COVID-19 THREATENS TO INCREASE CANCER MORTALITY—HERE IS WHAT WE CAN—AND MUST—DO

This January, the American Cancer Society reported the sharpest drop in U.S. cancer mortality ever recorded. Between 2016 and 2017, the death rate from cancer fell 2.2%, continuing the trajectory of a 29% decline in cancer mortality since 1991.
Help close the coronavirus data gap. Enroll in the ASCO COVID-19 Registry today.

To address the coronavirus data gap, ASCO established the *American Society of Clinical Oncology Survey on COVID-19 in Oncology Registry*. The ASCO Registry will help the cancer community learn more about the treatment and outcomes of cancer patients with COVID-19, and how COVID-19 is impacting the delivery of cancer care. Participating practices receive a modest per-case payment to cover the expenses of participation.

**ASCO COVID-19 Registry Highlights:**

- Collects baseline and follow-up data on COVID-19 impact
- Delivers periodic reports with key findings
- Will provide insight about cancer and COVID-19 outcomes
- Qualifies as an accepted clinical trial registry for improvement activities under the Merit-Based Incentive Payment System (MIPS)

"The cancer care community must seize this opportunity to build a new knowledge base that will inform cancer care and treatment decisions during future disease outbreaks. We encourage every practice to share their experience."

– Richard L. Schilsky, MD, FSCT, FACP, FASCO
ASCO Chief Medical Officer and Executive Vice President

"The ASCO Registry provides true insight into what our patients with COVID-19 are experiencing in terms of delays in their cancer care, and the potential effects on their oncologic outcomes. We’ve also found it incredibly user-friendly."

– Alexander Spira, MD, PhD, FACP
Virginia Cancer Specialists Medical Oncologist & Director of VCS Research Institute & Phase I Trial Program

**THERE’S STILL TIME**

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COVID-19 THREATENS TO INCREASE CANCER MORTALITY
HERE IS WHAT WE CAN—AND MUST—DO

This January, the American Cancer Society reported the sharpest drop in U.S. cancer mortality ever recorded. Between 2016 and 2017, the death rate from cancer fell 2.2%, continuing the trajectory of a 29% decline in cancer mortality since 1991.

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Within a month after ACS reported those numbers, the COVID-19 pandemic hit, sending shockwaves through the already fragmented U.S. healthcare system. The pandemic could potentially reverse a decades-long downward trend in cancer mortality. We must not let this happen.

Specifically, we must ensure patients can get indicated screenings they need to detect cancer early, prevent it when possible, and save lives. We must also make sure that cancer patients continue their treatment regimens already underway uninterrupted and initiate new treatment for cancer when needed.

We have our work cut out for us—patients are understandably worried about seeking care during the pandemic, which has caused the death of nearly 200,000 people in the U.S., and continues to claim the lives of around 1,000 people in the country every day. These numbers do not adequately reflect the collective trauma and depth of our loss.

As we continue to mourn the lives lost due to the pandemic and adapt our lives to the measures necessary to keep one another safe, we must recommit to lifesaving preventive measures such as screening for cancer. Every year, cancer kills 600,000 people in the U.S. These lives, too, are invaluable. The risk of a significant reduction in screenings, a proven method to reduce mortality from cancer, is too great to bear.

Any significant drop in screenings could have profound consequences. Routine colonoscopies that led to the removal of noncancerous colorectal polyps reduced mortality from colorectal cancer by 50%, according to a study published in the New England Journal of Medicine.

Screening exams also enable health care providers to detect and treat malignancies early, when they are often more responsive to therapy. A study published in the journal Cancer found that routine mammograms reduced a woman’s risk of dying from breast cancer within 10 years of her diagnosis by 41%, and also led to a 25% reduction in being diagnosed with advanced breast cancer, which is much more difficult to treat.

According to a 2016 study published in the British Journal of Cancer, screening for cervical cancer has prevented nearly 68% of would-be deaths from the disease.

To gain the lifesaving benefits of routine screening, we must safely resume scheduling patients for these exams—or risk a worse outcome in some individuals.

**How we got here**

As the pandemic peaked in waves around the country, healthcare organizations and local officials released policies to delay elective procedures. For many, “elective procedures” included routine screening exams. These measures were necessary for providers to assess the threat of COVID-19, or for hospitals with active COVID-19 wards to redirect staff and resources towards virus-infected patients.

Now, patients continue to delay preventive screenings for many reasons. At first, patients were told to postpone screenings by their healthcare providers, so they did. But even as hospitals have developed protocols to deliver routine care in a much safer environment, screening rates remain too low, and ultimately bad outcomes could result in lives lost.

Again, this is understandable. Even in the best of times, we are not capitalizing on the full potential of prevention measures that we know work. As of 2015, screenings for breast, cervical and colon cancer fell short of targets set by the Office of Disease Prevention and Health Promotion.

These, of course, are not the best of times. The pandemic temporarily brought routine screenings to a halt. That type of inertia is dangerous, especially as the pandemic intensifies factors that make barriers to care worse. Patients tend to seek less care in an economic downturn—they conserve their health care dollars for acute issues and emergencies.

Patients across the world are now suffering from economic hardship. The World Bank predicts the global economy will shrink by 5.2% this year, and that the U.S. economy will contract by 6.1%. Moreover, up to 12 million Americans may have lost their employer-sponsored health insurance during the pandemic, according to the Economic Policy Institute, adding to people’s financial stress.

Besides the economic hardship triggered by the pandemic, patients are sometimes afraid. The background noise of COVID-19 can drown out other health concerns. With a lack of clear direction and/or conflicting messages, some patients have been receiving inconsistent information about how and when to resume health care services.

With state and local healthcare leaders overburdened with the requirements of the pandemic response, it leaves few stakeholders to bang the drum about the importance of screening for cancer—and cancer screening is needed to maintain the health and wellbeing of individuals in the U.S., the healthcare system, and the country as a whole.

**What we risk if we fail**

Already, COVID-19 has halted cancer screenings to a degree that could negatively affect outcomes. Researchers estimate that mammograms, a crucial
tool for early detection of breast cancer, have dropped anywhere from 75% to 95% since March 2020. Pandemic-related screening delays could cause an excess of 10,000 deaths over the next 10 years, National Cancer Institute director Ned Sharpless told STAT this past June—resulting in a 1% increase in expected deaths for the decade.

As of June, cancer screenings had not returned to their pre-COVID-19 levels, according to data from the Epic Health Research Network. Breast, colon and cervical cancer screenings remained 29%, 36%, and 35% lower than expected, respectively.

In short, we risk a significant increase in the number of deaths and poorer outcomes from cancer if we don’t successfully address these issues during the pandemic.

**Getting the story straight**

Our challenge is to earn patients’ trust, so that they can safely and cost-effectively resume screening procedures for cancer.

Healthcare leaders need to explain measures they are taking to ensure a low infection risk at clinical facilities that offer screenings.

We must also assure individuals that discovery of a malignancy or a pre-malignant lesion can be safely treated in the clinic or hospital. Early studies show that cancer patients undergoing chemotherapy or other treatments are not at increased risk of mortality from COVID-19. Although, outcomes data is emerging from large cohort studies that will address this issue much more carefully in the next several months.

We must adhere to social distancing and mask-wearing policies in clinical facilities and communicate those policies clearly to patients and their family members. We must make such small steps as scheduling appointments and negotiating with payers as easy as possible, since every barrier to care takes on added weight during COVID-19.

It can be difficult for people to grasp the harm of not doing a procedure. But forgoing cancer screenings has the potential to derail the country’s decades-long progress in lowering cancer mortality. COVID-19 has been destructive enough. We must not let it stop measures to detect early disease—the most effective method we have to prevent deaths from cancer.

In order to understand better the impact of COVID-19 on cancer patients, the Hollings Cancer Center here at the Medical University of South Carolina (@muschollings) in Charleston joined the COVID-19 and Cancer consortium (CCC19) and is one of 120 institutions in the country collecting data on adult patients (18 and older) with cancer who have been diagnosed with COVID-19.

This is being done in order to collect and disseminate prospective, granular, uniformly organized information on cancer patients and survivors who are diagnosed with COVID-19—at scale and as rapidly as possible to understand, in real time, how this disease is affecting cancer patients.

**And please don’t forget:**

There are several steps we can all take to reduce our risk of getting cancer:

- Don’t use tobacco in any form or expose yourself to second-hand smoke. Cancers linked to tobacco use make up to 40% of all cancers, so avoiding this exposure can have a huge benefit.
- Eat a healthy diet that includes fruits and vegetables. If you choose to drink alcohol, do so in moderation, and limit intake of processed meats.
- Maintain a healthy weight and stay physically active. Any amount of physical activity is helpful, but to maximize benefit, the Mayo Clinic recommends getting at least 150 minutes per week of moderate activity or 75 minutes per week of vigorous aerobic activity.
- Protect yourself from exposure to the sun and avoid tanning beds or sun lamps at all costs.
- Get vaccinated for hepatitis B and the human papilloma virus (HPV) at the recommended ages. Avoid risky behaviors that can lead to infections known to increase your risk of cancer, like unprotected sex or the sharing of needles used by others.
- Seek routine medical care, as noted above, that includes regular self-exams and screenings for various types of cancers, such as cancer of the skin, colon, cervix and breast. These preventive exams increase your chances of discovering cancer early, when treatment is most likely to be successful.
- Do not hesitate to ask your doctor about the best cancer screening schedule for you based on your medical and family history.

Remember, if we collectively, as a population, adhere to all of these recommendations, we could reduce cancer globally by as much as 40-50%—today, without any further advances in diagnostics or treatment.
The unprecedented COVID-19 pandemic makes it possible to compare and contrast the public health and political responses to previous health crises.
The most obvious comparison is to the influenza epidemic of 1918-19, which took the lives of 675,000 Americans in less than two years.

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

Disease and death from smoking take years, even decades to occur. Deaths from COVID-19 can occur within days or weeks, albeit in less than 2.9% of victims, most of whom have comorbid conditions such as hypertension, obesity, and emphysema.

As we assess the 50-year War on Cancer that was declared when President Richard M. Nixon signed the National Cancer Act of 1971, some parallels and lessons from the past that can be gleaned from anti-smoking campaigns and applied to the efforts against COVID-19.

As defiant and skeptical as President Trump may be of the preventive behavioral measures that all health agencies agree are the first step to contain the spread of the virus, his magical-thinking approach mirrors the playbook of previous presidents to ending the cigarette pandemic, even decades after it was recognized as the nation’s leading avoidable cause of death and disease.

Should anyone really be surprised that when it comes to public health and health care, money and politics take precedence over science?

In early April, no sooner had Anthony Fauci, of the White House COVID-19 Task Force, come to the conclusion that all Americans, not just front-line health workers and patients, needed to wear face masks, practice social distancing, and wash their hands to prevent the spread of COVID-19, President Trump began subverting this message by retweeting Fauci’s original assertion in March that mask-wearing by the general public was not yet necessary.

By mid-summer, Trump had rejected the recommendations by the Centers for Disease Control and Prevention on protecting meat processing plant workers, teachers, other school personnel, and children from COVID-19. Trump not only muted, muzzled, and marginalized the CDC, he had also become its de facto spokesperson.

Even as he has publicly played down the ease of spread and the adverse health consequences of COVID-19, last week we listened to the recording of his February interview by reporter Bob Woodward, in which Trump acknowledged the ferocity of the new virus.

This called to mind the response by another president to the efforts by the top health official in his administration to launch the federal government’s first anti-smoking campaign. In January 1978, U.S. Secretary of Health Education and Welfare Joseph A. Califano, Jr., announced that HEW would “place the weight of its scientific authority behind programs to inform the public—especially the young—about why they should not smoke and how they can quit if they wish. As the chief health officer of government, I have the duty to see that we do just that.”

Within weeks, Califano’s efforts were being undermined by President Jimmy Carter, who traveled to North Carolina to assure tobacco famers that the government would make cigarette smoking “even safer than it is today.” As Califano’s campaign continued to gain momentum, and after HEW published the most comprehensive indictment yet of cigarette smoking in its 1979 Surgeon General’s Report, Carter fired Califano. There was little doubt that the main reason was his fervent anti-smoking stance.

“Should anyone really be surprised that when it comes to public health and health care, money and politics take precedence over science?”

The present-day Republican-led opposition to state and local ordinances mandating the wearing of face masks in public places is akin to the vocal opposition in 1964 to federal legislation to require an understated warning on the side of cigarette packs (“Caution: Cigarette Smoking May Be Hazardous to Your Health”).

The staunchest opponents of the warning were not just the cigarette manufacturers and tobacco state congressmen, but also the American Medical Association, which claimed that the public was already well informed about the dangers of smoking.

In those days, Republican Sen. Jesse Helms were beating back anti-smoking bills introduced by Democratic Sens. Ted Kennedy and Dick Durbin and Reps. Henry Waxman and Ron Wyden. Today, we can take in the spectacle of Republican Sen. Rand Paul (a physician) and Republican House Members Matt Goetz, Luis Gohmert, and Mark Meadows deriding the recommendation to wear face masks.
All four contracted COVID-19, with Gohmert blaming his infection on having to wear a mask.

At his nationally televised town meeting on Sept. 15, in which he claimed that “herd mentality” could make the virus “disappear,” Trump also claimed that the repeated putting on and taking off a mask could increase the chances of becoming infected with COVID-19.

The other two physicians in the Senate, Republicans John Barrasso and Bill Cassidy, have stood behind Trump every step of the pandemic. In May, Barrasso, an orthopedic surgeon until he was appointed to the Senate in 2007, cited his medical background to support Trump’s call to end COVID-19 containment shutdowns and echoed Trump’s comment that “we cannot allow the cure to be worse than the disease.”

Granted, oversimplifying the comparison between the response to COVID-19 and the fight against smoking risks reducing it to a body count competition. Yet, that is just what Stanford historian Robert Proctor did in a book review in the July 7 issue of JAMA:

“It all seems so February. Cigarettes remain the leading preventable cause of death, but that morbid fact is easily lost in more pressing pandemics. It is worth keeping in mind that even if the novel coronavirus 2019 (COVID-19) ends up killing 200,000 people in the U.S., that number will not be even half the annual toll from cigarettes, which still kill half a million Americans every year.”

Such a comment is as simplistic and cold-hearted as any of Trump’s unempathetic pronouncements downplaying the catastrophic impact of COVID-19. One hears echoes of the claim that the virus “will just disappear,” but smoking will remain.

The bigger killer

Sadly, this is the same narrative that all too many individuals who work in the field of “tobacco control” have used for other emerging health crises such as the rapid rise in obesity, namely that smoking is always the bigger killer.

They seem to see other health issues as a threat to their turf. Proctor calls the assertion that his smoking dog is bigger than your COVID dog an “enduring constancy” and insists that “scholars need to pay more attention to cigarettes, even in these distressing days of plague.

“Any focus on disease that ignores the cigarette or the cigarette industry is like pretending to have an interest in malaria while paying no attention to mosquitoes or swamps. Nicotine addiction is likely to outlive coronavirus, shackling millions in chains that lead to suffering and death. The havoc wreaked on human health is worse than any virus.”

Nathan Schachtman, an attorney and lecturer at Columbia Law School who has written on tobacco litigation, is appalled by Proctor’s claim. “This type of comparison between COVID-19 and smoking is inapposite,” he says. “COVID puts me at risk from even a brief encounter with an infected person. I have no control as an individual over the risk of this infectious disease; it absolutely requires coordinated action by government. We can all agree that both smoking and COVID are public health problems, while refraining from making inane comparisons. The thing about COVID-19 is that a pandemic ensures that there will be innocent victims—people who did not assume the risk, but had the risk of death and disability foisted upon them by fellow citizens.”

Two hundred thousand deaths—in addition to hundreds of thousands of potential “long-haulers” suffering from crushing fatigue, lung and heart damage, and other problems—caused by a single pathogen in just six months extrapolates to 300,000 deaths this year, plus a lingering morbidity comparable to that caused by cigarette smoking. And there is no cure in sight, but rather false promises by the president of a breakthrough vaccine “just around the corner” … before Election Day.

“Instead of trying to make the case that smoking is worse than COVID-19, we should instead be applying the lessons we’ve learned from anti-smoking efforts to reduce the toll of COVID-19,” argues Michael Siegel, professor of community health sciences at Boston University School of Public Health. “Most obviously, the chronic conditions of emphysema and cardiovascular disease that help COVID take hold are frequently due to smoking. The successes and failures of the past five decades of anti-smoking actions are playing out now in the daily COVID-19 death tallies.”

Writing in Financial Times on Aug. 4, Sir Richard Feachem, who served as under-secretary-general of the United Nations and founding executive director of the Global Fund to Fight AIDS, Tuberculosis, and Malaria, warns that counting on a COVID-19 vaccine to come to our rescue soon is “not only unlikely but is a dangerous assumption on which to plan the overall response to the pandemic.”

Politicians and vaccine developers have incentives to reinforce this assumption, he notes, in spite of the long odds against a vaccine with high efficacy, a protracted duration of protection, a convenient dosing schedule, and the ability to administer billions of doses.

Is this not reminiscent of the never-ending quest for the Holy Grail of the safe cigarette? Can anyone doubt that the biggest failure in the history of the National Cancer Institute is not to have dispelled the myth that filtered cigarettes can prevent lung cancer?
New Health Warnings Unneeded

WASHINGTON, D.C.—Legislation being considered in the House and the Senate to require new health warnings on cigarette packages is unnecessary and ill-conceived. Edward A. Horrigan Jr., chairman and chief executive officer of R. J. Reynolds Tobacco Co., has told Congress.

Horrigan, in separate testimony before committees in the House and Senate, noted that proponents of the bills say their purpose is to inform the public of the dangers of smoking.

"In fact," Horrigan said, "virtually everyone is aware of the claimed dangers of smoking." He cited a 1981 Gallup survey that found "90 percent of the population agrees that cigarette smoking is harmful."

Horrigan emphasized that the level of awareness of smoking and health far exceeds public awareness of perhaps all major contemporary issues facing this country.

For example, he said, less than 25 percent of the public knows what the First Amendment is or what it deals with. One-third do not know whether the Federal budget is balanced. Horrigan said, and 36 percent are not aware that the U.S. must import oil to meet energy needs.

"The facts clearly show that the public has been made aware of the so-called health hazards of smoking, and that people are in a position to make a free and informed choice on whether or not to smoke," said Horrigan.

He called the bills punitive measures "directed against the manufacturers of a lawful product." They appear "designed to lead toward the prohibition of smoking," RJR's chairman testified.

Free Choice

Horrigan, as chairman of the executive committee of the Tobacco Institute, is the cigarette industry's chief spokesman, had philosophical problems with the health warnings: They seriously erode the principle of free choice in a democratic society, Horrigan said. In effect, they say that if you don't conform, you are uninformed, and that the government must take corrective action, he said.

"In denying a person's right to reject official information, the bill betrays its fundamental prohibitionist motives," Horrigan said. Such legislation is "a thinly veiled effort further to harass and ultimately eliminate an important American industry."

Four Hearing Days

The bills in question were introduced in the House by Rep. Henry A. Waxman (D-Calif.) and in the Senate by Republican Sens. Orrin G. Hatch (Utah) and Bob Packwood (Or.). They call for the current health warnings to be replaced by a rotational system of up to seven warnings, speaking about cigarette smoking and heart disease, cancer, emphysema, and pregnancy outcome.

Other sections of the bills would establish the government's Office on Smoking and Health by statute (it has been threatened by budget cuts); force cigarette manufacturers to place warnings on exported cigarettes; and, in the House version, legislate that all ingredients used in cigarette manufacturing be listed on the pack.

Three TV stars—Amanda Blake, John Forsythe, and Bob Kershaw—and a panel representing voluntary health organizations that support the bill began the testimony on the first day of hearings in the House by Waxman's Subcommittee on Health and Environment.

Witnesses for the Administration emphasized their assessment of the health dangers of smoking on the second day of House hearings and at the one day Senate hearing. They said that the Reagan Administration is still studying the bills. Another Senate hearing is expected.

The tobacco industry spokesman Horrigan testified on day three of the House hearings and at the Senate hearing. Congressional participation in the hearings has been light.

Rep. Harold Rogers (R-Ky.), who attended one day of the hearings, said the Waxman bill is "the most complete and significant in constitutional aspects." It would, he said, set up a "brainwashing operation to sway free people on what they should or should not do."

Rep. Thomas J. Billett (R-Va.), who attended all three days of House hearings, emphasized that "no market research exists to show that the new warnings will cut consumption."

"Shouldn't we get evidence first," he asked?

Additional Stories

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Additional evidence is needed to prove that the current warning label is not adequate, Rep. William E. Danne- meyer (R-Calif.) said at a hearing: At the Senate hearing, Sen. John P. East (R-N.C.) called the legislation a "bad bill." He said, "We are a little weary of being punched bags for those who look on this as the only health issue in the U.S."

Other Congressmen who have spoken out against the legislation include Sens. Jesse A. Helms (R-N.C.) and Reps. W. Eugene Johnston III (R-N.C.) and L. H. Fountain (D-N.C.). Sen. Walter (Dod) Huddleston (D-Ky.) issued a statement saying the bill should be set aside "as an unwarranted and untimely intrusion."

Swedish Experience

"There is also strong evidence from the standpoint of behavioral science," Horrigan said, that the new system of legal warnings might "erode awareness" of the claims against smoking.

He cited the example in Sweden, where five years ago the government began a rotating warning system that is the model for the bills being considered in the U.S. Congress. "The fact is," Horrigan said, "according to the Swedish government, cigarette consumption has risen each year since the new system was implemented there in 1977."

"Why substitute a proved and unproved system for the present law?" Horrigan asked.

Continued on Page Two
Following the release of the 1964 Surgeon General’s Report, there was a dramatic increase in advertising claims by the tobacco companies implying that filtered cigarettes were safer than non-filtered ones.

This campaign extended to Hollywood, where TV and movie heroes and heroines smoked filtered brands while the crooks and tramps smoked non-filters. Alas, the history of the filter is at the heart of why the reduction in smoking has been so slow.

Beginning in the early-1950s, when the devastating reports of the impact of smoking on health were making front-page news and beginning to drive down cigarette sales, the tobacco industry took the upper hand by proclaiming in full-page newspaper advertisements across the U.S. that it would fund research to identify and remove any harmful ingredients from cigarette smoke.

By the late 1960s and throughout the 1970s, the National Cancer Institute’s research efforts on smoking were almost entirely directed toward finding a safer cigarette. This dead-end research didn’t get the ax until 1980, when Vincent De Vita became director of NCI and began shifting the focus of smoking research to getting heavy smokers to quit.

Even then, a far more heavily funded NCI research project in the 1980s was “chemoprevention,” which aimed to reduce lung cancer in smokers with large doses of vitamin A. The highly promoted study was halted when it was found that this caused an increase in lung cancer.

The unequivocal conclusion of the landmark 1964 U.S. Surgeon General’s report on smoking and health that cigarettes cause lung cancer and other diseases was to have ended a debate that had raged for decades.

Instead, the tobacco industry made a preemptive strike by funneling a total of $18 million over 14 years to the American Medical Association—the only major health organization to withhold its endorsement of the report—in a research program to identify and remove any possible harmful components of cigarette smoke.

### Unholy alliances

Why did the AMA choose not to campaign against smoking, but rather to conduct the same kind of research that the report had already found sufficient for its indictment of smoking?

It did so in order to remain in the good graces of tobacco state senators, whom it counted on to help prevent the creation of Medicare by Congress. This, in turn, leads to another villain that has gone unnoticed: the insurance industry, which never lifted a finger to fight smoking, even long after a small Massachusetts insurer, State Mutual Life Assurance Company, offered the first non-smoker discount after the SG report came out in 1964.

Because the anti-smoking narrative has been revised as a great victory instead of an abject failure, the rogues’ gallery is endless. One of the genuine leaders was the fearless Sen. Maureen Neuberger, who castigated not just the tobacco companies but also the see-no-evil, hear-no-evil, speak-no-evil AMA in her 1964 book *Smoke Screen: Tobacco and the Public Welfare*.

The AMA/tobacco industry collaboration distributed research funds to dozens of universities to keep scientists in their laboratories and not out testifying to the need to end smoking. Columbia University, although not a participant as an institution with the AMA program, went so far as to market a patented “super-filter” that it claimed would remove the cancer-causing “tar” and prevent lung cancer. It didn’t.

Essentially the same kind of players that fought efforts to pass clean indoor air legislation or bills to ban or restrict cigarette advertising and promotion are at it again with COVID-19.

The filter con endures to the present day. Ninety-nine percent of cigarettes sold are filtered brands, in spite of the fact that filters likely increase the risk of death and disease from smoking by virtue of the smoker needing to inhale more deeply—and by fostering complacency about the dangers of smoking.

Essentially the same kind of players that fought efforts to pass clean indoor air legislation or bills to ban or restrict cigarette advertising and promotion are at it again with COVID-19. The cigarette companies’ filter and low-tar hucksterism is not unlike the touting by Trump of oleander, hydroxychloroquine, zinc, bleach, Lysol, and UV light for the prevention of COVID infections.

Meanwhile, Trump’s COVID-19 advisers include individuals untrained in infectious disease, notably retired Stanford radiologist Scott Atlas. In a scathing op-ed in the *Los Angeles Times* on Sept. 10 by Stanford epidemiologists Steven Goodman and Melissa Bondy, co-signed by all of their epidemiology colleagues.
at the university, the authors castigate Atlas for recommending less COVID-19 testing and less mask-wearing in indoor public spaces, as well as for downplaying the nonfatal health risks of the virus and its transmissibility by children.

The Washington Post and The New York Times were criticized by an editorialist at The Wall Street Journal for questioning Atlas’ fitness and credentials, even though Atlas got the job after espousing his unconventional views on Fox News. Both the Journal and Fox News are controlled by the pro-Trump Murdoch family, whose patriarch Rupert Murdoch served on the board of Philip Morris from 1989 to 1998; Philip Morris executives in turn have served on the board of Murdoch's News Corp.

To think that in 1854, fully 40 years before Robert Koch discovered the bacterium that causes cholera, a lone London obstetrician named John Snow identified the source of a cholera outbreak with pencil, paper, and shoe leather.

By interviewing surviving family members of many of the more than 500 victims, he realized that the fatalities were clustered around a single water pump in Broad Street, from which most of the victims had obtained their household supply.

Countless lives were saved when the pump was ordered shut, over the objections of the water companies, which blamed the cholera epidemic on “bad air,” or miasma. Religious zealots blamed divine intervention. Ironically, it was a minister, Rev. Henry Whitehead, who at first contended that the outbreak was not caused by tainted water but by God’s will, who surprised himself to discover that the cause was a soiled diaper emptied into a leaky cesspool near the pump.

More than half a century after the causes of the epidemic of lung cancer and emphysema became known through epidemiologic studies, the tobacco industry, like the water companies of Snow’s London, insisted that their product was not to blame. They were backed up by administration after administration as the cigarette—and its tax revenues—became a mainstay of the economy.

Arguably the best single summary of government policy on smoking came from the United Kingdom’s Royal College of Physicians in the 1971 sequel Smoking and Health Now to its pioneering report on smoking and health in 1962: Castigating the government for spending little to educate the public about the dangers of smoking—a tenth of the amount spent on traffic safety.

The report dryly observes, “It seems that Ministers, while accepting the evidence that cigarette smoking is dangerous to health, are guided in their actions by the view that the risks are regrettable but inevitable consequences of a habit which they believe to be an essential source of revenue.”

“Liberate Michigan”

The economy-over-lives approach to COVID-19 by the current president is reminiscent of other administrations’ approach to curbing smoking.

“College football, get out there and play football,” Trump said on Aug. 11, when the only major universities left whose officials had given the season a green light—in the Atlantic Coast and Southeastern conferences—are located in the very region with the least adherence to personal COVID-19 health precautions and a steady rise in the number of cases.

By his masks-be-damned rallies and his tweets to "Liberate Michigan!" and other battleground states with Democratic governors from the inconvenience of wearing a mask and washing hands, Trump has become a 21st century Typhoid Mary, a super-spreader of COVID-19 through his crowded campaign rallies.

By stoking the embers of anti-scientific thinking for years in regard to the safest and most effective vaccines, by mocking the wearing of masks and social distancing, and by claiming that there is a COVID-19 vaccine just around the corner, Trump has undermined confidence in the safety and efficacy of any such rushed-out vaccine by those who would normally support vaccination.

In addition, HHS and FDA have been corrupted by political pressure to approve hydroxychloroquine and convalescent plasma as treatments for COVID-19 in spite of the absence of safety data. Fauci has been told to refrain from stating that children can transmit COVID-19. And CDC has been forced to walk back recommendations on school reopening and contact tracing, and its venerable publication, MMWR has been censored by the administration.

On June 23, Financial Times published the marvelously understated headline, “Resistance is low at U.S. disease-control body.” This week we finally learned that the source of this chaos and the sharp decline in the public’s and health professionals’ confidence in the CDC has been a troubled Trump appointee, Michael Caputo, a far-right conspiracy-monger and protégé of convicted felon Roger Stone.

It is déjà vu all over again. In 1987, one of us (AB) would be told upon assuming a faculty position at Baylor College of Medicine that he could not use his academic affiliation when speaking publicly on smoking and that he should “consider getting into something more socially acceptable, like cocaine.”

This meant, of course, that studying illicit drugs—not cigarettes—was where the grant funding was—and don’t you keep messing with the folks at the to-
tobacco companies who have influence over Capitol Hill and the NIH!

One year later, he would be offered the editorship of the journal of the American Academy of Family Physicians, American Family Physician—contingent on his not speaking publicly on the subject of smoking.

The AAFP was a recipient of advertising revenue from food subsidiaries of RJ Reynolds and Philip Morris. AB turned down the job.

Politics, money—and COVID-19

What is the fairest way to compare strategies to contain the virus with the efforts to reduce cigarette smoking? Why not begin with those who are made ill by a known agent through no fault of their own, as well as through willfully misleading directives by elected officials?

The turning point in the effort to reduce cigarette smoking came in the early 1980s, when studies in Japan and Greece found that long-term exposure to cigarette smoke could cause lung cancer in a person who did not smoke.

Certainly, those individuals who were involuntarily exposed to cigarette smoke over many years at the workplace and who developed terminal lung cancer or emphysema would be unequivocal innocent victims of smoking.

What about those who contract COVID-19?

The only ones in this population who aren’t unequivocally innocent victims are those who refuse to wear masks, practice physical distancing, wash hands frequently, and refrain from participating in social gatherings, political rallies, or protest demonstrations.

Another way to look at smoking-related deaths is through the number of those who had chosen to continue to smoke in spite of knowing that it could kill them.

One could argue that nicotine addiction is too powerful to overcome, and that, therefore, all of the blame must be laid at the feet of tobacco industry executives and the leaders of allied businesses that have engaged in the promotion of cigarettes in spite of the dangers.

But what about the accountability of public health agencies, which are tasked both with curbing infectious outbreaks and improving the health of the entire population? If a commissioner of health were found to have failed to allocate funds to mosquito control after an outbreak of West Nile, dengue, St. Louis encephalitis, or zika, then that individual would be held partially responsible for the cases that resulted—and criminally negligent if the funds were deliberately withheld because the commissioner didn’t believe that mosquitoes were the vector, or if he or she pocketed the money.

Analogously, why shouldn’t a health commissioner or health agency that chooses not to allocate funding to discourage smoking be held accountable for a failure to reduce tobacco-related deaths and diseases and/or cigarette consumption? Fanciful? But if the number of avoidable cause of death and disease in the health district doesn’t receive sufficient funding, then why shouldn’t there be accountability?

Although Surgeon General Luther Terry called for appropriate remedial action on smoking in 1964, it wouldn’t have been 25 years before every state had even a single individual assigned to reduce smoking.

Nor were health department commissioners permitted to endorse efforts to pass clean indoor air regulations to protect nonsmokers.

And what about academia, organized medicine, and the voluntary health organizations, such as the American Cancer Society? What did they do as the battles over restrictions on cigarette advertising heated up in the 1980s? Most were nowhere to be found.

“We were duped”

Individual tobacco product liability lawsuits brought against the tobacco industry beginning in 1983 by New Jersey attorney Mark Edell (Cipollone v Liggett Tobacco Group Inc.), followed by class action suits brought by several state attorneys general in the mid-1990s, began to expose the myth of organized medicine as an enemy of Big Tobacco.

In a TV interview in 1996, the president of the American Medical Association, Lonnie Bristow, famously claimed, “We were duped.”

This is in spite of the AMA having accepted cigarette ads in its journal from the early-1930s to the mid-1950s, the same time period when the epidemiological and pathological research showing the association between smoking and disease was being published.

This was also in spite of the publication of the Surgeon General’s Report in 1964, following which the AMA, as noted here, spent 14 years conducting research funded by the tobacco industry in lieu of taking action or even calling for action against smoking, apart from advising the public not to smoke in bed.

Since the 1980s, product liability litigation brought against the tobacco industry has been based on when the industry first knew that cigarettes were harmful and what they then did to deceive the public.

Even though everyone and his uncle is now aware of the lethal dangers of smoking and its toll on society, the ques-
tion that is not taught in public health schools or acknowledged by public health organizations, is, “When did the medical and public health communities learn about the harmfulness of cigarettes and what did they do about it?”

The much-avoided answer is that the public health community knew no later than the 1930s through the epidemiologic work of Raymond Pearl at Johns Hopkins and the clinical reports of Alton Ochner at Tulane.

Beginning in 1942, the Federal Trade Commission even held hearings on deceptive health claims in cigarette advertising.

But did the American Medical Association, the American Public Health Association, medical schools, schools of public health, the American Cancer Society, or federal public health agencies launch anti-smoking efforts? An emphatic no.

This failure to own up to the health community’s failure in the mid-20th century has been willfully ignored by the professional field known as “tobacco control” that emerged in the 1990s.

Tobacco control devotes most of its efforts to research, the bulk of which is aimed at providing the basis for regulatory or legislative approaches to reduce tobacco use and exposure to tobacco smoke, something called “tobacco regulatory science” by inside-the-Beltway bureaucrats. Touting the public health achievement of reducing the prevalence of cigarette smoking among adults from 42.7% in 1964 to 18.1% 50 years later, the authors of an editorial in JAMA on Jan. 8, 2014, claim that “much of the progress stems from the rigorous development of evidence-based tobacco control policies that now serve as a robust foundation for public health action.” Come again?

In fact, much of the progress in tobacco control, most notably in protecting the public from exposure to others’ smoke by the passage of clean indoor air laws, occurred in the 1970s, 1980s, and 1990s—long before the creation in 2014 of 14 mostly university-based “centers of excellence in tobacco regulatory science,” each given $20 million by the FDA.

It is anathema, we realize, to suggest that allocating more money to attack a health problem is not the answer, but when it comes to ending the smoking pandemic the overwhelming preponderance of funds has gone into research, not action.

The public health community, including schools of public health, government health agencies, and organizations of state and territorial health officials only joined the efforts against smoking in the mid-1990s, as public opinion of the tobacco industry became increasingly unfavorable.

Yet these groups have perpetuated a false narrative wherein giant-killing heroes in public health triumphed over a rogue industry, which for most of the 20th century kept the truth about the addictive, debilitating, and lethal consequences of cigarettes away from the public.

The current generation of workers in tobacco control, predominantly those with master’s degrees in public health who work for health departments, has been led to believe that anti-smoking efforts began with the creation of The Truth campaign in the late-1990s as the result of the Master Settlement Agreement (MSA) between the state attorneys general and the tobacco industry that gives money to the states each year to fight smoking.

In reality, the $256 billion-MSA was a pennies-on-the-dollar back tax. More tragically, today just 1.9% of MSA funds go to address tobacco problems, and much of that is for salaries. Ominously, the MSA actually assures a dependence by the states on tobacco industry money in perpetuity, and only an infinitesimally small amount of it has gone to fight smoking.

There is scant paid mass media advertising against smoking or vaping. Only a few states have passed legislation that dedicates a portion of cigarette taxes to reduce cigarette smoking and other forms of nicotine addiction.

“A Frank Statement”

It is this background that one needs to keep in mind to understand the public health efforts to counter cigarette smoking and its promotion today, as well as how it has begun to tackle COVID-19.

Finding the solution to ending either the smoking pandemic or the COVID-19 pandemic is not a moonshot for which one simply pours money into academic research and health department data collection.

The smoking and health issue has been settled for nearly 60 years, yet 37 million Americans still smoke and they’re younger on average than ever. That’s partly because funding media messages to enhance knowledge and change attitudes that lead to improvements in health behaviors isn’t happening.

The government itself only began running paid mass media messages in 2012 for its TIPS for Smokers quit-smoking campaign—by all accounts a successful one—with a budget that only permits a few months of TV messages per year.

One gets the sense that those in public health don’t trust any information on the history of the smoking pandemic that does not come from the tobacco industry documents, as if the very same public exposés of the tobacco industry’s disingenuous denial of smoking’s
Lung Cancer Remains A Mystery

Nine eminent physicians and scientists submitted testimony to Congress stressing that cigarette smoking is not the proven cause of lung cancer. "Lung cancer like many other human cancers, remains a biological mystery," said Sheldon C. Sommers, M.D., a prominent New York pathologist who was called to testify. The others submitted statements.

Sommers, scientific director of the Council for Tobacco Research in New York City, told a U.S. House of Representatives subcommittee that "epidemiologic studies report a statistical association between cigarette smoking and lung cancer." But, Sommers stressed, "the biomedical experimentations does not support the smoking causation hypothesis."

Sommers testified at a hearing considering replacing the current cigarette health warning with seven different warnings.

Dr. Arthur Furst, a University of San Francisco researcher, consultant to the Veterans Administration, and former surgeon and surgical consultant for the Veterans Administration, Dr. Jack Matthews, Farris stated, in submitted testimony, "I believe that, when we know how and what causes cancer, maybe we'll find that cigarette smoking has little or nothing to do with the genesis of carcinomas of the lung."

"It is clear that the smoking and health controversy has not been resolved," Farris stated. He stressed that "the problem won't be solved by legislation or the courts." Genetics may determine who gets lung cancer and who doesn't, Henry Rothchild, M.D., a specialist in genetics, said in his statement.

If such genes can be isolated, "it will be a major step forward in unraveling the mystery of lung cancer causation," Rothchild said.

A former medical director of the U.S. Public Health Service, Dr. Kathern McDonald Herrold, said in her statement that any claims that smoking causes lung cancer must remain only theories.

Herrold, who participated as a pathologist in one of the original large population studies on smoking and health, said there is no correlation between various lung cancer cell types and the amount smoked.

Also, she said she found no relation between the number of deaths from lung cancer and when smoking began, the number of years of smoking, or the number of cigarettes smoked per day.

In contrast to claims that there is a dose response relationship between smoking and lung cancer — that the number of cigarettes smoked, the higher the risk of developing lung cancer. More research is needed in the field of smoking and lung cancer, Herrold said.

A North Carolina biostatistician, Dr. Lawrence L. Kupper, said he does not believe a causal relationship between smoking and lung cancer has been scientifically established. He called for "evidence free from all bias," saying and "a Congressional finding to the contrary does not alter that situation."

Eleanor Macdonald, a professor emeritus of epidemiology, also warned Congressmen not to try to "legislate scientific fact."

"It is becoming increasingly clear that there is no single, simplistic answer to the question of what causes respiratory cancer," Macdonald said. "It is hardly in the best interest of either science or government to create the illusion that an attack on a single lifestyle factor will provide the solution for such a complex problem."

Hiram T. Langston, a thoracic surgeon, summed up the written statements by saying, "I believe very strongly that we do not know the cause or causes of cancer of the lung."

Charges that smoking causes lung cancer are so familiar that very few people may realize that there is strong evidence to the contrary. I find that evidence to be persuasive," Langston said.

Scientists Doubt Ads Cause Smokers To Start

Cigarette advertising ranks at or near the bottom of factors playing a role in determining smoking behavior, according to written testimony submitted to a House subcommittee considering new cigarette health warning labels.

Virginia psychopharmacologist Barbara Brown told the Subcommittee on Health and the Environment that smoking behavior involves the interaction of several influences. She believes the reasons people decide to smoke has to do with a person's constitutional makeup.

However, she stressed, "Congress must understand that even the so-called experts don't know enough about why people behave the way they do... and how that behavior relates to the individual's health."

Charles D. Spielberger, University of South Florida psychologist, wrote that his studies of smoking behavior of college students rank advertising at or near the bottom of a listing of 10 factors involved in initiation of smoking. Peer group pressures and the smoking of family members are the most important factors, he said.

Once smokers have been warned of the health consequences of smoking—and his studies showed no influence in smokers to "reject the idea," he said—they engage in a risk assessment system to determine their future smoking behavior, behavioral researcher Sherwin J. Feindel testified.

God-Given Right

The fact that people continue to smoke despite the prevalence of health warnings does not mean they do not understand the warnings, John E. O'Toole, chairman of the board of Poise, Cone & Beling Communications, Inc., the fourth largest U.S. advertising agency, wrote.

"I'm a consumer and I resent government officials wondering what to do with me next if I understand but choose to ignore a disclaimer they've forced an advertiser to put in his ad," he said. "It's my God-given right. I have information any salesman presents me with— and an ad, remember, is a salesman."

Boston University sociologist Peter L. Berger's testimony linked the continuing efforts to regulate smoking behavior with the "long-term campaign of stigmatizing and even criminalizing smoking."

Smoking/Pregnancy Charges Unproven

The medical director of the largest ongoing U.S. study of smoking and pregnancy outcome has told Congress that this research "did not indicate an increased risk of abortion and stillbirths among smoking pregnant women."

Besa J. van den Berg, M.D., director of Child Health and Development Studies at the School of Public Health, University of California at Berkeley, told a Congressional subcommittee that the studies are not "supportive of the stated increased risk of birth defects" among babies of women who smoke.

A bill being considered by the subcommittee, to "strengthen" cigarette warning labels, would advise that smoking may result in birth defects or spontaneous abortion. Her research does not support that statement, van den Berg said.

Smaller Babies

In other testimony, a British pediatrician engaged in the study of infant birth weights, questioned the claim that cigarette smoking by pregnant women causes smaller babies.

Oliver G. Brooke, M.D., said that cigarette smoking may have little or no influence on birth weight. "It is possible that smokers eat less or worse than nonsmokers, and that this is the cause of the association between smoking and reduced birth size," Brooke said.

L. G. S. Rao, Ph.D., a Scottish researcher, also stressed in his testimony that poor nutrition, and not smoking, might be the key to why mothers in poorer social groups have smaller babies.

Finally, Prof. Jean D. Gibbons argued that the scientific evidence is inadequate to claim that women who take birth control pills and smoke are more likely to suffer heart damage than nonsmokers.
dangers—by muckraking journalist George Seldes in the 1940s; writer Roy Norr in *The Christian Herald* and *The Reader’s Digest* and Harvard University Medical School’s Daniel Rutstein in *The Atlantic Monthly* in the 1950s; and Sen. Maurine Neuberger on the floor of the U.S. Senate and *New Yorker* writer Thomas Whiteside in the 1960s—were chopped liver.

So, it has always been in getting to the bottom of the tobacco tragedy. By 1963, when the Surgeon General’s advisory committee was reviewing the world’s literature on smoking, there were 7,000 articles in scientific journals.

But Luther Terry’s call upon the release of the Surgeon General’s report smoking and health on Jan. 11, 1964 for “appropriate remedial action” to begin reducing smoking in the U.S. went largely unheeded by the federal government until Surgeon General Jesse Steinfeld issued a Non-Smokers Bill of Rights in 1971 (after HEW Secretary Elliott Richardson had tried to block him from doing so), and then not until 1978, when Califano launched his crusade.

Meanwhile, the NCI’s safer cigarette research program fit the tobacco industry’s agenda, first described and disseminated in a full-page advertisement in newspapers across the country in 1954 after cigarette sales flattened on the heels of growing evidence that smoking caused lung cancer.

Headlined “A Frank Statement,” the ad from the newly formed Tobacco Industry Research Committee downplayed the experiments on mice that “have given wide publicity to a theory that cigarette smoking is in some way linked with lung cancer in human beings.”

The committee wrote that “we feel it in the public interest to call attention to the fact that eminent doctors and research scientists have publicly questioned the significance of these experiments.

“Distinguished authorities point out:

- “That medical research of recent years indicates many possible causes of cancer.”
- “That there is no agreement among the authorities regarding what the cause is.”
- “That there is no proof that cigarette smoking is one of the causes.”

Asserting, “We accept an interest in people’s health as a basic responsibility, paramount to every other consideration in our business,” the committee pledged “aid and assistance to the research effort into all phases of tobacco use and health.”

In addition, the industry lured cancer researcher Clarence Cook Little, a longtime managing director of the American Cancer Society, to become the committee’s director and the industry’s scientific face.

The industry’s stated aim for the next half century would be to eliminate any possible harmful ingredients in tobacco smoke.

Meanwhile, as millions would die from cigarette smoking, the industry introduced a plethora of filters, low “tar” products, “reduced emission” cigarettes, and “mild,” “light,” and “ultra-light” brands, none of which made smoking safer.

Indeed, on Aug. 17, 2006, Federal Judge Gladys Kessler found the cigarette companies had violated civil racketeering laws over a 50-year period by deceiving the public about the dangers of smoking by manipulating the design of cigarettes and suppressing research.

Not long after C. Everett Koop became Surgeon General in 1982, he felt it necessary to point to the body of irrefutable evidence that smoking caused death and disease—compelled, because of the Tobacco Institute’s never-ending theme song, “we need more research.”

Among the TI’s most infamous claims in its pamphlets published in the 1970s and 1980s came in response to the growing evidence that mothers who smoked during pregnancy were twice as likely to have low-birthweight babies. The Institute insisted that many women preferred to give birth to lighter babies because they were easier to deliver.

“We need more research”

By the late-1970s, the Tobacco Institute had a team of spokespersons who fanned out across the country seeking debates on TV and radio stations with local physicians about the validity of claims about the dangers of smoking.

One such spokesperson was Charles Waite, a former assistant surgeon general of the U.S. Navy.

On May 12, 1977, in a three-hour match-up with one of us (AB) on a Miami radio show hosted by chain-smoking Larry King, Waite kept repeating variations of the same mantra, “We just don’t know that cigarette smoking causes lung cancer and other diseases. We wish we did know. We need more research.”

King agreed with him.

By the early-1980s, the industry was at it again, having invented an array of “smokers’ rights” groups, which in effect spoke for the last rites of the very people the industry’s products were killing.
“When you survey the biomedical literature of the past 30 years, you have to be impressed with the extraordinary amount of evidence that has been generated to prove the causal relationship between cigarette smoking and some two dozen disease conditions,” Koop said, “The medical literature holds an inventory of more than 50,000 studies regarding smoking and health. The overwhelming majority of them clearly implicates cigarette smoking either as a contributing cause or the primary cause of illness and death.

“No one knows for certain, though a PubMed search of the terms “smoking,” “cigarettes,” “tobacco,” and “vaping” yields 349,592 references. (A Google Scholar search yields more than 3 million.)

But by the late-1980s, the facts were still not enough to deter a new breed of abrasive radio and TV talk show hosts from stoking resentment over the abrogation of Americans’ freedom to smoke. Even as the airline smoking ban of 1988 became one of the most popular pieces of legislation ever passed by Congress, shock jocks Morton Downey, Jr. and Rush Limbaugh mocked “anti-smokers” and boasted about their love of smoking. Both men were later diagnosed with lung cancer.

**Fox News, Sinclair and the anti-mask movement**

Listening today to Fox News’ downplaying of the severity of the COVID-19 pandemic and the criticism of face mask mandates and other measures we know can help prevent infections is akin to reliving that era of cowardice.

The even more ardent Trump-supporting Sinclair Broadcast Group of 191 TV stations across the U.S. has one-upped Fox by promoting a documentary that claims that Anthony Fauci helped manufacture and spread COVID-19.

The political system has made it impossible to put the very obvious and simple preventive measures as the first priority.

Yes, research is good, even essential, but it’s not a substitute for wearing masks.

In his July 2 column in The New York Times, Nicholas Kristof wrote that in the face of coronavirus “Americans are acting curiously helpless... We don’t seem willing to assert independence from a virus that in four months has killed more Americans than the Korean, Vietnam, Gulf, Afghanistan and Iraq wars did over 70 years.”

The cost of distribution of free masks, he added, would be negligible, compared to the cost of hospitalizations. Repudiating Trump’s assertion that mask-wearing is simply a “personal choice,” Kristof warns that “in a time of plague, shunning a face mask is, like driving drunk, putting everyone in your path in danger.”

The U.S. has failed with the least educated portion of the population on both smoking and COVID-19. By virtue of its high COVID-19 rate of infection and the virus’ high death toll, has the U.S. become a shithole country?

It would appear that the number of studies it would take to change the minds of “anti-anti-smokers” or anti-maskers verges on infinity. But just how many studies on smoking have been published?

No one knows for certain, though a PubMed search of the terms “smoking,” “cigarettes,” “tobacco,” and “vaping” yields 349,592 references. (A Google Scholar search yields more than 3 million.)

To what extent have the 300,000 additional papers published in the past 40 years—and the enormous amount of funding to conduct them—led to improved health?

It has taken more than 50 years to flatten the mortality curve of lung cancer, in spite of having known all along the best single evidence-based action for entirely preventing lung cancer and other tobaccogenic diseases.

Research by one of us (ES) in the early-1990s found numerous cross-connections among the members of the Surgeon General’s advisory committee for the 1964 report, the AMA’s Education and Research Fund to administer grants from the tobacco industry, and the Tobacco Industry Research Committee (renamed the Council for Tobacco Research in 1964).

The result was to pad the nests of pet institutions and delay any meaningful action for another 14 years while such important-sounding research was going on.

We knew what we needed to do in 1964, and we didn’t do it. Now, incredibly, with COVID-19 we are witnessing the same foot-dragging of politicians, the same payouts to vested interests, and the same fear on the part of academia and organized medicine in speaking truth to power.

The case can be made that most of the legislation to protect public health on smoking, notably clean indoor air laws, had been passed by the 1990s. Where, then, were the public health funding resources for reducing smoking directed through the years? Invariably they were put into more research, and, with the exceptions of California and Massachusetts, not into the purchase of mass media space to promote not smoking.

Signed by President Obama in 2009, the Family Smoking Prevention and Tobacco Control Act gave the FDA regulatory authority over tobacco products—the
first federal legislation on tobacco since the 1988 airline smoking ban.

But far from standing up to Big Tobacco, Congress was doing the bidding of Philip Morris, the biggest champions of the bill.

The measure mainly regulates new and potentially less hazardous tobacco products, but does not apply these same regulatory standards to the most irredeemably harmful form of tobacco, existing cigarettes, which take the lives of upwards of half a million Americans a year.

In other words, Marlboro was grandfathered in. Thus, FDA devotes more effort to attacking e-cigarettes than cigarettes. Incredibly, this agency which regulates cancer drugs and can remove them from the market, now is charged with approving for market the latest variations of cigarettes by Philip Morris and other cigarette manufacturers.

As for other funding to reduce smoking, Bloomberg Philanthropies awarded Johns Hopkins over $300 million to do more research and to support anti-smoking legislation around the world, as well as more than $100 million to the D.C.-based Campaign for Tobacco Free Kids for its anti-smoking lobbying and public education efforts.

As with the government, engaging mass media education takes a back seat to the safe sinecure of research.

The MSA-funded Truth campaign (formerly the American Legacy Foundation, established with $2.5 billion in settlement funds) also spends most of its budget on research, with a modest amount going for paid mass media, but with restrictions on the mention of tobacco company names and cigarette brand names.

**Sorely needed: political resolve**

We propose a new concept for evaluating the impact of public health interventions. The calculation would include the length of time between when the public health community had sufficient evidence for a specific intervention, the degree of commitment and proportionate allocation of resources for implementing the intervention (as opposed to solely writing policy papers and getting more research grants); the manpower involved, the buy-in and coordination among health, business, media, academic, and political entities; the proportion of the population that learned about the intervention; the proportion of this group that ignored it; and so forth.

By our estimate, this would put the reduction of smoking as one of the worst failures in public health.

This sad state of affairs is bemoaned by Ed Anselm, an assistant professor of medicine and public health at Icahn Mount Sinai School of Medicine who teaches medical students about smoking.

“Tobacco control advocates often proclaim that the 50% recent reduction in smoking since the first Surgeon General’s Report on Smoking and Health in 1964—from over 40% of the population then to less than 20% today—was a success,” he notes. “Given that over 50 years later the excess deaths attributed to tobacco in the United States still exceeds 500,000 per year, it would be more appropriate to call this a continuing disaster. The various books in recent years about the history of cigarette smoking and efforts to end it may make interesting reading, but they certainly do not offer anything actionable for students new to this troubling story.”

Every single president, Democrat or Republican—Johnson, Nixon, Carter, Reagan, Bush, Clinton, Bush, and Obama—passed the buck on the tobacco pandemic. In stark contrast to the $2 trillion CARES Act and other allocations to address COVID-19, Congress has never approved any significant funding to fight smoking.

Historians, including Robert Proctor, claim that we need know more about the dirty doings of Big Tobacco, but Anselm suggests instead that “what we really need to know is how to obtain the social and political resolve to change things. At a time when people are proclaiming that ‘Black Lives Matter,’ the truth is that very few lives matter when balanced against profit.”

The cigarette—and COVID-19—is too important, here and now, to be left to historians to write the same old narrative.

And make no mistake, the similarity between Trump’s CDC and the CDC in the 1970s, when Big Tobacco was king of the hill, is chilling. In 1977, the federal government’s information resource on smoking for the public and physicians alike, the National Clearinghouse on Smoking and Health, was located in the basement of a small house near CDC in Atlanta.

When one of us (AB) visited that year with its director, Dan Horn, an epidemiologist who had co-authored landmark studies on smoking and lung cancer in the 1950s, he explained the balancing act he had to perform:

“If we only produce pamphlets and posters, then people will be suspicious. But if we become too visible in raising the alarm about smoking, we’d be shut down in a minute.”

His words were prophetic, but for a different pandemic and a different president.
HOLA COVID-19 study focuses on disruption of cancer care in Latin America

As of September, more than 270,000 deaths have been confirmed in Latin American countries due to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.
Brazil and Mexico are among the top four countries with the highest death toll due to COVID-19, along with the United States and India. It is believed that Latin American countries are especially vulnerable due to high levels of inequality and poverty, crowded living conditions in urban areas, lack of sanitation, slow and uneven governmental response, and strained healthcare systems.

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

Among Latinos, the cancer screening rate is already low, and COVID-19 may have significantly worsened this situation. Our study seeks to highlight the barriers and struggles that hematologists and oncologists have faced during this health crisis.

As Latinas in medicine, we want to give our colleagues in Latin America a voice and share the challenges they face during COVID-19, particularly with regard to cancer care.

**Evolution of care during COVID-19**

Our study is a cross-sectional survey of how hematology-oncology practices in Latin America have adapted during the COVID-19 pandemic. We are also interested in describing the changes in the routine management of patients with cancer, from diagnosis to completion of therapy.

Additionally, we would like to evaluate the implementation of telemedicine in developing countries.

The survey was distributed widely across Latin American countries, and it includes perspectives from all oncology subspecialties, from medical oncology to surgical oncology.

The survey was launched on Aug. 4, 2020, and it was available for four weeks. Currently, data accrual has been completed and the data are being analyzed.

Our study team is composed of a group of practicing oncologists and cancer care specialists representing nearly all Latin American countries. Team members publicized our study and recruited participants via social media platforms, email, and other local physician communication methods.

Participants were provided a link to complete the anonymous online questionnaire in their language of preference. The questionnaire was available in English, Spanish and Portuguese.

We aim to have these results by fall 2020.

### Challenges amid a pandemic

With the arrival of a second wave of infections, it is imperative that we learn where the provision of care was most disrupted.

Identifying the challenges that our colleagues faced during these unprecedented times will help create policies to improve cancer care and address the long term effects of the pandemic in cancer care.

The obstacles that COVID-19 has brought to developing countries have been different from the ones that first-world countries have faced while caring for patients with cancer.

It is imperative for Latin American oncologists to shed light on these barriers to improve the delivery of care during this pandemic, and future global health crises.

The long-term importance of the HOLA COVID-19 study is twofold. Primarily, current trends in population and environmental changes suggest that the influence of climate change, and its societal impact, will predict the onset of more frequent and severe global pandemics.

Therefore, understanding how these events affect at-risk healthcare systems will allow for better preparedness and contingency plans—to sustain care for vulnerable populations.

Secondly, analyzing the current changes to clinical practices and cancer care delivery will allow us to prepare and understand how the COVID-19 pandemic will directly affect the long-term outcomes of patients with cancer. It is time to give Latin America a voice!
Sleckman spoke with Paul Goldberg, editor and publisher of The Cancer Letter.
Barry Sleckman reflects on difficult months in Birmingham

“...

If we get a lot more infection here with the opening of schools, we may have to do things like close screening facilities temporarily, because of the potential risk. It’s possible. But I don’t think it’s going to influence care.

“...
On Jan. 6, Barry P. Sleckman’s started his job as director of the O’Neal Comprehensive Cancer Center at the University of Alabama at Birmingham.

It was the next logical career step for the scientist whose work focuses on understanding how DNA double strand breaks are generated and repaired. He had advanced from associate director of the Meyer Cancer Center at Weill Cornell Medicine to director of a storied NCI-designated comprehensive cancer center.

A month later, a moving truck bearing Sleckman’s beloved road bike arrived, and on a glorious day, Sleckman went out on a spin through Birmingham, a city where you can ride all year. A mile and a half into the ride, something happened. He doesn’t know what, and he hasn’t gone back to investigate. Maybe the tire got caught up in some object, or, less likely, a car was involved. Sleckman ended up with a concussion and a broken left arm. The helmet was in smithereens, indicating that the outcome could have been much worse.

While Sleckman was on the mend, COVID hit Alabama.

“In April, like everyone else we were pretty much broadsided by COVID. Nobody was prepared,” Sleckman said to The Cancer Letter. “Everyone had to get prepared while dealing with the acute infections. So, now we know. We’ve seen.

“So, there’s a bit more information now, and plans in place. I’m pretty comfortable that if we could provide seamless cancer care during March and April, when it was just a war zone mentality, everywhere from the standpoint of understanding how to deal with it, we’ll be able to do it in the future.

“But it could raise challenges again. If we get a lot more infection here with the opening of schools, we may have to do things like close screening facilities temporarily, because of the potential risk. It’s possible. But I don’t think it’s going to influence care.”

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

Paul Goldberg: First, congratulations. I like to check in with the new cancer center directors quickly, but things have been pretty hectic for some reason. How has it been for you?

Barry P. Sleckman: Overall—very good. I arrived in January, and then, in early February, the moving truck arrived with my beloved road bike. And they unpacked. The Sunday after that was a beautiful day in February. I was finally living again in a city like St. Louis, where I could ride my bike all year round.

And so, Sunday afternoon, I got my gear together, got out on the bike, got about a mile-and-a-half down the road, and the next thing I remember is a young woman standing over me with a cell phone asking if she should dial 911.

Ouch...

BPS: And I said, “Yes, please. I’ll pay for the call.” And, basically, I broke my left arm right up by the humeral head completely. The orthopedic surgeon—a shoulder doc—said it was the worst break he’s seen. And I now have 15 screws and a plate. And then, while recovering from that, COVID hits. So, if you consider it in that line, I’m doing pretty well.

Well, at least you got a mile-and-a-half ride out of it.

BPS: Yeah. I’m going to have to focus on golf now. But the problem, biking is good for me physically and mentally.

Golf is good physically, because I walk, but it’s not good mentally because it is a frustrating sport.

Things have been great starting this job. Getting to know people, getting to know what’s going on in the institution, what are the things you have to deal with right away, and what are the things that you can wait a little while to deal with. And then pacing yourself for the ultra-marathon.

One thing that has been very clear to me is that the administration of the University of Alabama at Birmingham School of Medicine and the UAB Health System and the UAB faculty are all very committed to the cancer mission, and there is great potential for growth here in both cancer research and cancer care. I am very excited about this.

As a new cancer center director, you are facing the challenges nobody has faced before. And COVID threatens to undo decades of progress in lowering cancer mortality (The Cancer Letter, June 19, 2020). I’m sure you are giving this a lot of thought.

BPS: That prediction from the NCI, that particularly in breast and colon cancer, there might be an extra 10,000 deaths over the next 10 years due to delays from COVID...
I think COVID touches the process in a couple of ways.

The most urgent was that some cancer patients were not coming in for care because they were afraid that they could be infected.

We’ve done everything possible to make sure that everyone here who needs care gets care—and got care even through the period after getting initially hit by COVID, while we were putting procedures in place to mitigate the potential risk.

Even during those times—March and April—where a lot of elective procedures in the hospital were not being done, cancer care was still going on as normal a pace as possible, including therapeutic clinical trials.

And we kept all of the therapeutic trials—which are research, but also standard of care for cancer patients and often the only treatment option—we kept them open, except for those that the sponsors actually closed during that period.

But now, the cancer operation is essentially fully functional, with new methods in place to limit the potential risk for infection, of course. And a lot more telemedicine. If there is anything good that will come from this disaster, it’s that it really furthered our telemedicine efforts exponentially.

What would have likely taken 10 years to do at the slow regulatory pace was compressed into a month. And now, it’s a very common approach for taking care of patients that don’t require testing or physical exams.

We’re fully back in motion for cancer care right now. Now, that’s today. But, as I remind people, it’s still unclear what will happen in the next six months. In the next month, a lot of students are going to be returning to school. College students are going to return here, and kids are going to go back to school.

And if what some people are predicting occurs, then we could creep back up again. And if we start to have a much higher rate of infection and a lot of people in the hospital with COVID, then, of course, that will potentially compromise the care activities.

But again, the first things that will be compromised will be elective procedures, and cancer’s not really elective. It’s urgent.

Let’s go back one step here—to telemedicine. How much telemedicine do you do?

BPS: Right now, about 30% of follow-up visits for medical oncology are now telemedicine.

Is the billing okay? Are they paying?

BPS: Well, I can’t speak specifically to that, as from the professional fees. But, of course, if patients don’t come to the clinic, there’s no facility fee.

So, the bottleneck now becomes the physician—and it’s an opportunity for growth? Hire more physicians and do a greater volume?

BPS: Exactly. There’s always a bottleneck. It’s like a chemical reaction with multiple steps. There’s always a rate-limiting step. You can do something to fix that rate-limiting step, and that’s great, but then something else becomes a rate-limiting step.

There’s space, there’s physicians, there’s ability to promote access—and all these things have to be juggled up at the same time. You can’t just say, “Well, we want to double the number of patients we see, so we’ll hire twice as many physicians” without having the clinic space.

What can you do about the problem of potentially seeing another spike in cancer over the next decade? What can you do at UAB to get patients screened?

BPS: Okay, but like any other healthcare system, we’re space-crunched. We could see more patients, but in order to do that, we need more clinic space, and we need more physicians.

Our clinic space has been pretty much saturated in the past. But now, with 30% to telemedicine, that means that there’s potentially more clinic space, with the caveat that we can’t have the waiting room full of people due to safety issues.

Also, telemedicine visits still require the physician’s time. So, there’s that balance. We have a little more space, because people are not coming in, but we also need the physician effort to be able to now see new patients in that space and be able to do follow-up through telemedicine.
BPS: We have started that. Let's just take breast cancer as an example. They closed the mammography facility in March and April, because, obviously, they had to get procedures in place to do it safely. And they simply put off the mammograms those months.

And what I'm told is that a lot of the women who were scheduled for those two months are now being rescheduled. They'll be delayed a little bit. I can't tell you what the probability that a two-month delay will lead to something that is not as treatable.

What we need to do is aggressively remind people that it's important to be screened. So, if you missed a screening, talk to your doctor, whether you're here or somewhere else in Alabama, and arrange for a place to go now that's safe when it's the right time to be screened.

And don't just say, "Okay, I'll pass this year and do it next year".

I would imagine, without knowing how the epidemiologists at the NCI calculated that, that they probably had some assumptions. And some of those assumptions were probably that people would put off screening.

With a colonoscopy, you get that every 10 years. I just turned 60, so I need to see up for one of those now. And if I said, "Okay, I'm going to pass now and wait 'til I'm 70," that would be a problem.

That's a problem.

BPS: Also, remember that prediction was not just based on screening. They also considered issues around treatment and access to treatment in order to come up with that 10,000 additional deaths.

You have seen not one, but two spikes in Alabama. What do you expect in the coming months and how will it play out? Since you are an infectious disease guy, I should ask you how this thing will end.

BPS: Well, first, I would echo Tony Fauci. I'm not sure that we've seen two spikes. I think that it's just a continuum. And I would consider it an equilibrium, and that equilibrium can be tilted by different events to either higher or lower.

And I think right now we're trending down.

Certainly, the thing that I look at the most is the number of hospital admissions. The number of positive people that are coming up is dependent on how good your testing is, and how available it is. That's a fact.

But the number of people in the hospital is a good indication of the number of new cases of people that are getting sick enough to be hospitalized. And that number crept up from April to mid-July, but now has been coming down, and I hope it will continue to come down.

I honestly think that we will live with COVID at some level until there's an approach for it—a vaccine, most likely.

A drug, historically, seems less likely, but certainly possible. And we're going to have to learn how to live with it. And we're going to have to learn how to take care of patients with COVID, hopefully at a smaller level, for a while.

If you're as old as me, you remember, back when AIDS came out, and it was really a catastrophic disease, initially striking young men with this pneumo-

nia that would kill them. Nobody knew anything about it. Everyone thought it was probably infectious, and so, these people were isolated and whatnot, until we learned about it. And we still haven't cured AIDS, but it's a chronic disease now. And we've learned to live with it and take care.

Now, COVID is not a chronic disease, like HIV. But my point is in strategic planning, if we say, "All right, we're going to plan on two years from or a year-and-a-half, there will be no COVID," I'm not sure that that's a sober strategic plan.

I think a better one would be to just try to do whatever's possible to limit the number of cases and develop protocols for taking care of those patients.

But I think the next potential threat from COVID to cancer care for us, again, is this opening of schools. And we'll have to see what happens. And if it does increase the number of cases and it increases the number of hospitalizations, that could impact our ability to provide care—obviously. Look at New York City during the peak. New York Presbyterian was completely full of COVID patients.

Right. So, what are you doing to prepare for this? Do you have any thoughts about how this needs to be handled nationally?

BPS: We have a great COVID team here, which is run by the health system. Actually, the vice president for cancer, whom I work with, was put in charge of a big piece of this, because he's such an exceptional administrator. And so, they have a plan in place. They have a plan for testing. They have plans for increasing testing, if needed. They have contingency plans, like were put in place for April for using other facilities, if need, for patients and for procedures.
We’re hoping that those plans won’t have to be put into place, but I’m pretty comfortable.

In April, like everyone else we were pretty much broadsided by COVID. Nobody was prepared.

Everyone had to get prepared while dealing with the acute infections. So, now we know. We’ve seen. There’s lots of paradigms for cities that have had dramatic increases. There’s a lot learned from that. It’s talked about a lot amongst people who are leaders of health systems, how to deal with it.

So, there’s a bit more information now, and plans in place. I’m pretty comfortable that if we could provide seamless care during March and April, when it was just a war zone mentality, everywhere from the standpoint of understanding how to deal with it, we’ll be able to do it in the future.

But it could raise challenges again. If we get a lot more infection here with the opening of schools, we may have to do things like close screening facilities temporarily, because of the potential risk. It’s possible. But I don’t think it’s going to influence care.

And as far as what’s going on in the rest of the country, I have no comment. Pick an area. I think that this—the face mask—is not an imposition on my personal freedom—and I wear it.

The amount of news in both the media and in social media, that is just all over the place from the standpoint of recommendations, is unprecedented. Most people are just confused, and they hold on to this idea, “Well, the healthcare experts are telling us different things every month. We can’t trust them.”

When I am asked by family members and friends, I say, “No, you can trust them. That is the natural course of understanding an infection.”

Again, if you go back to HIV when it first came out, for two years, we had no idea what it was. And people put things into place to try to limit that disease through experience. And then, through learning and through trials, but initially through experience. So, look around and say, “Okay, which countries have done the best?”

And then do what they do. Don’t ask why. Just do it.

How is UAB different from all the other cancer centers? What does it do that others don’t?

BPS: I spent 17 years at Wash U. I was there when they got their first grant, although I was a little pup then, so I just helped write the immunology part and joined that leadership probably about four years after they got the grant. And continued there until I left in 2015.

One of the things that attracted me a lot to UAB was the similarity to Wash U. And that may sound strange, but in a way, it was like the challenges that are here were very similar to the challenges that I was part of at Siteman. The community is about the same size. The motivation of the community to have a cancer center in their community was similar.

The culture of the community not wanting to drive more than 10 miles to do anything, which is very important when you consider strategic planning for health care, as we learned in St. Louis, is similar. The institutional culture is quite similar. The notion that individual success is important, but the only way that we can do great things is as a team or group is quite similar. This has made me feel very comfortable and very much at home here from the start.

And lastly, and I think incredibly important for the next 20 years, UAB, like Wash U, is the only academic provider of oncology care in the metropolitan area. And I think this is critically important, because the care of cancer patients is becoming more and more academic.

Consider clinical trials 20 years ago: you got into a clinical trial, you had no sense really that it was going to benefit you. You were participating in the trial to help people learn about the cancer you
had in a way that may help others who get the same cancer.

And if you did have some miraculous effect on your tumor, it was such an unusual thing that you were all the morning talk shows, talking about how amazing it was that your tumor went away.

But with the advent of immunotherapy and other therapies this changed...

Actually, one of the first real targeted therapies was Gleevec—not to take anything away from that—which I think was huge. Something where knowledge of the molecular basis of a cancer was used to treat the cancer. But then, going on to immunotherapy, people with lethal cancers are walking around today, because they were in a clinical trial. People with non-small cell lung cancer, people with metastatic melanoma, walking around, because they were in a clinical trial.

When friends call me and they say, “Well, so-and-so has cancer. They went to see their doctor,” I always say, “Did the doctor say anything about clinical trials?” And if they say no, I say, “You go find another doctor.”

Because to me, offering a clinical trial is really part of the standard of care, and it’s not just for people who fail upfront treatment now. Immunotherapy is given with standard of care treatment upfront in trials, and some people on these trials are having good outcomes.

My point is that, to just say, “Okay, I have a small nodule in my breast, stage 1 breast cancer. I’m just going to be treated locally. It doesn’t matter.”

Twenty years ago, that was probably true. But now, you might go to a cancer center, where they say, “You have a great prognosis, but 5% or 10% of people with really benign lesions will recur five or 10 years down the line. And we have a trial. Maybe a personalized vaccine trial, where we’re looking to see whether this will decrease the rate of recurrence. Would you like to participate in that?”

That’s just a hypothetical example, but people participating in that may end up not recurring five or 10 years from now as a result.

So, I tell everyone, “You should at least be seen at an NCI-designated comprehensive cancer center, no matter how trivial your cancer is. Just go and listen to people who are going to tell you about potential trial opportunities that may help you now, or mitigate potential recurrence years down the road.”

You have a catchment area that’s just enormous, a lot of Deep South. How do you manage that?

BPS: First of all, we must be dominant in the Birmingham metropolitan region. I think that people always want national recognition. Every institution wants to be nationally recognized, right?

But, we need to be locally dominant first? It’s very hard to be nationally recognized if you’re not locally dominant providing the very best care to the people in our own back yard.

The real responsibility of this cancer center is to Alabama and then next to Mississippi. We would love to take care of anyone in the country, but Mississippi is really the carbon copy of Alabama when it comes to cancer. You consider Alabama and Mississippi together, and look at the statistics, it’s bad for many common cancers. Smoking and lung cancer, prostate cancer, breast cancer. So, I would say that a goal would be, number one, make sure that we can provide NCI-designated quality cancer care to Alabama. And then, potentially, extend to Mississippi. People in Mississippi really do not have easy access to an NCI-designated cancer center for their care, so we need to do whatever possible to fill this void.

And I would say something about catchment, which I think is important. The O’Neal Comprehensive Cancer Center was one of the first eight in 1972. And I think Alabama’s a catchment area, because we’re in Alabama—the entire state.

If you look at some of the old cancer centers, [they cover] the entire state. But, given what is expected of a cancer center to work in a catchment area, it’s very challenging to have the whole state be your catchment area and to be able to provide cancer care to everyone across the state.

And we’re working as hard as we can. We get people from all over the state, thanks to the health system developing affiliations where we can provide cancer care and in particular cancer trials. Providing these clinical trials is still a work in progress, and it will be.

I’m actually kind of excited about that, because I watched that happen as Siteman, where they expanded their reach in Missouri, and so, I think I understand the roadmap for making that happen here.

Has COVID had financial impact on UAB and at the cancer center level, and how are you managing it?

BPS: I can’t really speak to the financial impact on UAB. I think it will depend a bit on how they will traverse the students coming back, because institutions derive a lot of revenue from students. And not just students taking courses online, but student activities, eating in the dining halls, and all that.

So, I think it’s still an unknown how much it will impact the institution. It
impacted the health system quite a bit, but then some of that was offset by the federal relief for COVID.

For the cancer center, I think that the potential impact could be in raising money for special programs, like pilot grant programs, clinical research programs. We have several events every year to raise money for the cancer center, which I’m sure you can imagine have been turned into Zoom events.

For strategic purposes, we are projecting that we will end up making about half of what we made in the past.

Oh, my.

BPS: Now, before you say, “Oh, my,” that’s just, for me, a worst case scenario. We need to come up with an idea of how much money we’re going to have to invest in pilot grants and whatnot.

From some sources, we plan for half. I don’t think it’s going to be worse than that. So, I’d like to know what’s the worst-case scenario.

I think that we might have to tighten the belt a little in the next year or two, but I think we’re going to get past that.

Well, the cancer center is the part of the institution that makes money still. So, you might have it easier, you would think.

BPS: I think you have to consider revenue from different sources. So, there’s patient care revenue, and then that goes into recruiting and all.

But what I really consider is the most important thing that a matrix cancer center does, is to support initiatives that faculty have started around the institution, which are things that are moving up. And then the cancer center comes in and just catalyzes that to move at a more rapid rate.

And it does it through pilot grants, to allow people to use shared resources, through supporting clinical trials activities, through all of that. And we use monies that come from endowments, monies that come from grateful patients, and monies that come through fundraising events, either our own or philanthropic groups that we work with, like the Breast Cancer Research Foundation of Alabama, Mike Slive Foundation and the American Cancer Society. As you know, some groups like ACS are struggling now.


BPS: To say the least. Foundations that raise money through events are all going to raise, probably, less money over the next year or two. But I think we just need to get a picture for what we think the worst-case scenario will be, and then we plan for that, and we’re happy if it’s anything better than that.

That’s a good way of looking at it. What role can cancer experts play in COVID research? In March, The Cancer Letter was writing a lot about it: there was a lot of discussion about the convergence of oncology and immunology and infectious disease. So, it’s September now. Has this convergence occurred? It is occurring?

BPS: Well, I think the convergence you talk about will be quite a while, before it parses itself out. You ask how does oncology influence COVID? Anybody can work on COVID. Scientists are smart people, and if they think they have a good idea and you’re willing to give them some money, they’ll work on it.

So, there are a lot of people working on COVID now that are not virologists or immunologists, or anything like that. So, I’m not going to comment on that.

But I would say that one important area, of course, especially if COVID is with us for a while, like it might be, without a vaccine, even at a low level, is obviously, how does being on immunotherapy impact your ability to deal with COVID?

So, that is an extremely important question that will need to be figured out, if in fact COVID exists in our environment for years to come.

So, what would it mean to be on checkpoint blockade or CAR T-cell if you’re exposed to COVID? Would you be a lot worse off? And that’s something that I know people are starting to look at now, and there are various proposals to study that.

And then, the other influence, of course, is sociologic, which is, especially in Alabama, where there are a lot of underserved patients in communities that may not be as well-informed, and they may just generally be afraid to come in.

So, there has to be a certain amount of education, and we’re doing that now. Actually, we got a supplement from the Cancer Center Support Grant to do exactly that. And so, there is a process in place to start to educate underserved populations about getting appropriate cancer screening and cancer care in the setting of COVID.

I think those are two areas where oncology definitely crosses over with COVID. And there certainly could be plenty of
people that were doing cancer research who think they have a great idea about COVID. I hear that a lot of my previous colleagues, who were working on cancer research, are doing COVID work. That’s great.

They’re smart, they think they have a good idea. Who knows? Perhaps they’ll come up with something good.

**Has NCI been helpful through this?**

**BPS:** Been helpful with the COVID issue?

**BPS:** Just surviving this.

**BPS:** When all this hit, a lot of institutions, including our own, said, number one, stop basic research, because it’s a risk to have people in the labs working together. And then the question was whether we should stop clinical trials, too. This can often be the mindset. “Oh, we’re going to stop clinical research, too.” Many people think the clinical trials is research, so it can be put it off too.

I jokingly say to people that the real problem with the Clinical Trials Office now is that it’s called the Clinical Trials Office. It should really the Innovative Therapy Office, and people would think of it differently.

Clinical trials, when you say to some patients, they think, “Oh, you’re going to do an experiment on me, make me a guinea pig.” When you say it to administration, they say, “Oh, that’s research. I got it. It’s important, but if we have to stop it it’s no big deal.”

The NCI came out on their website with a clear statement that they consider, as hopefully more and more people will, that they consider cancer clinical trials to be part of therapy, and in some cases the only thing we can offer to patients.

So, they said, “Look, you have to do what you have to do, but we would recommend that you do everything possible to continue to offer therapeutic clinical trials to cancer patients through COVID.” And we did.

Our institutional leaders agreed with this and we continued to keep as many cancer therapeutic clinical trials open as possible. Our accruals went down in March and April. But they’re back up now, and we did everything we could. So, I think that’s something that the NCI really helped with.

The NCI also got money through the Paycheck Protection Program and has been able to fund grants that are related to understanding both the sociologic and the biologic intersection between COVID and cancer and that has also been important.

But I think the most important thing they did was the messaging about trials and cancer care.

**What about basic science?**

**BPS:** In COVID?

**BPS:** Cancer, and maybe COVID. In your institution right now, are you coming back up?

**BPS:** We’re back up. There are still protocols about the number of people in lab, social distancing and limiting in person meetings to limit risk. This is perhaps not the best thing for basic science, but it’s the best thing for our health right now. Hopefully we’ll eventually get back to the point, where people can sit around the coffee machine and talk about crazy ideas that become important scientific discoveries. But, for now we are moving forward and that is good.

**Is there anything that we’ve missed? Anything you’d like to add?**

**BPS:** In this day and age, it really matters where you’re treated first. And I’m biased, because I’m a cancer center director. But I think more so than even 20 years ago, it really matters to be seen in an NCI-designated comprehensive cancer center.

And so, with that in mind, one of the big challenges for us, and, I think, actually, an emphasis of the current leadership at the NCI, the program leadership at the Cancer Centers Program, is to be able to make that care available to everyone in your catchment area.

So, we used to say in academic medicine, “Well, if you come here, we’ll take care of you.” And the reality is, not everyone can come here. They can’t, for one reason or another. Could be geography and other barriers, etc.

And so, we have to work through our outreach program and through the health system to be able to make cancer care accessible to everyone and available to everyone in our catchment area, and for us that is the state of Alabama. This will be a main focus for us for the next 10 years.

**Thank you.**
The UPMC Hillman Cancer Center (HCC) and Department of Medicine, part of the University of Pittsburgh and UPMC, seek a transformative leader to serve as Chief of the Division of Hematology/Oncology (“Division”) and Professor of Medicine with tenure. An Endowed Chair is also available for the qualified candidate. The successful candidate will lead the division of Hematology/Oncology and build on the excellence of our 66 member faculty, representing 16 specialties, in meeting our clinical, educational and research missions. The UPMC Hillman Cancer Center treats over 41,000 new adult and pediatric cancer cases annually. It is the academic and research hub within the expansive UPMC HCC network of 71 clinical sites, 28 of which participate in over 500 cancer clinical trials across Western PA, including the primary research sites in Pittsburgh (UPMC Shadyside, UPMC Presbyterian, UPMC Children’s Hospital of Pittsburgh, UPMC Magee-Womens Hospital).

With over 300 members from across the University of Pittsburgh, the Hillman Cancer Center comprises 7 research programs in basic, translational, clinical, and population sciences, 12 shared resources that receive funding from our NCI Cancer Center Support Grant (https://hillmanresearch.upmc.edu/research/) and a funding base exceeding $125 million. In 2019, the University of Pittsburgh ranked #6 in overall NIH funding, and the UPMC HCC scored in the Exceptional range on its recently renewed NCI P30 CCSG. The Division also houses an NCI T32 grant, and newly renewed UM1/U24 phase I grants and NCTN LAPS UG1 grants. Newly initiated collaborative integration of activities between HCC and the NSABP, based in Pittsburgh, provide exciting opportunities for driving clinical research in breast and GI cancers.

We seek a demonstrated and innovative leader with Hematology/Oncology leadership experience in a division, program and/or institute of an NCI-designated comprehensive cancer center, with a proven track record of success in the role. The successful candidate will:

- Be recognized as a leader and innovator in the field of medical oncology.
- Be an established independent investigator with interdisciplinary NCI-funded translational research.
- Have a proven track record of managing clinical trials as a PI and clinical trials operations at an institutional level.
- Have a long-standing track record of significant publications and extramural grant funding.
- Have a strong record in management, teaching and mentoring graduate students, postdoctoral fellows and junior faculty members.
- Have outstanding communication and interpersonal skills.

**Position Responsibilities**

- Recruit nationally recognized leaders in medical oncology and translational cancer research.
- Develop innovative approaches to cancer research and treatment.
- With the UPMC Hillman Cancer Center Director and senior leadership, advance and implement the Hillman Cancer Center strategic plan and integrate with that of the Division of Hematology/Oncology.
- Direct overall faculty management of the Division by expanding and enhancing clinical research programs, integrating and coordinating care delivery throughout the Division and across the health system, and assessing the feasibility of new programs, products, and services.
- Facilitate extensive collaborations with departments in the school of medicine and other disciplines across the university and cancer center is expected.
• Develop and implement programmatic goals for the Division, including leading and managing performance improvement activities.

• Monitor critical clinical success factors for the Division, including financial indicators, customer satisfaction, quality, and compliance with goals.

• Monitor faculty productivity with respect to research, publications, peer-reviewed extramural funding, and active participation in enrolling patients to clinical trials.

• Serve as key contact point for faculty issues related to the Division by regularly interacting and communicating with Hillman Cancer Center senior leadership, clinical and research leadership, physician clinical and research operations, system quality improvement and other service and department leaders.

• Establish, coordinate, and maintain an organizational structure which promotes multi-disciplinary collaborative practices, participatory involvement, innovation, fiscal accountability, strategic planning and development, outcome-focused goal setting, adequate and effective resource allocation, community involvement, and customer service.

• Develop, implement, and evaluate programs to promote the recruitment, retention, professional development, scholarly activity and continuing education of Division faculty.

• Serve as mentor to clinicians and researchers of all stages in Division when appropriate.

• Oversee the development of the Division’s annual academic operating budget, develop cost containment strategies and monitor the disbursements and generation of funds in the Division on an ongoing basis.

• Participate in Hillman Cancer Center and Department of Medicine research and clinical activities, residency and fellowship training, and participate in tumor boards.

Required Qualifications

• MD or equivalent degree from an accredited professional school.

• Board certified in Medical Oncology and eligible to obtain a license to practice medicine in PA.

• Qualifications to achieve Professor with tenure academic rank at the University of Pittsburgh.

• Five (5) or more years contributing to leadership of clinical operations with a successful track record demonstrating increased strategic responsibility in a complex, academic healthcare organization.

• Leadership roles in professional organizations.

• Strong communication, organizational and interpersonal skills.

• Demonstrated ability to build strong, sustainable partnering relationships.

• Demonstrated experience working with and fostering a diverse faculty, staff, and trainee environment or commitment to do so as a faculty member.

Located in the city of Pittsburgh (routinely ranked as one of the top most livable and affordable U.S. cities), the Hillman Cancer Center (previously known as the University of Pittsburgh Cancer Institute) is an exceptionally rated, NCI-designated Comprehensive Cancer Center serving a catchment area of 29 Western Pennsylvania counties that provides unique opportunities to collaborate with clinical and translational research programs involved in cancer patient care.

To apply for this position, please send a cover letter and your curriculum vitae to Hillman Director, Robert L. Ferris, MD, PhD, care of thompsonla3@upmc.edu. Please reference “Division Chief” in your application. Applications will be reviewed on an ongoing basis until the position is filled, following the receipt of all required materials. The University of Pittsburgh is an Affirmative Action/ Equal Opportunity Employer and values equality of opportunity, human dignity and diversity, EOE, including disability/vets.

Robert L. Ferris, MD, PhD
Director, UPMC Hillman Cancer Center
c/o Lola Thompson, 5150 Centre Avenue, Suite 500
Pittsburgh, PA 15232
412-623-3205
Carpten spoke with Matthew Ong, associate editor of The Cancer Letter.
John Carpten: Inaugural AACR report calls for legislative action on disparate burden of cancer

I do believe that whether or not we’re there now, or whether we get there in the future, that by diversifying the workforce, we will have a better chance of impacting, for instance, diversity in clinical trials.

John D. Carpten, PhD
Chair, AACR Cancer Disparities Progress Report 2020 Steering Committee,
Chair, AACR Minorities in Cancer Research Council;
Professor and chair of translational genomics,
Director, Institute for Translational Genomics,
University of Southern California Keck School of Medicine
The American Association of Cancer Research Sept. 16 published a comprehensive report on disparities in cancer, describing in deep detail the outsized toll that cancer exacts on racial and ethnic minorities and other underserved populations.

The document, AACR Cancer Disparities Progress Report 2020: Achieving the Bold Vision of Health Equity for Racial and Ethnic Minorities and Other Underserved Populations, is the first of its kind from the professional society. AACR’s virtual congressional briefing is available here.

“We tried our best to spell out some of those things that we hope that our leaders and individuals in leadership positions and in positions of influence can see and read,” John D. Carpten, chair of both the AACR Cancer Disparities Progress Report 2020 Steering Committee and the AACR Minorities in Cancer Research Council, said to The Cancer Letter. “I think there’s a lot to unpack.

“We’re living in an incredible time right now. I’m not saying incredible in a good way; I’m saying, in an incredible time,

### U.S. Cancer Health Disparities at a Glance

<table>
<thead>
<tr>
<th>Adverse differences in numerous measures of cancer burden exist among certain population groups in the United States. Examples of such disparities include:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>111% and 39% HIGHER RISK</strong></td>
</tr>
<tr>
<td><strong>20% and 38% MORE LIKELY</strong></td>
</tr>
<tr>
<td><strong>TWICE AS LIKELY</strong></td>
</tr>
<tr>
<td><strong>TWICE AS LIKELY</strong></td>
</tr>
<tr>
<td><strong>3.5X HIGHER</strong></td>
</tr>
<tr>
<td><strong>&lt;HALF AS LONG</strong></td>
</tr>
<tr>
<td><strong>35% HIGHER</strong></td>
</tr>
<tr>
<td><strong>70% MORE LIKELY</strong></td>
</tr>
</tbody>
</table>
Recent studies have shown that delays in cancer screening, diagnosis, and treatment will negatively impact health outcomes for many patients, in particular those from racial and ethnic minorities. In 2016, the overall cancer death rate among racial and ethnic minorities was 33 percent higher than the overall cancer death rate for whites. By 2016, it was 14 percent higher. Many studies and initiatives are beginning to provide insight into the factors that contribute to cancer health disparities.

The report notes the following areas of progress in the reduction of cancer health disparities:

- Differences in the overall cancer death rate among racial and ethnic groups are less pronounced now than they have ever been. In 1990, the overall cancer death rate for African Americans was 33 percent higher than the overall cancer death rate for whites. By 2016, it was 14 percent higher.
- Recent studies have shown that racial and ethnic disparities in outcomes for some types of cancer could be eliminated if all patients have equal access to standard treatment.
- Tailored outreach and patient navigation can help reduce disparities across the spectrum of cancer care.
- Several studies and initiatives designed to address gaps in our knowledge about cancer biology in diverse populations are underway, including AACR Project Genomics Evidence Neoplasia Information Exchange (GENIE) and the National Cancer Institute-funded African American Breast Cancer Epidemiology and Risk (AMBER) Consortium.
- Over the past two decades, diversity-focused training and career development programs have enhanced racial and ethnic diversity in cancer training.

"I think some of the other important aspects are related to socioeconomic issues, how the financial impact of not addressing disparities—I think we presented some data where a study is done looking at healthcare costs between 2003 and 2006—was at the level of a trillion dollars," Carpten said. "So, that can't be ignored."

In an effort to eradicate the social injustices that are barriers to health equity, the report concludes with a call to action to policymakers and all stakeholders to:

- Provide robust, sustained, and predictable funding increases for the federal agencies and programs that are tasked with reducing cancer health disparities.
- Implement steps to ensure that clinical trials include a diverse population of participants.
- Support programs to make sure that the healthcare workforce reflects and appreciates the diverse communities it serves.
- Prioritize cancer control initiatives.
- Work with members of the Congressional Tri-Caucus—comprising the Congressional Asian Pacific American Caucus, Congressional Black Caucus, and Congressional Hispanic Caucus—to pass the provisions included in the Health Equity and Accountability Act.

"What we hope is that, along with this progress report and all of these other societal issues that we're facing and dealing with, that we can expose these things and begin to identify solutions together," Carpten said. "And to see real resources, hard dollars be brought to bear on solving these problems and addressing these issues."
Carpten spoke with Matthew Ong, associate editor of The Cancer Letter.

Matthew Ong: Thanks for your work on this incredibly important report. What’s unique about the AACR Cancer Disparities Progress Report, and what are your takeaways?

John Carpten: It gives us, I think, the opportunity to really provide the public with a baseline of where we are in our understanding of cancer disparities. Where are we? What progress have we made? What gaps remain? And then, as a field, where do we think action could be taken, what action could be taken to allow us to be more efficient and more effective in addressing and ultimately eliminating cancer disparities?

So, to have the opportunity to present this in an open form with public input and questions and comments that included access to our legislators is just unbelievable and such an incredible opportunity for AACR and the field of cancer health disparities to really capture their interest, to really let them know how serious of an issue this is. It’s also an update on the research that’s ongoing and the steps that we need to take. From my perspective, that’s what we had hoped to do, and I think we were able to accomplish today.

In terms of takeaways, I think, undoubtedly, including the patient advocates and their stories as part of the briefing, as well as part of the panel, and then finally, to have them provide their stories in detail in video format, To me, that was the heart and the foundation of the entire day, as I looked at the questions...
Increasing Cancer Risk

Research has identified numerous factors that increase an individual’s risk for developing cancer. By modifying behavior, individuals can eliminate or reduce many of these risks and thereby reduce their risk of cancer. Developing and implementing additional public education and policy initiatives could help further reduce the burden of cancers related to preventable cancer risk factors.

**TOBACCO SMOKING**
~19.4%
of cancer diagnoses are caused by smoking tobacco.

**EXCESS BODY WEIGHT**
~7.8%
of cancer diagnoses are related to individuals being obese or overweight.

**ALCOHOL**
~5.6%
of cancer diagnoses are caused by alcohol consumption.

**ULTRAVIOLET LIGHT**
~4.7%
of cancer diagnoses are a result of exposure to ultraviolet light from the sun or tanning devices.

**DIET**
~4.2%
of cancer diagnoses are related to individuals having poor dietary habits.

**CANCER-CAUSING PATHOGENS**
~3.3%
of cancer diagnoses are related to infection with one of several cancer-causing pathogens.

**PHYSICAL INACTIVITY**
~2.9%
of cancer diagnoses are related to individuals getting insufficient physical activity.

Data from (57)
Hispanics (24) (see numerous other types of cancer are significantly higher among cancer, lung cancer, prostate cancer, colorectal cancer, and States including the five most common types of cancer—breast U.S. citizens live in Puerto Rico (23). An additional 3.1 million Hispanic and are the largest racial or ethnic minority population group Hispanics comprise about 18 percent of the U.S. population in the United States (13). An additional 3.1 million Hispanic rate than white women (12). This knowledge is vital if we are to eliminate disparities in lung cancer for African American men. develop targeted approaches to tobacco control that will help American women being more likely to be diagnosed at a later stage of disease, when treatment is less likely to be successful, while African American women smoke cigarettes at a lower rate than white women (12). These differences with white men and 12 percent lower among African American men compared with white men, and it is 14 percent lower among African American women compared with white women (12). These differences in incidence rates, poorer access to new, cutting-edge contribute to incidence rate disparities (12). In addition to differences in colorectal cancer screening among African Americans disproportionate increase in the breast cancer incidence rate and for populations with differing degrees of ancestry from continental United States and Hawaii is highly diverse. For November 2018 SEER data submission, posted to the SEER website, April 2019. *Both sexes unless otherwise specified Data from: SEER Cancer Statistics Review 1975-2016 (Howlader N, Noone AM, Krapcho M, Miller D, Brest A, Yu M, Ruhl J, Tatalovich Z, Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). SEER Cancer Statistics Review, 1975-2016, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2016/, based on November 2018 SEER data submission, posted to the SEER website, April 2019.

## Table 1

### Table 1: Disparities in Incidence and Death Rates between African Americans and Whites for Selected Cancer Types

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>African Americans</th>
<th>Whites</th>
<th>Rate Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple myeloma</td>
<td>14.3</td>
<td>6.4</td>
<td>2.23</td>
</tr>
<tr>
<td>Prostate, males</td>
<td>172.8</td>
<td>102.0</td>
<td>1.69</td>
</tr>
<tr>
<td>Stomach</td>
<td>9.6</td>
<td>5.7</td>
<td>1.68</td>
</tr>
<tr>
<td>Liver and intrahepatic bile duct</td>
<td>11.9</td>
<td>7.4</td>
<td>1.61</td>
</tr>
<tr>
<td>Colorectal</td>
<td>45.5</td>
<td>36.5</td>
<td>1.25</td>
</tr>
<tr>
<td>Pancreas</td>
<td>15.7</td>
<td>12.7</td>
<td>1.24</td>
</tr>
<tr>
<td>Kidney and renal pelvis</td>
<td>19.2</td>
<td>15.7</td>
<td>1.22</td>
</tr>
<tr>
<td>Cervix uteri, females</td>
<td>7.4</td>
<td>6.3</td>
<td>1.17</td>
</tr>
<tr>
<td>Lung and bronchus</td>
<td>57.4</td>
<td>51.0</td>
<td>1.13</td>
</tr>
<tr>
<td>Breast, females</td>
<td>128.2</td>
<td>132.7</td>
<td>0.97</td>
</tr>
</tbody>
</table>

### Table 2: Disparities in Incidence and Death Rates between Hispanics and Whites for Selected Cancer Types

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Hispanics</th>
<th>Whites</th>
<th>Rate Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver and intrahepatic bile duct</td>
<td>12.6</td>
<td>7.4</td>
<td>1.7</td>
</tr>
<tr>
<td>Stomach</td>
<td>9.9</td>
<td>5.7</td>
<td>1.7</td>
</tr>
<tr>
<td>Cervix uteri, females</td>
<td>9.6</td>
<td>6.3</td>
<td>1.5</td>
</tr>
<tr>
<td>Childhood cancer</td>
<td>18.4</td>
<td>19</td>
<td>1.0</td>
</tr>
<tr>
<td>Gallbladder</td>
<td>1.1</td>
<td>1.1</td>
<td>1.0</td>
</tr>
<tr>
<td>Thyroid</td>
<td>14</td>
<td>15.3</td>
<td>0.9</td>
</tr>
<tr>
<td>Colorectal</td>
<td>32.9</td>
<td>36.5</td>
<td>0.9</td>
</tr>
<tr>
<td>Prostate, males</td>
<td>84.6</td>
<td>102.0</td>
<td>0.8</td>
</tr>
<tr>
<td>Breast, females</td>
<td>98</td>
<td>132.7</td>
<td>0.7</td>
</tr>
<tr>
<td>Lung and bronchus</td>
<td>27.7</td>
<td>51.0</td>
<td>0.5</td>
</tr>
</tbody>
</table>

in the comments that were coming through, and even all of the emails and text messages that I've received since the briefing closed.

So, many people spoke to how incredible the patient advocates were, and how it personalizes the issue in such a way that I think will help us gain the type of support that we need to help us address these issues. And, of course, having the videos from our legislators was also incredible. It was also obvious that a number of the questions had a common theme.

I think some of the questions around being careful as we consider the study of cancer health disparities, because it is multifactorial and how we have to take into account both the standpoint of the social aspects that drive cancer disparities, as well as genetic ancestry, which is brought to bear on the biological side of cancer health disparities.

But, importantly, as was mentioned by our panel members, is that those two things do go hand-in-hand and could possibly have an impact on each other. And that’s one of the areas that the field needs to move towards, which is these very comprehensive, interdisciplinary, or multidisciplinary study designs.

What are some of the cornerstone data points from the survey that you’d like to highlight?

JC: That’s a great question.

I think one would be the lack of diversity in clinical trials. I think that is an area that’s central to an agenda for cancer health disparities research going forward—how do we work towards increasing diversity in clinical trials?

The report provides some really important information, when we consider the impact that certain cancer disparities exact on various communities and populations and the lack of appropriate representation in clinical trials and biomedical research cohort studies.

And how, without having those data on the value of increasing diversity, we’re losing an opportunity to gain a broader understanding of the efficacy and impact of these various therapies for all people.

I think some of the other important aspects are related to socioeconomic issues, how the financial impact of not addressing disparities—I think we presented some data where a study is done looking at healthcare costs between 2003 and 2006—was at the level of a trillion dollars. So that can’t be ignored.

And so, the report includes quite a bit of information on the numbers, the lack of diversity when we look at a general population representation, versus representation in the workforce. And it talks about some of the programs that are in place to help work towards mitigating that, but also the fact that we need to do better.

Finally, the call to action drives home the points that we think are really important—that we would like to work with Congress to ensure that there’s growth in biomedical research funding, specifically in cancer health disparities, that we are working towards governmental initiatives to help us drive more diversity in clinical trials, and again, to advance and increase diversity in the workforce.

We need to ensure that legislation is put in place to ensure that cancer disparities have a significant place in the development of new policies. And so, the call to action is really the critical part of this document.

It’s noteworthy that the gap in the overall cancer mortality rate between Blacks and whites has more than halved since the ’90s, while the proportion of racial and ethnic minority patients in NCI-funded clinical trials has nearly doubled over about the same period (The Cancer Letter, June 26, 2020). What do these trends point to, and what’s been working?

JC: I think I mentioned early in my keynote that we’ve made progress. We’ve seen a 26% reduction in cancer mortality rates since the declaration of the war on cancer.

But I think, even when you look at those particular numbers that you just men-
13 percent of the U.S. population (13). For more than four decades, African Americans have had a higher overall cancer death rate than all other racial and ethnic groups in the United States. An estimated 202,260 African Americans were diagnosed with cancer and 75,030 died from the disease in 2019 alone (12).

For many of the most common types of cancer, including breast, lung, prostate, and colorectal cancers, incidence and/or death rates are higher among African Americans than other racial and ethnic groups (see Table 1, p. 14). One of the most striking examples of cancer-specific disparities is that African American men have prostate cancer incidence and death rates that are more than 1.5 times and more than 2 times those for men of any other race or ethnicity, respectively (12). The disparity in prostate cancer mortality between African American men and men of any other race or ethnicity was recently shown to be greatest for those diagnosed with low-grade prostate cancer (14). There are many factors that contribute to the high burden of

**FIGURE 1**

Overall Cancer Death Rate Differences Are Narrowing

The age-adjusted overall cancer death rate for each of the racial and ethnic groups for which cancer statistics are collected by the National Cancer Institute’s Surveillance, Epidemiology, and End Results Program has been declining steadily since 2000. The extent of the decline has varied among the different groups, with the greatest overall cancer death rate decline (30 percent) occurring among African Americans (yellow line) and the least (11 percent) occurring among American Indians/Alaska Natives (red line). The declines in the overall cancer death rates for whites (green line), Hispanics (dark blue line), and Asians/Pacific Islanders (light blue line) were all about 20 percent.
A striking example of cancer health disparities is that prostate cancer incidence among African American men is nearly 70 percent higher than among white men. Unfortunately, two recent clinical trials testing new therapeutics for the treatment of prostate cancer recruited fewer than 10 percent of patients who were African American.

**Underrepresentation of African Americans in Recent Prostate Cancer Clinical Trials**

![PROSTATE CANCER INCIDENCE, PER 100,000](chart)

**PERCENTAGE OF REPRESENTATION IN CLINICAL TRIALS**

![Percentage of Representation in Clinical Trials](chart)

Data from (4)
tioned, there’s also evidence that gets presented at ASCO, we have large phase III definitive clinical trials for prostate cancer, which is among the most significant disparities, and there’s 3% minority representation in those clinical trials.

So, I think there’s one way to look at things where they’re broader, especially when it comes to clinical trials that are related to chemotherapy. But we think about some of the more innovative drug development programs.

When we think about targeted therapies, we think about immunotherapeutics. I don’t think the numbers are as they seem. I think those numbers could be dug into a little bit deeper, and we’ll see that this is definitely a significant issue and challenge that we need to overcome.

Also, we’ve heard a lot from NCI about excess cancer deaths from COVID-19, but how will the pandemic change our outlook on cancer mortality, where disparities are concerned and in terms of where the burden of cancer is going to fall over the next decade? In that context, what have you learned about the disparate impact of COVID-19 on communities of color?

JC: I think the jury is still out. We’re still early. I think, undoubtedly, we know that there’s clear evidence that there are disparities in SARS-CoV-2, incidence rates and death rates among many underrepresented minorities and the medically underserved, which we consider people who don’t have private insurance.

We also know that many of the safety net hospitals that reside and serve many of these underserved communities are under-resourced.

Of course, those are the facilities where many of these individuals receive their cancer care, and these health systems are considerably overburdened by COVID-19. And so, what’s happening is that many services, elective services like screening, have been put on hold, or delayed. And many elective procedures that could be surgeries for early stage cancers are being delayed, and in some cases canceled, because of the overburdening of the health system due to COVID-19.

So, undoubtedly, we will see a significant impact in cancer overall in the coming years, because of these issues.

But more than likely, we can almost guarantee that there’ll be a heavier burden on the underrepresented and underserved communities, because of the fact that they are already dealing with a situation where their care is coming from under-resourced healthcare facilities.

We are more than likely going to see an exacerbation of these disparities in the coming years because of the pandemic.
How does the survey illustrate the importance of diversity in leadership and in a workforce in oncology? And specifically, how have these diversity-focused training and career development programs over the past two decades made a difference on the overall cancer mortality for communities of color?

JC: That’s a great question. In terms of something having impact and making a difference,

I can only speculate that yes, some of the growth that we’ve seen and advancements towards diversifying the workforce have likely had some impact on some of the improvements we’ve seen in outcomes, but it’s modest at best. Because, when you look at the numbers, they’re still critically low.

Has there been progress? Absolutely. I wouldn’t be sitting here on the phone with you if there had not been progress, but we still can’t ignore the fact that the pipeline is still a bit limited, even for those students that get through K through 12 into undergraduate.

Are they able to be competitive for internships and research positions, such that if they do decide to move on into a higher education, whether it be medical school or otherwise, do they have the credentials that are needed to be competitive?

I have to give a lot of kudos to our historically black colleges, particularly those that have medical schools, for their work in supporting the development of careers for doctors and health professionals of color.

And I think that you’re right, I do believe that whether or not we’re there now, or whether we get there in the future, that by diversifying the workforce, we will have a better chance of impacting, for instance, diversity in clinical trials.

Perhaps a diversification of the workforce will help us in our efforts to increase diversity in clinical trials.

Because, we know that there are trust issues involved in some of the limitations of certain individuals wanting to participate in clinical trials. So, at the
Disparities in Health and Quality of Life after a Cancer Diagnosis

Several segments of the population are disproportionately affected by cancer- and cancer treatment–related health complications that adversely affect health and quality of life after a cancer diagnosis. Examples of these disparities include the following:

<table>
<thead>
<tr>
<th>TWO-FOLD INCREASED RISK</th>
<th>African American women had a two-fold increased risk of breast cancer–related lymphedema (swelling in the arms that can cause pain and problems in functioning) compared with white women (306).</th>
</tr>
</thead>
<tbody>
<tr>
<td>23% MORE LIKELY</td>
<td>Cancer survivors who lived in rural areas were 23 percent more likely to report psychological distress compared with those in urban areas (307).</td>
</tr>
<tr>
<td>50% MORE LIKELY</td>
<td>Colorectal cancer survivors who had low socioeconomic status were 50 percent more likely to report clinically significant anxiety and depression compared with those who had high socioeconomic status (308).</td>
</tr>
</tbody>
</table>

end of the day, there is a relationship between those two things.

What we hope to do through the AACR and other partnering organizations is to work hard towards developing new programs that offer equitable opportunities to minorities, for access to funding, to grants, to fellowships, access to internships, as well as trying to work towards ways to better mentor and develop the careers of minority scientists towards successful careers in biomedical research and health professions such as oncology.

We tried our best to spell out some of those things that we hope that our leaders and individuals in leadership positions and in positions of influence can see and read.

I think there’s a lot to unpack. We’re living in an incredible time right now. I’m not saying incredible in a good way; I’m saying, in an incredible time, where social aspects related to social injustices have, arguably, an all-time-high spotlight, where the COVID-19 pandemic has brought into full view disparities in health care.

And so, there’s a convergence of all of these things happening right now. What we hope is that, along with this progress report and all of these other societal issues that we’re facing and dealing with, that we can expose these things and begin to identify solutions together.

And to see real resources, hard dollars be brought to bear on solving these problems and addressing these issues. So, access to resources, bringing everyone to the table so that everyone has a voice is another important thing that people of influence can do.

By diversifying these conversations, perhaps we can come up with more creative and innovative approaches to solving these problems.

Did we miss anything?

JC: We’re really excited and honored to have the opportunity to share with the world the progress and a vision for addressing understanding and ultimately eliminating cancer disparities.

This is a historic first-of-its-kind document, and it will provide our legislators with some of the information and evidence that they need to help guide them on this really important issue, and to ensure that resources are brought to bear towards helping us solve this issue.

What is your message to leaders at healthcare institutions—federal agencies, academia, industry, advocacy—who are reading this? What can we learn from the past?

JC: I think one important part is the call to action.
**Disparities in Cancer Treatment**

Research is constantly powering the development of new cancer treatments. However, several segments of the U.S. population have been found to be disproportionately less likely to receive standard recommended cancer treatments. Examples of these disparities include:

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>50% LESS LIKELY</strong></td>
<td>Patients with intrahepatic cholangiocarcinoma who are Black are <strong>50 percent less likely to have surgery</strong> compared with patients who are white (47).</td>
</tr>
<tr>
<td><strong>29% LESS LIKELY</strong></td>
<td>Women with ductal carcinoma in situ who live in rural areas are <strong>29 percent less likely to receive radiotherapy</strong> after breast conserving surgery compared with women who live in urban areas (254).</td>
</tr>
<tr>
<td><strong>27% LESS LIKELY</strong></td>
<td>Among patients with locally advanced soft tissue sarcoma treated with limb sparing surgery, those without health insurance were <strong>27 percent less likely to receive neoadjuvant or adjuvant radiotherapy</strong> compared with those who had commercial insurance (255).</td>
</tr>
<tr>
<td><strong>50% LESS LIKELY</strong></td>
<td>Patients with metastatic bladder cancer who are of low socioeconomic status are <strong>50 percent less likely to receive chemotherapy</strong> compared with those of high socioeconomic status (256).</td>
</tr>
</tbody>
</table>

**Disparities in Cancer Surgery**

- African American breast cancer patients undergoing mastectomy surgery are **significantly less likely to have breast reconstruction** compared with white patients (267).
- African American and Hispanic patients with rectal cancer are **less likely to undergo sphincter-sparing surgery** compared with white patients (268).
- African American and Hispanic patients with early-stage cervical cancer are **more likely to forgo surgery**, which is the standard of care, compared with white patients (17% and 12% vs 9% respectively) (269).
- African American and Hispanic patients with early-stage lung cancer are **less likely to undergo curative-intent surgery** compared with white patients (270).
- Hispanic patients with potentially resectable esophageal cancer are **significantly less likely to receive surgery** compared with white patients (46% vs. 60%) (400).
Francis Collins: “We’ve just got to get this done. Because people are dying and time is passing.”

By Alexandria Carolan

NIH Director Francis S. Collins said he expects at least one of the vaccines against COVID-19 to be proven safe and effective by the end of 2020.
I think, along with my good colleague, [National Institute of Allergy and Infectious Diseases Director] Tony Fauci—I would say I’m cautiously optimistic that by the end of 2020—one or more of these vaccines will have been proven to be safe and effective," Collins said during the Sept. 16 virtual Rally for Medical Research.

Six vaccines for COVID-19 are either in phase III trials or about to enter phase III trials, Collins said during the virtual rally.

The rally was organized by American Association for Cancer Research.

"Each of those [are] planning to enroll or [are] already enrolling 30,000 participants—half of them getting placebo, half getting vaccine," Collins said. “We’re watching closely, of course, then, to see what is the way in which this vaccine works in the real world. Does it, in fact, show the appropriate safety? And that’s going to be a very high bar indeed. And is it effective? Does it prevent people from getting sick with SARS-CoV-2 infections?"

The Centers for Disease Control and Prevention Director Robert Redfield Sept. 16 said that vaccinations against COVID-19 will not be widely available until the middle of next year.

"Of course, if a vaccine turns out not to be successful, we’ll have to throw those away. But it is a good investment, given the timetable we’re up against," Collins said. “Although we knew pandemics were around the corner, this one is really quite a striking example of the kind of thing we hoped would not happen. But science is our best hope for pushing that back."

Collins listed the initiatives the government has launched to fight the virus:

- ACTIV—(Accelerating Coronavirus Therapeutic Interventions Vaccines), a government and industry collaboration to develop a research strategy for prioritizing and speeding development of the most promising COVID-19 treatments and vaccines.
- RADx, an initiative to speed innovation in the development, commercialization, and implementation of technologies for COVID-19 testing.
- Operation Warp Speed, a government vaccine development initiative that aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021.

During the virtual rally, Collins said Congress and NIH are acting quickly on COVID-19.

"I’ve got to say, as somebody who’s been part of NIH now for 27 years, seeing all of this come together this year is truly breathtaking," Collins said. “Nobody’s worried about who’s going to get the credit. We’ve just got to get this done because people are dying and time is passing.

"I’m really pleased to see the way in which our community, and that’s all of you and the Congress, we’ve all gotten together to do this thing of using science to address this—and science is our best hope right now."

The text of Collins’s talk follows:

I want to thank the American Association for Cancer Research for their hosting, and many other advocacy organizations that have joined together here on Rally Day. I particularly want to thank the members of Congress for their steadfast championship for biomedical research—both parties, both houses, making medical research a very high priority, and recognizing that this is something that the government can do that otherwise wouldn’t happen.

The consistent funding increases for NIH over the course of the last several years have put us in a very strong position to respond to challenges.

And goodness knows, we’ve had a challenge with COVID-19. And on top of that, Congress has found it possible in the midst of everything else, to recognize that we could go even faster, with some additional resources, and an additional $3.5 billion have been put into the research engine, to allow us to do things with COVID-19 we otherwise would not have been able to do.

My goodness, what a remarkable series of advances have been happening in record time.

It was only Jan. 10, where that sequence of the virus SARS-CoV-2 was first posted. Within a couple of days, the scientists at the Vaccine Research Center had designed a vaccine based upon the messenger RNA approach, a relatively novel approach that was actually developed, in part, based upon what we learned about Ebola, and now it could be brought forward for this new really serious challenge.

Sixty-three days later, the first patient was being injected in the phase I trial, blowing away by many months, the record previously held for going from
as we can, and the vaccine is the best way to get there. But of course, we also need to work on therapeutics.

In that regard, a partnership that has been set up and has been operating with remarkable speed just since April—the partnership called ACTIV—Accelerating Coronavirus Therapeutic Interventions Vaccines—has been one of the more gratifying things that I’ve been part of in my 11 years as your NIH director, bringing together 20 pharmaceutical companies, the FDA, the CDC, multiple NIH institutes, the Veterans Administration, the Department of Defense, BARDA—all of this managed by the Foundation for NIH—and every body, basically 24/7, determined to figure out how to prioritize the most promising therapeutics, and get them into rigorous clinical trials as soon as possible.

We are now in the midst of figuring out which of those things can work. For antibodies, do they need to be working in an inpatient, or would you rather start in an outpatient? What about anticoagulants—are there ways that we can do a better job of helping people who get very sick, where we know blood clotting is a problem?

All those things underway in a record-speed-setting kind of protocol—and doing this with master protocols—where we have really clear ideas about what the endpoints are going to be, and how to assess them.

I’ve got to say, as somebody who’s been part of NIH now for 27 years, seeing all of this come together this year is truly breathtaking. And nobody’s worried about who’s going to get the credit. We’ve just got to get this done, because people are dying and time is passing.

"Here we are now, with six vaccines that are either already in phase III trials, or will be soon in the next couple of months—three different technologies, which is good. You want to have this diversity of approaches."

that kind of recognition of a pathogen to having a trial started.

That pace has continued, as you know. Here we are now, with six vaccines that are either already in phase III trials, or will be soon in the next couple of months—three different technologies, which is good. You want to have this diversity of approaches.

Each of those [are] planning to enroll or [are] already enrolling 30,000 participants—half of them getting placebo, half getting vaccine.

We’re watching closely, of course, then, to see what is the way in which this vaccine works in the real world. Does it, in fact, show the appropriate safety? And that’s going to be a very high bar indeed. And is it effective? Does it prevent people from getting sick with SARS-CoV-2 infections?

This is going to be a very important few months as everyone knows. I think, along with my good colleague, [National Institute of Allergy and Infectious Diseases Director] Tony Fauci—I would say I’m cautiously optimistic that by the end of 2020—one or more of these vaccines will have been proven to be safe and effective.

And we are already, because of Operation Warp Speed, planning for success by spending hundreds of millions of dollars to prepare doses of each of these vaccines to be distributed to those highest risk individuals.

Of course, if a vaccine turns out not to be successful, we’ll have to throw those away. But it is a good investment given the timetable we’re up against, and the fact that at the time I’m speaking to you, almost 200,000 people have died from this disease.

We want to put an end to all of the death and suffering from this as fast as we can, and the vaccine is the best way to get there. But of course, we also need to work on therapeutics.

In that regard, a partnership that has been set up and has been operating with remarkable speed just since April—the partnership called ACTIV—Accelerating Coronavirus Therapeutic Interventions Vaccines—has been one of the more gratifying things that I’ve been part of in my 11 years as your NIH director, bringing together 20 pharmaceutical companies, the FDA, the CDC, multiple NIH institutes, the Veterans Administration, the Department of Defense, BARDA—all of this managed by the Foundation for NIH—and everybody, basically 24/7, determined to figure out how to prioritize the most promising therapeutics, and get them into rigorous clinical trials as soon as possible.

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I’ve got to say, as somebody who’s been part of NIH now for 27 years, seeing all of this come together this year is truly breathtaking. And nobody’s worried about who’s going to get the credit. We’ve just got to get this done, because people are dying and time is passing.
I might also say another area that the Congress has helped us do is to get into the diagnostic areas. With that regard, something called RADx, rapid acceleration of diagnostics, has made it possible just in a few short weeks, since this started in late April—to find a total now of 16 new technologies that started out in small businesses or academic labs, and are now scaling up to be able to deliver, potentially a couple of million tests a day, that are point of care, that are rapid, that are reasonably cost effective.

That can range everywhere from a CRISPR based effort, to the usual RT-PCR to viral antigen test.

We need, of course, that kind of capacity, in order to find out who’s infected and to quickly respond. And all of that’s also part of our research agenda.

I’ve got to say, some of those technologies, I have to look at with a little bit of a sense of pride, because they depend on things we learned in the Human Genome Project about how to work with nucleic acid.

Because, of course, COVID-19, as an RNA virus, has a nucleic acid that is our best opportunity for diagnostics using technologies that originally came out of the Genome Project.

That’s one of the reasons we can do this as quickly as we can. And it is now 30 years, or it will be in a couple of weeks, since the original start of the Genome project in 1990—and who would have thought that it would have all of these spin-offs 30 years later, including tackling this unprecedented global pandemic. But we need everybody engaged.

I’m really pleased to see the way in which our community, and that’s all of you and the Congress, we’ve all gotten together to do this thing of using science to address this—and science is our best hope right now.

So, who knew, when we gathered a year ago, having a lovely time there, face-to-face, that this was looming out there just a couple months later, and it would change everything for the way in which we lead our lives, and how we plan our research, and all the things that are currently around us that give us a great sense of concern.

I think there’s no question that all of us will look back on 2020 as a memorable year and not in necessarily a good way. It was a dark year in terms of the havoc created by this unexpected coronavirus and its rapid spread, and its ability to be passed from person to person with such ease. Nothing like this was quite anticipated.

Although we knew pandemics were around the corner, this one is really quite a striking example of the kind of thing we hoped would not happen. But science is our best hope for pushing that back.

NIH will continue to strive to be that city on a hill that’s supported by this Congress, and lighted up by the brilliance and the determination of our bold, innovative, dedicated, and tireless scientists. So, thank you, all of you for what you were doing to keep those fires of ingenuity burning. Science is truly our best hope to get through this, and we will get through this.
Emily Tonorezos named head of NCI’s Office of Cancer Survivorship

Emily S. Tonorezos was named director of the NCI Office of Cancer Survivorship.

Tonorezos joins NCI from Memorial Sloan Kettering Cancer Center and the Weill Cornell Medical College, where she was director of the Adult Long-Term Follow-Up Program for survivors of childhood and young adult cancers.

Her research focuses on cardiometabolic consequences of cancer therapy, childhood and young adult cancer survivorship, diet and nutrition, and care coordination for this population. She was also co-leader of the International Guideline Harmonization Group for the metabolic syndrome guidelines, and she led a recent international effort to develop recommendations for adult survivors of heritable retinoblastoma.

Tonorezos replaces interim director Deborah Mayer, who led the office after retirement of Julia Rowland.

Electra Paskett named director of the Alliance Cancer Control Program and PI for the Alliance NCORP Research Base

Electra D. Paskett was named director of the Alliance Cancer Control Program and principal investigator for the Alliance NCORP Research Base.

Paskett is the Marion N. Rowley Professor of Cancer Research and director of the Division of Cancer Prevention and Control in the College of Medicine at The Ohio State University. She is also professor of epidemiology in the OSU College of Public Health.

Paskett has been a leader of Alliance cancer control programs since 2011 when the group was founded by the merger of the American College of Surgeons Oncology Group, Cancer and Leukemia Group B, and the North Central Cancer Treatment Group. Most recently, she served as chair of the Alliance Health Disparities Committee and multiple-PI of the Alliance NCORP Research Base.

ACCC announces 2020 Innovator Award winners

The Association of Community Cancer Centers has named five recipients of the tenth annual ACCC Innovator Awards, highlighting the year’s leading-edge strategies to challenges faced by oncology programs and practices across the country.

The eight ACCC Innovator Award winners feature programs across the multidisciplinary team in cancer care. The awards were given out at the ACCC’s 37th virtual National Oncology Conference Sept. 14-18.

Winners were selected based on the potential of their program to have a real-world impact on the delivery of cost-effective, patient-centered care with replicable solutions in the areas of care coordination and quality improvement, technology, patient engagement, innovative training and staffing models, the provision of supportive care services, and collaborative practice agreements.

The ACCC 2020 Innovator Award winners are:
- **Integration of Prehab, Rehab, and Prospective Surveillance into Interdisciplinary Teams;** Beaumont Health System, Beaumont Cancer Institute. This program improves the patient experience, reduces hospital length of stay, and facilitates early identification of physical impairments, functional limitations, and/or treatment restrictions. Other outcomes include reduction of cancer-related fatigue, lymphedema, and falls, and non-opioid pain management.

- **A Nurse Navigator-Led Community-Based Cardio-Oncology Clinic;** Franciscan Health Cancer Center, Indianapolis. This program manages the cardio-toxic side effects of more than 1,000 cancer patients. Working in collaboration with medical oncologists and other members of the multidisciplinary team, the cardio-oncology team helps keep oncology patients in treatment and improves patient quality of life.

- **Leveraging a 3D Lung Nodule Educational Tool to Reduce Patient Distress;** Maine Medical Center Cancer Institute. The use of a 3D lung nodule tool as part of shared decision-making facilitated high quality communication, improves patient knowledge about malignancy risk, reduces emotional distress, and improves quality of life. A geriatric nurse practitioner partnered with an art student to design and implement the 3D model.

- **Reducing ED Visits and Hospital Admissions after Chemotherapy with Predictive Modeling of Risk Factors;** Mercy Cancer Care, St. Louis. After conducting a retrospective review to identify clinical variables associated with increased risk of hospital admissions and emergency department visits, Mercy Cancer Care developed and implemented a predictive algorithm that stratifies patients according to their 30-day risks. A daily dashboard report identifies all patients as high, intermediate, or low risk.

- **Onboarding Experienced Non-Oncology Nurses to Address Staffing Shortages;** Development of a Transitional Oncology Training Academy; Miami Cancer Institute. This 12-week academy gives nurses the knowledge and skills to transition to radiology, blood and marrow transplant, outpatient infusion oncology, and Phase I/II research on a Precision Medicine Unit. The academy prepares participants for the ONS/ONCC Chemotherapy Immunotherapy Certificate.

- **Improve Oral Oncolytic Workflow and Reduce Treatment Delays with a Pharmacist Collaborative Practice Agreement;** St. Luke’s Cancer Institute. This pharmacy resident pilot project supported the creation and implementation of an oral oncolytic collaborative practice agreement that expanded pharmacist scope of practice, decreased turnaround time for processing prescriptions, improved provider satisfaction, and decreased patient prescription costs.

- **Utilizing Technology to Identify Patient Co-Morbidities and Reduce Hospital and ED Admissions;** University of Arizona Cancer Center Tucson. A multidisciplinary team identified chemotherapy regimens administered in the inpatient setting that could be safely administered in the outpatient setting, and implemented a transition plan that reduced inpatient medical resources and chemotherapy costs, decreased inpatient bed stay, lower infection rates, improved quality of life, and decreased overall cost of care—conservatively estimated at almost $6 million.

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**NCI, NIBIB award contracts to develop innovative digital health technologies for COVID-19**

NIH has awarded seven contracts to companies and academic institutions to develop digital health solutions that help address the COVID-19 pandemic.

The seven digital health solutions are:

- **Evidation Health Inc.:** A health measurement platform for analyzing a wide range of patient-consented data, including self-reported data and wearable device data, to detect COVID-19 and differentiate it from the flu.

- **IBM:** An integrated solution that supports sophisticated contact tracing and verifiable health status reporting, yielding an array of key research data that simultaneously empowers users and facilitates research.
awardee’s program and demonstration of utility in response to the pandemic. If all seven projects were to move into the second phase, the total value of the contracts in this network would be $22.8 million. The awardees have one year to complete both phases.

The proposed digital health tools will leverage multiple data sources, including wearable devices and COVID-19 diagnostic and serology test results. Each organization will share data and other assets in an NIH-supported central data hub in ways that protect individuals’ privacy. To spur additional research, researchers will have access to data stored in the hub.

Because the collection of large digital health datasets has potential privacy implications, there is an emphasis on providing adequate privacy protections that allow personal health data to be collected without compromising civil liberties.

Lois Travis awarded $5.7 million from NCI to study chemo-induced hearing loss, toxicities
Lois B. Travis, the Lawrence H. Einhorn Professor of Cancer Research at IU School of Medicine, has been awarded a five-year, $5.7 million NCI grant to evaluate long-term health outcomes for cancer patients who receive platinum-based chemotherapies.

An expert on cancer survivorship, Travis leads the ongoing study that could lessen cancer treatment side effects for millions of patients.

Nearly 6 million patients globally are diagnosed with a cancer each year, in which first-line therapy potentially includes highly toxic, platinum-based chemotherapies. While the treatment may lead to hearing loss, ringing in the ears, numbness in hands and feet and other side effects, it is the only proven cure for the vast majority of testicular cancer patients.

When IU’s Lawrence Einhorn developed a revolutionary therapy for testicular cancer in the 1970s, he flipped the 95% mortality rate for the disease to a 95% survival rate. His regimen of platinum-based cisplatin and two other drugs continues to be the standard care for testicular cancer. Einhorn is the Livestrong Foundation Professor of Oncology at IU School of Medicine and a physician scientist at the IU Simon Comprehensive Cancer Center.

Travis, Einhorn and a team of researchers from other cancer centers are following more than 2,000 testicular cancer survivors who are part of the largest clinical cohort of germ cell cancer survivors worldwide. The alliance of researchers leads The Platinum Study, which was established through a previous NCI grant awarded to Travis in 2012.

“We have shown with audiometric examination that 80 percent of the patients had hearing loss with one in five classified as severe to profound, levels at which hearing aids are recommended,” Travis said. Additionally, researchers found that 56 percent of patients had nerve damage called neuropathy and 40 percent had tinnitus or permanent ringing in their ears.

With this grant, researchers will tap into the existing cohort of patients who are part of the Platinum Study. The median age at diagnosis for testicular patients is 30, and the cohort’s median age now is 37. As patients age, researchers will continue to follow health changes, including if they are more susceptible to age-related hearing loss.

“We will examine the role of genetic variants in the platinum toxicities to try to identify high-risk subgroups,” Travis said.

The team of investigators wants to understand better which patients are at higher risk for these adverse outcomes and the daily effects of the toxicities.

“The goal is to follow this cohort for many decades to characterize the longitudinal trajectory of toxicities related to platinum-based chemotherapy,” she said. “For the first time, we will evaluate the impact and severity of the hearing loss and tinnitus on the patients’ physical, emotional and social functioning.”

Patients will complete questionnaires to track the different facets of their lives that are affected by hearing loss, or pain and numbness associated with neuropathy, as well as other toxicities. Researchers will also investigate the social and emotional consequences of the constant ringing in the ears, such as difficulty sleeping or concentrating.

Additionally, researchers will continue to analyze previously collected patient blood samples to track platinum levels, which can remain in the body for decades after chemotherapy is completed.

“Platinum is not completely excreted and is believed to be held in several body reservoirs. As tissue is remodeled with age, platinum regains access to the circulation,” Travis explained. “We will continue to measure the residual serum platinum levels.”

While cisplatin is used for many cancers, Travis notes that the testicular cancer patient cohort offers researchers a unique opportunity to study the toxicities.

“If we want to improve our understanding of long-term cisplatin-related toxicities, this is an ideal population,” she said. “When doing genetic studies, we know that all patients received about the same cumulative dose of cisplatin. We can then consider: who developed hearing loss and who didn’t, and what genetic and other factors are associated with this outcome?”

Ultimately, Travis hopes this research can determine which patients are most likely to experience adverse effects from cisplatin and then provide guidelines that could decrease damaging side effects, such as duration of treatments or improved symptom management.

Collaborators include researchers from Memorial Sloan Kettering Cancer Center (Darren Feldman), Dana-Farber Cancer Institute (Neil Martin), University of Pennsylvania (David Vaughn), University of South Florida (Robert Frisina), Vanderbilt University (Nancy Cox), University of Chicago (Eileen Dolan), Princess Margaret Hospital (Robert Hamilton), the Royal Marsden Hospital (Robert Huddart), University of Rochester (Chunkit Fung), Loyola University (Heather Wheeler), Harvard School of Public Health (Howard Sesso), and the British Columbia Cancer Agency (Christian Kollmannsberger).
Katz, An, Kurian awarded $3.7 million in Moonshot funds to address genetic testing among families

A new $3.7 million grant, as part of the Beau Biden Cancer Moonshot Initiative, will support a clinical trial designed to test a personalized family genetic risk navigation support platform.

The trial will be extended to all first- and second-degree relatives of 900 patients in Georgia and California in whom genetic testing identified a variant indicating an elevated hereditary cancer risk.

“This study has enormous potential to improve cancer prevention and early detection in families at high risk of hereditary cancer syndromes. Targeting genetic risk evaluation in families where a cancer susceptibility gene has been identified may be the most cost-effective approach to reduce the burden of cancer through prevention,” principal investigator Steven J. Katz, co-leader of the health behavior and outcomes program at the University of Michigan Rogel Cancer Center, said in a statement.

The study team will develop and evaluate the Family Genetic Health Program, a technology assisted, personally tailored education and communication tool to facilitate genetic risk evaluation and management between patients and their relatives.

The team will compare outcomes of the program with and without direct assistance from a personal genetic navigator. The trial will also assess various cost levels to understand the best price point.

In addition to Katz, the principal investigators are Allison W. Kurian, of Stanford University and Lawrence An, of the Rogel Cancer Center.

The study leverages a unique project led by Katz and Kurian, The Georgia California Genetic Testing Linkage Initiative, which has partnered with NCI Surveillance, Epidemiology and End Results regional registries, commercial genetic testing companies and academics to link genetic testing results to all patients diagnosed with cancer in the two states over six years.

YCC receives $1.2 million NIH grant to fund gene imaging research

Yale Cancer Center has received an Exploratory Developmental Grant from NIH to fund 3D gene imaging research.

The three-year, $1.2 million R33 award will help support research on multiplexed imaging of chromatin folding and RNA profiles in cancer and lead to new biomarkers for cancer diagnosis, prognosis, and treatment. The NIH R33 funding provides a second phase for the support for innovative exploratory and development research activities.

“This funding will make a significant impact as it will help open up new opportunities to study the 3D genome in cancer, including the clonal diversity of chromatin architectures in cancer and gene expression regulation mechanisms by 3D chromatin organization,” Mandar Muzumdar, assistant professor of genetics and medicine at YCC, researcher at the Yale Cancer Biology Institute and co-principal investigator, said in a statement. “We hope to apply these technologies in future clinical trials to validate their utility in human cancer biospecimens.”

“Our plan is to help better define cancer cell states, and in turn lead to the discovery of new prognostic and predictive biomarkers,” Siyuan (Steven) Wang, assistant professor of genetics and cell biology at YCC and co-PI said in a statement. “The research may also offer new avenues for chromatin-targeted approaches for cancer prevention and therapy.”

YCC receives $175k research grant from Breast Cancer Research Foundation

Yale Cancer Center has received a one-year, $175,000 research grant from the Breast Cancer Research Foundation to study reducing re-excisions for breast conserving therapy for women following surgery for breast cancer.

Principal investigator of the grant, Mehran Golshan, joins three other YCC BCRF funded researchers: Melinda Irwin, Lajos Pusztai, and David Rimm.

This grant reflects the need to find ways to reduce unnecessary re-excisions during their treatment that leads to delay in initiation of adjuvant therapy, increase in costs, negative psychological impact, more women choosing mastectomy and higher infection rates,” Golshan, deputy chief medical officer for Surgical Services at Smilow Cancer Hospital and YCC, and interim director of the Breast Center at Smilow Cancer Hospital, said in a statement.

During breast conserving surgery, the need for re-excision occurs between 15-
25% of the time. When removing a breast tumor, surgeons strive for clean margins. That means targeting not only the tumor, but also excising the surrounding border of tissue. Margins are clean if no cancer cells are found at the outer edge of that tissue.

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**Five researchers receive shared $9 million grant from Aligning Science Across Parkinson’s initiative**

A multi-institutional team of scientists has received a grant from the Aligning Science Across Parkinson’s (ASAP) initiative to use stem cells to study how risk factors accumulate and interact to drive Parkinson’s disease (PD).

The team is led by Lorenz Studer, of Memorial Sloan Kettering Cancer Center, and includes including Gist Croft, of The NYSCF Research Institute; Vikram Khurana, of Brigham and Women’s Hospital, and a NYSCF – Robertson stem cell investigator; Jian Peng, of University of Illinois at Urbana-Champaign; and Joseph Powell, of Garvan Institute of Medical Research.

The team will receive $9 million over three years to take a comprehensive look at the interplay between genetics, aging, and different brain cell types underlying individual risk for PD in a project entitled, “Defining the cellular and molecular determinants of variable genetic penetrance in Parkinson’s disease.”
Navigating a cancer diagnosis is difficult, and even more so during a global pandemic.

For example, hand sanitizer and masks, both essential for immunocompromised individuals, are harder to purchase as going to public places takes on even more increased risk.

Commonplace daily routines, such as mass transit, air travel, grocery shopping and doctor visits have become major barriers for cancer patients, whose concerns about contracting COVID-19 have prevented, complicated and, unfortunately, even delayed cancer treatments for some patients.

And the delays in routine cancer screenings and resulting diagnoses are anticipated to have long-lasting effects.

Throughout my clinical and professional career, I’ve devoted my work to improving the everyday challenges cancer patients and their caregivers face.

As a pediatric oncologist in training, I always tried to put myself in the shoes of the patients’ parents and understand what care I would want for my child.

I brought this passion to my work in pharmaceutical development. Currently, at Astellas, we recognize the complexities of the cancer journey and know that, in addition to medicine, patients need comprehensive care.

Our oncology team is continuously looking to change cancer care by developing new medicines for patients with difficult to treat tumors, from hematologic malignancies to solid tumors.
Beyond this important work, Astellas also seeks ways to improve everyday life for people with cancer. An important program that brings cancer care ideas and concepts to life is the Astellas Oncology C3 (Changing Cancer Care) Prize.

Seeking ideas with the greatest potential to impact cancer care

Now in its fifth year, the Astellas Oncology C3 Prize is a global competition that seeks to discover the best ideas beyond medicine that can address the unique challenges of the cancer experience for patients, caregivers and their loved ones.

We are proud to continue to fund the most innovative ideas—from any individual or organization—to make every day better for people impacted by cancer.

This year, the C3 Prize is particularly interested in sourcing ideas that address the unique challenges that the COVID-19 pandemic has presented for people with cancer.

We will award $200,000 to three winners ($100,000 to the Grand Prize winner and $50,000 to two Innovation Prize winners) with the most groundbreaking ideas.

I am inspired by all previous nominees and winners, but as a pediatric oncologist, the Nanny Angel Network, an organization that aims to provide peace of mind, stability and normality for families with cancer through a volunteer corps who provide in-home childcare for moms and dads with cancer, is one that resonates with me in particular.

After Nanny Angel Network won the Grand Prize in 2019, the organization launched a new system to train volunteers online, which is even more important during the COVID-19 pandemic.

Additionally, the grant enabled the organization to offer remote child life specialists, hundreds of meal deliveries, a virtual homework club and “camp in a box.”

These are all unique solutions to the challenges in childcare COVID-19 has presented, and are exactly the type of innovative ideas we hope to see in this year’s applications.

Join the movement

Anyone can join the C3 Prize movement—it is not just for tech and academic applicants or for complex solutions. We’re open to the best ideas that can have great impact and are accepting applications until Sept. 28.

If you, or someone you know has an idea, I encourage you to apply at www.C3Prize.com and make a difference in cancer care.

We will award $200,000 to three winners ($100,000 to the Grand Prize winner and $50,000 to two Innovation Prize winners) with the most groundbreaking ideas.
Korean study examines the combined impact of aspirin, metformin, and statin’s impact on lung cancer risk

The combined use of aspirin, statins, and metformin is associated with decreased lung cancer incidence and mortality, according to a study published in the Journal of Thoracic Oncology, the journal of the International Association for the Study of Lung Cancer.

All three medications are common—approximately 35 million people take a statin to control cholesterol; more than 120 million people take metformin to control diabetes and between 6 and 10 million people take aspirin daily.

The aim of this study was to investigate the associations of aspirin, metformin, and statins with lung cancer risk and mortality using population-based nationwide cohort data from The Korean National Health Insurance Services database was used in the present study. The KNHIS is a universal health care system that covers the entire Korean population of 50 million.

“To our knowledge, no study has evaluated aspirin, statins, and metformin use and their combined impact on lung cancer incidence and mortality,” lead study author Dong Wook Shin, of the Sungkyunkwan University School of Medicine, said in a statement.

Shin and his colleagues (Jihun Kang and Su-Min Jeong) examined 732,199 Koreans from the Korean National Health Insurance Services database. The patients were followed between January 2004 and December 2013. Lung cancer incidence and mortality were identified using a registered lung cancer diagnosis code (ICD-10 code C34) and the Korean National Death Registry.

To address the combined associations of these cardiovascular drugs with lung cancer risk and mortality, the researchers categorized the cohort into eight groups, based on exposure to aspirin, statins, and metformin.

Combined use of aspirin, statins, and metformin was associated with decreased lung cancer incidence (aHR 0.83, 95% CI, 0.69–0.99) and mortality (aHR 0.83, 95% CI, 0.70–0.99) compared with non-users.

“When these cardiovascular drugs were used in combination, their protective associations with lung cancer risk and related mortality were augmented and the magnitude of effect increased with increasing duration of medication use,” Shin said in a statement.

During 2012-2013 (the most recent period in the study), study participants taking all three medications were 3.4% (23,163 out of 676,520).

“Interestingly, the inverse association of combined use of aspirin, statins, and metformin was prominent, and the longer the duration of combined use, the more protective the association. This finding is in line with a study demonstrating that aspirin and metformin synergistically inhibit lung cancer cell proliferation by activating AMP-activated protein kinase, which plays a critical role in regulation of lipogenesis in cancer cells,” Shin wrote.

Shin theorized that concomitant use of aspirin, statins, and metformin concurrently inhibits multiple pathways related to lung cancer cell growth and proliferation resulting in favorable associations with lung cancer risk and mortality.

Cigarette smoking associated with worse outcomes for bladder cancer patients after surgery

Patients treated for bladder cancer with a surgery known as radical cystectomy have worse outcomes if they are smok-
The research suggests that as long as a person is not smoking at the time of chemotherapy and surgery, they might do better,” Cacciamani said in a statement.

He also recommends that physicians monitor smokers more carefully post-surgery than other patients because they are more at risk for complications or death.

In addition, the study authors recommend that future studies or clinical trials involving bladder cancer chart patients’ smoking status to create a more accurate picture of what factors affect cancer survival and recurrence.

Cacciamani and fellow Keck Medicine researchers searched databases to select 17 studies that reported on the impact of tobacco smoking on chemotherapy response and survival outcomes of 13,777 patients following radical cystectomy. Of these patients, 40.8% were active smokers at the time of the surgery, 14.1% former smokers and 45.1% had never smoked or were not smoking at the time of the surgery.

The study showed that active smokers responded worse to chemotherapy and had higher mortality rates, both in general and specifically from bladder cancer, and a higher rate of bladder cancer recurrence than patients who never smoked or were not smoking at the time of surgery.

In general and specifically from bladder cancer, and a higher rate of bladder cancer recurrence than patients who never smoked or were not smoking at the time of surgery.

Former smokers also fared worse in these categories than those who had never smoked, even though the differences were less significant.

“The research suggests that as long as a person is not smoking at the time of che-

Partner Therapeutics begins phase III study of leukine + ipilimumab and nivolumab frontline melanoma

The EA61411 study conducted by ECOG-ACRIN Cancer Research Group has begun its phase III portion.

Partner Therapeutics Inc. sponsors the study.

EA6141 (NCT02339571) is a randomized controlled study of Leukine (sargramostim, yeast derived rhu-GM-CSF) in combination with ipilimumab and nivolumab for the front line treatment of melanoma.

The restart was based on results of ECOG-ACRIN’s planned interim efficacy and safety analysis of survival data from the first 250 patients enrolled in the study. FDA granted orphan drug status to Leukine in Sept. 2019, for the potential treatment of stage IIb-IV melanoma.

EA61411 is led by study chair F. Stephen Hodi, director of the Center for Immunology and director of Cutaneous and Clinical Translational Research at H. Lee Moffitt Cancer Center and Research Institute.

“GM-CSF has unique immunomodulatory properties that have the potential to substantially benefit patients with cancer,” Hodi said in a statement. He added “This study in the front line setting is intended to confirm and broaden the findings in the randomized phase II trial EA1608, which demonstrated improved efficacy and toxicity when sargramostim was added to ipilimumab.”

ECOG-ACRIN launched the phase II/III EA6141 study in Sept. 2015. In the study, patients with stage III/IV unresectable melanoma are randomized to receive standard of care treatment with nivolumab and ipilimumab with or without sargramostim. The primary endpoint is overall survival. ECOG-ACRIN planned for the interim trial pause after 240 patients were enrolled, to assess efficacy.

The group paused enrollment in June 2017 and the interim analysis is now complete. Based on the findings of the interim analysis, the ECOG-ACRIN Data Safety Monitoring Committee has given the go ahead to start the enrollment into the phase III portion of the study. The total planned enrollment is 600 patients. The study remains blind-
ed and no data will be released until completion.

“The prior data with sargramostim supporting improvement in survival and reduction in immune-related toxicity, as observed in the E1608 study, highlights the importance of further clinical evaluation in combination with checkpoint inhibitors,” Tarhini said in a statement.

ECOG-ACRIN previously reported results of Study E1608, a phase II study in which patients with advanced stage melanoma received a combination of sargramostim and ipilimumab or ipilimumab alone. Among 245 patients, the addition of sargramostim led to longer survival (median 17.5 vs 12.7 months, HR 0.64).

Leukine is not approved for the treatment of melanoma.

Despite progress, adolescents and young adults face substantial cancer disparities by race/ethnicity

A new report examining cancer in adolescents and young adults defined as diagnoses occurring during ages 15 to 39, provides updated estimates of the contemporary cancer burden in this age group, predicting that 89,500 cases and 9,270 deaths will occur in 2020 in the United States. The report appears in CA: A Cancer Journal for Clinicians.

AYAs with cancer are frequently grouped with older or younger patient populations and/or presented in aggregate, masking the wide heterogeneity in cancer occurrence within this population. To address this issue, American Cancer Society investigators also examined cancer incidence, survival, and mortality among AYAs by race/ethnicity and for smaller age groups (15-19, 20-29, and 30-39).

Cancer incidence rates among AYAs are highest in those who are non-Hispanic white (83 per 100,000 population during 2012-2016) and lowest in those who are Asian/Pacific Islander (54 per 100,000 population) for both sexes. This reflects higher rates in non-Hispanic white AYAs for thyroid cancer, testicular tumors, and melanoma compared to other major racial/ethnic groups. Unlike adults ages 40 and older, however, female breast cancer incidence rates in non-Hispanic Black AYAs are 14% higher than those in non-Hispanic white AYAs (25.9 vs 22.3 per 100,000 population).

The authors also note that despite patterns in overall incidence, cancer mortality rates are highest in non-Hispanic Black AYAs, particularly females (12.6 per 100,000 vs 9.2 in non-Hispanic white persons), reflecting substantial survival disparities to those who are non-Hispanic white. The largest 5-year cancer-specific survival disparities occur among those who are non-Hispanic Black compared with non-Hispanic whites for acute lymphocytic leukemia (57% vs 71%, respectively) and female breast cancer (78% vs 89%, respectively).

By age group, the cancer incidence rate in AYAs increased during the most recent decade (2007-2016) overall but showed signs of stabilizing among men in their 20s. The rise is largely driven by thyroid cancer incidence rates, which rose by approximately 3% annually among those aged 20 to 39 and 4% among those aged 15 to 19 years. Incidence increased for several cancers linked to obesity, including kidney (3% across all age groups), uterine corpus (3% in group aged 20-39 years), and colorectum (0.9%-1.5% in the group aged 20-39 years).

In contrast to incidence, cancer mortality rates among AYAs for all cancers combined declined in the past decade (2008 through 2017) by 1% across sex and age groups except females aged 30 to 39, among whom rates remained stable due to a flattening of declines in breast cancer mortality. Mirroring incidence, mortality rates increased during the most recent 10 data years (2008-2017) for colorectal and uterine corpus cancers.

Other highlights from the report include:

- Adolescents (aged 15-19 years) are more likely to be diagnosed with cancers associated with childhood, such as Hodgkin lymphoma, while those aged 20 to 39 years are more likely to be diagnosed with adult cancers, such as breast. Thyroid cancer is the only cancer predicted to rank among the three most commonly diagnosed cancers in each AYA age group in 2020.
- Leukemia continues to be the leading cause of cancer death in ages 15 to 29 years. Among ages 30-39 years, breast (women) and colorectal (men) cancers are the leading cancer causes of death.
- Melanoma incidence rates during 2007-2016 rapidly declined in ages 15 to 29 (4%-6% annually, on average). However, among ages 30-39 years, rates declined only slightly among men and remained flat among women.
- Overall 5-year relative survival in AYAs for all cancers combined (83%-86% across age groups)
is similar to that in children (84%), but masks lower survival for several cancer types, such as acute lymphocytic leukemia (ALL; 60% vs 91%, respectively).

The report notes an increasing body of evidence that tumors in AYAs are molecularly distinct from those in younger or older populations, suggesting differences in etiology and in treatment options. In addition, studies have shown that compared to childhood cancer survivors, AYAs have a higher risk of progression and death from their original cancer. Compared to older cancer patients, AYAs have a higher risk of long-term and late effects including infertility, sexual dysfunction, cardiovascular disease, and other future cancers. However, further research in these areas is needed.

The authors say that progress in reducing cancer morbidity and mortality among AYAs could be improved with more equitable access to health care, as AYAs are more likely than other age groups in the U.S. to be uninsured. Increased clinical trial enrollment, expanded research, and improved awareness among clinicians and patients of early symptoms and signs of cancer could also accelerate progress.

Study: Rubbery properties help RNA nanoparticles target tumors efficiently and quickly leave body

A new study by researchers at The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute demonstrated that RNA nanoparticles have elastic and rubbery properties. These properties explain why these particles target tumors so efficiently and why they possess lower toxicity in animal studies.

RNA nanoparticles show great promise for the targeted delivery of anticancer drugs. Understanding their structure and behavior is essential for their possible future use.

This study, published in the ACS Nano, reveals that RNA nanoparticles have elastic and rubbery properties that enable the molecules to stretch and return to their normal shape. Researchers say that these properties could help the particles target tumors by enabling them to slip through the poorly formed walls of tumor blood vessels and enter a tumor mass.

The researchers further proved that the same rubbery properties enable the RNA nanoparticle to slip through the kidney filters to excrete into the urine half hour after systemic injection, thereby eliminating them from the body relatively quickly. That, in turn, could reduce retention of the anticancer agent in vital organs, lowering an agent’s toxicity.

“We show that RNA nanoparticles have a flexibility that allows for the assembly of molecular structures that have stretchable angles,” study leader and corresponding author Peixuan Guo, professor in the College of Pharmacy and the Sylvan G. Frank Endowed Chair in Pharmaceutics and Drug Delivery, said in a statement. Guo also is in the OSU-CC – James Translational Therapeutics Research Program.

“These findings demonstrate the rubbery properties of RNA nanoparticles and why these molecules hold great promise for industrial and biomedical applications, especially as carriers for targeted delivery of anticancer drugs,” Guo, who directs Ohio State’s Center for RNA Nanobiotechnology and Nanomedicine, said in a statement.

For this study, Guo and colleagues tested the elasticity of nucleic acid polymers by stretching and relaxing individual RNA nanoparticle, while subjecting RNA nanoparticles to elasticity studies using dual-beam optical tweezers built in Guo lab. They used animal models to study the biodistribution, excretion and retention of RNA nanoparticles. This included measuring excretion of the particles in urine, along with the study on the effect of their shape and size.

Key findings include:

- RNA nanoparticles are stretchable and shrinkable, like rubber, even after repeated extension and relaxation with multiple repeats by optical tweezers.
- In animal models, RNA nanoparticles show stronger cancer targeting and lower accumulation in healthy organs when compared to gold and iron nanoparticles of similar size.
- Also in animal models, within half an hour after systemic injection, RNA nanoparticles that were 5, 10 and 20 nm in size were filtered by the kidneys and retained their original structure in urine, even though the upper limit of kidney pore size for filtration is generally 5.5 nm. This suggests that the larger RNA nanoparticles slipped like rubbery and amoeba through filtration pores, then returned to their original size and shape in urine.

Other researchers involved in this study were Chiran Ghimire, Hongzhi Wang, Hui Li, Mario Vieweger and Congcong Xu, The Ohio State University.
Rhenium NanoLiposomes receives Fast Track Designation from FDA for glioblastoma treatment

FDA has granted Rhenium NanoLiposomes Fast Track Designation for the treatment of patients with recurrent glioblastoma.

Plus Therapeutics Inc. sponsors Rhenium NanoLiposomes (RNL). RNL previously received orphan drug designation from the FDA for RNL for the treatment of patients with glioblastoma.

"With this designation in hand, we intend to move into cohort six of the trial, one key step closer to bringing forth a novel therapy for these patients," Marc Hedrick, president and chief executive officer of Plus Therapeutics said in a statement.

RNL is being evaluated in the NIH/NCI-supported, multi-center ReSPECT phase I dose-finding clinical trial (NCT01906385). The ReSPECT trials' data and safety monitoring board approved the Plus Therapeutics to proceed to cohort six of the trial, which includes increasing both the drug volume and radiation dose to 8.8 milliliters (mL) and 22.3 millicuries (mCi), respectively.

RNL is designed to safely, effectively, and conveniently deliver a very high dose of radiation, of up to 25 times greater concentration than currently used external beam radiation therapy, directly into the brain tumor for maximum effect.

Elicio Therapeutics and Moffitt collaborate to study AMP-CD19 + CD19 CAR T cells

Elicio Therapeutics and Moffitt Cancer Center are collaborating to characterize combination therapies pairing Elicio's CD19 Amphiphile and a universal FITC Amphiphile with CD19 CAR T cells.

The research will be led by Marco Davila, associate member of the Blood and Marrow Transplant and Cellular Immunotherapies Department and Medical Director of Cell Therapies at Moffitt.

"Despite high initial response rates, patients with B-cell malignancies have limited durable long-term disease control," Christopher Haqq, Elicio's executive vice president, head of research and development, and chief medical officer, said in a statement.

Davila's laboratory is uniquely positioned to evaluate lymph node targeted immunotherapy. His team evaluates CD19+ malignancies in mice with a normal immune system and normal lymph nodes, which is an advantage over more common mouse models conducted in immunosuppressed mice. Positive results would set the stage for clinical trials combining AMP-CD19 with market-ed CD19 CAR T cells to increase response rate and durability.

"Our research, as well as research by other groups, suggest one avenue for improving outcomes for lymphoma patients treated with gene-engineered T cells is to combine this therapy with other agents to enhance response," Davila said in a statement. "We believe the highly novel AMP vaccine holds great promise as a combination to increase the efficacy of T cells targeted to B cell malignancies and look forward to developing and evaluating this therapy at Moffitt."

The AMP-CD19 is a CAR binding peptide modified to traffic into lymph nodes for display on native immune cells. AMP-CD19 can activate engineered T cells, enhance their persistence, and proliferation, as well as enhance their activity in treatment of B-cell malignancies including diffuse large B cell lymphoma and acute lymphocytic leukemia.

The AMP modification reprograms the biodistribution of peptides by the addition of an albumin binding and cell membrane insertion domain, which results in improved trafficking into lymph nodes where dendritic cells take in the peptides and present them to the CAR T receptors on the surface of T cells.

Elicio is broadly developing AMP technologies, with ELI-002 targeting solid tumors with mutated KRAS in oncology, the universal adjuvant ELI-004 (AMP-CpG) enhancing efficacy across oncology and infectious disease applications, and discovery programs identifying solid tumor AMP CAR T combinations. In addition, the combination of both Elicio’s Amphiphiles (AMPS) with CAR T cells led to synergy that enhanced solid tumor CAR T therapy in mice (Ma et al., 2019; Singh et al., 2019).
UCSD, Cofactor Genomics collaborate to improve patient outcomes in metastatic head and neck cancer

Physicians at the University of California, San Diego School of Medicine and Cofactor Genomics are working to improve the ability to predict tumor response to immunotherapy in recurrent and metastatic squamous cell carcinoma of the head and neck.

Guiding and prioritizing therapy selection is especially important given last year’s FDA approval of pembrolizumab as a first line treatment for RM-HNSCC.

The partnership is led by Ezra Cohen, chief of the Division of Hematology-Oncology at the UCSD Moores Cancer Center. Cofactor’s recently-patented Predictive Immune Modeling technology will be used in the research.

The clinical care pathway for recurrent and metastatic head and neck cancer patients relies on using underpowered, antiquated technologies for treatment decisions. New tools that provide physicians with higher confidence in therapy selection are needed.

The terms of the partnership include providing Cofactor Genomics with access to patient specimens and clinical metadata, a resource well-curated by the team at UCSD. The data generated in this collaboration will further expand clinical evidence presented earlier this year by Washington University physicians, where Cofactor’s technology showed superiority over the incumbent PD-L1 IHC assay in predicting responders to therapy.

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