street or from other illicit or social sources. Do not modify or add any substances, such as THC or other oils, to vaping products, including those purchased through retail establishments."

The signals coming from the mice study are concerning, researchers say. Mice exposed to smoke for about a year developed cancer and precancerous lesions at a significantly higher rate.

"What we have found is that mice exposed to e-cigarette smoke for 54 weeks developed lung cancer and precancer change[s] in bladder tissue," the study's first author Moon-Shong Tang, professor in the Department of Environmental Medicine, Department of Medicine, and Department of Pathology at NYU Langone Health, said to *The Cancer Letter*.

The mice were separated into three groups:

- **Group one** (45 mice) was exposed to ECS generated from e-juice, containing 36 mg/mL of nicotine dissolved in isopolypropylene glycol and vegetable glycerin at a one-to-one ratio.
- **Group two** (20 mice) was exposed to isopolypropylene glycol and vegetable glycerin (Veh), the ingredi-

ents found in e-juice. This group did not include nicotine.

- **Group three** (20 mice) was exposed to filtered air.

Most notably, the study found that:

- Nine of 40 (22.5%) mice from the first group exposed to ECS for 54 weeks developed lung adenocarcinomas,
- Twenty-three of these 40 (57.5%) mice developed bladder urothelial hyperplasia.

Comparatively:

- Lung cancer jumped from 5.6% to 22.5% in the control group versus the ECS group. None of the mice in the Veh group developed lung tumors.
- Bladder urothelial hyperplasia jumped from 6.3% in the group exposed to Veh versus 57.5% of mice in the ECS group. None of the control group developed bladder urothelial hyperplasia.

"That's a precancerous change—a very high percentage," Tang said of the mice who developed hyperplasia. "Bladder hyperplasia is a jump from 6% jump to almost 60%. That's a ten-fold jump."

The Tang et al. study is an important initial finding indicating that exposure of mice to e-cigarette aerosols containing nicotine may be carcinogenic, said NCI's Johnson.

"This study used a small number of animals, and strong statistical significance for lung tumors was achieved only by combining control groups," Johnson said to *The Cancer Letter*. "A larger effect was seen for bladder hyperplasia but it's not known whether this early stage of premalignancy would progress to more advanced stages.

"As the authors acknowledge, a larger size animal study is needed to determine how well these preliminary results repeat. While the amount of aerosol exposure over the course of the mouse

study may have been much higher than the amount in typical e-cigarette users, the study does suggest that e-cigarette aerosols could be carcinogenic.”

In a [2017 study](#), Tang and colleagues found that nicotine induces DNA dam-

smokers. They are less harmful than cigarettes, but they are not safe.”

Anthony Alberg, professor and chair in the Department of Epidemiology and Biostatistics at the University of South Carolina Arnold School of Public Health,

Blum said it’s harmful to continue to defend these products as part of a harm-reduction strategy. The best way to quit smoking is to go cold turkey, he said.

“Although it’s very early, and, frankly, sad to say, we do need more research, I think it’s caused me to stop and say, ‘Why are we wasting our time defending e-cigarettes because of the industry’s claim [about harm reduction]?’” Blum said.

The American Cancer Society agrees that more research is needed.

“In this study, mice who inhaled e-cigarette aerosol, including nicotine, developed more lung cancers than expected. It is unclear what this study means for people who use nicotine-containing e-cigarettes, including JUUL products, which always contain nicotine,” said Victoria Stevens, scientific director of epidemiology research at ACS.

“Firm conclusions about cancer risk in people cannot be made from only one animal study—more research in both animals and people is needed,” Stevens said. “The bottom line is that we already know e-cigarette use should not be considered safe. The best choice is to avoid using any tobacco product, including e-cigarettes.”

Tobacco companies have been funding research ventures into harm reduction. Philip Morris, for example, committed \$1 billion over 12 years through the Foundation for a Smoke-Free World, prompting critics to describe the venture as a cynical strategy to coerce scientists and market new ways of consuming tobacco (*The Cancer Letter*, [Oct. 6, 2017](#)).

Alas, the talk of the danger of e-cigarettes may contribute to their allure.

“If you keep on saying how dangerous it is, they love it,” Blum said. “The manufacturers really sort of love it because that feeds into the danger point of view as opposed to the stupid point of view.”



**The human, the policy-maker, has to consider this very seriously. Because the mechanism, the chemical from nicotine, causes lung cancer in mice.**

– Moon-Shong Tang



age and inhibits DNA damage repair in human cells. The most recent study concludes that nicotine, though widely thought to be non-carcinogenic, in addition to e-cigarette smoke, “may induce lung and bladder cancer.”

“Nicotine getting into the cell transforms and becomes nitrosamine. And nitrosamine, further metabolized, becomes a DNA damaging agent, and DNA damage. All of these effects are mediated by the nitrosamine. That’s a crucial step,” Tang said.

“The human, the policy-maker, has to consider this very seriously. Because the mechanism, the chemical from nicotine, causes lung cancer in mice.”

## Implications for cancer

Former FDA Commissioner Gottlieb said the animal study attempts to isolate nicotine’s effects on cancer, and “is subject to extensive prior studies, many more rigorous than this one,” he wrote in a [tweet](#).

As to the risk from vaping, Gottlieb [said](#) that “it should be assumed that vapor alone causes some lung injury, a reason why these products should be used by adults and be positioned as an alternative for currently addicted adult

said this research is important to document the potential for harm in humans.

“Eventually we need human data to characterize specifically the human effects. But these studies are particularly important now when we don’t have that kind of human evidence,” Alberg said to *The Cancer Letter*.

It took decades to demonstrate that tobacco smoke in traditional combustible cigarettes causes cancer in humans, resulting in the landmark 1964 Surgeon General’s report that linked smoking with lung cancer and heart disease.

Alan Blum, director of The University of Alabama Center for the Study of Tobacco and Society, said researchers and policymakers don’t need to wait that long to act on e-cigarettes.

“I don’t think we need to wait for three generations to see whether this is going to cause even a fraction of the problems that smoking has taken,” Blum said to *The Cancer Letter*. “I don’t think an infinite number of studies are ever going to show that vaping is worse than cigarette smoking, but what we’re finding seems to surprise a lot of people that it’s worse than just inhaling water vapor or glycerin vapor and some flavorings and some nicotine.”



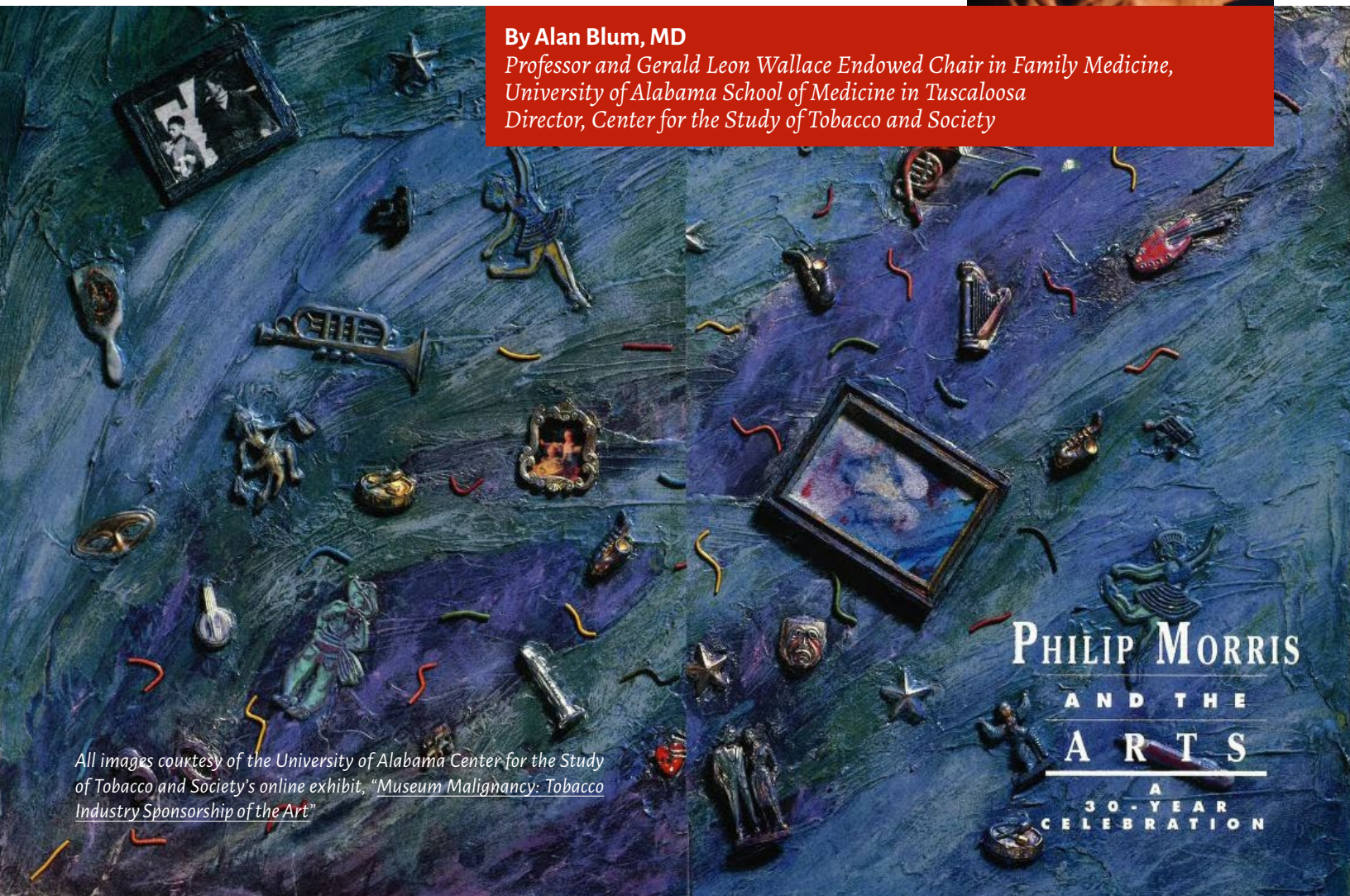
GUEST EDITORIAL

# Museum malignancy: What the Sacklers and Philip Morris have in common



By Alan Blum, MD

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*All images courtesy of the University of Alabama Center for the Study of Tobacco and Society's online exhibit, "Museum Malignancy: Tobacco Industry Sponsorship of the Art"*

PHILIP MORRIS  
AND THE  
ARTS  
A  
30-YEAR  
CELEBRATION



Since March 2018, P.A.I.N. (Prescription Addiction Intervention Now), an organization founded in 2017 by photographer Nan Goldin, has held demonstrations at art museums in New York, Washington, DC, Boston, London and Paris to protest their acceptance of money from the Sackler family, owners of Purdue Pharma, a company that been accused of fomenting the prescription opioid addiction crisis.

More than 200,000 deaths attributed to prescription opioid overdoses have been reported since the company's introduction of the narcotic medication OxyContin in 1995. More than 47,000 prescription opioid deaths are predicted to occur in the U.S. in 2019.

Yet this horrific toll represents less than a tenth of the number of deaths from cancer, heart disease, and emphysema in the U.S. each year due to cigarette smoking. And in contrast to the caustic criticism directed at the Metropolitan Museum of Art, the Guggenheim, the Freer-Sackler Gallery of the Smithsonian Institution, and others for cozying up to the Sackler family, the arts community has remained silent for more than 50 years when it comes to the solicitation by these very same bastions of culture of tens of millions of dollars from the nation's largest cigarette manufacturer, Philip Morris, maker of the world's top-selling brand, Marlboro.

*The New York Times* reported on May 15 that the Sackler family trust has donated more than \$80 million to arts and sciences since 2010. *Mother Jones* reported on March 23 that the Guggenheim accepted at least \$6.4 million from the Sackler family between 2001 and 2017.

On P.A.I.N.'s webpage, the group declares, "We're committed to holding the manufacturers of the opioid crisis and speaking for the hundreds of thousands of voices that have been silenced by the epidemic." P.A.I.N.'s manifesto includes the following:

"The Sacklers have ignited the largest public health crisis in American history. They must be held accountable for the harm they've done and are now attempting to unleash on a global scale.

"We demand that all museums, universities and institutions worldwide publicly refuse future funding from the Sackler family.

"We demand that all museums, universities and institutions worldwide remove their Sackler signage.

"We demand an immediate response from the museums and institutions that bear the Sackler name. To remain silent is to be complicit.

"We thank the museums and institutions that have cut ties with Sackler funding and urge all cultural institutions to follow their example and to divest from dirty money."

### Wrongly tarred with the same brush?

Goldin's and P.A.I.N.'s crusade to end the acceptance of ill-gotten gains from the sale of prescription opioids seems well-intentioned. The toll taken by these drugs is tragic.

Ironically, on P.A.I.N.'s webpage, a photograph of Nan Goldin smoking a cigarette accompanies her account of having undergone treatment for addiction to OxyContin.

Moreover, as *Wall Street Journal* arts critic Terry Teachout observed in a Feb. 27 column "Museums and Shaming," P.A.I.N.'s take-no-prisoners targeting of the Sackler family includes the philanthropy of the late Arthur Sackler, MD, who was not connected to OxyContin, which was introduced nearly a decade after his death in 1987.



The Brooklyn Museum of Art, 1998.

Thus, the Arthur M. Sackler Gallery of the Smithsonian and the Sackler Wing at the Metropolitan Museum of Art, sites of P.A.I.N. protests, were not funded by prescription opioid money.

Goldin would argue that Sackler's development of marketing strategies aimed at prescribers of the tranquilizers Valium and Librium beginning in the 1950s, as described by reporter Patrick Raddon Keefe in the *New Yorker* in 2017 ("The Family that Built an Empire of Pain"), set the stage for the aggressive promotion of OxyContin.

But the picture is further complicated, in my opinion, by the fact that Arthur Sackler was an arch-enemy of the tobacco industry, and from the 1960s to the 1980s he wrote numerous no-holds-barred editorials in his biweekly national newspaper for doctors, *Medical Tribune* (circulation 600,000), calling for tough action on the part of leaders in government, the mass media, the American Cancer Society, and hospitals against cigarette smoking and its promotion.

In a Sept. 11, 1978, editorial, "An American Tragedy," Sackler railed against the "governmental schizophrenia in respect to cigarette smoking." He noted the irony of the U.S. government spending "\$600 million to subsidize tobacco crops and promote cigarette sales" while "the beneficiaries of this largesse, the cigarette companies, are trying to prevent HEW [the Department of Health, Education, and Welfare] from spending a mere \$20 million to try to cut down the tragedy of lung cancer and heart disease associated with cigarette smoking." Sackler condemned the "weasling of the U.S. delegation to the World Health Assembly," headed by HEW Secretary Joseph A. Califano, Jr., for refusing to support a ban on cigarette advertising.

Sackler also accused President Carter of hypocrisy. "The spokesman for this administration, which claims to herald a new day in our political life, one free of rhetoric and double talk, of less bureaucracy and amenability to big business lobbies, was quick to proclaim the Constitutional right of newspapers to accept cigarette advertising and suggested, in the face of increasing governmental limitations on advertising of medical and therapeutic procedures, that when it comes to cigarette advertising restriction, 'this touches on freedom of the press.'"

"What an obscenity to call upon the American Constitution to try to support those who are seeking to addict young people to a dangerous addicting substance which has brought the tragedies of cancer and heart disease to so many American families. What hypocrisy to ask at the very same time for more restrictive regulations on the actions of physicians and the use of their medicines as they fight against these and other deadly diseases."

The irony that Arthur Sackler's family would itself similarly be accused of addicting Americans is obvious. For that matter, it's possible that the motive behind Sackler's editorial was self-interest, i.e. aimed at fending off attacks

on pharmaceutical advertising. But the parallels between the stated goals of litigation brought by the state attorneys general against the tobacco industry in the 1990s (i.e., allegedly to recover the costs of caring for victims of smoking) and the goals of today's lawsuits against prescription opioid manufacturers are also worth considering.

The lawsuits by the states, counties, cities, and tribes against Purdue and the Sacklers do not demand that OxyContin be withdrawn from the market.

To the contrary, as *The New York Times* points out (Oct. 12, "Bankruptcy Judge Pauses State Suits Against Purdue and Sacklers"), they want prescriptions of the drug to continue so that all profits would go to pay the plaintiffs for the costs of the opioid epidemic.

Shades of the Master Settlement Agreement (MSA) between the state attorneys general and the tobacco industry in 1998! For far from wanting to kill the goose that laid the golden eggs, the attorneys general effectively wanted the states to get a piece of the action... in perpetuity. As a result, instead of using a significant portion of the ongoing annual MSA payments to the states to fight smoking—less than 2% of it has been used for this purpose, state legislatures have become dependent on cigarette money in order to reduce budget deficits.

The *Times* also points out that although Purdue and the Sacklers have been "labeled as progenitors of the crisis," the company claims that during the peak of the opioid epidemic between 2013 and 2016, it manufactured only 4% of prescription painkillers in the US. And it points out that its products were approved by the FDA and monitored by the Drug Enforcement Administration.

The plaintiffs and P.A.I.N. have also not directed their wrath or held demonstrations at the giant retail drugstore chains such as CVS, several of whose

outlets were forced to close because of poor narcotic dispensing oversight, or Walgreens, which still sells cigarettes in its 8,000 stores.

Nor have they included medical societies whose journals accepted millions of dollars in advertising revenue to promote OxyContin and other prescription opioids.

## A pusher becomes a patron

Although Philip Morris (which changed its name to altruistically-sounding Altria in 2003) began contributing to arts groups in Richmond, VA, home of its largest cigarette manufacturing plant, in the late-1950s, the payments that the cigarette maker has since made to nearly 200 art museums throughout the nation (plus countless dance troupes, opera companies, repertory theaters, libraries, and ethnic arts organizations)—the most cultural funding by any corporation—dramatically increased following publication of the landmark Surgeon General's Report on Smoking and Health in 1964.

For the past half-century, then, the money doled out by this super-patron of the arts has helped burnish the company's nicotine-stained image and deflected attention away from the enormous body of peer-reviewed scientific evidence implicating cigarettes as the nation's leading preventable cause of death and disease.

Lucre from the maker of Marlboro cigarettes has paid off by buying the complacency of opinion leaders. To put this funding into perspective, the \$12.8 million that Philip Morris handed out to art museums and cultural groups in the U.S. at a high point of corporate charitable giving in 2002 represented just .001% (or one one-thousandth of one percent) of the nearly \$12 billion in profits from the company's cigarette sales that year. *The Guardian* reported

on March 29 that, in 2018, Altria donated \$3.8 million to the arts, while paying \$5.4 billion in dividends to shareholders.

Moreover, donations to art museums are tax deductible, so it doesn't cost shareholders a cent.

To be sure, the company has never hid its main intention. In an address to a conference on business and arts in 1979, Philip Morris chairman of the board George Weissman said, "For our company—perhaps for American business in general—this is only the beginning. The future will see an ever-closer partnership between business and the arts. The passing of the giant private patron,

of Philip Morris largesse for its Whitney Biennial and other exhibitions, gushed:

"Philip Morris became not just an art patron but one that stood at the cutting edge of contemporary sensibility...

"By becoming a patron of the arts, therefore, Philip Morris became a contributing member to many communities, many constituencies, and many good causes, a fact that was soon signaled by the shower of awards and tributes that began to descend upon the company...

"It is personally gratifying and encouraging because it gives great credibility to the hope that the people who ulti-

exhibition at the museum, "Champions of American Sport," which was curated by the Smithsonian and principally underwritten by Philip Morris.

In my remarks, I provided a brief overview of the insidious involvement of tobacco companies in sports. I cited the decades of aggressive marketing by Philip Morris aimed at associating its cigarette brands with athletic prowess, notably through Marlboro ads featuring National Football League stars Frank Gifford, Sam Huff, and others. I pointed out that 14 of the 24 Major League Baseball stadiums in 1980 had huge Marlboro billboards—all placed at key camera angles in order to be picked up on TV screens as a way of circumventing Congress' 1971 ban on tobacco advertising on TV (R) Reynolds' Winston brand was on 8 billboards; only two stadiums lacked cigarette ads).

Drug abuse among professional athletes was receiving considerable attention in the mass media, I noted, and Major League Baseball was trying to have it both ways: trumpeting its anti-drug addiction programs on the one hand while helping push America's leading lethal addiction, cigarette smoking, on the other.

The response to my objections by the Chicago Historical Society's board of trustees was total silence, but the museum director pulled me aside afterwards to thank me for speaking out against the veritable takeover of his museum by Philip Morris—complete with ashtrays and give-away packs of Marlboro in the galleries.

Sponsorship of both sports and the arts were crucial parallel marketing strategies for Philip Morris in the decades following Congress's 1971 ban of cigarette advertising on television.

The first major women's professional tennis circuit, established in 1971 during the rise of the women's rights move-



For the past half-century, then, the money doled out by this super-patron of the arts has helped burnish the company's nicotine-stained image and deflected attention away from the enormous body of peer-reviewed scientific evidence implicating cigarettes as the nation's leading preventable cause of death and disease.



the emergence of the corporation as the controller of an enormous new medium of world-wide communications, the growing awareness of the corporation's potential and responsibility for enlightenment, the ever-widening scope of the corporation's horizons—these are factors that will cement lasting relationships with the arts."

In his foreword to Philip Morris and the Arts: A 30-Year Celebration, a coffee table book published by the cigarette maker in 1989, Tom Armstrong, the director of the Whitney Museum of American Art, a longstanding recipient

mately support the arts will assist not for private gain or corporate profit but with a realization that life in the United States will be enriched and expanded through an appreciation and understanding of our cultural resource."

The Smithsonian Institution has been one of the longest continuous solicitors and recipients of cigarette sponsorship money.

I first began raising concerns about the ethics of tobacco industry sponsorship of museums as at the annual meeting of the Chicago Historical Society in 1980 on the eve of the opening of a traveling

**Lift up your heart.**  
THE AMERICAN COLLECTIONS: THE PAPACY AND ART 1993-95

**It's so simple for some folks.**  
THE FLOWERING OF AMERICAN FOLK ART 1776-1876 1974

**Precious Legacy.**  
JEWEL DISEASES FROM THE CLUCCI FOUNDATION COLLECTION 1993-95

**Bearden plays Bearden.**  
WISDOM BEARDEN 1958-1980 1982

**Johnny Apple seeds of the dance.**  
THE JOHNNY APPLEBY NATIONAL TOUR 1981-85

**See the South you've never seen.**  
PAINTINGS IN THE SOUTH 1941-1960 1984-85

**So ordinary, so extraordinary.**  
CLAUDE LORRAIN: THE ART AND THE ARTIST 1980-82

**Sometimes style is everything.**  
FASHION AND DESIGN OF GEORGINA CONWAY 1980-1982 1984-85

**Go! Go! Go!**  
CHAMPIONS OF AMERICAN SPORT 1981-82

**"Take an object."**  
DISEASING THE OBJECT: DISSECTING THE OBJECT, DISSECTING THE SUBJECT 1977-78

**It takes art to make a country great.**  
100 CENTURIES OF PROGRESS IN ART 1977

**Which is "primitive"? Which is "modern"?**  
THIRTEENTH-TO 20TH-CENTURY ART 1984-85

**We have a very simple reason for sponsoring them:  
It takes art to make a company great. Philip Morris Companies Inc.**

(If you were pleased, or moved, or touched, or enlightened by any of the art exhibitions or performing arts groups we've sponsored, we're glad. We were, too.)

Makers of Marlboro, Benson & Hedges 100's, Merit, Parliament Lights, Virginia Slims and Players; Miller High Life Beer, Lite Beer, Löwenbräu Special and Dark Special Beers, Meister Bräu and Milwaukee's Best; 7UP, Diet 7UP, LIKE Cola and Sugar Free LIKE Cola.

Advertisement for 10 Philip Morris-sponsored art exhibitions. *TIME Magazine*, 1995.



DOC protesting at the Metropolitan Museum of Art, 1983.

ment, was sponsored by Philip Morris' Virginia Slims cigarettes. Proceeds from the Jan. 14, 1977 Virginia Slims tournament were gratefully received by the Broward County chapter of the American Cancer Society.

By the 1980s, George Washington University and Boston University, among other educational institutions with medical schools and cancer centers, were hosting Virginia Slims tournaments.

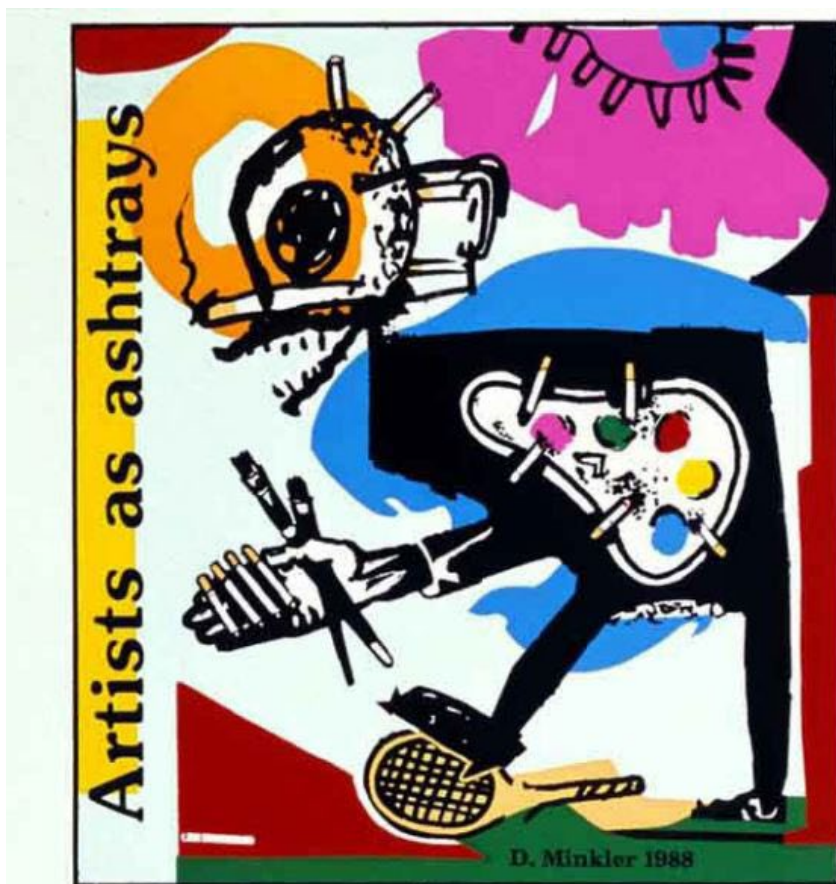
In 1990, Mervyn Silverman, MD, the medical director of the American Foundation for AIDS Research (amFAR) posed for photographs at the Virginia Slims of Houston holding an oversized check from Philip Morris. In 1994, MD Anderson president Mickey LeMaistre, MD, permitted his name to be listed as a

member of the "Virginia Slims Legends Medical Advisory Committee," along with six other physicians, including Michael DeBakey and Denton Cooley.

### Buying respectability... and complacency

The epitome of chutzpah by the cigarette maker was its sponsorship of "The Vatican Collections: The Papacy and Art" at the Metropolitan Museum of Art in 1983. In protest, I led 35 other physicians and students in a "house call" at the museum.

An article in *The New York Times* about our action quoted a spokesperson for the archdiocese of New York as saying, "the sponsor is not Philip Morris as a cigarette company, but Philip Morris



This poster is the first in a series of art works aimed at ending the leading cause of preventable death -- the tobacco industry. Comments and artist's participation welcomed. Please write DOC, (Doctors Ought To Care), P.U. Project, PO Box 31604, Houston, Texas, 77231-1604.

**Like a magician**, we don't miss a trick. Through our growing patronage of sports and culture, the public's perception of us is changing.

For instance, we realized we could improve our image and increase smoking among women and girls by attaching our Virginia Slims brand name to professional tennis. In the same way, we've increased the sales of cigarettes among blacks by sponsoring institutions like the Studio Museum of Harlem and the Alvin Ailey American Dance Theater.

Emphysema and bronchitis? *Shazam!* Now we're the Whitney Museum of Art and the Joffrey Ballet. Lung cancer and heart disease? *Presto!* Now we're Marlboro Country Music and National Public Radio.

Heck, we're not a tobacco company, we're a Patron of the Arts. That's why we at Philip Morris say, **"It takes art to make complacency great."**

#### Philip Morris Companies Inc.



Makers of Marlboro, Virginia Slims, Benson & Hedges 100's, Merit, Parliament Lights, Miller Beer, Lowenbrau, Jello, Post Cereals, Sanka, and other General Foods products. A DOC ad fake.

DOC counter-advertisement with art by Doug Minkler and copy by Alan Blum.

Inc.' Since the corporation's \$3 million grant is to the museum, he said, 'the Vatican does not have any necessity to answer' such objections."

In 1987, Philip Morris opened a branch of the Whitney Museum of American Art in the lobby of the company's headquarters across from Grand Central Station. I once asked a class of sixth-graders visiting an exhibition there, "Kids, what does Philip Morris make?"

One little girl eagerly raised her hand and said, "I know: Paintings!"

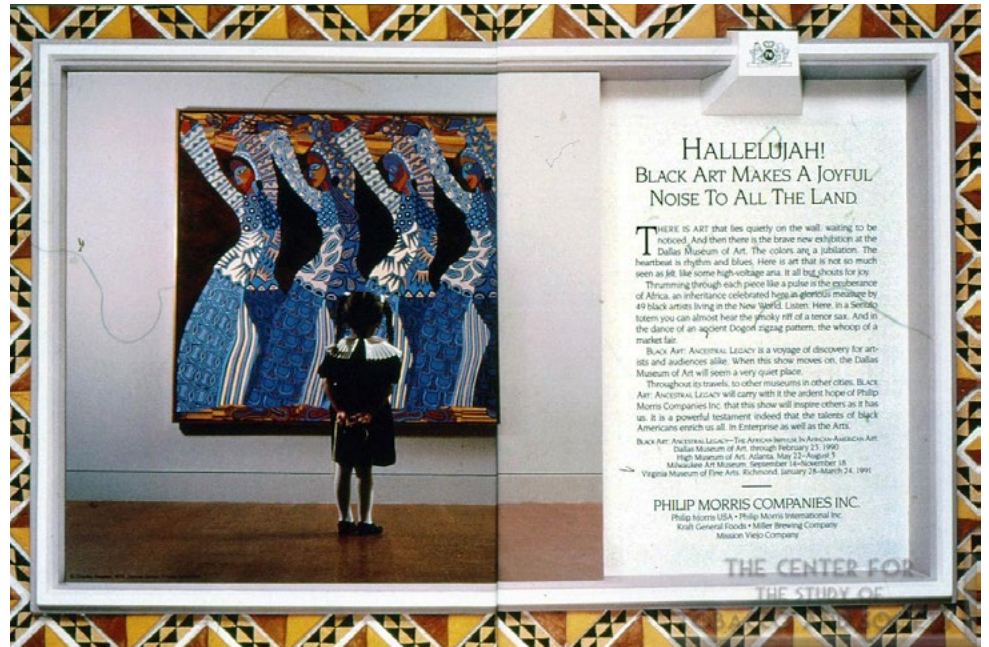
By 1988, the company was so widely recognized as the leading benefactor of the arts that its CEO, Hamish Maxwell, was emboldened to write the following in the sponsor's introduction to the exhibition "Picasso and Braque: Pioneering Cubism," at the Museum of Modern Art:

"Philip Morris is pleased to help present this tribute to the enduring value of creativity, experimentation, and innovation, qualities that we think are as important to business as they are to the arts. For whether the year is 1908 or 1989, in a rapidly changing world, not to take risks is the greatest risk of all."

The company even coined the slogan, "It takes art to make a company great," which it included in full-page color advertisements it purchased in major magazines and newspapers. In response, Berkeley artist Doug Minkler and I created a counter-advertisement, "Artists As Ashtrays," with the suggestion for a more accurate Philip Morris motto, "It takes art to make complacency great."

In 1994, when the New York City Council was debating a bill to ban smoking in restaurants and most other public places, Philip Morris not only threatened to move its headquarters and its 2000 employees back to Richmond, but also leaned on the arts organizations it funded to lobby and testify against the bill. Some did, as reported by *The New York Times* in a front-page story on Oct. 5, 1994 entitled, "[Philip Morris Calls in IOUs in the Arts.](#)"

According to Chin-tao Wu in her 2002 book, "[Privatizing Culture: Corporate Art Intervention since the 1980s](#)," "By dispensing money as widely as Philip Morris had been doing, the tobacco companies were buying the critical silence of arts bureaucrats and their institutions..."



“

By selling more Marlboros, it will be able to sponsor more art and buy more complacency. And, by buying more complacency, Philip Morris will be able to sell more Marlboros.

”

“This is the moment, I would argue, at which the ‘cultural capital’ accumulated by the corporation is transferred, in the most naked manner, to political power, at the service of corporate economic interests.”

In 2007, while on a gallery tour at the Whitney, along with 30 other visitors, of an exhibition by artist Kara Walker, I asked a question of the docent as she praised the artist’s biting depictions of the exploitation of African Americans during the centuries of slavery and to the present.

“But why would the museum and the artist permit Philip Morris, a cigarette company, to sponsor this exhibition, considering that the smoking-related death rate from lung cancer and heart disease is so much higher among African Americans?”

The docent remained silent for several seconds, then resumed the tour.

With the implementation by the administration of Mayor Michael Bloomberg of further restrictions on cigarette smoking and the sale and promotion of tobacco products in New York City, Philip Morris finally made good on its

threat to move its headquarters back to Richmond in 2007—thus taking nearly all of its arts funding dollars with it.

*The New York Times*, which had published hundreds of advertisements for Philip Morris-sponsored arts events over the preceding 25 years, conceded in an editorial, “End of An Era in Arts Funding:”

“We’ve always hated the basic product that Philip Morris sells, which has harmed millions of smokers and non-smokers at immense cost. We’ve also admired its diverse and relatively un-fearful support of the arts. There is no disputing its generosity, even though we shuddered at how easily large amounts of cash can buy neutrality and, eventually, respectability in a very influential part of the community...”

“The loss of Altria gives the art world a chance to shake its addiction to what has, in fact, always been tobacco money. Yes, that money was spent in the public interest, supporting institutions and programs and exhibitions that have greatly enriched us all culturally. But it’s also worth wondering about the real costs of that funding—the fact that for so many institutions Philip Morris

ceased to mean tobacco and came to mean mainly a reliable check.”

The taxpayer-supported Smithsonian Institution has continued to solicit and accept funds from Altria, which remains one of its \$25,000-a-year corporate sponsors. In recent years, the company has sponsored exhibitions at the U.S. National Portrait Gallery and the Renwick Gallery.

Altria also gave the Smithsonian National Museum of African American History and Culture one of the largest initial donations—“\$1 million plus”—and, according to *The Guardian*, it gave \$500,000 to the museum for its exhibition, “Double Victory: The African American Military Experience.” The irony of African Americans having been disproportionately afflicted with lung cancer and the main targets of the company’s menthol brands has apparently been lost on the museum’s officials and curators.

A current exhibit at the Smithsonian National Museum of American History, “More Doctors Smoke Camels,” consisting of several nostalgic cigarette advertisements from the 1940s and 1950s with images of physicians lighting up, does not acknowledge the Smithsonian’s ongoing solicitation of money from Philip Morris or the cigarette company’s ongoing aggressive marketing of Marlboro around the world.

There’s no question that tobacco money has been an even stronger addiction for art museums than that from the maker of prescription opioids. Why else would already wealthy museums have needed more and more of it?

Singling out the Sackler family for condemnation is problematic. The arts philanthropy that the late Arthur Sackler initiated in the 1970s—two decades before OxyContin was introduced—had nothing whatsoever to do with burning any of Purdue Pharma’s brand

names. It was about the family name—the thing called immortality.

In stark contrast, Philip Morris, which still uses the arts to reach opinion-leaders and help stave off efforts to prevent it from hooking a new generation on Marlboro and JUUL (the cigarette-maker bought a third of JUUL Labs Inc. last year), continues to crank out Marlboros. By selling more Marlboros, it will be able to sponsor more art and buy more complacency. And, by buying more complacency, Philip Morris will be able to sell more Marlboros.

I can understand why Nan Goldin is directing her ire at the aggressive marketers of prescription opioids. I only wish she would put out her cigarette, and, diversifying her efforts, lead a protest against its maker.

**TOBACCO COMPANY  
SPONSORSHIP OF THE ARTS...  
—THINK AGAIN.**



**Museum Malignancy: Tobacco Industry Sponsorship of the Arts**, an online exhibition curated by Blum, explores the collaboration between art museums and the maker of the world’s top-selling cigarette, Marlboro.

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## IN BRIEF



## Brown named Syapse chief medical officer



Thomas D. Brown was named chief medical officer at Syapse.

Brown joins Syapse from the Swedish Cancer Institute at Providence St. Joseph Health, where he served as executive director of SCI and led the establishment of the SCI Personalized Medicine Program. Brown also served in leadership roles across PSJH, including co-chair of the PSJH Cancer Leadership Council and co-chair of the PSJH Genomics Initiative.

Brown's clinical and research efforts have been focused on gastrointestinal

malignancies, broad developmental therapeutics in oncology, specifically phase I and II clinical trials, and health care policy and global medicine.

Prior to SCI, Brown served as professor of medicine and chief operating officer at the University of Arizona Cancer Center. He also spent a decade at MD Anderson Cancer Center, where he was a professor of medicine, and served as both deputy head and head ad interim of the Division of Cancer Medicine, as well as vice president for international programs.

While on the faculty at Duke University, Brown was one of the founding members of the multi-disciplinary GI cancer program, and of a southeast regional clinical trials consortium. Brown began his career as a faculty member at the University of Texas Health Science Center at San Antonio, working as a member of its phase I program, and serving as an executive officer within the Southwest Oncology Group where he was responsible for coordination of SWOG's phase II portfolio.

## Barker, Fingert, Hayes-Jordan and Vadaparampil named to NCAB

The White House has named the following individuals to the National Cancer Advisory Board:



**Anna D. Barker**, director of Arizona State University Transformative Healthcare Networks, co-director of the Complex Adaptive Systems Initiative and as a professor of practice within the School of Life Sciences. She is also a former NCI deputy director.



**Howard Fingert**, a long-time biotechnology company executive who now works as an industry consultant. Fingert is a member of the NCI Clinical Trials and Translational Research Advisory Committee and a former industry representative on the FDA Oncologic Drugs Advisory Committee.



**Andrea Hayes-Jordan**, chief of the Division of Pediatric Surgery at the UNC School of Medicine, and surgeon-in-chief at the North Carolina Children's Hospital.





**Susan T. Vadaparampil**, associate center director of Community Outreach, Engagement, & Equity at Moffitt Cancer Center. She joined the Moffitt faculty after completing postdoctoral training at the NCI. Her work is focused on health disparities.

## Virginia Tech announces cancer research initiative

Virginia Tech has developed a strategy to increase cooperation and connections among its more than 30 cancer research teams, help recruit additional cancer researchers, provide access to state-of-the-art shared research resources, foster relationships with institutions and agencies recognized as world leaders in cancer treatment and research, and enhance the already substantial cancer research funding at the university.

“By looking at the totality of Virginia Tech’s efforts, the optics reveal a broad, diverse landscape of faculty members and expertise across colleges, centers, and institutes being applied to solve the health issues and social problems caused by cancer,” Michael Friedlander, vice president for health sciences and technology, said in a statement.

Virginia Tech has 22 active cancer research awards from NCI with an annual value of \$4.3 million.

More than 30 research teams are distributed across its Blacksburg-Roanoke campus with affiliations that include the Fralin Biomedical Research Institute at VTC, the College of Science, the College of Agriculture and Life Sciences, the College of Engineering, the Virginia-Maryland College of Veterinary Medicine, the Fralin Life Sciences Institute, and the Virginia Tech Center for Drug Discovery.

In addition, synergies continue to flourish with Carilion Clinic, Virginia Tech’s clinical partner.

“With Carilion’s expansive plans for growth to improve health care in the region, along with the recent announcement regarding a new Carilion children’s facility for specialty services, Virginia Tech expects additional opportunities for collaborations and partnerships in children’s health will increase, including cancer research and care,” Friedlander said.

Virginia Tech will now create a new strategic focus on cancer in children while it continues to develop cross-cutting research throughout the university and strategic relationships with federal agencies, private industry, and community partners — all aimed at the development of successful diagnostics and treatments for cancer.

Friedlander cited a relationship with Children’s National Hospital in Washington. Its neonatology program is ranked No. 1 in the country.

“Virginia Tech and Children’s National have a long history of collaboration, including joint NIH research grants, shared intellectual property, and shared scientific advisory efforts,” said Friedlander, who is also the executive director of the Fralin Biomedical Research

Institute. “We fully expect to become more engaged in the rich innovation ecosystem in the Washington, D.C., area as we move forward.”

The university plans to recruit several new research teams to work on pediatric brain cancer research.

The new cancer research effort will be coordinated through Virginia Tech’s Office of the Vice President for Health Sciences and Technology, which is under the Office of the Executive Vice President and Provost.

## Ribas, Jaffee, Eshhar, Samelson, Seed and Weiss share Coley awards for immunology

The Cancer Research Institute has presented awards to seven scientists:

### 2019 William B. Coley Award for Distinguished Research in Tumor Immunology

**Antoni Ribas**, of the University of California, Los Angeles, and **Elizabeth M. Jaffee**, of Johns Hopkins, shared the William B. Coley Award for Distinguished Research in Tumor Immunology.

Ribas is a professor of medicine, surgery, and molecular and medical pharmacology at UCLA and director of the Tumor Immunology Program at Jonsson Comprehensive Cancer Center.

He received the award in recognition of his efforts to spearhead the clinical adoption of checkpoint immunotherapy, his complementary research that has defined mechanisms and identified biomarkers of response and acquired resistance to PD-1 blockade therapies,

and his development of stem cell-based adoptive cell therapies.

Jaffee is a deputy director, Sidney Kimmel Comprehensive Cancer Center, associate director, Bloomberg-Kimmel Institute for Cancer Immunotherapy, Johns Hopkins University.

She received the award for research focused on novel vaccine approaches that overcome immune tolerance to cancers and her development of both genomic and proteomic methods to identify new pathways and biomarkers associated with the initiation and progression of pancreatic cancers.

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### 2019 William B. Coley Award for Distinguished Research in Basic Immunology

The Coley award for basic immunology went to four researchers for their collective contributions to identifying and elucidating the role of the T cell antigen receptor zeta chain as a key T cell signaling molecule and its application to CAR T-cell therapy. They are:

**Zelig Eshhar**, professor of chemical and cellular immunology, Weizmann Institute of Science; **Lawrence E. Samelson**, chief of the NCI Laboratory of Cellular and Molecular Biology, Center for Cancer Research; **Brian Seed**, professor of Genetics, Harvard Medical School and investigator, Center for Computational and Integrative Biology, Massachusetts General Hospital; and **Arthur Weiss**, investigator, Howard Hughes Medical Institute; and Engleman Distinguished Professor, Department of Medicine, University of California, San Francisco.

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### 2019 Frederick W. Alt Award for New Discoveries in Immunology

The Frederick W. Alt Award went to **Shane Crotty**, professor at the Division of Vaccine Discovery, La Jolla Institute

for Immunology, in recognition of his body of scientific research contributing to our understanding of the underlying immunology of vaccines, particularly the development of potent antibody responses and immune memory, and his elucidation of the important role of CD4+ “helper” T cells in these processes.

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## Cambridge’s Nik-Zainal wins Josef Steiner Cancer Research prize



The Dr. Josef Steiner Cancer Research Prize 2019, goes to Serena Nik-Zainal from the Department of Medical Genetics, University of Cambridge.

Nik-Zainal won the award, originally also known as the “Nobel Prize for Cancer Research,” for her successful application to accelerate holistic cancer genome interpretation towards the clinic with collaborators Paul Calleja and Ignacio Medina.

Thanks to her research, mutations in cancer tumors can be analyzed using new bioinformatic methods, which enables new approaches to targeted therapies. The prize will be awarded on Oct. 18 at the University of Bern. Nik-Zainal will present her work under the title

“Accelerating holistic cancer genome interpretation towards the clinic”.

In a statement, Nik-Zainal said:

“The rate-limiting step in cancer genomics today is not the ability to perform sequencing. It is the expertise in performing downstream analysis and making a clinically-useful interpretation, that remains the hurdle between genomic technology and the clinical context.

“Our research efforts began with showing that the totality of mutagenesis from large cohorts of whole genome sequenced tumors could reveal mutational signatures, imprints left by mutagenic DNA damage and repair processes that have occurred through cancer development. Subsequently, our team focused on experimentally validating these analytical concepts in cellular model systems. We examined mechanisms of mutagenesis related to DNA repair defects and of environmental mutagens. The powerful combination of computational analytics and experimental insights helped to drive the development of clinical computational tools to interpret whole cancer genomes more effectively.

“At the Clinical School, University of Cambridge, the Josef Steiner Award will help us enhance translation of our expertise and develop novel, clinically meaningful algorithmic tools. We seek to consolidate our current knowledge into infrastructure that is appropriate for the future. We are building a more automated foundation, that can be referred back to at any point, and that will scale with more data coming. It needs to be more user-friendly for the next generation of clinicians and scientists to explore and be suitable for advanced data analytics. We will be able to focus on asking novel biological and clinical questions of these large datasets and ultimately, accelerate making clinically-relevant progress.”

## Backman named associate director for research technology at Northwestern



Vadim Backman was named associate director for Research Technology and Infrastructure at the [Robert H. Lurie Comprehensive Cancer Center of Northwestern University](#).

In addition to this new role, Backman, the Walter Dill Scott Professor of Biomedical Engineering at the McCormick School of Engineering and Applied Sciences, will continue to serve as leader of the Cancer and Physical Sciences Program at the Lurie Cancer Center.

As associate director, Backman will oversee Lurie Cancer Center's infrastructure for interdisciplinary programs and initiatives, which include the [center's 16 Shared Resources that foster basic, clinical and translational research](#). He will also lead the development of innovative tools, technologies and services to support emerging disciplines across the cancer center.

Backman succeeds Milan Mrksich, the Henry Wade Rogers Professor, who was recently named Northwestern University's interim vice president for research.

An expert in biomedical optics, Backman has developed numerous imaging technologies. Through his nanocytology technique, he developed a simple, easy-to-use test for diagnosing multiple forms of cancer at the earliest stage of disease formation. He leads Northwestern's new Center for Physical Genomics and Engineering, focused on the entirely new field using optical imaging and computational genomics to reprogram the genome's chromatin, which regulates gene expression.

## City of Hope provides cancer support services to Amazon employees

City of Hope announced a partnership to provide a range of enhanced cancer support services to Amazon employees in the U.S.—including a dedicated phone line staffed by oncology nurses, specialized support for complex cancers and diagnosis and treatment plan review.

Amazon employs more than 275,000 people across the U.S.

The services include:

- **Cancer Support Line**

Whether an employee has a question about the side effects of treatment or needs emotional support, a dedicated team of cancer care nurses is available to answer questions and provide information. Employees can call about their own diagnosis or if a family member is diagnosed with cancer.

- **Expert Review**

Employees can benefit from this subspecialized expertise in their own communities by requesting that a

City of Hope physician review their diagnosis and treatment plan and provide a written recommendation to the patient's treating physician regarding the clinical appropriateness of the proposed therapeutic approach. If appropriate, City of Hope physicians will recommend improvements to the proposed treatment plan, including recommendations for—and interpretation of—genetic/genomic testing, identification of potential clinical trials and therapeutic options. An employee may also choose to go to City of Hope for an in-person evaluation with its premier physicians.

- **City of Hope Accountable Precision Oncology Program**

City of Hope specialists work with Amazon's health plans to support the care of patients with the most complex cancers. City of Hope cancer experts directly engage local primary oncologists to provide a recommendation for appropriate genetic testing and accurate interpretation of test results and advice for optimal treatment, including the appropriate use of the most leading edge, targeted therapies.

## NCI grant UNC to help patients navigate costs of cancer care

NCI has awarded a four-year, more than \$1.87 million grant to University of North Carolina Lineberger Comprehensive Cancer Center researchers to study the impact of implementing financial navigation services at five rural cancer centers in North Carolina to help patients cope with the financial burden, or financial toxicity, related to cancer care.

Building on pilot studies launched at the North Carolina Cancer Hospital,

UNC Lineberger's Stephanie Wheeler, and Donald Rosenstein, will use the grant to connect cancer patients with potential financial support resources in Carteret, Dare, Jackson, Lenoir, and Nash counties.

The study is an extension of an ongoing investigation by UNC Lineberger researchers into the cost that cancer care places on patients through the direct costs associated with treatment, lost income or wages, the psychological burden associated with high-cost care as well as potentially harmful behavioral strategies that patients might use to cope with costs, such as skipping treatment. Collectively, researchers refer to this impact as financial toxicity.

Wheeler reported at the American Society of Clinical Oncology's Quality Care Symposium last year on the results of a national survey of more than 1,000 women with metastatic breast cancer that was funded by Pfizer and the National Comprehensive Cancer Network.

Nearly a third of these women lacked insurance, and many felt "significant" or "catastrophic" financial effects from cancer. Rosenstein and Wheeler realized that this problem extends well beyond metastatic disease and breast cancer.

The team, led by Wheeler and Rosenstein, mapped the process of applying for financial assistance, and it became clear patients needed a trained professional to help navigate these resources. The need for financial navigation also was identified as a priority by a statewide network of oncology naviga-

tors, whose role was to support cancer patients as they transitioned from active care into survivorship.

Informed by work led by researchers at the Fred Hutchinson Cancer Research Center and published in the *American Journal of Managed Care*, the team tested a financial navigation program for 50 patients at the North Carolina Cancer Hospital. In this pilot program, funded by the UNC Center for Health Innovation, researchers screened patients for financial risk and then had a social work-trained financial navigator work with the patient to assess their financial needs and identify potential resources to help them.

The results of the study have not yet been released, but researchers said their early data show that having a financial navigator eases patients' anxiety and connects them to resources that help to reduce measurements of financial toxicity.

"The striking thing was that nearly everyone we screened in the cancer clinic showed signs of financial stress or risk," Rosenstein said.

The new grant is a follow-up to that study to see if financial navigation can be disseminated to rural areas, Rosenstein said. They will be partnering with Carteret Health Care in Carteret County, Harris Regional Hospital in Jackson County, The Outer Banks Hospital in Dare County, UNC Lenoir Health Care in Lenoir County, UNC Cancer Care at Nash in Nash County, and the Patient Advocate Foundation.

## Third Edition of Cancer Atlas highlights patterns and inequities in cancer burden

The American Cancer Society, Union for International Cancer Control and International Agency for Research on Cancer have published The Cancer Atlas, 3rd edition, an overview of cancer around the globe.

The document, released at the World Cancer Leaders' Summit in Nur-Sultan, Kazakhstan, can be downloaded [here](#). In addition to the printed report, the information is included on this [interactive website](#).

The atlas highlights distinct patterns and inequities in the cancer burden around the world; outlines the risk factors that are driving cancer patterns; and details the prospects for cancer prevention and control. The theme of the current edition is "Access Creates Progress."

Cancer is the leading or second-leading cause of premature death (under age 70) in 91 countries. Based on expected population growth and aging alone, the number of global cancer cases is expected to increase by 60% in 2040. More widespread distribution of lifestyle factors such as smoking, unhealthy diet, and physical inactivity are likely to make that number considerably larger.



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However, significant disparities exist in randomized clinical trial participation with clinical trial populations skewing younger and healthier than real-world patient populations, with limited ethnic and gender diversity. In an analysis of more than 300 randomized clinical trials, the median age of trial participants was 6.49 years younger than the disease population.<sup>1</sup>

This disparity is particularly prevalent in oncology trials. For example, the median age of patients with advanced non-small-cell lung cancer is 70 years; however, the elderly are significantly underrepresented in clinical trials where the median age of participants is 60.9 years.<sup>2</sup> The use of younger patients in trials means that the safety and efficacy data are often not generalizable to the real-world population.

As a result of differences in comorbidity, functional status, toxicity, and pharmacokinetics associated with this age gap, the survival and disease progression benefits demonstrated in the younger clinical trial population may not be seen in an increasingly elderly population of patients with advanced NSCLS. Given this disparity, what are the best outcomes we can actually expect in clinical practice?

## Expanding the use of pragmatic trials in oncology

While RCTs remain the gold standard for the assessment of safety and efficacy, the industry must identify alternate methods of gaining insight into treatment patterns and performance.

The complexity of the oncology treatment landscape offers an opportunity for the industry to expand the use of real-world evidence to provide critical information about how new treatments perform in real clinical settings. RWE

has been used successfully to support new and supplemental indications. It may also have the ability to inform post-market use and safety monitoring as adverse events for new drugs may not emerge until the treatments are available in clinical practice, when a



**The complexity of the oncology treatment landscape offers an opportunity for the industry to expand the use of real-world evidence to provide critical information about how new treatments perform in real clinical settings.**



larger number of patients receive them and for a longer duration than in clinical trials.

As the FDA finalizes guidelines for the use of RWE to support regulatory decisions, we must also work look at expanding RCT eligibility to include real-world patient populations to capture data on the day-to-day usefulness of drugs.

Pragmatic trials offer the ability to test treatment options on more representative patient populations with fewer exclusions for common conditions that could affect outcomes in practice. The use of pragmatic clinical trials, focusing on the correlation between treatments and outcomes in real-world clinical settings, has increased significantly over the past several years, particularly in chronic diseases.

For example, AIRWISE and REDEEM are large pragmatic clinical trials designed to provide real-world data on broad populations of COPD and diabetes patients, respectively, not captured from traditional RCTs.

As pragmatic studies continue to demonstrate that real-world data can be analyzed and compared to outcomes expected under a RCT in other areas of medicine, it is reasonable to expect that they can be effectively used in oncology as well.

The FDA has signaled openness to this approach in its recent RWE Program Framework and the expansion of the RCT DUPLICATE demonstration project, designed to use RWE to attempt to replicate the results of 30 RCTs. The goal of this project is to help inform the FDA's standards for using RWE in regulatory decision-making and identify when and where RWE can provide estimates of treatment safety and efficacy.

## Assess data integrity and verification

To understand the treatment of oncology patients, it is critical to evaluate clinical data points as well as elements of the patient-centered outcomes, such as adherence rates, persistence and time on treatment, toxicities and functional status among others.

This information, along with key demographic and patient characteristics, is widely available through real-time tracking of clinical and claims data elements across unified electronic health

record and reimbursement systems. Payers and other healthcare professionals have long used real-world data for health economics and outcomes research (HEOR) to make decisions about access, coverage, reimbursement and formulary placement for treatments.

In a recent [blog article](#), the editor in chief of the *ASCO Daily News* suggested the industry needs a reality check about the use of RWD: “to be useful, the data need to be accurate, consistently collected, and verifiable to a level comparable with what we expect from a prospective clinical trial...Without doubt, there are highly reliable big data sets, derived from multiple centers, abstracted according to consistent validated protocols with robust quality assurance and verification strategies. These sets are a valuable resource with great potential for research and care delivery...Otherwise, we run the risk that incomplete or inaccurate data derived from inherently biased, or poorly characterized, patient populations gain a new respectability as real-world data.”

The ability to transition the use of RWD from patient management to observa-



**The ability to transition the use of RWD from patient management to observational studies to support regulatory filings will be based on validating data quality.**



tional studies to support regulatory filings will be based on validating data quality. McKesson is working with the Friends of Cancer Research, biopharma companies and other industry stakeholders to create rigorous standards for defining regulatory-grade data and quality assessment.

This starts with setting standards for data provenance, documenting the origin and tracing the lineage of the data. This includes validating structured data with chart notes to ensure that the data is consistent, complete and representative of the target patient populations.

The initial Friends' RWE pilot project demonstrated that different datasets could be used to extract real-world endpoints in a consistent manner. In order to further characterize the role real-world endpoints may play in measuring treatment effect size, pilot project 2.0 will examine the ability of different real-world endpoints to detect treatment effectiveness in real-world patient populations.

In addition to rigorously maintaining quality, RWD must also be evaluated for the appropriateness of EHR data sets. While there are hundreds of EHRs in clinical use today, not all will be suitable for use as a source of RWD.

McKesson's [iKnowMed](#) oncology EHR, which captures outpatient medical histories from community oncology practices treating approximately one million

patients per year, has successfully been used to help understand the real-world utilization and outcomes associated with a number of oncology agents. However, that same data set may not have clinically relevant information regarding a cardiovascular therapy.

## Emerging opportunities for RWE in oncology

RCTs remain the gold standard for gathering safety and efficacy data to support regulatory decisions; however, timely, cost-effective recruitment of representative patient populations is increasingly challenging in oncology.

As pragmatic studies continue to demonstrate the ability to analyze treatment patterns and outcomes in other areas of medicine, oncology should welcome the ability to use regulatory-grade data to gather evidence generalizable to oncology patients in real-world clinical settings.

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## CLINICAL ROUNDUP



## UCLA opens CAR T-cell trial focused on the most common types of lymphoma, leukemia

The UCLA Jonsson Comprehensive Cancer Center has launched a CAR T-cell [immunotherapy trial](#) that will attack cancer cells by simultaneously recognizing two targets—CD19 and CD20—that are expressed on B-cell lymphoma and leukemia.

By launching a bilateral attack instead of using the conventional single-target approach, researchers are hoping to minimize resistance and increase the life expectancy for people diagnosed with these cancers.

“One of the reasons CAR T cell therapy can stop working in patients is because the cancer cells escape from therapy by losing the antigen CD19, which is what the CAR T cells are engineered to target,” Sarah Larson, a health sciences clinical instructor in hematology/oncology at UCLA Health and the principal investigator on the trial, said in a statement “One way to keep the CAR T cells working is to have more than one antigen to target. So, by using both CD19 and CD20, the thought is that it

will be more effective and prevent the loss of the antigen, which is known as antigen escape, one of the common mechanisms of resistance.”

Up to two-thirds of the patients who experience relapse after being treated with the FDA-approved CD19 CAR T-cell therapy develop tumors that have lost CD19 expression. UCLA researchers are identifying and testing new strategies like this one so many more patients can benefit from the therapy.

In [preclinical studies](#) led by Yvonne Chen, an associate professor of microbiology, immunology, and molecular genetics at UCLA and the sponsor of the trial, the team was able to show that by simultaneously attacking two targets, the engineered T cells developed in her lab could achieve a much more robust defense compared to conventional, single-target CAR T cells against tumors in mice.

Chen’s team designed the CARs based on the molecular understanding of the CAR’s architecture, the antigen structure and the CAR/antigen binding interaction to achieve optimal T cell function. This design helps the T cells have dual-antigen recognition to help prevent antigen escape.

“Based on these results, we’re quite optimistic that the bispecific CAR can achieve therapeutic improvement over the single-input CD19 CAR that’s currently available,” said Chen, who is also the co-director of the Jonsson Cancer Center’s Tumor Immunology Program and a member of the [UCLA Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research](#).

This first-in-humans study will evaluate the therapy in patients with non-Hodgkin’s B-cell lymphoma or chronic lymphocytic leukemia that has come back or has not responded to treatment. The goal is to determine a safe therapeutic dose.

Patients enrolled in the trial will have their white blood cells (T cells) collected intravenously then reengineered in the laboratory so the T cells can produce tumor-specific receptors (CARs), which allow the T cells to recognize and attack the CD19 and CD20 proteins on the surface of tumor cells. The new “smarter and stronger” T cells are then infused back into the patient and primed to recognize and kill cancer cells.

The trial is currently only offered at UCLA.

## Results from STELLAR trial in MPM published in *The Lancet Oncology*

Novocure said the results from the STELLAR trial were published in *The Lancet Oncology*.

The STELLAR trial was a prospective, single-arm trial including 80 patients that studied the use of Tumor Treating Fields, delivered via the NovoTTF-100L System, in combination with pemetrexed plus cisplatin/carboplatin as a first-line treatment for patients with unresectable, locally advanced or metastatic malignant pleural mesothelioma.

Data showed a median overall survival of 18.2 months (95 percent CI, 12.1 months-25.8 months) for patients treated with NovoTTF-100L and pemetrexed plus cisplatin or carboplatin. One- and two-year survival rates were 62.2 percent (95 percent CI, 50.3 percent-72.0 percent) and 41.9 percent (95 percent CI, 28.0 percent-55.2 percent), respectively. No serious systemic adverse events were considered to be related to the use of NovoTTF-100L. The most common mild to moderate adverse event was skin irritation beneath the transducer arrays.

“The STELLAR trial demonstrated encouraging overall survival results with



no increase in systemic toxicity observed in MPM patients treated with Tumor Treating Fields and standard chemotherapy,” Giovanni Luca Ceresoli, head of pulmonary oncology at the Humanitas Gavazzeni Hospital in Bergamo, Italy, and principal investigator in the STELLAR trial, said in a statement. “The median overall survival of 18.2 months is impressive given that MPM is a tumor with a dismal prognosis and few effective therapeutic options.”

Median progression free survival was 7.6 months (95 percent CI, 6.7 percent-8.6 percent) for patients treated with NovoTTF-100L and pemetrexed plus cisplatin or carboplatin. There was a 97 percent disease control rate in patients with at least one follow-up CT scan performed (n=72). 40 percent of patients had a partial response, 57 percent had stable disease and 3 percent had progressive disease.

## **IASLC invites comments on “Multidisciplinary Recommendations for Pathologic Assessment of Lung Cancer Resection Specimens Following Neoadjuvant Therapy”**

The International Association for the Study of Lung Cancer announced an open comment period for the “IASLC Multidisciplinary Recommendations for Pathologic Assessment of Lung Cancer Resection Specimens Following Neoadjuvant Therapy” paper.

The paper has been made available [here](#) to provide an opportunity for public review of new draft recommen-

dations. The open comment period runs from Oct. 14 to Nov. 7.

With the recent growing number of neoadjuvant therapy clinical trials for non-small cell lung cancer, there is a great need for standardization of specimen processing since major pathologic response has consistently been shown to be an important prognostic indicator.

The purpose of the paper is to outline detailed recommendations on how to process lung cancer resection specimens and to define pathologic complete response including major pathologic response and pathologic complete response following neoadjuvant therapy.

“Currently there is no established guidance on how to process and evaluate resected lung cancer specimens following neoadjuvant therapy in the setting of clinical trials and clinical practice,” Giorgio Scagliotti, past president of the IASLC and co-author of the paper, said in a statement. “There is also a lack of precise definitions on the degree of pathologic response, including MPR or pCR.”

IASLC is making an effort to collect such data from existing and future clinical trials. These recommendations are intended as guidance for clinical trials, although it is hoped they can be viewed as suggestions for good clinical practice outside of clinical trials, to improve consistency of pathologic assessment of treatment response.

The recommendations were developed by the IASLC Pathology Committee in collaboration with an international multidisciplinary group of experts in medical oncology, thoracic surgery and radiology.

“We are crossing an exciting period of preclinical and clinical research around thoracic oncology. Targeted therapies and immunotherapy have greatly improved survival expectations in advanced disease and we believe they can equally generate benefit in the systemic therapy of earlier stages of the disease,”

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Scagliotti said in a statement. “Our initiative aims to use rigorous experimental conditions to analyze tissue specimens, collected in the context of already performed or ongoing neoadjuvant studies with targeted therapies and immunotherapy, to generate a diagnostic algorithm to be used in all subsequent studies in order to accelerate the scientific information about the clinical benefit produced by the neoadjuvant approach.”

## Expert second opinion improves reliability of melanoma diagnoses

Getting a reliable diagnosis of melanoma can be a significant challenge for pathologists. The diagnosis relies on a pathologist’s visual assessment of biopsy material on microscopic slides, which can often be subjective.

Of all pathology fields, analyzing biopsies for skin lesions and cancers has one of the highest rates of diagnostic errors, which can affect millions of people each year.

Now, a study led by UCLA researchers, has found that obtaining a second opinion from pathologists who are board certified or have fellowship training in dermatopathology can help improve the accuracy and reliability of diagnosing melanoma, one of the deadliest and most aggressive forms of skin cancer.

“A diagnosis is the building block on which all other medical treatment is based,” Joann Elmore, a professor of medicine at the David Geffen School of Medicine at UCLA and researcher at the UCLA Jonsson Comprehensive Cancer Center, said in a statement. “All patients deserve an accurate diagnosis. Unfortunately the evaluation and diagnosis of skin biopsy specimens is challenging with a lot of variability among physicians.”

In the study, led by Elmore and colleagues, the value of a second opinion by general pathologists and dermato-

pathologists were evaluated to see if it helped improve the correct diagnostic classification.

To evaluate the impact of obtaining second opinions, the team used samples from the Melanoma Pathology Study, which comprises of 240 skin biopsy lesion samples. Among the 187 pathologists who examined the cases, 113 were general pathologists and 74 were dermatopathologists.

The team studied misclassification rates, which is how often the diagnoses of practicing US pathologists disagreed with a consensus reference diagnosis of three pathologists who had extensive experience in evaluating melanocytic lesions. The team found that the misclassification of these lesions yielded the lowest rates when first, second and third reviewers were sub-specialty trained dermatopathologists. Misclassification was the highest when reviewers were all general pathologists who lacked the subspecialty training.

“Our results show having a second opinion by an expert with subspecialty training provides value in improving the accuracy of the diagnosis, which is imperative to help guide patients to the most effective treatments,” said Elmore, who is also the director of the UCLA National Clinician Scholars Program.

Elmore is now studying the potential impact of computer machine learning as a tool to improve diagnostic accuracy. She is partnering with computer scientists who specialize in computer visualization of complex image information, as well as leading pathologists around the globe to develop an artificial intelligence (AI)-based diagnostic system.

Michael Piepkorn of the University of Washington School of Medicine is the study’s first author. Raymond Barnhill of the Institut Curie is the co-senior author.

The study was published in *JAMA Network Open* and supported by NCI.

## DRUGS &amp; TARGETS



## Xenikos receives Fast Track designation for T-Guard for steroid-refractory SR-aGVHD

The Dutch company Xenikos B.V. said FDA has granted Fast Track designation to T-Guard, Xenikos's product designed to treat steroid-refractory acute graft-versus-host disease in patients following allogeneic stem cell transplantation.

T-Guard is designed to reset the body's immune system in life-threatening T cell-mediated conditions, including transplant-related rejection, acute solid-organ rejection, and severe autoimmune disease. T Guard consists of a combination of toxin-conjugated monoclonal antibodies that target CD3 and CD7 molecules on T cells and NK cells.

Preclinical and early clinical testing have shown that T-Guard can specifically identify and eliminate mature T cells and NK cells with minimal treatment-related side effects, the company said. T-Guard's action is short-lived, thereby significantly reducing the patient's vulnerability to opportunistic infections, compared to currently available ther-

apies. Xenikos has completed a phase I/II study for the second-line treatment of SR-aGVHD in patients following hematopoietic stem cell transplantation.

The results of the study showed that one week of T-Guard treatment triggered a strong clinical response and doubled the 6-month overall survival rate, the company said. These results were published in *Biology of Blood and Marrow Transplantation*.

A U.S. phase III registration trial involving patients with SR-aGVHD following allogeneic stem cell transplantation will begin soon, and T-Guard has been granted Fast Track designation by the FDA, as well as Orphan Drug Designation status in both the EU and the U.S.

## Flatiron announces clinical decision support application through Epic's App Orchard

Flatiron Health announced the availability of its clinical decision support and pathways application, Flatiron Assist, in the [App Orchard](#).

Flatiron Assist supports oncologists in selecting therapies in line with best clinical practices, including the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology, and in identifying potentially relevant clinical trials.

The integrated regimen selection workflow allows clinicians to quickly confirm the clinical data needed to determine adherence to guidelines. Health system administrators can use the clinical data collected by this tool to streamline the prior authorization process, measure variation in care across a practice or health system, and report pathways compliance to payers.

"The rapidly evolving treatment landscape and increasing payer reporting requirements make it challenging for busy oncologists to efficiently get the best treatments to their patients," James Hamrick, senior medical director, Flatiron Health, said in a statement. "Flatiron Assist is an EHR-integrated tool that puts the doctor and the patient at the forefront, enabling evidence-based treatment selection, efficient payer authorization, and insight into care patterns across practices and health systems."

Available now in the App Orchard, Flatiron Assist is a SMART on FHIR application that will launch from the patient's chart in Epic, eliminating the need for duplicate data entry outside the electronic medical record. Flatiron Assist pulls available demographics, diagnosis, and cancer-specific data, such as staging, from Epic and, based on those inputs, surfaces evidence-based therapy options and clinical trials for each patient. Once the oncologist chooses a treatment regimen in Flatiron Assist™, the selected regimen is automatically opened in Epic.

"Integrating NCCN's recommendations into point-of-care apps like Flatiron Assist puts the latest evidence and multidisciplinary expert knowledge at the fingertips of oncologists everywhere," Robert W. Carlson, CEO of NCCN, said in a statement. "NCCN Guidelines are the most frequently updated medical guidelines in any discipline; they should also be the most accessible. The convenience of Flatiron Assist can give doctors more time to engage in shared decision making in order to determine which guideline-concordant treatment plan offers the most benefit."

Additional information is available [here](#), and [here](#).