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# Amy Reed, physician and patient who “moved mountains” to end widespread use of power morcellation, dies at 44

By Matthew Bin Han Ong

When Amy Reed enrolled at the University of Pennsylvania medical school in 2001, she could not have possibly imagined that she would save more lives as a patient than as a physician.



The final phase of her medical education began on Oct. 17, 2013, when Reed, then 41, checked in at Brigham & Women's Hospital—her husband's workplace at that time—to undergo a common gynecological procedure that would fundamentally redefine her career, and, ultimately, consume her life.

Reed, a Pennsylvania native, died May 24 from complications stemming from disseminated uterine cancer. She was 44.

"I always wanted to be a doctor when I was little," Reed said to me on a sweltering July afternoon in 2015. "I wanted to go into medicine and be a doctor and fix things, and cure the world."

Reed's dream came true, albeit not in the way she envisioned.

Weeks after her "minimally invasive" surgery at Brigham, Reed learned that dozens of nodules of uterine sarcoma were growing throughout her abdominal cavity.

Upon confronting her surgeon, Reed learned that a handheld device—a power morcellator—was used during the procedure. At first glance, the morcellator might be mistaken for a steampunk rendition of a glue gun, except for the long cylinder of spinning blades that protruded from the main body. It was designed for the purpose of slicing fibroids and uterine tissue into easily removable fragments.

Staring at her pathology report and subsequent scans, Reed and her husband, Hooman Noorchashm, put two-and-two together. She was an anesthesiologist, and her husband, a cardiothoracic surgeon. They both earned PhDs in immunology from the University of Pennsylvania.

Reed wasn't the first woman to be mortally wounded by this device, but she and Noorchashm were the first to publicly make the connection between the mechanical shredding of uterine tissue

and the dissemination of previously undiagnosed malignancies—a conclusion that they would've most likely missed had they not been physicians.

By connecting the cause and effect and going on to the next step—waging a high-profile public health campaign—Reed and Noorchashm changed the standard of care in gynecology, saving an uncounted number of lives.

Reed's doctors at the time said that her case was an exception. It was improbable: she turned out to be an extremely rare statistic: one in 10,000. You are really, really unlucky, Amy, they said.

We are very sorry, Brigham officials said, in response to Reed's concern that upstaging of malignancies might be a systemic occurrence, that some of the 50,000 to 100,000 women who were undergoing power morcellation every year were being gravely harmed. Over 80 percent of black women and nearly 70 percent of white women develop fibroids at least once in their lifetime.

"Do you know if this has happened to other women?" Reed and Noorchashm asked. "You need to stop this surgical procedure if this is happening."

No, Amy, it's bad luck, she was told. It's like being struck by lightning.

But the Harvard-affiliated hospital didn't let on that another of its patients, Erica Kaitz, was dying from the same disease that afflicted Reed—aggressive leiomyosarcoma—at the same time that Reed and Noorchashm were confronting the Boston hospital's administrators.

The lightning, it turned out, had struck twice—in the same city, at the same hospital.

Reed never met Kaitz. They were both living in Boston, and they were young. Neither knew, then, that their stories

would change medical practice—or that they would share a similar fate.

"The medical story was almost a carbon copy of Erica's, including the complications at the end," said Erica's husband, Richard Kaitz. "They were exactly the same: tumor blocking the kidneys, abdominal tumor that couldn't be controlled. It's exactly the same story. Those seeds were planted through the morcellation, clear as day."

One thing set the women apart: Erica underwent morcellation at Brigham slightly over a year before Amy wanted her uterus and symptomatic fibroids removed.

"If, by some twist of fate, Amy had been diagnosed before Erica and their paths reversed, I am confident Erica would have been spared morcellation and would still be here with us," Kaitz said to me when I called to talk about Reed's life. "Whether Amy and Erica could've successfully lived with leiomyosarcoma on a long-term basis like so many others that we know without the morcellation, we'll never know.

"But I think the likely answer to that is, yes. Would they have had a cancer to manage? Yes. Could they have lived a life of 10, 20, 30 years managing that cancer and even awaiting breakthroughs and treatment? Yes.

"That was taken away from them by morcellation. It was never discussed with us, it was never discussed with Amy, and none of us have ever really heard of it at the time. It's just an overwhelmingly sad day."

It is, of course, perilous to hypothesize about what might have been. By the same token, it's hard to characterize the whirring power morcellator as the right tool for extraction of sarcomas.

It's a question of assumptions. Should the surgeon assume that the fibroids are benign? Or should they be assumed to be cancerous?

Erica died on Dec. 7, 2013. Reed lived for three years seven months and eight days after her surgery.

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**A**my Josephine Reed was born in Bristol, PA. She had seven siblings. Her mother, the former Joann Tunis, was a pharmacist, and her father, William Reed, was a computer programmer.

As a child, Amy was, in her words, a “very enthusiastic-for-life kind of kid.”

“I always wanted to have a lot of kids when I was little. I imagine I’m someone who likes to build and create. I was always interested in building things,” Reed said to me on that July afternoon, nearly two years after her cancer diagnosis.

By then, I was deep into covering the power morcellation controversy Reed had brought to light. A video of our conversation is posted [here](#).

After graduating from Pennsylvania State University in 1995, she went on to pursue her PhD at the University of Pennsylvania.

“I applied to the University of Pennsylvania, among other schools, and I interviewed at Penn. I enrolled there in the fall, and that’s where I met Hooman. We were classmates.”

Reed and Noorchashm married in 2001.

“When I was in college, I wanted to go to medical school, but my advisor, he said, ‘It’s really difficult to get into medical school. You probably won’t get into medical school,’” Reed said. “Four years later, I decided towards the end of my graduate school tenure that I really didn’t want to work on mice the rest of my life.

“I finished my MD and PhD in a total of 10 years, which wasn’t bad,” Reed said.

“I applied for a residency in anesthesia and got a spot at Penn, which was nice, because Hooman, at that point, was a surgical resident. Then, Hooman proceeded to match as a cardiothoracic fellow at Brigham & Women’s Hospital. So, we went up there.”

In 2011, Reed was offered a teaching job at Harvard Medical School and a clinical position at Beth Israel Deaconess Medical Center, another Harvard-affiliated hospital.

Reed and Noorchashm described their initial years in Boston as challenging, but rewarding. They felt that they could achieve anything, that they were invincible—unaware that acrimony would soon emanate from the same hallowed halls they had dedicated their lives to.

Reed credits her maternal grandmother’s family with instilling in her a robust work ethic.

“She was a farmer, and I would work summers at her sister’s farm,” Reed said. “There was a roadside stand, and we’d sell fruits and vegetables. I think those were my formative years for work ethic.

“I remember, once—mind you, this was a roadside vegetable stand—I had shown up to work and I was putting up my hair, just in ponytails. I was walking up to the stand and I got yelled at, because they weren’t paying me to do my hair.

“That was just kind of the approach, like, I didn’t get paid to sit down. You were always expected to be working hard, and working on doing something. It wasn’t about you.”

These same principles would hold true three decades later, when Reed committed her remaining time to saving other women from the hazardous practice that hastened the end of her life.

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**R**eed and Noorchashm told me that they quickly became disillusioned with Brigham. In numerous interviews, they described how their disappointment quickly morphed into outrage.

Instead of setting an example by ending the practice of power morcellation, one of the most prestigious medical institutions in the world—their very own workplace—seemed to be trying to convince them to accept the bad-luck explanation or, perhaps, go away.

No, this is not how it ends, Reed and Noorchashm decided. We won’t stop until we get to the bottom of this matter, the couple said.

They started a national campaign by first engaging The Wall Street Journal in December 2013, alerting the public, for the first time, to a health issue that would prove to encompass much more than a single medical device and a single institution.

I first met Reed and Noorchashm on June 30, 2014, after corresponding via phone and email for two months.

“This interview is very important, you know why?” Noorchashm said to me at the time. “Partly because of the topic, but partly because these are the first few hours in our new house.”

The couple had moved into an 18th century farmhouse in Yardley, PA. They left Boston to continue their careers in Philadelphia.

Noorchashm had resigned from Brigham, and Reed was recuperating from surgery and chemotherapy. They were chin-deep in a polarizing war against Brigham, device manufacturers, and the gynecology establishment.

Reed was now at the University of Pennsylvania and Noorchashm at Thomas Jefferson University.



**AMY REED AND HOOMAN NOORCHASHM OUTSIDE THEIR HOUSE IN YARDLEY, PA, ON JUNE 30, 2014, EIGHT MONTHS AFTER SHE UNDERWENT POWER MORCELLATION. THE VIDEO OF THE INTERVIEW IS POSTED [HERE](#).**

Their campaign against power morcellation was getting results. In April 2014, FDA issued an advisory, concluding that the risk for dissemination of occult uterine sarcoma via morcellation was one in 350—almost 30 times higher than the rate touted by pro-morcellation advocates and gynecology professional societies.

That first story evolved into a three-year investigation at The Cancer Letter, which resulted in a series of stories, "[How Medical Devices Do Harm](#)."

In the years I've known him, Noorchashm has fired off thousands of scathing emails to Brigham administrators, FDA officials and House and Senate members—anyone he considered a friend or foe—always copying the press. I believe his nickname, The Hoomanator, was coined by a friend.

The vast majority of Hoomanograms were anything but polite, and the acidic content of these emails was often prefaced by provocative subject lines:

"Your ethical lapse and negligence." "Outrageous!" "Your corruption." "The Fouled Ethics of Your Specialty." "Do read with care."

Academic decorum was the least of their concerns—what Reed and Noorchashm went on to learn in 2014 and 2015 horrified them:

- They learned, for example, that Reed wasn't the first woman to be harmed at Brigham. Erica Kaitz had been harmed earlier and had died. Almost immediately, Kaitz's Brigham surgeon, Jon Einarsson, had started a registry trial designed to enroll 400 patients across several partner institutions to test an experimental "bagged" method for performing power morcellation. The study was suspended in November 2014, after The Cancer Letter reported that Brigham did not apply for an FDA exemption to conduct the high-risk study. The authors ultimately reported that leakage was observed in 9.2 percent of the cases.
- J&J subsidiary Ethicon, the primary manufacturer of power morcellators, was informed of the dangers of the device in 2006 by Robert Lamparter, a retired pathologist from central Pennsylvania. Ethicon dismissed Lamparter's report, and did not pull the devices from the market until July 2014.
- Michael Muto, the Brigham physician who referred Reed for the procedure, had authored a 2012 study finding that four out of 1,091 patients—or about one in 273—showed evidence of peritoneal dissemination of leiomyosarcoma after undergoing power morcellation. The couple said they felt betrayed: Muto did not communicate these findings prior to referring Reed for morcellation. My efforts to contact Muto were unsuccessful, and Brigham ultimately stopped communications with The Cancer Letter on the subject of power morcellation, citing legal advice.

- Brigham did not report the harm caused to Kaitz or Reed to FDA, as required by federal patient safety laws. In fact, until Reed filed her report in December 2013, no one had informed the agency of any adverse events resulting from power morcellators for the over 20 years that the device had been on the market. Since then, hundreds of patients and families, at least 300, have since come forward claiming harm. FDA has logged at least 285 reports.

It was a perfect systemic failure ushered into existence by negligence at every level, Noorchashm would often say to me. A multi-headed demon had entered our home, he would say.

Reed and Noorchashm made many enemies.

In August 2014, Karl Storz threatened to take legal action against Reed and Noorchashm for their aggressive campaign. The following year, when Reed sought treatment at Brigham, hospital administrators declared the couple a security threat, subjected them to a physical search, and mandated that they be followed by a security detail while Reed was being treated for her distant metastatic tumors at Brigham.

Brigham's executive vice president, Ron Walls, called Reed and Noorchashm's advocacy a "campaign of distortions." The New England Journal of Medicine published snide commentary by Lisa Rosenbaum, a Brigham cardiologist, who labelled the couple "availability entrepreneurs." Reed engaged in "N-of-1 Policymaking," Rosenbaum wrote, and exploited "reporters eager to break stories of transgression." Noorchashm gave up his "promising surgical career for a mission of offering comfort to people undone by illness," Rosenbaum wrote.

But the couple also made many friends and allies: the patient advocacy and

cancer community rallied to their cause, and scientific consensus was largely on their side. Minimally invasive gynecologists continue to dispute FDA's risk estimate, but as far as the larger medical community was concerned, the case was settled. One high-powered study after another provided a critical mass of evidence that bolstered the FDA estimate.

A Boston judge issued a restraining order against Brigham, forcing the hospital to lift all security requirements against its own patient—a truly unusual event. Former Rep. Mike Fitzpatrick (R-PA) pushed for stricter patient safety and adverse event reporting laws. A Congressional subcommittee, FDA, the Federal Bureau of Investigation, and the Government Accountability Office launched investigations.

An argument can be made that Reed and Noorchashm were, for the most part, victorious:

- In November 2014, within a year of the couple's campaign, FDA severely restricted the use of power morcellators, declaring that the devices should no longer be used for hysterectomies or fibroid removal in the vast majority of women getting these procedures. The use of power morcellators dropped by nearly 80 percent after FDA's guidance document, according to [Columbia University researchers](#).
- In December 2015, FDA initiated inspections at 17 hospitals—including Brigham—to review their compliance with medical device adverse events reporting requirements. The agency found that the vast majority of those hospitals did not file timely reports of injuries and deaths caused by medical devices. The agency decided against taking punitive action.
- In June 2016, Fitzpatrick and Rep. Louise Slaughter (D-NY) introduced

legislation to strengthen federal requirements for reporting adverse outcomes caused by medical devices and to increase access to legal recourse for patients harmed by Class III high-risk devices. The legislation wasn't folded into the 21st Century Cures Act.

- In February 2017, the GAO released a [49-page report](#) concluding that FDA's passive reliance on self-reporting by hospitals and device manufacturers allowed harm caused by power morcellators to go unnoticed for over two decades—likely contributing to injury and deaths of hundreds of women. "I think it's a failure because reports were not being filed ... I'm hoping this was a wake-up call," Marcia Crosse, director of the health care team at GAO, said to me.

But victory wasn't complete, Reed and Noorchashm said.

They did not succeed at getting the procedure banned, and gynecologists can continue to perform power morcellation at their discretion, deterred only by the threat of medical malpractice lawsuits if harm is caused. Also, a sizable number of gynecologists believe that the campaign was a publicity stunt, and that the risk was overblown, Noorchashm said. Reed, Noorchashm, and Kaitz sued Brigham, and dozens of women around the U.S. sued their local hospitals.

"Amy was such a passionate, dedicated, and selfless advocate for the anti-morcellation campaign," Kaitz said. "She took so much time away from her family and other professional pursuits as well to make the world a safer place for others. That's really an incredible legacy that she's left, and the progress that she and Hooman made is just astronomical on a relatively short time.

"They moved mountains and basically stopped a major medical practice. On



top of that, she was obviously an incredible mother, physician, compassionate caregiver, and wife to Hooman.”

Fitzpatrick was stunned when he found out about Reed’s death.

“Dr. Amy Reed was the most impactful of any constituent I met or had the duty to represent,” Fitzpatrick said. “She taught and she cared. She fought and she made incredible change. Some of my former colleagues castigated basic truths that she brought to their attention, but she never gave up. At the same time, other colleagues only privately acknowledged but could not find the strength to support the truth publicly.

“And so, Amy was the strength not only in her own struggle, and the struggle of public health, but for numerous public and elected officials across the country. They would be well advised to attempt to follow the courage of her life and the impact of her convictions.

“There are so few in life who live their lives with such dignity and compassion and selflessness, and who, at the same time, dedicate every waking hour to care for their family, all while serving such a noble public purpose: saving lives, and righting wrongs.”

His voice cracked.

“Dr. Amy Reed has been, very publicly, a health care hero for our nation and, privately, nothing short of inspirational.”

Reed’s sarcoma remained largely manageable for about three years.

During the first year, her cancer appeared to be in remission. In 2015 and 2016, she underwent multiple surgeries and radiotherapy to treat a growing number of metastatic lesions. Noorchashm played a significant role in her care, testing immunotherapeutic

agents with the hope that they might find one that would work.

On April 3, a large, recurrent abdominal tumor that could not be excised had ruptured and hemorrhaged when she showed up for a routine CT scan at a Penn Medicine community radiology center in Bucks County.



There are so few in life who live their lives with such dignity and compassion and selflessness, and who, at the same time, dedicate every waking hour to care for their family, all while serving such a noble public purpose: saving lives, and righting wrongs.



Reed suffered cardiac arrest and remained in a coma for five days.

Noorchashm worked frantically to revive her. “Fuck, not like this, Amy. Not like this!” he recounted in an email. “Need to say goodbye. Need to tell her I’m sorry we weren’t able to cure this. Need to tell her I’m sorry for all the things I could’ve been to her and done for her but hadn’t.”

Reed was flown to the Hospital of the University of Pennsylvania, where she stayed for eight weeks, before returning home on May 19. She was last conscious the morning of May 24.

“We’ve been at this for four years,” Noorchashm said to me that afternoon, a few hours before her death at 8:09 p.m. “We’ve had time to adapt and adjust to what is to come. We will miss Amy dearly. Amy has been the center of my existence since I met her. We’re going to miss her all the time. But Amy’s death is a warrior’s death. It’s not

a tragedy where we want people to feel sorry for us.

“She has lived life with passion, and she’s fought when she has seen things that are wrong. There’s really no mourning going on here, there’s sadness, but we are not going to become victims of our circumstance. Amy Reed

is someone who rose to the very top of what she was doing and she fell to arrogance, hubris, carelessness, and she fell to a natural disaster.

“But then she fought. This was her fight. I wrote a lot, but she was my muse for the past three years. This was her voice, this was who she was.”

On that humid July afternoon in 2015, in her new house, Reed paused to listen to the sky. Her six children, Nadia, Ava, Joseph, Joshua, Luke and Ryan, were playing in the backyard pool.

“Is that thunder?” she asked me. “Do you mind if I kick the kids out of the pool for 15 minutes?”

She opened the kitchen door and stepped away from the camera.

“Hey guys, that’s thunder.”

# Trump would cut over 20 percent of NIH, NCI budgets in new FY18 proposal

By Matthew Bin Han Ong

The White House has proposed cutting \$7.2 billion from the NIH budget, with \$1.2 billion coming out of NCI—a proposal that, if supported by Congress, would eviscerate the cancer research enterprise in the United States, critics say.

NIH stands to lose 21 percent in the Trump administration's updated fiscal 2018 budget proposal, which would reduce the NIH budget to \$26.92 billion. Also, the White House proposes to cut \$1.2 billion from NCI's budget—a 20 percent loss.

The budget proposal, which was released May 23, comes on the heels of the FY17 omnibus spending bill, in which Congress approved a \$2 billion increase for NIH (The Cancer Letter, [May 5](#)).

In a budget blueprint published in March, the administration proposed cutting NIH by 18.3 percent. At the time, the blueprint, titled "America First," provoked immediate backlash from research organizations and luminaries in oncology. The final budget proposal seeks slash even more money from NIH.

In recent weeks, The Cancer Letter spoke with former NCI directors, scientists, advocates and legislators. A summary of these conversations appear on pages 14 and 15.

Other federal health agencies also stand to lose significant resources, or risk being completely defunded in the White House's budget proposal, which aims to cut federal spending by \$3.6 trillion over 10 years. The following agencies are slated to have their total discretionary budget authority reduced by:

- **FDA:** \$854 million
- **Centers for Disease Control and Prevention:** \$1.315 billion
- **Health Resources and Services Administration:** \$602 million

The Agency for Healthcare Research and Quality is, once again, on the cutting block: the \$425 million agency that plays a central role in the implementation of the Affordable Care Act would be eliminated in President Donald Trump's budget proposal. Trump may succeed—for at least three times over the past eight years, the House has tried to defund the 27-year-old federal agency, which pays for patient-centered outcomes research and monitors the manner in which medicine is practiced in the U.S. (The Cancer Letter, [June 26, 2015](#), [July 20, 2012](#)).

The proposal would also reduce Medicaid funding by more than \$600 billion.

"The President's proposed budget is extremely disappointing, but we remain encouraged by bipartisan support from Congress that resulted in increased NIH and NCI funding in both

FY 2016 and FY 2017,” said Daniel Hayes, president of the American Society of Clinical Oncology. “ASCO strongly opposes the Administration’s proposed cuts to federal agencies that support biomedical research and Medicaid for Fiscal Year 2018.

“Such extreme reductions to programs that are critical to research will fundamentally damage our nation’s progress in treating patients and will irreversibly harm our nation’s already fragile biomedical research infrastructure. Cutting critical federal support at this time will jeopardize Americans’ health and our country’s scientific leadership and economic growth.”

The federal government should be doubling its commitment to cancer research, instead of taking steps backward, said Jonathan Hirsch, president and founder of Syapse, a precision medicine company.

“Even if the Trump budget proposal never fully comes to fruition, as is likely, it will still make an impact—forcing NIH to stall programs that physicians and patients rely on,” Hirsch said to The Cancer Letter. “We stand at the precipice of major breakthroughs in areas like cancer research, and NIH is critical to moving those forward.”

## Proposal would limit reimbursements for NIH grants

The president’s budget proposal also seeks to limit reimbursements from the federal government for auxiliary expenses associated with NIH research grants. At current rates, these indirect costs, also known as “facilities and administrative costs,” can be reimbursed at up to 50 or 60 percent of the grant amount.

“The NIH and NCI cuts would be achieved largely by capping overhead

costs associated with federal research funding,” according to the American Society for Radiation Oncology. “Implementing an unrealistic cap on these administrative dollars would result in fewer jobs for researchers, especially for early career scientists, and less support for clinical trials. More dangerously, it could cause entire research programs to shut down.”

NIH reimburses institutions, based on that rate for each grant that the institution receives, to help cover some of those associated expenses of research, said Tannaz Rasouli, senior director of public policy at the Association of American Medical Colleges.

“Cutting F&A funding would mean that you’re cutting critical support for things like building and maintaining high-tech labs, the high-speed data processing and storage that’s associated with research, cutting security for sensitive and dangerous chemicals and microbes, or radiation safety, or hazardous waste disposal,” Rasouli said to The Cancer Letter. “I mean, which of those things would you want to cut; right? You cannot cut those things and still be able to conduct the research.”

Every three or four years, the federal government regularly audits and assesses reimbursement rates negotiated between institutions and the HHS or the Office of Naval Research to determine the appropriate federal share of the cost, Rasouli said.

“Cutting F&A would result in institutions being unable to afford continuing research at the same capacity that they have up until this point,” Rasouli said. “Unfortunately, we think the consequence would simply be that less research would happen.”

The White House proposal would limit the reimbursement rate for grants to a cap of 10 percent of total research, Rasouli said.

“It’s actually a little ambiguous in the language in terms of how they actually plan to go about this,” Rasouli said. “What they have said is that they would like to essentially limit the reimbursement that institutions receive for these facilities and administrative expenses. It’s still unclear to us what exactly that means, and how exactly they plan to move forward with that.

“Regardless, the notion itself that they’re planning to limit the reimbursement that institutions receive is something that is very troubling to our community and, quite frankly, to the overall research enterprise, because it is premised on the assumption that you can separate out the facilities and administrative expenses and still be able to move forward with research in the same way as before.

“That’s simply not true. The reality is, if you’re going to cut facilities and administrative expenses, you’re simply cutting the research. You’re going to make it more difficult for research to move forward. A cut to F&A is a cut to the research itself.”

## Health care, research groups: Trump’s budget is tone-deaf

The proposed cuts are shocking, especially the reduction to the NCI budget, said Michael Caligiuri, president of the American Association for Cancer Research, director of The Ohio State University Comprehensive Cancer Center, and chief executive officer of the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute.

“This is extremely concerning, especially when factoring in all of the efforts that took place last year to establish the important goals and objectives of the transformative Beau Biden Cancer Moonshot initiative,” Caligiuri said. “If we are to accelerate the pace of re-

search so that new, more effective therapies become available to patients, and also improve our ability to prevent cancer and detect it at an early stage, robust, sustained, and predictable annual funding increases for the NIH will be required.

“We are appalled that the Trump administration would include in its budget a proposal that would risk irreversibly harming our nation’s ability to further understand the complexity of cancer and postpone the development of lifesaving therapies for patients.”

The White House’s proposed budget is an imbalanced, heavy-handed approach to bolstering national defense at the expense of other American priorities, including the research and innovation crucial to national security, said Research!American President and CEO Mary Woolley.

“Instead of weakening our nation with this approach, we urge the 115th Congress to negotiate a bipartisan budget deal that will ensure that both defense and non-defense priorities are sufficiently funded,” Woolley said. “Consistently, surveys show how highly Americans rank securing better health and quality of life; the President’s blueprint is tone-deaf to that reality.”

“Congress recognizes the urgency in keeping research for health at the forefront of national priorities, as it has signaled with back-to-back, significant increases for the NIH in FY16 and FY17. Strong bipartisan support for research must continue in FY18, and at the same time, Congress should act to lift the budget caps that threaten to hamstring non-defense discretionary appropriations.”

According to a study conducted by United for Medical Research, the cuts proposed in the first “Skinny Budget” draft in March would, if enacted, lead to a loss of nearly 90,000 jobs and \$15

billion in economic activity compared to 2016.

“Simply put, less funding for NIH means fewer Americans leading healthy, productive lives,” said UMR President Lizbet Boroughs. “These cuts



**We are appalled that the Trump administration would include in its budget a proposal that would risk irreversibly harming our nation’s ability to further understand the complexity of cancer and postpone the development of lifesaving therapies for patients.**



also will slow an engine for U.S. economic growth. NIH-funded research, conducted at academic and medical institutions in communities in every state, directly and indirectly supported almost 380,000 jobs and \$65 billion in economic activity across the United States in 2016 alone.”

The proposed cuts to CDC would affect the following programs: immunization, public health preparedness, infectious and chronic disease, and disease monitoring and outbreak response, according to the National Association of County and City Health Officials, which represents nearly 3,000 local health departments.

“The President’s budget cuts, if enacted, would negatively impact the health and safety of communities across the country,” said Laura Hanen, interim executive director and chief of government affairs at NACCHO. “This is a document that in theory embodies the values and priorities of the nation. Unfortunately, the emphasis is not on preventing disease and ensuring long and

healthy lives of Americans, particularly those most vulnerable.”

The massive proposed reduction in Medicaid funding would limit patient access to health coverage and care, ASTRO officials said.

“Multiple studies have demonstrated a link between inadequate health insurance and delayed cancer diagnosis and treatment, ultimately resulting in higher mortality rates,” ASTRO officials said in a statement. “New limits on coverage for cancer patients will restrict their access to the treatments they need and deserve. Inadequate coverage also leads to higher costs that are felt throughout the economy.”

“These substantial reductions in support for medical research and care would destabilize the progress toward finding cures and negatively impact cancer patients across the country.”

## FY 2018 WHITE HOUSE BUDGET PROPOSAL FOR NIH, BY INSTITUTES AND CENTERS

<i>dollars in millions</i>	2016 /1 /2	2017 /3	2018 /5	2018 +/- 2017
<b>Institutes/Centers</b>				
National Cancer Institute	5,206	5,505	4,474	-1,031
National Heart, Lung and Blood Institute	3,109	3,110	2,535	-575
National Institute of Dental and Craniofacial Research	413	415	321	-94
National Inst. of Diabetes & Digestive & Kidney Diseases	1,964	1,955	1,600	-355
National Institute of Neurological Disorders and Stroke	1,693	1,693	1,356	-337
National Institute of Allergy and Infectious Diseases	4,797	4,621	3,783	-838
National Institute of General Medical Sciences	2,509	2,509	2,186	-323
Eunice K. Shriver Natl. Inst. of Child Health & Human Development	1,338	1,337	1,032	-305
National Eye Institute	707	715	550	-165
National Institute of Environmental Health Sciences: Labor/HHS Appropriation	693	692	534	-159
National Institute of Environmental Health Sciences: Interior Appropriation	77	77	60	-18
National Institute on Aging	1,596	1,597	1,304	-294
Natl. Inst. of Arthritis & Musculoskeletal & Skin Diseases	541	541	418	-123
Natl. Inst. on Deafness and Communication Disorders	422	422	326	-96
National Institute of Mental Health	1,517	1,545	1,245	-301
National Institute on Drug Abuse	1,049	1,075	865	-210
National Institute on Alcohol Abuse and Alcoholism	467	467	361	-105
National Institute of Nursing Research	146	146	114	-33
National Human Genome Research Institute	513	518	400	-118
Natl. Institute of Biomedical Imaging and Bioengineering	343	346	283	-64
Natl. Institute on Minority Health and Health Disparities	280	279	215	-64
Natl. Center for Complementary and Integrative Health	130	131	102	-29
National Center for Advancing Translational Sciences	684	684	557	-127
Fogarty International Center	70	70	--	-70
National Library of Medicine	395	394	373	-21
Office of the Director	1,571	1,620	1,452	-168
Buildings and Facilities	129	129	99	-30
National Institute for Research on Safety and Quality /5			379	+379
<b>Total, Program Level</b>	<b>32,358</b>	<b>32,593</b>	<b>26,920</b>	<b>-5,674</b>

<i>dollars in millions</i>	2016 /1 /2	2017 /3	2018 /5	2018 +/- 2017
<b>Less Funds from Other Sources</b>				
PHS Evaluation Funds (NLM)	-780	-780	-780	--
Type 1 Diabetes Research (NIDDK) /4	-150	-140	-150	-10
Patient-Centered Outcomes Research Trust Fund /5			-107	-107
<b>Total, Discretionary Budget Authority</b>	<b>31,428</b>	<b>31,674</b>	<b>25,883</b>	<b>-5,791</b>
<b>Appropriations</b>				
Labor/HHS Appropriation	31,351	31,597	25,823	-5,917
Interior Appropriation	77	77	60	-18
Full-Time Equivalent /6	17,723	18,105	18,352	+247

1/ In addition, the FY 2016 Zika Response and Preparedness Act (P.L. 114-223) provided \$152 million in supplemental resources to NIH for Zika response and preparedness activities.

2/ Reflects the annualized level of the Continuing Resolution that ended April 28, 2017, including the across the board reduction, the 21st Century Cures Act, and directed transfers.

3/ These mandatory funds were appropriated in P.L. 114-10, the Medicare Access and CHIP Reauthorization Act of 2015.

4/ The FY 2018 Budget consolidates Agency for Healthcare Research and Quality (AHRQ) within NIH as the National Institute for Research on Safety and Quality. AHRQ previously received mandatory funds transferred from the Patient-Centered Outcomes Research Trust Fund to implement section 937 of the Public Health Service Act. This institute is proposed to receive the mandatory resources from the Patient-Centered Outcomes Research Trust Fund in FY 2018 (\$107 million).

5/ Full time equivalent levels exclude AHRQ in FY 2016 and FY 2017, and include FTE consolidated from AHRQ in FY 2018.



I just don't see this as having any legs whatsoever. I think there is no support for it in Congress. It illustrates to me this president's ignorance of government, and his lack of discipline to even begin to study how things work. It's just more campaigning.

**John Porter**  
*Former House appropriator who oversaw the doubling of the NIH budget*



This is a very anti-science budget that I think surprised a lot of us to go way beyond issues about energy, climate, to the NIH, which has always been something that, luckily, seemed to be very bipartisan in its support.

**Richard Klausner**  
*Biotechnology entrepreneur and former NCI director*



Congress can fight over this, but the bottom line is the leader of our country has communicated his priorities, and those priorities set us back decades.

**Patricia Goldsmith**  
*CEO of CancerCare*



When we went to Congress 25 years ago and began asking for more money for breast cancer, it wasn't just throwing more money at the problem. Our message was, this is exactly how much we you need to appropriate, this is why. We did our homework, we had a plan.

**Fran Visco**  
*President of the National Breast Cancer Coalition*



Research, we know, saves money ultimately. The great advocate Mary Lasker once said, 'If you think research is expensive, try disease.'

**Ellen Sigal**

*Chair and founder of Friends of Cancer Research*



This would inevitably have negative effects on patients. I don't think that we can expect that the private sector or the philanthropic sector are going to be able to fill in these gaps.

**Nancy Davidson**

*President of the American Association for Cancer Research*



You're going to devastate future cures, and you're going to devastate our talent pool of young researchers that do that science. That will make us a second-rate scientific country. That shouldn't be acceptable to anybody.

**Blase Polite**

*Chair of the American Society of Clinical Oncology Government Relations Committee*



It's also going to be the cancer center directors saying to their members of Congress, 'What the hell, do you understand what this is going to do to the economy of our local district?'

**Ryan Hohman**

*Vice president of public affairs at Friends of Cancer Research*



Whether it's a Democratic administration or a Republican administration, I would have tried to be pretty agnostic to the party in control and merely focus my vision on doing the best that we can to be sure we have managed well and done our best to communicate the good news of what we have accomplished and the opportunities at our doorstep.

**John Niederhuber**

*Former NCI director, Executive vice president & CEO, Inova Translational Medicine Institute*





## OBITUARY

# H. Jean Khoury, 50, hematologist and pioneer in leukemia research, dies

By Fadlo R. Khuri

H. Jean Khoury, an expert in hematologic malignancies at Winship Cancer Institute of Emory University, died May 22, after a year spent battling cancer. He was 50.

Khoury, whose work focused on chronic myeloid leukemia, acute leukemia, and myelodysplastic syndrome, joined Winship in 2004 as director of the Leukemia Program, director of the Division of Hematology, and associate professor in the Emory School of Medicine. In 2009, he was promoted to professor in the Department of Hematology and Medical Oncology, and was later named to the R. Randall Rollins Chair in Oncology.

Born in Beirut, Khoury came to Emory from Washington University in St. Louis, where he served on the faculty after completing a fellowship in hematology-oncology. He earned his medical degree from the Université Catholique de Louvain in Brussels and completed a residency in internal medicine at Memorial Medical Center in Savannah, Georgia.

I recruited Jean Khoury to Winship while serving as Chief of the Division of Hematology and Medical Oncology and Deputy Director of Winship. I first met him in December of 2003, when Jean was serving on the faculty at Washington University in St. Louis.

Ned Waller had come back from a visit to St. Louis bubbling with energy after meeting Jean, and he was absolutely convinced we had our future chief of hematology. So I actually attended a meeting of the American Society of Hematology for the first time since my fellowship, and was most impressed with Jean.

But how could anyone not be impressed? He had everything: a track record of exceptional clinical interventions, publications at a young age, impeccable clinical skills by all accounts, an incredibly humble and sincere approach, and the ability to look you in the eye and speak with such quiet certitude that I simply knew, perhaps even more than he did at the time, that I was in the presence of a wonderful human being who was naturally a real leader.

Jean would grow to be so much more, including a pioneer in molecular targeting of leukemias, with more than 140 publications. He led and completely revitalized the Division of Hematology and the Leukemia Program of the Winship Cancer Institute of Emory University. His extraordinary skill and compassion as a physician, as a clinical investigator, and as a mentor led to

many accolades and awards, including being named the inaugural holder of the Randall Rollins Chair, and election to the Alpha Omega Alpha medical honor society. He served with great distinction in several major international leadership roles at the American Society of Bone Marrow Transplantation and the American Society of Hematology, and was Section Editor for Hematology for Cancer, a journal I edit, for many years.

“While we all knew Jean as an outstanding clinician who was beloved by his patients, and a true innovator in treatment, what he kept more quiet was his impact on colleagues and trainees as a mentor,” said Sagar Lonial, chair of Emory’s Department of Hematology and Medical Oncology and Winship’s chief medical officer. “The list of people from all over the world who have reached out to me speaking about his role in their career development is so impressive. He was an amazing teacher and colleague and that is what drew people to him.”

His mentorship skills were not limited to the medical field. He was was a Master with Taekwondo Kukkiwon certi-

fied 4th degree black belt, avid runner and bicyclist.

What you always want in a leader is someone who is not afraid to be wrong, to take risks. Being wrong disrupts the pattern, and Jean was very brave. He didn't like business as usual, and that showed in the way he took about re-developing the hematology division, the leukemia program, and his interactions with the transplant division, with faculty, and all across Winship.



**While we all knew Jean as an outstanding clinician who was beloved by his patients, and a true innovator in treatment, what he kept more quiet was his impact on colleagues and trainees as a mentor. He was an amazing teacher and colleague and that is what drew people to him**

"Jean was a transformative figure for our hematology division, taking the team to a new level in conducting cutting-edge research while providing compassionate patient care," said Amelia Langston, medical director and section chief of the Winship Bone Marrow and Stem Cell Transplant Program, and executive vice chair of the Department of Hematology and Medical Oncology. "He led and taught by example, and we continued to learn from him even in the face of his illness. His blend of curiosity, determination, caring, and humor will leave a lasting imprint on all of us."

Khoury pioneered the development of personalized treatment for CML patients and better approaches to improve quality of life for survivors. His research focused on drug development in leukemia and MDS, genomic abnormalities in leukemia, development of cost-ef-

fective practice models, and outcome analysis of bone marrow transplant.

He conducted several leukemia and bone marrow transplant clinical trials, including pivotal trials that led to approval of drugs such as imatinib, dasatinib, and nilotinib. Khoury received the Georgia Cancer Coalition Distinguished Cancer Scholarship, allowing establishment of the Hematological Disorders Tissue Bank at Emory, which now contains annotated germline and somatic

Poised and polite, my friend, the erudite and always calm and collected professor, asked me to contact him as soon as possible. As soon as I saw the message, I called him, and he and Angela told me he had esophageal cancer.

Jean gave it every shot, his best shot, like everything else he did in life, for 14 months. He died at home with his family by his side. He is survived by his wife, Angela Abboud-Khoury, and three children, Mikhail, Iman, and Alya.

In lieu of flowers, the family requests that contributions be made to a new fund at Winship Cancer Institute that will memorialize the life and work of Khoury by supporting a fellowship program that was so meaningful to him. Please send contributions, marked in Memory of Dr. H. Jean Khoury, to Winship Cancer Institute of Emory University, Office of Gift Records, Emory University, 1762 Clifton Rd. NE, Suite 1400, Atlanta, GA 30322. You may also make a gift to the fund online.



A memorial service will be held on Wednesday, May 31, at 4:30 p.m. at Glenn Memorial Church at 1652 North Decatur Rd.

#### **Visitation/Prayer Service**

A.S. Turner & Sons  
2773 North Decatur  
Decatur, Georgia 30033  
Friday, May 26, 6-8 p.m.

#### **Funeral Service**

Greek Orthodox Cathedral of the Annunciation  
2500 Clairmont Road, NE  
Atlanta, Georgia 30329  
Saturday, May 27, from 10-11 a.m.

*The author is president of the American University of Beirut.*

samples from more than 800 patients with various hematological disorders.

Jean came to my Inauguration in Beirut, and many years before that, we attended his daughter Alya's baptism in the ancient town of Byblos. Our families spent many holidays and vacations together over the years, and he was the consummate host, master of ceremonies, and organizer in chief, as he was at work.

Less than six weeks after he had proudly given our AUB, Emory, MD Anderson, Colorado, Dana Farber, and Wisconsin crowd a tour of the history and beauty of Beirut, culminating in a soirée in his apartment before coming to the celebration dinner at AUB's Marquand House, I got a message from Jean that filled me with dread.

# ODAC votes 12-4 to recommend approval for kinase inhibitor used after completion of trastuzumab

By Paul Goldberg

The FDA Oncologic Drugs Advisory Committee May 24 voted 12-4 to recommend approval of neratinib for the extended adjuvant treatment of adult patients with early-stage ERBB2-positive breast cancer who have received prior adjuvant trastuzumab-based therapy.

The drug, which has the trade name Nerlynx, is sponsored by Puma Biotechnology Inc.

Neratinib is a kinase inhibitor that irreversibly binds to epidermal growth factor receptors, Human Epidermal Growth Factor Receptor 2, and HER4.

FDA hasn't been consulting ODAC except in cases where applications present vexing problems. In this case, the drug's history—transfer of ownership from Wyeth to Pfizer to Puma as well as multiple protocol revisions—made it difficult to measure the magnitude of treatment benefit.

There are currently no approved therapies which improve upon the benefits of trastuzumab for HER2-positive patients in the adjuvant setting.

FDA appears to have taken steps to run statistical analyses to demonstrate that the drug, in fact, appeared to con-

vey a benefit of some uncertain magnitude, and ODAC, for its part, overwhelmingly accepted this notion.

ODAC also accepted the company's approach to overcoming the agent's most significant toxicity—grade 3 diarrhea. The company argued that it sets in early and can be managed through pre-treatment.

Brian Rini, ODAC acting chair and an oncologist at the Department of Hematology and Medical Oncology Cleveland Clinic Taussig Cancer Institute Glickman Urological and Kidney Institute, said the drug appeared to show modest activity and a manageable toxicity profile.

"I think what we heard was that there were the concerns about toxicity—specifically diarrhea," Rini said. "I think the sponsor provided some compelling data about toxicity being relatively relatively manageable, and short-lived.

As I say to all my patients, you give your consent every time you get your treatment. So, you can stop, and the toxicity goes away.

"There is concern by the group—and I share that—that there is a relatively modest effect here, although it's within the range of other drugs in the adjuvant setting," Rini said at the meeting. "And I think to me the most compelling was just the consistency both within and across analyses by the sponsor and FDA that this small benefit was real and potentially durable.

"Although, noting the toxicity, the number of people to treat in order to prevent one recurrence could be quite high. We weren't given that number, but it would be quite high.

"And then I think the most consistent concern from everyone—and I hear it—is about the label being too broad. I hear that loud and clear. But I think

there was a small, durable benefit, and that's why I voted yes."

In the company's registration trial, 2,840 women with early stage HER2-positive breast cancer who had previously received adjuvant treatment with trastuzumab were randomized 1:1 to receive either neratinib (n=1420) or placebo (n=1420).



There is concern by the group—and I share that—that there is a relatively modest effect here, although it's within the range of other drugs in the adjuvant setting. And I think to me the most compelling was just the consistency both within and across analyses by the sponsor and FDA that this small benefit was real and potentially durable.



The primary endpoint was invasive disease-free survival (iDFS) within 2 years and 28 days.

The primary analysis demonstrated a statistically significant stratified hazard ratio of 0.66 (0.49, 0.90) observed with an estimated 2.3% absolute difference in iDFS at two years (94.2% on

the neratinib arm vs. 91.9% on the placebo arm).

The sponsor and FDA noted that there may be a difference in the magnitude of benefit based on hormone receptor status [HR-positive HR=0.49 (0.31, 0.75), HR-negative HR=0.93 (0.60, 1.43)]. However, this is an exploratory subgroup analysis.

As the agent bounced from sponsor to sponsor, major amendments to the protocol included:

- Study population enriched with high-risk patients
- Study follow-up time shortened from 5 years to 2 years; analysis changed from event-driven to time-driven
- Reconsent process introduced to extend follow-up to 5 years post randomization.

Though FDA clearly didn't encourage Puma to submit the application, the agency tried to present an even-handed case.

The agency's sensitivity and tipping point analyses appeared to show that the statistical issues identified were unlikely to have a large impact on the study's overall results.

"There remains some uncertainty regarding the true magnitude of the treatment effect since the primary analysis (truncated at 2-years follow-up) observed a hazard ratio of 0.66 (95% CI: 0.49, 0.90) which changed to 0.68 (95% CI: 0.51, 0.91) with the exploratory updated 2-year analysis and the exploratory 5-year analysis observed a hazard ratio of 0.73 (95% CI: 0.57, 0.92)," the [FDA analysis](#) states.

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## IN BRIEF



## Carl June to receive ASCO's Karnofsky award, Eric Winer—Bonadonna award, Brian Druker—Science of Oncology award



Carl June, will receive the David A. Karnofsky Memorial Award and Lecture at the ASCO annual meeting, to be held June 2-6.

June is the director of the Center for Cellular Immunotherapies at the Perelman School of Medicine and the director of the Parker Institute for Cancer Immunotherapy at the University of Pennsylvania. His work is focused on the mechanisms of lymphocyte activation related to immune tolerance and adoptive immunotherapy for cancer and chronic infection.

In 2011, his research team published findings detailing a new therapy in which patients with refractory and relapsed chronic lymphocytic leukemia were treated with genetically engineered versions of their own T cells. The treatment is now being used with promising results to treat children with refractory acute lymphoblastic leukemia.

In other awards to be presented at the meeting:

- **Eric Winer** will receive the FASCO Gianni Bonadonna Breast Cancer Award and Lecture. Winer is a professor of medicine at Harvard Medical School and holds several appointments at Dana-Farber Cancer Institute.
- **Brian Druker** will receive the Science of Oncology Award and Lecture. Druker is the director of the Knight Cancer Institute at Oregon Health & Science University, JELD-WEN Chair of Leukemia Research, and an investigator of the Howard Hughes Medical Institute. His work helped pioneer the practice of precision, or personalized, cancer medicine, by performing preclinical studies and leading clinical trials that were instrumental to the development of imatinib.
- **Patrick Loehrer** will receive the Allen S. Lichter Visionary Leader Award and Lecture. Loehrer is the director of the Indiana University Melvin and Bren Simon Cancer Center and the associate dean for cancer research at the Indiana University School of Medicine. He was the founding chair of the Hoosier Oncology Group (now Hoosier Cancer Research Network) for two decades, which conducted trials in 20 countries around the world. Loehrer specializes in the treatment of a variety of cancers including testis, bladder, colon, pancreas, and, most notably, thymic, a rare cancer of the thymus gland. His research on the drug ifosfamide led to its approval by FDA.
- **Michael Link** will receive the Pediatric Oncology Award and Lecture. Link is a pediatric hematologist/oncologist, is the Lydia J. Lee Professor in Pediatric Oncology at the Stanford University School of Medicine. His research interests include the biology and treatment of non-Hodgkin lymphomas and Hodgkin disease, as well as clinical management of bone and soft tissue sarcomas in children. Link was an associate editor of the Journal of Clinical Oncology for 10 years, and is a former ASCO president.
- **Dean Brenner** will receive the ASCO-American Cancer Society Award and Lecture. He is the Kutsche Family Memorial Professor of Internal Medicine at the University of Michigan. His work is focused on eicosanoids, primarily in the colonic mucosa as mechanistic therapeutic targets and as biomarkers for drugs, nutritional extracts, and dietary interventions aimed at reversing or delaying carcinogenesis progression. Because of the dearth of useful endpoints to define preventive therapeutic efficacy, he has emphasized biomarker discovery and validation platforms that enable interrogation of molecular carcinogenesis events in representative models of human biology.

- **Jean-Pierre Droz** will receive the B.J. Kennedy Award and Lecture for Scientific Excellence in Geriatric Oncology. Droz has dedicated his work to the integration of geriatric assessment in decision making for treating older people with cancer and was key in the development of geriatric oncology in France and other countries acting through the International Society of Geriatric Oncology. Droz was an attending physician at the Léon-Bérard Comprehensive Cancer Centre and professor of medical oncology at the Claude-Bernard-Lyon 1 University in Lyon, France. Now in retirement, he is an attending physician of medical oncology in hospitals in French Guiana and teaches at the French Guiana and West Indies University Medical School.
  - **Allen Lichter** will receive the Distinguished Achievement Award. Lichter served as ASCO's chief executive officer from 2006 to 2016, has held two significant leadership roles at the University of Michigan, including chair of the Department of Radiation Oncology and dean of the Medical School, and was the director of the Radiation Therapy Section of the NCI's Radiation Oncology Branch. Lichter's research at NCI helped advance the use of lumpectomy plus radiation as an alternative to mastectomy in the local management of breast cancer and his work at Michigan established the clinical utility of three-dimensional treatment planning and conformal dose delivery.
  - **Lowell Schnipper** will receive the Special Recognition Award. Schnipper is a clinician-scientist and medical educator, is the Theodore W. and Evelyn G. Berenson Professor Emeritus at Harvard Medical School, the immediate past clinical director, Cancer Center, and chief of the Division of Hematology/Oncology at the Beth Israel Deaconess Medical Center in Boston. As the founding chief of oncology at the Beth Israel Hospital, he and his colleagues developed a highly sought after training program focusing on clinical and translational research. Schnipper's research interests range from bench to bedside and have contributed to the understanding of the mechanism of action and resistance to antiviral and anti-neoplastic therapies, genomic instability in cancer, and most recently, quality and value in cancer care.
  - **Ross Donehower** will receive the Excellence in Teaching Award. Donehower has led the hematology oncology fellowship program at Johns Hopkins University. Donehower has spent more than 30 years at Hopkins and currently serves as the Ludwig Professor of Clinical Investigation in Cancer.
  - **Susan Weiner** will receive the Partners in Progress Award. Weiner is the founder and director of The Children's Cause for Cancer Advocacy. Throughout her career, she has acted as an advocate for young patients with cancer and their families by pressing for innovative and efficient pediatric oncology drug development, early clinical trials, and quality care for survivors of childhood cancer. **Olufunmilayo Olopade** will receive the Humanitarian Award. Olopade is a medical oncologist and internationally renowned expert in breast cancer, serves as Walter L. Palmer Distinguished Service Professor of Medicine and director of the Center for Innovation in Global Health at The University of Chicago. Her laboratory research is focused on defining molecular mechanisms of cancer through studies of genetic and nongenetic factors contributing to tumor progression in at-risk individuals from diverse populations.
  - The Women Who Conquer Cancer Mentorship Award will go to **Mary Gospodarowicz** the medical director at Princess Margaret Cancer Centre and regional vice president of Cancer Care Ontario, and Elizabeth Shpall, director of the Cell Therapy Laboratory and Cord Blood Bank, and deputy chair of the stem cell transplantation and cellular therapy at the M.D. Anderson Cancer Center. Gospodarowicz recently served as president for the Union for International Cancer Control. Her research interests focus on the role of radiation therapy in lymphomas, prostate cancer, bladder cancer, and testis cancer clinical trials. Shpall has served as the founding president for the Foundation of Accreditation of Cellular Therapy and as past president of the American Society for Blood and Marrow Transplantation.
- The Fellow of the American Society of Clinical Oncology distinction goes to:
- Robert Bast
  - Monica Bertagnolli
  - Linda Bosserman
  - George Browman
  - Ezra Cohen
  - Michael Fisch
  - James Frame
  - James Ford
  - Timothy Gilligan
  - Shawn Dana Glisson
  - David Graham
  - Stephen Grubbs
  - Melissa Hudson
  - Arti Hurria
  - Paul Jacobsen
  - Kim Allyson Margolin
  - Jeffrey Meyerhardt
  - Tony Mok
  - Howard Ozer
  - Edith Perez
  - Abram Recht
  - Steven Rosen
  - Hope Rugo
  - Howard Sandler
  - Charles Shapiro
  - Frances Shepherd

- Catherine Van Poznak
- Jaap Verweij
- Katherine Virgo
- Jeffery Ward
- Dan Sayam Zuckerman

## ACR Gold Medals go to Bruce Hillman, John Patti, and Jeffrey Weinreb

The American College of Radiology Gold Medal, which recognizes distinguished and extraordinary service to the ACR or to radiology, went to Bruce Hillman, John Patti, and Jeffrey Weinreb.

- **Hillman** is a professor of radiology and medical imaging and public health sciences and former chair of radiology at the University of Virginia, Charlottesville, and founding and current editor-in-chief of the Journal of the American College of Radiology. The author of the seminal investigative work on self-referral and inappropriate utilization developed new methods of data analysis and interpretation, paving the application of health services research methodologies to imaging. He is the founding chair of the American College of Radiology Imaging Network, which conducted landmark studies demonstrating the value of digital mammography for breast cancer screening and computed tomography for colon and lung cancer screening.
- **Patti** is a senior lecturer in radiology at Harvard Medical School and thoracic radiologist at Massachusetts General Hospital. During his ACR leadership tenure, he championed and facilitated many critical and acclaimed ACR programs and initiatives, including the Radiology Leadership Institute, the Harvey L. Neiman Health Policy Institute, the American Institute of Radiologic Pa-

thology, ACR Select, and created the ACR Commission on International Relations. An expert in imaging economics and health policy, Patti widely communicated the myriad and complicated financial issues related to radiology, advocating for fair payment policies and the understanding of the critical value radiologists contribute to patient care.

- **Weinreb** is a professor and vice chair for strategic planning in the department of radiology and biomedical imaging at Yale-New Haven Hospital/Yale School of Medicine, Weinreb is considered a pioneer in developing clinical magnetic resonance imaging. He has been a strong advocate for maintaining and further developing the ACR Appropriateness Criteria and championed participation in the American Board of Internal Medicine Choosing Wisely initiative.

In other awards, Berend Slotman and Jacob Sosna, of Jerusalem were named Honorary Fellows.

- **Slotman** is a professor and chair of radiation oncology at VU Medical Center in Amsterdam and widely known for his work on lung cancer and for broadening the field of stereotactic ablative radiotherapy.
- **Sosna** is chair, division of imaging, at Hadassah Hebrew University Medical Center in Jerusalem. He established three facilities for clinical and scientific studies: one for 3-D imaging, one for experimental CT and one for applied radiology.

Pamela Wilcox, of Ridge received the Distinguished Achievement Award for notable service to the College and the profession. Wilcox served as ACR executive vice president of quality and safety, retiring in 2016 after 28 years of service to the College. She managed the ACR mammography accreditation program, which greatly influenced the

development and passage of the 1992 Mammography Quality Standards Act.

In a related development, Alan Kaye, of Bridgeport, Conn., Advanced Radiology Consultants and Yale New Haven Children's Hospital, was elected president of ACR and Lawrence Liebscher, of Waterloo, Iowa, Cedar Valley Medical Specialists, was elected vice president.

## A \$100 million gift establishes a UChicago institute focused on microbiome and immunity



Members of the Duchossois Family Foundation, including (back row, from left) Craig Duchossois, Janet Duchossois, Ilaria Woodward, Jessica Swoyer Green, Dayle Duchossois Fortino, (seated, from left) Ashley Joyce, Richard Duchossois and Kimberly Duchossois.

*Photo by Richard Shay*

The University of Chicago received a \$100 million gift that will establish The Duchossois Family Institute: Harnessing the Microbiome and Immunity for Human Health.

The institute will bring together the university's strengths in genetics, immunology, microbiome research, and computation to develop research and interventions focused on optimizing health.

The gift was made by the Duchossois Group Inc. Chairman and CEO Craig

Duchossois, his wife Janet Duchossois, and The Duchossois Family Foundation.

The Duchloss family first provided support to UChicago in 1980, when Richard Duchossois established the Beverly E. Duchossois Cancer Fund in memory of his wife. In the years since, the family has given \$37 million to the medical center to drive innovation and transformative care, including a named professorship and several cancer research funds, as well as a \$21 million gift in 1994 to establish the Duchossois Center for Advanced Medicine.

The Duchossois gift is the single largest in support of UChicago Medicine, and it is the fourth gift of \$100 million or more to the University of Chicago.

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## NCI awards Fred Hutch \$24 million to operate contact center for patients

NCI awarded \$24 million to Fred Hutchinson Cancer Research Center to continue operating the NCI's primary public access point for cancer information in both English and Spanish.

With the new contract, the Contact Center will emphasize clinical trial education and referrals, increasing outreach to medically underserved populations and integrating innovative communication technologies.

"We are constantly adapting to meet people's information-seeking needs," said Nancy Gore, director of the Contact Center, which provides free phone and online help to cancer patients and their families. "The sophistication of our clients has certainly increased over time because of what they've been able to access and read online about their conditions before contacting us. Now they often need to know how or whether specific information applies

to their case, and that's where we are able to provide additional context and education, including questions to take back to their health care provider to help further their understanding."

NCI originally established contact centers at several NCI-designated cancer centers throughout the country; the first call was taken in 1976. The Contact Center at Fred Hutch joined this effort in 1981, and eventually became the sole operator in 2009, when NCI consolidated existing operations into a single Contact Center.

Gore has worked at the Contact Center at Fred Hutch for 23 years and manages a team of about 65 employees, including cancer information specialists who answer inquiries and oncology-certified nurses who provide technical assistance on interactions and are members of the training team for new staff.

The group handled close to 92,000 inquiries last year, 48 percent by phone and 43 percent by live chat. While the number of calls has decreased over time — a trend seen at other contact centers — questions through the live-chat option are on the rise. The Fred Hutch team also responds to questions that come through email, which makes up 8 percent of inquiries. A sliver of inquiries, 1 percent, come through social media. People can reach the service Monday through Friday, 9 a.m. – 9 p.m. ET by calling 1.800.4.CANCER (800.422.6237), through online live chat or by email on NCI's website [www.cancer.gov](http://www.cancer.gov). Bilingual (English-Spanish) staff members are available on all access channels.

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## Karmanos wins federal grant renewal for membership in Prostate Cancer Clinical Trials Consortium

The Barbara Ann Karmanos Cancer Institute has competed and been selected by scientific peers for a four-year grant renewal from the Department of Defense to continue membership in the prestigious Prostate Cancer Clinical Trials Consortium program.

Elisabeth Heath will direct Karmanos' involvement in the consortium. Heath is leader of the Genitourinary Oncology Multidisciplinary Team, associate center director of Translational Sciences, and the Patricia C. and E. Jan Hartmann Endowed Chair for Prostate Cancer Research at Karmanos and Wayne State University School of Medicine.

The Prostate Cancer Clinical Consortium Award is a peer-reviewed, competitive grant. Peers include scientific researchers at universities and cancer centers across the nation. This year, only seven sites were funded, down from 11 sites in 2013.

Karmanos has been part of the consortium since 2008. The budget amount for the new four-year grant is \$1.2 million. Heath's co-principal investigator is Ulka Vaishampayan, director of the Eisenberg Center for Translational Therapeutics and co-investigators are Isaac Powell, and Lance Heilbrun, of Karmanos and WSU SOM.

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## NCCN funds two studies through collaboration with AstraZeneca to evaluate effectiveness of osimertinib

The National Comprehensive Cancer Network Oncology Research Program has funded two investigators from NCCN member institutions through a collaborative scientific research relationship with AstraZeneca to further evaluate the clinical effectiveness of



osimertinib in the treatment of epidermal growth factor receptor-positive non-small cell lung cancer.

The following studies were awarded funding through NCCN ORP:

- Daniel Gomez, of MD Anderson Cancer Center, “Randomized Phase II Trial of Osimertinib with or without Local Consolidation Therapy for Patients with EGFR-mutant Metastatic NSCLC (NORTHSTAR).”
- Pasi Jänne, Dana-Farber/Brigham and Women’s Cancer Center, Massachusetts General Hospital Cancer Center, “A Phase II Study of Osimertinib in Combination with Selumetinib in EGFR Inhibitor Naïve Advanced EGFR Mutant Lung Cancer.”

Submissions were peer reviewed by the NCCN Osimertinib Scientific Review Committee.

The funded concepts were selected based on several criteria, including scientific merit, existing data, and the types of studies necessary to further evaluate the efficacy of osimertinib.

NCCN ORP draws upon the expertise of investigators at the NCCN member institutions and their affiliates to facilitate all phases of clinical research. This research is made possible by collaborations with pharmaceutical and biotechnology companies in order to advance therapeutic options for patients with cancer. To date, this research model has received more than \$60 million in research grants and supported more than 140 studies.

## Saint Luke’s and Washington University School of Medicine announce clinical trials affiliation

Saint Luke’s Cancer Institute announced an affiliation with Washington University School of Medicine in St. Louis effective June 1, 2017, giving Saint Luke’s cancer patients expanded access to clinical trials beginning in late summer.

Saint Luke’s Cancer Institute is part of Saint Luke’s Health System which consists of 10 hospitals and campuses in the Kansas City area and the surrounding region.

### DRUGS & TARGETS



## Keytruda gets accelerated approval based on a genetic feature—first such action

In an unprecedented, fast-tracked review, FDA granted accelerated approval to a treatment for patients whose cancers have a specific genetic feature.

This is the first time the agency has approved a cancer treatment based on a common biomarker rather than the location in the body where the tumor originated.

Keytruda (pembrolizumab) is sponsored by Merck & Co.

The drug’s most recent indication is for the treatment of adult and pediatric patients with unresectable or metastatic solid tumors that have been identified as having a biomarker referred to as microsatellite instability-high (MSI-H) or mismatch repair deficient.

This indication covers patients with solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options and patients with colorectal cancer that has progressed following treatment with certain chemotherapy drugs.

“This is an important first for the cancer community,” said Richard Pazdur, acting director of the Office of Hematology and Oncology Products in the FDA’s Center for Drug Evaluation and Research and director of the FDA’s Oncology Center of Excellence. “Until now, the FDA has approved cancer treatments based on where in the body the cancer started—for example, lung or breast cancers. We have now approved a drug based on a tumor’s biomarker without regard to the tumor’s original location.”

MSI-H and dMMR tumors contain abnormalities that affect the proper repair of DNA inside the cell. Tumors with these biomarkers are most commonly found in colorectal, endometrial and gastrointestinal cancers, but also less commonly appear in cancers arising in the breast, prostate, bladder, thyroid gland and other places. Approximately 5 percent of patients with metastatic colorectal cancer have MSI-H or dMMR tumors.

Keytruda was approved for this new indication using the accelerated approval pathway, under which the FDA may approve drugs for serious conditions where there is unmet medical need and a drug is shown to have certain effects that are reasonably likely to predict a clinical benefit to patients.

Further study is required to verify and describe anticipated clinical benefits of Keytruda, and the sponsor is currently conducting these studies in additional patients with MSI-H or dMMR tumors.

The safety and efficacy of Keytruda for this indication were studied in patients with MSI-H or dMMR solid tumors enrolled in one of five uncontrolled, single-arm clinical trials. In some trials, patients were required to have MSI-H or dMMR cancers, while in other trials, a subgroup of patients were identified as having MSI-H or dMMR cancers by testing tumor samples after treatment began.

A total of 15 cancer types were identified among 149 patients enrolled across these five clinical trials. The most common cancers were colorectal, endometrial and other gastrointestinal cancers. The review of Keytruda for this indication was based on the percentage of patients who experienced complete or partial shrinkage of their tumors (overall response rate) and for how long (durability of response).

Of the 149 patients who received Keytruda in the trials, 39.6 percent had a complete or partial response. For 78 percent of those patients, the response lasted for six months or more.

Bert Vogelstein, co-director of the Ludwig Center at the Johns Hopkins Kimmel Cancer Center and a Lustgarten Foundation Distinguished Scholar who helped direct this study, described the therapy as “the first example of ‘personalized immunotherapy.’ A specific immune treatment can now be recommended for patients based exclu-

sively on the genetic characteristics of their tumor. If the tumor shows a repair defect, then it is very likely that it will respond to this drug, regardless of how advanced the cancer is at the time of treatment.”

It is estimated that approximately 1 in 50 advanced pancreatic cancer patients have MMR in their tumors that make them candidates for this type of therapy.

The study was conducted at the Johns Hopkins Bloomberg-Kimmel Institute, funded in part by the Lustgarten Foundation, “This is an incredibly important step forward and we are delighted to have had a key role in its success,” said David Tuveson, director of Research for the Lustgarten Foundation. “Patients have responded very well to this drug. This is the beginning of personalized medicine for pancreatic cancer patients.”

## Debiopharm acquires antibody-drug conjugate compound from ImmunoGen

Debiopharm International and ImmunoGen, Inc. announced that Debiopharm has acquired ImmunoGen’s IMGN529/DEBIO 1562, a clinical-stage anti-CD37 ADC for the treatment of patients with B-cell malignancies, such as non-Hodgkin lymphomas.

Under the agreement, ImmunoGen received a \$25 million upfront payment for IMGN529/DEBIO 1562 and is entitled to a \$5 million milestone payment to be paid after completion of the transfer of ImmunoGen technologies related to the asset, which the parties expect to achieve by the end of 2017.

In addition, ImmunoGen is eligible for a second success-based milestone payment of \$25 million upon IMGN529/DEBIO 1562 entering a phase III clinical trial.

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