

# TCL

THE CANCER LETTER

Inside information on cancer research and drug development

Vol.

47

No.

21

MAY 28, 2021

[www.cancerletter.com](http://www.cancerletter.com)



## PROMINENT GI ONCOLOGIST AXEL GROTHEY WAS FORCED OUT OF MAYO CLINIC FOR UNETHICAL SEXUAL RELATIONSHIPS WITH WOMEN HE MENTORED

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Individual subscriptions \$555 per year worldwide. Group subscriptions required for institutional distribution. To subscribe, [click here](#).

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**PROMINENT GI ONCOLOGIST AXEL GROTHEY  
WAS FORCED OUT OF MAYO CLINIC FOR  
UNETHICAL SEXUAL RELATIONSHIPS WITH  
WOMEN HE MENTORED**

**THREE REPRIMANDS LATER, HE RETAINS LEADERSHIP—  
AND MENTORSHIP—POSITIONS**

*By Alexandria Carolan and Paul Goldberg*

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

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

Three reprimands notwithstanding, Grothey has kept his appointment as co-chair of the NCI National Clinical Trials Network's Gastrointestinal Steering Committee, an influential group that reviews ideas for clinical trials and helps determine the priorities in federally funded clinical research in GI oncology.

After *The Cancer Letter* informed NCI officials about Grothey's track record and requested comment, NCI Director Ned Sharpless removed him from the steering committee effective May 27.

"We cannot, and will not, tolerate sexual harassment within the agency, at research organizations that receive NIH funding, or anywhere else NIH-funded activities are conducted," Sharpless said to *The Cancer Letter*. "Based on the information we now have, I have, effective immediately, terminated Dr. Grothey's membership on the NCI Gastrointestinal Cancer Steering Committee."

Grothey's publications haven't skipped a beat. An [editorial](#) he wrote solo appeared in the *New England Journal of Medicine*. And he has published papers in *The Lancet*, the *Journal of Clinical Oncology*, and *JAMA Oncology*. According to [PubMed](#), Grothey authored 32 publications in 2020, and 12 so far in 2021. His name figures on 12 abstracts that will be presented at the 2021 annual meeting of

the American Society of Clinical Oncology next week.

West Cancer Center, where Grothey landed as director of GI cancer research, has named him [medical director](#) of OneOncology Research Network, an organization that conducts clinical studies across a network of community oncology practices (*The Cancer Letter*, [March 29, 2019](#)).

If you were working at Mayo at the time of Grothey's departure, chances are you wouldn't have known why he had left. On May 31, 2018, an email to the Mayo faculty and staff said merely that Grothey "has decided to leave" for an unspecified destination and offered these arguably perfunctory parting words: "We wish Dr. Grothey well in his future endeavors."

Documents obtained by *The Cancer Letter* during a six-month investigation make it possible to observe the sequelae of Grothey's sexual misconduct, showing that the GI oncologist was, in fact, reported to Mayo's Human Resources, which conducted an internal investigation.

That investigation found that Grothey's "pattern of conduct demonstrated a failure on his part to establish and maintain appropriate professional boundaries with people who viewed him as a mentor." This finding was not made public, and Grothey was given a choice between resigning and being terminated.

The number of HR complaints against Grothey is not publicly known. *The Can-*

*cer Letter* doesn't disclose names of individuals who have been subjected to sexual misconduct.

Grothey's misconduct came into public view for one reason only:

Two women, both employed by Mayo, decided to take the extra step and moved their grievance outside the hospital system, to the Minnesota Board of Medical Practice, which launched a separate investigation. That investigation turned up evidence, generated files, and produced a reprimand that was ultimately published on the board's [website](#).

The Minnesota reprimand then triggered investigations in Tennessee and Arizona, two states in which Grothey was also licensed to practice. These investigations generated hundreds of pages of documents.

A timeline based on documents obtained by *The Cancer Letter* makes it possible to observe the final phase of Grothey's career at Mayo, his actions at that institution, his departure, and his efforts to rebuild his career.

The timeline appears on [page 6](#), with documents available for download.

All documents in the public record are also available in a [372-page PDF](#).

The investigation by *The Cancer Letter* shows that, in three separate questionnaires that Grothey filled out while trying to obtain a Tennessee license, he didn't acknowledge having resigned as a result of an internal investigation at Mayo.

Earlier this week, when *The Cancer Letter* called Grothey to discuss his departure from Mayo, he first paused to close a door, presumably in his office.

Before ending the conversation—stating that he wished to bring in an

attorney—Grothey acknowledged the inappropriate sexual relationship with a fellow.

“I feel very uncomfortable talking about this right now. What brought this up? This has upended my life so much. Why is this being brought up by *The Cancer Letter* right now?” Grothey said to a reporter. “Because, you know, things were actually settled, and everything’s done, and I’m not sure why this is coming up right now.”

*The Cancer Letter* sent Grothey a series of questions, which remained unanswered at deadline. The questions are available [here](#).

“Mayo Clinic does not discuss personnel matters about current or former employees publicly. We have a well-established process for investigating and acting on concerns that employees may express about behavior in the workplace,” a Mayo spokesperson said to *The Cancer Letter*. “Mayo Clinic also complies with legal reporting requirements with regulatory boards when such reports are warranted.”

In a paper [published](#) in *Mayo Clinic Proceedings* last year, the institution summarized the handling of sexual harassment claims on its campuses in Rochester, Arizona, and Florida.

The clinic reports having received 153 allegations between 2017 and 2019.

More than half of these allegations—88—were “substantiated following investigation and resulted in corrective action,” the paper states.

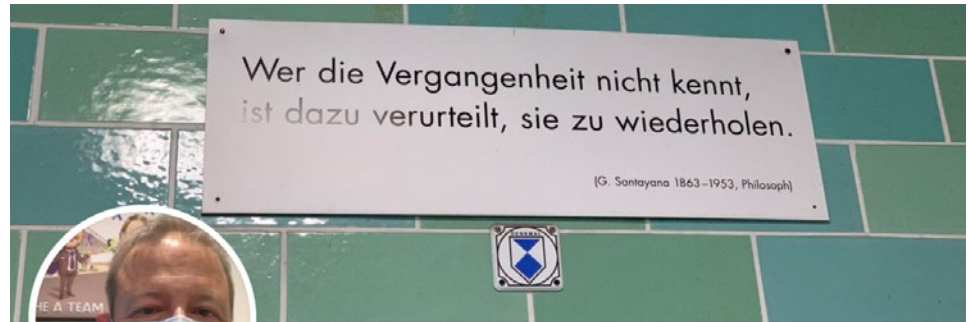
Of these, 31—including nine physician-scientists—received formal coaching; 22—including three physician-scientists—received warnings; and 35—including 10 physician-scientists—were terminated from employment or resigned before termination.

Notably, the paper doesn't separate those who were terminated from employment and those who were allowed to resign under threat of termination.

*The Cancer Letter* asked Charanjit S. Rihal, chair of the Mayo Clinic Personnel

Committee and the corresponding author on the paper, to explain the reasons for combining these two cohorts, and asking him to separate the data on those who were fired from those who were allowed to move to another, perhaps unsuspecting, institution.

*Continues on page 11 →*



**Axel Grothey**

@agrothey

Passionate about justice & tolerance, teaching & educating oncologists, caring for cancer patients, learning from mistakes. Opinions and statements are my own.

📍 Tennessee, USA 📅 Joined March 2009

416 Following 3,635 Followers



**Axel Grothey** @agrothey · Jul 22, 2019

I 100% support the #MeToo movement without hesitation. What I don't like is when it is abused and perverted for personal or political gain. Missing #AlFranken



**Jane Mayer** @JaneMayerNYer · Jul 22, 2019

Al Franken was forced to resign from the Senate in just 3 weeks: here's the back story that the public never learned: [newyorker.com/magazine/2019/...](https://www.newyorker.com/magazine/2019/...)



**Axel Grothey**

@agrothey

A great show with many important messages! Sexual assault, me too, narcissism, abuse of power...



**HuffPost** @HuffPost · Aug 12, 2019

"The Boys" features a sexual assault scene that puts the abuse of power into perspective. [huffp.st/OLp75Kb](https://huffp.st/OLp75Kb)



**Axel Grothey's**

**path of sexual**

**misconduct, reprimands,**

**and job changes**

## May 31, 2018

### Grothey resigns from Mayo

An email from Mayo's Alberts states: "Dr. Grothey has informed us that he has decided to leave Mayo Clinic effective May 30, 2018. We wish Dr. Grothey well in his future endeavors." ([Alberts's email](#))

### Sarah Cannon job is announced, but falls through

Grothey is appointed director of Gastrointestinal Cancer Research at Sarah Cannon Research Institute. The appointment is announced in a press release, but the job offer is retracted. ([Businesswire press release](#))

## Aug. 14, 2018

Tanios S. Bekaii-Saab, consultant within the Division of Hematology/Oncology and Department of Internal Medicine at Mayo Clinic Scottsdale, submits a recommendation to the Tennessee board, in support of Grothey's licensure. ([Tennessee public records](#))

## Aug. 7, 2018

Lee Schwartzberg, the research institute medical director of West Cancer Center and chief medical officer of OneOncology, submits a recommendation to the Tennessee Board of Medical Examiners, in support of Grothey's licensure. ([Tennessee public records](#))

## April 3, 2018

Grothey is issued a medical license in Arizona. ([Arizona MD profile page](#))

## March 17, 2018

### Promotion doesn't happen

In an email, Stephen Alberts, chair of the Division of Medical Oncology, deputy director for clinical research at Mayo Clinic Cancer Center, writes: "Due to unforeseen circumstances, Axel Grothey will not begin his new role as Chair, Arizona Division of Hematology and Medical Oncology, in Arizona next week as originally anticipated."

Later that day, a complaint from a colleague about Grothey is received by Mayo administration. ([HR complaint](#))

## May 2018

The Minnesota Board of Medical Practice receives the second of two complaints filed by a Mayo colleague.

## March 2018

The Minnesota Board of Medical Practice receives the first of two complaints filed by a Mayo colleague.

## Feb. 2, 2018

### Grothey is promoted

Axel Grothey, professor of oncology in the Mayo Clinic College of Medicine and Science at Mayo Clinic Rochester, is named chair of the Division of Hematology and Medical Oncology at Mayo Clinic Scottsdale. ([Mayo Clinic Alumni Association announcement](#))

## Feb. 13, 2018

Grothey is issued a temporary medical license in Arizona, valid from Feb. 13, 2018-Oct. 21, 2018. ([Temporary license approval](#))

## Aug. 15, 2018

### “NO” #1

In his international graduate application for a medical license in Tennessee, Grothey responds NO to this question:

“Have you ever had staff privileges at any hospital or health care facility that were ever revoked, suspended, curtailed, restricted, limited, otherwise disciplined, or voluntarily surrendered under threat of restriction or disciplinary action?” (*Tennessee international graduate application* [↗](#))

### Grothey lists West Cancer Center as employer

Grothey lists West Cancer Center as his intended place of employment in his application summary for Tennessee. (*Tennessee practitioner questionnaire* [↗](#))

## Sept. 11, 2018

### “NO” #2

In an application for a Tennessee license, Grothey responds NO to the following two questions:

- “Within the previous ten (10) years, have you ever had your hospital privileges revoked or involuntarily restricted for reasons related to competence or character by the hospital's governing body?”
- “Within the previous ten (10) years, have you ever been asked to or allowed to resign from or had any medical staff privileges restricted or not renewed by any hospital in lieu of or in settlement of a pending disciplinary action related to competence or character?”

(*Tennessee practitioner questionnaire* [↗](#))

## Oct. 8, 2018

### “NO” #3

In an application for a Tennessee license, Grothey again answers NO to the following questions:

- “Within the previous ten (10) years, have you ever had your hospital privileges revoked or involuntarily restricted for reasons related to competence or character by the hospital's governing body?”
- “Within the previous ten (10) years, have you ever been asked to or allowed to resign from or had any medical staff privileges restricted or not renewed by any hospital in lieu of or in settlement of a pending disciplinary action related to competence or character?”

(*Tennessee practitioner questionnaire* [↗](#))

## Oct. 23, 2018

### Tennessee board recommends denying Grothey a license

The Administrative Office of the Tennessee Board of Medical Examiners recommends that the board deny Grothey's request for a license. The reason: he hasn't completed U.S. residency training and isn't ABMS certified. (*Memorandum from the Tennessee Dept. of Health* [↗](#))



**Mar. 14, 2020**

### Minnesota reprimands Grothey

The Minnesota Board of Medical Practice reprimands Axel Grothey for engaging in “unethical or improper conduct” and “respondent agrees that the conduct cited above constitutes a reasonable basis in law and fact to justify the disciplinary action.” He is fined \$10,316.90 and is required to take a course on professional boundaries. ([Minnesota stipulation and order](#))

**April 8, 2020**

### Grothey informs the Tennessee board about the reprimand

Grothey updates his mandatory practitioner profile questionnaire in Tennessee. He informs the board that he was reprimanded in Minnesota for a “romantic relationship with physician colleague who was undergoing a fellowship.” ([Tennessee practitioner profile](#))

**June 10, 2019**

### Grothey acknowledges misconduct to Minnesota investigators

Grothey meets with the Minnesota Board of Medical Practice committee to discuss the ongoing investigation. He acknowledges having had sexual relationships with two colleagues, including one fellow. “Respondent acknowledged that his sexual relationship with Colleague #1 was a ‘mistake’ and that he enhanced Colleague #1’s career through the work they did together. Respondent acknowledged having a sexual relationship with Colleague #2 and that he had sexual relationships with other coworkers. Respondent stated that he is serving as a mentor in his current employment.” ([Minnesota stipulation and order](#))

**Jan. 31, 2019**

### Tennessee board issues Grothey a license under a declaratory order

The Tennessee Board of Medical Examiners signs an order to issue Grothey a full, unrestricted license. In the Findings of Fact, the board cites Grothey’s work as a “mentor for numerous oncology fellows,” as part of its reasoning. The board also notes that Grothey received a teacher of the year award at Mayo Clinic seven times. ([Final order from the Tennessee Dept. of Health](#))

**Apr. 3, 2019**

### NCI is informed about Grothey

One of the women from Mayo informs NCI about Grothey, who is a co-chair of the National Clinical Trials Network’s Gastrointestinal Committee. ([Email to NCI](#))

**May 6, 2019**

### NIH is informed about Grothey

One of the women from Mayo informs NIH about Grothey. ([Email to NIH](#))

## May 13-15, 2020

Grothey attends a three-day professional development course, “Maintaining Proper Boundaries,” offered by the Center of Professional Health at Vanderbilt University Center. ([Tennessee consent order](#))

## May 22, 2020

In Minnesota, Grothey petitions for “reinstatement of an unconditional license to practice medicine and surgery.” ([Minnesota order of unconditional license](#))

## June 16, 2020

### Grothey informs the Arizona board about the reprimand

Grothey applies for license renewal in Arizona. He informs the Arizona Medical Board about the Minnesota reprimand. The document, obtained by *The Cancer Letter*, is heavily redacted. ([Arizona Medical Board physician renewal questionnaire](#))

## July 29, 2020

### Tennessee reprimands Grothey

The Tennessee Board of Medical Examiners reprimands Grothey for “unprofessional, dishonorable or unethical conduct.” The board fines Grothey a maximum of \$2,000. Board members raise questions about why they didn’t know about Grothey’s conduct at Mayo at the time they issued him a license in Tennessee. He had answered “NO” repeatedly on questionnaires related to internal investigations. ([Tennessee consent order](#), [Video of the meeting](#))

## July 13, 2020

The Minnesota Board of Medical Practice’s Complaint Review Committee reviews Grothey’s petition and recommends reinstatement of an unconditional license. ([Minnesota order of unconditional license](#))

## Dec. 4, 2020

### Arizona reprimands Grothey

The Arizona Medical Board reprimands Grothey for “action that is taken against a doctor of medicine by another licensing or regulatory jurisdiction.” ([Arizona reprimand](#), [Notes from the board meeting](#))

## Sept. 12, 2020

Minnesota Board of Medical Practice approves an unconditional license for Grothey to practice medicine and surgery in Minnesota. ([Minnesota order of unconditional license](#))

## May 27, 2021

NCI Director Ned Sharpless fires Grothey from the NCTN’s GI Steering Committee, which he co-chaired.

→ Continued from page 5

Rihal didn't respond to multiple emails.

## Colleague #1 and Colleague #2

A quote from the American philosopher, novelist, and poet George Santayana, translated into German, figures on the cover photo on Grothey's Twitter bio:

*“Wer sich nicht seiner Vergangenheit erinnert, ist verurteilt, sie zu wiederholen.”* Those who cannot remember the past are condemned to repeat it.

Grothey appears to be a proponent of the #MeToo movement, Black Lives Matter, equitable health care, and other social justice issues, describing himself as a man “passionate about justice & tolerance, teaching & educating oncologists, caring for cancer patients, learning from mistakes.”

Documents assembled by Minnesota investigators identify one complainant against Grothey as “Colleague #1,” who was a second-year fellow when the sexual relationship with Grothey began. The other complainant, identified as “Colleague #2,” was also in a mentorship relationship with Grothey, documents state.

Minnesota documents show that, at a meeting with state officials, Grothey expressed regret, noting that he had advanced the woman's career:

“Respondent acknowledged that his sexual relationship with Colleague #1 was a ‘mistake’ and that he enhanced Colleague #1's career through the work they did together. Respondent acknowledged having a sexual relationship with Colleague #2 and that he had sexual relationships with other coworkers. Respondent stated that he is serving as a mentor in his current employment.”

Grothey's comment about having benefited the career of Colleague #1, if accurately conveyed in the Minnesota documents, may seem chillingly frank.

“It used to be one of the perks of the job—the lab director, the department chair get to hunt around the new crop of female students, even undergraduates. You see it still, but, to me, it's inexcusable that people don't take the protection of the vulnerable seriously,” Arthur Caplan, The Drs. William F. and Virginia Connolly Mitty Professor and founding head of the Division of Medical Ethics at NYU School of Medicine in New York City, said to *The Cancer Letter*.

Caplan said the state licensure boards in the U.S. don't communicate with each other nearly well enough.

“Wouldn't it be nice if we had a coordinated interstate system with all the information on it? It's like saying, ‘I killed five people as a drunk driver in Massachusetts, but I'll go get my license in Colorado now, because I don't have to tell them,’” Caplan said. “What are we, in the age of Charles Dickens, writing things on scrolls of paper? It's an electronic world, why aren't we all linked?”

“I'll tell you why: Because they lobby against it.”

The interstate system Caplan proposes would do nothing to root out misconduct among non-physician scientists and administrators, who aren't required to hold state-issued licenses.

“It should be called sexual abuse if it's a mentor-mentee relationship,” said Sidney Wolfe, co-founder of and senior advisor to Public Citizen's Health Research Group, who has studied sexual misconduct by physicians. “It's even worse for the mentees, because they have a clear tradeoff they believe they're making if they complain, because by the time it gets taken care of, so to speak—they may have lost their chance to get into

a residency, or if they are a resident, trying to get a fellowship, they've lost it.

“The reason it has not been in the news is obvious. Women are usually ashamed, embarrassed, horrified at making any of this public—and not a lot of medical boards have a range of ways in which they can complain to the medical board without going public,” Wolfe said to *The Cancer Letter*.

The decision to report sexual harassment isn't trivial, said Pamela Kunz, associate professor of internal medicine (medical oncology), director of the Center for Gastrointestinal Cancers, and vice chief of diversity, equity and inclusion for the section of medical oncology at Yale Cancer Center, who has been outspoken on this subject (*The Cancer Letter*, [Oct. 2, 2020](#)).

“It's really hard for these women and other victims to even know where to go. Do they go to their ombudsperson or Title IX office? Do they go to the graduate medical education office? Do they go to their department leadership?” Kunz said to *The Cancer Letter*. “Many women get passed along from one person to another, and then there really isn't accountability even within a system. And then there's often a desire for institutions to protect the brand rather than protecting the individual.

“There's a history of a lack of accountability. Institutions and perpetrators of sexual harassment need to be accountable,” Kunz said.

Trainees are vulnerable to sexual abuse and, as a rule, are unprotected by their institutions, said Pringl Miller, founder and president of Physician Just Equity, a nonprofit that provides peer support for physicians who experience harassment, discrimination, and retaliation.

“Most women and/or the underrepresented in medicine suffering from harassment and/or discrimination, do not

walk into those situations willfully,” Miller said to *The Cancer Letter*. “They find themselves in those situations because someone who has power over them abuses that power in the dependent and hierarchical relationships that exist in medicine. Victims feel powerless to defend themselves because of the very real consequences of having their careers derailed.”

“Survivors have to make a difficult decision weighing their safety, values, ethics and career over a temporary experience they don't feel comfortable with,” Miller said. “Survivors find themselves asking—‘Am I willing to sacrifice my career over this? Or am I going to succumb to what is being asked of me? They reflect to themselves, ‘I've worked so hard to get to where I am—I'm not going to let this situation stand in my way.’”

Shea Holman, director of law and policy at the Purple Campaign, a nonprofit focused on ending sexual harassment in the workplace, said many HR structures must be reworked to earn their employees trust.

“We advise and advocate for having multiple reporting channels, and making those reporting channels transparent, so that your employees actually know what their options are for reporting, where they can go, and whether they are anonymous or not,” Holman said to *The Cancer Letter*.

“Encouraging people to report is a huge part of addressing these issues and actually being able to bring people to justice when instances of sexual harassment have occurred.”

Clout within their institutions can make luminaries feel invincible, Holman said.

“Power can make an individual feel uninhibited, and thus more likely to engage in some sort of inappropriate behavior, and then lead to sort of coercive relationships, in which the individual

feels that they can't report, or they don't want to report, because they are afraid of what's going to happen to their career prospects, or they are afraid of some sort of organizational indifference or trivialization of the harassment.”

Caplan, Wolfe, Kunz, Miller, and Holman have no direct knowledge of the Grothey case.

A survey conducted by *The Cancer Letter* in 2020 shows that women who experienced gender bias and sexual harassment in academic medicine unanimously rated their institutions' response as inadequate (*The Cancer Letter*, [Oct. 2, 2020](#)).

Women are increasingly stepping into leadership roles in oncology. A survey conducted by *The Cancer Letter* and the Association of American Cancer Institutes finds that fewer than 20% of cancer center directors are women, but women account for 40% of deputy and associate directors (*The Cancer Letter*, [Oct. 9, 2020](#)).

## Grothey's Scottsdale promotion collapses

Grothey's downfall at Mayo occurred on the heels of a promotion.

On Feb. 6, 2018, Mayo [announced](#) that Grothey was named chair of the Division of Hematology and Medical Oncology at Mayo Clinic Scottsdale.

Records show that he rented an apartment at [Elite North Scottsdale](#), a place that, according to its website, is “seductively modern and newly renovated,” bustling with “elite energy,” and offering “spacious homes for agile lives.”

However, on March 17, an email from Stephen Alberts, chair of the Division of Medical Oncology and deputy director for clinical research at Mayo Clinic

Cancer Center, said that Grothey would not begin his role in Arizona as planned.

“Due to unforeseen circumstances, Axel Grothey will not begin his new role as Chair, Arizona Division of Hematology and Medical Oncology, in Arizona next week as originally anticipated. Please direct any questions or concerns you may have to me. Thank you, Steve.”

Documents obtained by *The Cancer Letter* show that later on the same day Mayo received a complaint about Grothey, and the complaint was passed on to Human Resources.

The complaint states:

Several current/former women at Mayo (myself included) have enough concrete information to have him fired 5x over.

Honestly, all Mayo would need to do is look into his email, pages, phone records, or use of Mayo funds, if they can even access any of this and are willing to deal with it head-on [...] he has bragged that he brings in so much that he is “untouchable.”

Currently, we are all living in fear... we know he has been reported previously and has a history of retaliation, and we are all vulnerable due to our personal situations. I'm really putting everything out there by saying anything at all, and I'd prefer not to say anything else but to live in peace while Mayo leadership does its job.

Based on everything I know, he is a huge liability to Mayo and should be let go as expeditiously as possible.

Six weeks later, in the morning of May 31, in an email to the faculty and staff, Alberts announces Grothey's departure from Mayo:

Dr. Grothey has informed us that he has decided to leave Mayo Clinic effective May 30, 2018. We wish Dr. Grothey well in his future endeavors. We are in the process of communicating his departure to patients to ensure continuity of care.

The email to Mayo staff didn't mention where Grothey might be going. That mystery cleared up later that afternoon, when Sarah Cannon Research Institute, a subsidiary of HCA Healthcare, announced in a [press release](#) that Grothey was named director of Gastrointestinal Cancer Research there.

The Sarah Cannon press release includes a quote from Grothey: "As a clinical researcher who has spent my career dedicated to advancing therapies for patients with gastrointestinal cancers, the mission of Sarah Cannon is firmly aligned with my goals and objectives. The opportunity to lead a program with access to a broad range of new therapies and a large number of patients is very exciting."

Meanwhile, the buzz about Grothey's departure from Mayo was spreading rapidly through the informal networks of oncologists, especially those working in GI.

Several physicians who, despite Mayo's efforts to keep the matter confidential, were made aware of the circumstances and contacted Sarah Cannon leadership, *The Cancer Letter* has learned.

The offer to Grothey was retracted shortly after the press release was issued, sources said.

## What it took to get a Tennessee license

The circumstances of Grothey's departure from Mayo were still not publicly known.

However, unbeknownst to anyone but the principals, two women had already taken the matter outside Mayo's walls and filed complaints to the Minnesota Board of Medical Practice, and its investigation had either begun or was about to. The board would take two years to complete the investigation and issue a reprimand.

State licensure boards and hospitals administer questionnaires that ask applicants whether they had ever been under an internal investigation or were allowed to resign as part of a deal with a hospital administration.

Grothey decided to obtain a license in Tennessee, but the challenge of getting a license there was formidable.

Grothey did his residency outside the U.S. and was not certified by the American Board of Medical Specialties. In Tennessee, doctors like him have to petition for a "declaratory order" to be able to practice in the state. It would seem that the board would have scrutinized his application with particular care.

Two-and-a-half months after his resignation from Mayo—on Aug. 15, 2018—Grothey answers "NO" to the following questions on the Tennessee licensure application:

- Have you ever had staff privileges at any hospital or health care facility that were ever revoked, suspended, curtailed, restricted, limited, otherwise disciplined, or voluntarily surrendered under threat of restriction or disciplinary action?

Three-and-a-half months after Mayo—on Sept. 11, 2018—Grothey answers "NO" to the following two questions on the Tennessee application:

- Within the previous ten (10)

years, have you ever had your hospital privileges revoked or involuntarily restricted for reasons related to competence or character by the hospital's governing body?

- Within the previous ten (10) years, have you ever been asked to or allowed to resign from or had any medical staff privileges restricted or not renewed by any hospital in lieu of or in settlement of a pending disciplinary action related to competence or character?

Four-and-a-half months after Mayo—on Oct. 8, 2018—Grothey once again answers "NO" to the same two questions on the Tennessee application:

- Within the previous ten (10) years, have you ever had your hospital privileges revoked or involuntarily restricted for reasons related to competence or character by the hospital's governing body?
- Within the previous ten (10) years, have you ever been asked to or allowed to resign from or had any medical staff privileges restricted or not renewed by any hospital in lieu of or in settlement of a pending disciplinary action related to competence or character?

By submitting the three questionnaires, Grothey attested "to the truth of each statement made in said application," documents show.

## "A mentor for numerous oncology fellows"

On Oct. 23, 2018, citing Grothey's status as an international applicant, the

““  
 We cannot, and will not, tolerate sexual harassment within the agency, at research organizations that receive NIH funding, or anywhere else NIH-funded activities are conducted. Based on the information we now have, I have, effective immediately, terminated Dr. Grothey’s membership on the NCI Gastrointestinal Cancer Steering Committee.””

– Ned Sharpless

Tennessee Board of Medical Examiners denied his request for a license.

Grothey petitions the board to reconsider, asking for a declaratory order. Grothey’s CV, submitted to Tennessee officials, shows him winning seven teacher of the year awards while at Mayo.

This is inconsistent with the Sarah Cannon press release and his biography which can be accessed on the [OneR](#) website. There, Grothey is said to have won five such awards. Without Mayo’s cooperation, which was denied to *The Cancer Letter*, it’s difficult to assess the significance of this discrepancy.

Recommendations from two leaders in the field of GI oncology helped Grothey’s case in obtaining a Tennessee license.

One of the letters of recommendation came from Grothey’s current boss, Lee S. Schwartzberg, the research institute medical director of West Cancer Center, and chief medical officer of OneOncology.

Writes Schwartzberg:

It is my distinct honor to recommend Dr. Axel Grothey for medical licensure in the State of Tennessee. I have known Dr. Grothey for fifteen years and have observed his care of patients. He is an outstanding physician with a strong sense of integrity, remarkable intellect, and a caring compassionate nature. I recommend him for licensure with the highest possible enthusiasm.

Another letter of recommendation was submitted by Tanios S. Bekaii-Saab, a colleague of Grothey’s from Mayo Clinic Scottsdale:

It is my pleasure to recommend Dr. Axel Grothey for medical licensure in the State of Tennessee. I have known Dr. Grothey for about 10

years, including as a Mayo Clinic colleague for the last two. Dr. Grothey has a great reputation amongst his patients and referring physicians as a highly competent, compassionate and caring physician. Dr. Grothey is one of the leading physicians and researchers.

Grothey received a full, unrestricted Tennessee license on March 19, 2019. The findings of fact supporting his licensure include the following:

Petitioner was a full professor at Mayo Clinic for eleven years and participated in training fellows. He acted as a mentor for numerous oncology fellows, and he was honored with a teacher of the year award at the Mayo Clinic on seven occasions.

## Mentorship reassessed

Meanwhile, the investigation in Minnesota continued.

On March 14, 2020, the Minnesota board published a more informative account of Grothey’s conduct at Mayo:

Respondent was a mentor to Colleague #1 while Colleague #1 was a fellow at the hospital. In the second year of Colleague #1’s fellowship, the relationship between Respondent and Colleague #1 became sexual.

Respondent was a mentor to Colleague #2 when they began a sexual relationship. Colleague #2 ended the relationship and asked Respondent to cease contact. Respondent continued and sent a gift to Colleague #2’s home.

The employer conducted an internal investigation which found Respondent’s “pattern of conduct demonstrated a failure on his part to establish and maintain appropriate

professional boundaries with people who viewed him as a mentor.”

The employer concluded that Respondent violated multiple policies and impacted the employment of the colleagues. Respondent resigned his employment after an employment committee recommended that he be terminated.

On June 10, 2019, Respondent met with the [Minnesota Board of Medical Practice] Committee to discuss his conduct. Respondent acknowledged that his sexual relationship with Colleague #1 was a “mistake” and that he enhanced Colleague #1’s career through the work they did together.

Respondent acknowledged having a sexual relationship with Colleague #2 and that he had sexual relationships with other coworkers.

Respondent stated that he is serving as a mentor in his current employment.

Before cutting off his conversation with a reporter, Grothey confirmed this account of his departure from Mayo.

“I had a—let me close the door—I had a relationship with a fellow, whom I mentored, and that was inappropriate,” Grothey said to *The Cancer Letter*. “I mean, there was an investigation, and they said it was inappropriate behavior, and they threatened me with termination, and that’s why I left.”

When asked whether he had ever been in a sexual relationship with someone he mentored, Grothey said, “Yes. That was the idea behind that.”

Asked whether he had been in a sexual relationship with someone who reported to him, Grothey said, “I think I need to stop the interview right now, because, I mean, this is way beyond what

I’m willing to talk about right now, without any lawyer.”

*The Cancer Letter* didn’t have an opportunity to ask why Grothey had—on three separate questionnaires—responded “NO” to questions, when, based on official documents and his own admission, the correct answer should have been “YES.”

In Minnesota, Grothey was reprimanded for “engaging in unethical or improper conduct,” fined \$10,316.90, and ordered to take a “pre-approved course on professional boundaries, and professional ethics.”

From May 12 to May 15, 2020, he took a three-day professional development course, “Maintaining Proper Boundaries,” over Zoom. The course is offered by the Center of Professional Health at Vanderbilt University Center.

“The course is designed to help clinicians who have had problems associated with maintaining proper sexual boundaries develop appropriate behaviors,” the course description states. “After participating in the Maintaining Proper Boundaries course, clinicians should be able to describe and discuss techniques for assessing personal potential for sexual boundary violations, strategies for recognizing the potential for sexual boundary violations in professional settings and approaches to avoiding sexual boundary violations.”

After Minnesota’s action, Grothey was also fined no more than \$2,000 by Tennessee. Arizona also issued a reprimand, but didn’t impose a monetary fine.

Public Citizen’s Health Research Group founder Wolfe says fines and reprimands of this magnitude are trivial.

“In terms of looking at medical boards, reprimands and fines are a slap on the wrist,” Wolfe said. “If you look at the kinds of things that result in reprimands

for many doctors, they’re the kinds of things that should cause them to lose their license.”

## “It’s not that we can do anything about it”

After the Minnesota reprimand, Grothey was required to notify Tennessee and Arizona about the ruling.

“In the event Respondent resides or practices outside the State of Minnesota, Respondent shall promptly notify the Board in writing of the location of his residence and all work sites,” the Minnesota stipulation and order states.

On April 8, 2020, nearly a month after the Minnesota reprimand, Grothey notified the Tennessee Board of Medical Examiners about the Minnesota ruling. Grothey updated his mandatory practitioner profile questionnaire:

Description of Violation: Romantic relationship with physician colleague who was undergoing a Fellowship.

Description of Disciplinary Action: License reprimanded with terms; assessed costs.

The Tennessee board reprimanded Grothey on July 29, 2020, for “unprofessional, dishonorable or unethical conduct,” and “disciplinary action against a person licensed to practice medicine by another state or territory of the United States for any acts or omissions that would constitute grounds for discipline of a person licensed in this state.”

The Tennessee board members asked why they had not looked closer at Grothey’s application when they reviewed his petition for declaratory order.

“I just want to point out that this was somebody who came before us and was granted a license under a declaratory

order, so they were looked at a lot closer. And not that we could have known," board member Deborah Christiansen, a physician at East Tennessee Children's Hospital, said at the meeting. "But obviously some of this was going on when we were looking at people's accolades to grant this gentleman a license.

"It's not that we can do anything about it, but it does bring to mind that when we grant a license we need to continue to scrutinize and look at that sort of thing," she said.

Several Tennessee board members asked whether Grothey should be required to undergo additional evaluation.

"Essentially, we are, in essence, mirroring [Minnesota's] discipline," Angela Lawrence, executive director of the Tennessee board, said during the meeting. "Obviously, the civil penalties are not as high, and he's already taken the professional boundaries course, so that's why I'm not requiring him to do that again."

In light of these sexual misconduct allegations, Grothey's continued role in leadership positions is concerning, said board member Stephen Lloyd, chief medical officer of Cedar Recovery, an addiction treatment company headquartered in Tennessee.

"These are really tough, when you get into these sexual boundaries cases, particularly where you have somebody in a superior position. We don't have to look far in society to see that," Lloyd said during the meeting.

"I'm extremely fine with us mirroring what Minnesota has done—but it doesn't look like they followed all the way through, and got an evaluation of our doc here for any kind of sexual issues," Lloyd said. "I would really challenge anybody that brought up, 'Well we can't do it because Minnesota didn't do it,' I certainly wouldn't want to be a

reciprocal state that took that attitude toward somebody that had, maybe, something we see on a national scale."

The subject of the three questionnaires was not brought up at the July 2020 meeting of the Tennessee licensure board. A video of the meeting is posted [here](#).

The Minnesota board granted Grothey an unconditional medical license on Sept. 12, 2020. He fulfilled the requirements of the Tennessee reprimand as of Sept. 14, 2020.

Arizona mirrored Minnesota's reprimand Dec. 4, 2020. James M. Gillard, an emergency physician and vice-chair of the Arizona Medical Board, questioned whether Grothey should be disciplined in the state, according to minutes of board discussions:

Vice-Chairman Gillard observed that this matter stemmed from action taken by the state of Minnesota against the licensee. He noted that other matters that resulted in the issuance of an Advisory Letter, that there was no patient care involved, and he questioned whether this matter warranted disciplinary action.

Others Arizona board members disagreed:

Dr. [Lois E.] Krahn stated her concerns regarding the physician's mentoring relationship with his colleagues with whom he was found to be involved, and she stated this could potentially affect the healthcare team.

Dr. [David C.] Beyer stated that the underlying issues raised in this Minnesota Board's case involving the physician's relationships with his mentees is serious and that he found disciplinary action was warranted in this matter.

Grothey now has unrestricted licenses in all three states.

## Grothey co-chairs NCTN's GI Steering Committee

Two women from Mayo reported Grothey's behavior to NCI and NIH, documents obtained by *The Cancer Letter* show.

They contacted NCI and NIH because—until Sharpless fired him on May 27, 2021—Grothey was a co-chair of the National Clinical Trials Network GI Steering Committee, a group that makes recommendations that can make (or break) careers of clinical researchers.

The women were concerned: What does Grothey's position to wield power on a federal level mean for them and others?

*The Cancer Letter* has obtained two letters—one sent to NCI April 3, 2019, the other to the NIH [Office of Grants and Funding](#) on May 6, 2019. The letters are edited to remove identifying details.

In the letter to NCI, one of the women said:

First of all, I am writing to you from a personal email as I have faced prior institutional retaliation for reporting harassment internally [...] and I don't want to assume any more career risks, so please keep my identity confidential for now.

My purpose for contacting you is that you were suggested to me as perhaps the best person to go with a concern shared by myself and several other women, on whose behalf I am writing.

On a high level, we were victims of ongoing harassment and assault and career retaliation by an individual who holds multiple leadership roles associated with NCI, including



currently chairing an NCI steering committee [...]

Even though our own experiences were reported to our institution at the time [...] which ultimately resulted in his dismissal from that institution, we are aware that he continues to hold these NCI-affiliated titles [...]

We are collectively frustrated that (1) his former institution did nothing to prevent or respond to our individual incidences of harassment for many years until we faced the institution head-on as a group and gave them no choice, and (2) despite his termination, he still holds esteemed positions in NCI and continues to slander his victims in the scientific community, including attempting to undermine their career advancement.

I'm aware of NIH's longtime and recently renewed verbal commitment to address sexual harassment and assault, but I'm not sure what the "right" process is to bring such information to NIH/NCI's attention in a formal way, and what safeguards are in place for our protection if we do so.

We have more than enough evidence and at least two of us are likely willing to talk, if it will result in some action that will prevent this from continuing, and if our protection could be assured.

If you are not the right person, could you please guide us (me, for now) to the right person or office?

An email response from a senior NCI official follows:

NIH does have a commitment to address sexual harassment in science and has recently updated its activities and efforts in this area. There is a general

update about these efforts in a letter from Dr. Collins, dated Feb. 28, 2019, that is posted on the NIH website the following URL:

<https://www.nih.gov/about-nih/who-we-are/nih-director/statements/update-nih-efforts-address-sexual-harassment-science>.

There is a confidential avenue through which any concerns that sexual harassment is affecting NIH-funded research can be communicated to NIH and or the HHS Office for Civil Rights. The information on how to use this confidential channel of communication is described in Dr. Collins's letter on NIH's website, but I have also copied that section from his letter below with the associated email link.

The letter refers to individuals who are principal investigators or other key personnel named on an NIH grant award, however, I think this avenue would be the best place for you to bring your concerns.

The NCI Steering Committees are not NIH grant awards; however, I believe the Chairs of the NCI Steering Committees do receive professional services compensation via a contract (the Steering Committees are administered by a different center at NCI from the branch/division in which I work), and the Steering Committees are involved in the evaluation of NIH/NCI-funded research, so this would seem to me the most appropriate communication channel for you to contact—at least to start the process.

There may be additional information on the NIH Anti-Sexual Harassment website that may be of help to you as well at: <https://www.nih.gov/anti-sexual-harassment>.

“

It should be called sexual abuse if it's a mentor-mentee relationship. It's even worse for the mentees, because they have a clear tradeoff they believe they're making if they complain, because by the time it gets taken care of, so to speak—they may have lost their chance to get into a residency, or if they are a resident, trying to get a fellowship, they've lost it.

”

—Sidney Wolfe



Power can make an individual feel uninhibited, and thus more likely to engage in some sort of inappropriate behavior, and then lead to sort of coercive relationships, in which the individual feels that they can't report, or they don't want to report.



—Shea Holman

I know NIH is working on creating additional ways for confidential sharing of information, as Dr. Collins's letter states, and hopefully these new channels of communication will be available soon.

I hope this information helps you bring your and others' concerns to the appropriate staff at NCI in the confidential manner that you need and I will certainly keep your identity confidential as you requested.

The complainant shared this correspondence with several colleagues. Subsequently, another woman sent a letter to the "grantee harassment" email address operated by the NIH Office of Extramural Research.

I'm writing this email to report a concern about an individual who maintains a position of leadership within the NIH. I was advised that this would be the most appropriate mechanism to report this concern.

My concern is regarding Dr. Axel Grothey who currently serves as the co-chair for the Gastrointestinal Steering Committee within the National Cancer Institute.

I was among multiple individuals who were victims of sexual harassment from Dr. Grothey while he was employed at my institution. This began when I was a trainee and continued for over a decade. As a result of his harassment, I lost mentorship, career advancement opportunities, and I faced a hostile work environment on a daily basis.

During the years in which the harassment occurred, I was too embarrassed, ashamed, and frightened to come forward to my employer. I feared more consequences that would further limit my career pos-

sibilities, since Dr. Grothey is a very influential figure in the field of GI oncology.

However, not coming forward is also my greatest regret. He went on to sexually harass more individuals, some of whom are supporting me in writing this letter and who may wish to share their own experiences with you at the appropriate time. Although I often feared for myself and at times still do, I wish I could have come forward sooner as this may have prevented others from being harmed by Dr. Grothey and going through similar experiences.

In early 2018, some of these individuals also came forward during an investigation that was conducted at my institution, which ultimately led to his resignation. The Minnesota Board of Medical Practice has also conducted their own investigation on this matter and the case is currently under review.

I am writing now with the intention of preventing other people from becoming victims of sexual harassment by Dr. Grothey. Given his long-time pattern of behavior to sexual harassment, I am very concerned that as long as Dr. Grothey remains in a position of leadership, the opportunity to harass another individual could easily happen again.

I ask that my confidentiality be respected as Dr. Grothey has retaliated against a victim of his harassment in the past, which unfortunately led to very negative consequences for that individual. I would be willing to speak with anyone from your institution on this matter.

NIH wasn't exactly helpful—the Office of Extramural Research sent an auto-

mated response and never followed up, the woman said.

Thank you for your correspondence in which you raise concerns about sexual harassment at your institution impacting NIH-funded research. NIH takes these concerns very seriously and plans to respond to this concern within the next 10-15 business days.

In the meantime, please note that NIH strongly encourages individuals to report allegations of sexual harassment or assault to the appropriate authorities, which may include your local police department or your organization/institution equal employment opportunity (EEO) or human resources offices. Individuals may contact the HHS Office for Civil Rights (OCR, <https://www.hhs.gov/ocr/index.html>) to obtain additional information and to file a complaint.

The NIH Director, Dr. Francis Collins, along with all of us at NIH are committed to addressing and eradicating sexual harassment in NIH-funded research. Please find additional information and resources on our Anti-Sexual Harassment webpage at <https://grants.nih.gov/grants/policy/harassment.htm>.

We appreciate that you have brought these important issues to our attention.

Sincerely yours,

NIH Office of Extramural Research

On a webpage, NIH cautions that it “cannot take personnel or legal actions for non-NIH employees.” NIH also does not guarantee confidentiality for those who report someone.

The page, “What to expect when notifying NIH,” explains how NIH follows up on complaints:

- NIH will follow up with the relevant applicant/grantee institution to request information such as:
  - ▶ Timeline to investigate details of the complaint to ensure no affect on NIH funded work,
  - ▶ Restrictions on persons designated on an award (such as access to the institutional facilities) and how these may affect the supported research
  - ▶ Steps taken to assure that NIH-funded work is being conducted in a safe and harassment free environment,
- OER will expect awardee institutions to provide a written response within 30 days of being notified.
- OER will continue to work closely with the grantee institution to ensure they maintain a safe and harassment free work environment conducive of high-quality research.
- NIH only shares information on a “need-to-know basis and will not share details of ongoing reviews.”
- Confidentiality cannot be guaranteed.

Karyn Goodman, the remaining co-chair of the GI Steering Committee following Grothey’s termination, said the hierarchical structure of medicine is harmful.

Goodman, who has no direct knowledge of the Grothey case, spoke with *The Cancer Letter* before he was removed from the steering committee.

“Academic medicine is, by design, a hierarchy. Since we have historically had more men in senior positions, it creates an inherent power differential that has put women in junior ranks at a disadvantage,” said Goodman, professor and vice chair for research and quality in the Department of Radiation Oncology at the Icahn School of Medicine at Mount Sinai, and associate director for clinical research at The Tisch Cancer Institute.

“I have seen this play out in so many ways in terms of gender discrimination and sexual harassment, and because the top level of decision-makers are also men, they are often willing to overlook the misbehavior when it is reported,” she said.

The GI Steering Committee is responsible for making junior faculty feel safe, she said.

“As leaders in academic medicine, we need to promote a safe environment for our junior faculty and hold people accountable for their transgressions,” Goodman said.

“The NCI, in particular, should be the paragon of virtue when it comes to equity issues and set the standard high for the rest of academic medicine to follow.”

# Congressionally Directed Medical Research Programs



## Melanoma Research Program Academy



## An Opportunity for Leadership

The Melanoma Research Program (MRP) is introducing a new opportunity to tackle melanomagenesis early in the disease progression while establishing a network for early-career investigators (Scholars) to interact with established leaders in the field. Through the Melanoma Academy Leadership Award and the Melanoma Academy Scholar Award, the MRP hopes to influence the next generation of melanoma researchers by catalyzing the growth and professional development of the Scholars through the interactive collaborative network of the Melanoma Academy (MA).

Partnering together, the Director and Deputy Director of the Melanoma Academy Leadership Award will lead Scholars along with their Career Guides toward a new vision of melanoma research. By integrating the Scholars, their Career Guides, and patient advocates into one community, the MA provides a potential for novel brainstorming approaches to melanoma and supportive collaborations for Scholars.

The opportunity of leadership cannot be overstated. The Director and Deputy Director positions offer the candidates exposure in the melanoma field, establishment of leadership in melanoma, and strong influence in the future, training, and research of the Scholars. The Academy Director and Deputy Director will catalyze the research and professional development of the Scholars in collaboration with their Career Guides, assess the progress of the Scholars, and facilitate communication and collaboration amongst all Academy members. The MA offers an extraordinary opportunity for the Director and Deputy Director to set their vision of the future of melanoma research.

***Investigators interested in applying to lead the future of melanoma research should apply to the FY21 Melanoma Academy Leadership Award program announcement (W81XWH-21-MRP-MALA).***

***Early-career independent investigators interested in applying to become a Scholar of the MA should refer to the FY21 MRP Melanoma Academy Scholar Award program announcement (W81XWH-21-MRP-MASA).***

***All investigators who are interested in applying to the Melanoma Research Program should refer to FY21 MRP Funding Opportunities: <https://cdmrp.army.mil/funding/mrp>.***

**<https://cdmrp.army.mil/mrp/default>**



# Bidens call for \$6.5B in ARPA-H funding during National Cancer Research Month

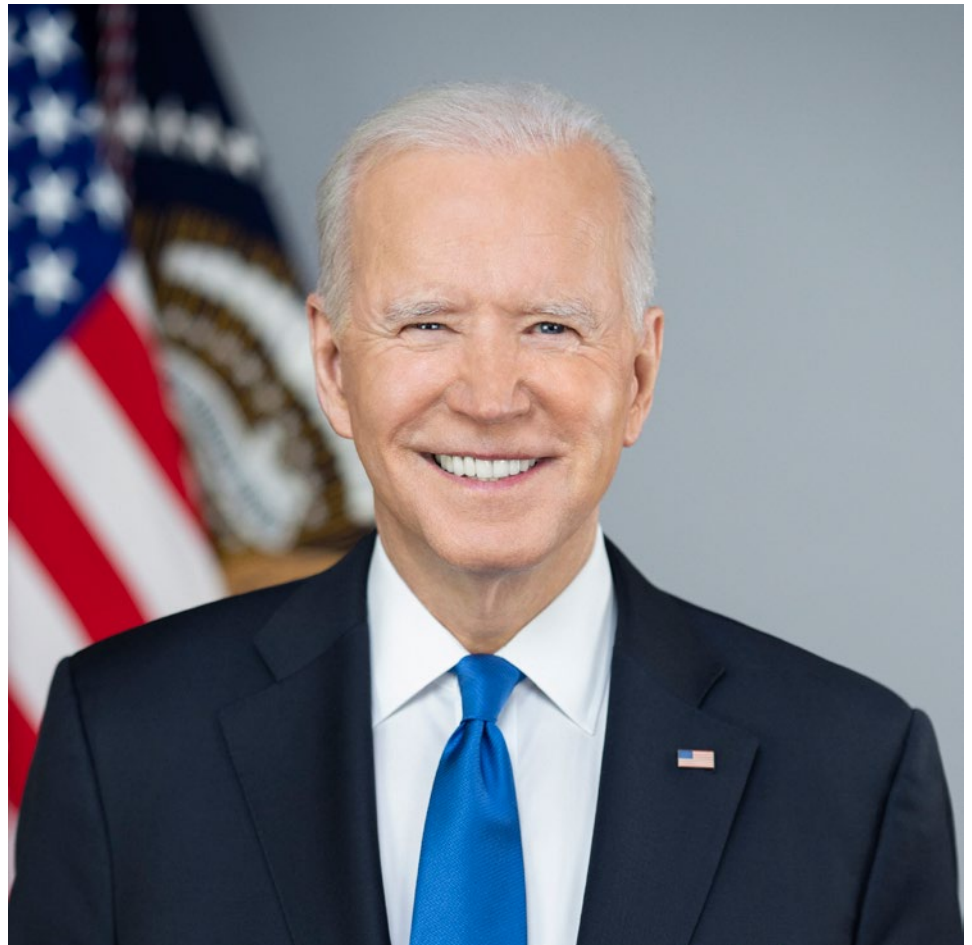
By Matthew Bin Han Ong and Alexandria Carolan

In an expression of support for increasing funding for cancer research and prevention, the Bidens earlier this week endorsed the National Cancer Research Month.

Thirteen years ago, the American Association for Cancer Research asked Congress to declare May the National Cancer Research Month. This declaration has made through congressional resolutions in 2007, 2011, and 2014, and efforts are underway to renew the resolution this year.

In a May 25 letter to AACR, President Joe Biden and first lady Jill Biden reiterate the White House's request to Congress to fund the \$6.5 billion Advanced Research Projects Agency for Health at the NIH (*The Cancer Letter*, [April 30](#), 2021).

"My Administration continues to push for groundbreaking discoveries and innovative treatments to make cancer a thing of the past," Biden wrote. "That is why I am asking Congress to fund the Advanced Research Projects Agency for Health at the National Institutes of Health, which would invest billions of dollars for one singular purpose: to develop breakthroughs that prevent, detect, and treat cancer and other deadly diseases."



Biden's full budget proposal for FY2022, expected May 28, has not been released at this writing (*The Cancer Letter*, April 9, 2021).

The statements from AACR, ASCO, AACI, and NCCS follow:



**Jon Retzlaff, MBA, MPA**  
*Chief policy officer,  
Vice president of science policy  
and government affairs,  
American Association for  
Cancer Research*

Each year, the AACR leads an effort to engage with policymakers, researchers, physician-scientists, patients, survivors, and other advocates to highlight the vital importance of funding for cancer research, especially at the NIH and NCI, through an initiative to celebrate May as National Cancer Research Month. The bipartisan support this effort receives is a testament to our nation's recognition that cancer research is saving more and more lives every day.

This year, we especially appreciate the leadership of Senators Dianne Feinstein (D-CA) and Shelley Moore Capito (R-WV) for introducing Senate Resolution 253, a resolution supporting the designation of May 2021 as National Cancer Research Month.

Their support helps to raise public awareness about today's exciting progress against cancer and the enormous promise for preventing and curing more cancers in the future because of cancer research.

In addition, we are also deeply grateful to President Biden for his strong letter of support in recognizing the importance of National Cancer Research Month, as well as for his extraordinary and ongoing commitment to ending cancer as we know it."



**Julie R. Gralow, MD, FACP, FASCO**  
*Chief medical officer,  
American Society of Clinical Oncology*

We continue to be encouraged by President Biden's deep commitment to end cancer as we know it. We've made incredible progress in the 50 years since the National Cancer Act of 1971 was signed into law, and in the past 30 years alone, the cancer death rate has fallen 31%. However, there is much more work to do. Even during a global pandemic, cancer remains the second most common cause of death in the United States. We are fortunate to be

living in a time when cancer research is flourishing – a time when our community does not lack for ideas or interest in conquering cancer. Unfortunately, funding for the National Cancer Institute (NCI) has not kept up with research opportunities and the potential for far greater progress. During this National Cancer Research Month, we are calling for a robust increase in funding for the NCI so that we can continue to provide hope for the millions of Americans personally impacted by cancer.



**Jennifer W. Pegher, MA**  
*Executive director,  
Association of American  
Cancer Institutes*

President Biden's recognition of May as National Cancer Research Month presents a unique opportunity for AACI and its 102 cancer center members to increase awareness of cancer research's central role in advancing progress for patients with cancer, across North America and around the world.

We continue to work with our champions in Congress, the president and his administration in extending our contributions to the federal government's accelerated effort to eradicate cancer.



**Shelley Fuld Nasso, MPP**  
CEO,  
*National Coalition for  
Cancer Survivorship*

I am pleased that President Joe Biden and First Lady Jill Biden have sent their best wishes regarding National Cancer Research Month. Of greater importance to the National Coalition for Cancer Survivorship (NCCS) is the unwavering commitment of the President and First Lady—every day, week, and month—to ‘ending this disease as we know it.’

By fighting for more resources for cancer research, identifying research priorities and promising research opportunities, and proposing innovations like the Advanced Research Projects Authority for Health, President Biden is identifying ways to accelerate progress in cancer research and to bring us a cure.

We at NCCS want the cancer research effort to focus on finding less toxic treatments and developing treatments that provide cancer survivors not only longer life but a high-quality life. We hope to ensure that the cancer survivorship experience is one of good life and good health and not one of dealing with late and long-term effects of cancer and cancer treatment.

We urge Congress to work with President Biden to generously fund cancer research and support innovations in cancer research. NCCS stands with the President in these efforts.”

**The full text of the Bidens’ letter follows:**

Jill and I send our best wishes to all those participating in National Cancer Research Month at the American Association for Cancer Research. Like so many others, cancer is deeply personal for our family. As President, I am committed to ending this disease as we know it. Organizations like AACR are crucial partners in the fight to end cancer. We are on the cusp of breakthroughs that will save lives, and we must continue our efforts to support the research needed to find a cure.

Despite the incredible advancements we have made in recent years, cancer remains the second leading cause of death in the United States. Behind this statistic are millions of Americans who know the distress of receiving a cancer diagnosis and millions more who watch family members or friends courageously fight this disease—but too often succumb to it. Cancer is brutal and cruel. It inflicts an incalculable human toll on patients and their loved ones—a toll that strikes communities of color at disproportionately high rates.

My Administration continues to push for groundbreaking discoveries and innovative treatments to make cancer a thing of the past. That is why I am asking Congress to fund the Advanced Research Projects Agency for Health at the National Institutes of Health, which would invest billions of dollars for one singular purpose: to develop

breakthroughs that prevent, detect, and treat cancer and other deadly diseases. The hard work and dedication of organizations like AACR are crucial to making this vision into a reality.

While we have made incredible progress against this indiscriminate disease, we must also reaffirm our national commitment to preventing cancer, improving treatments and the delivery of care, and finding a cure. This includes efforts to advance research, increase prevention, promote early detection, enhance treatment, and support the needs of cancer survivors and caregivers.

It is within our power to end cancer as we know it. The mission of AACR to prevent and cure cancer serves as a beacon of hope for thousands of patients, families, and survivors. Thank you for your continued commitment and life-changing work.



**While we have made incredible progress against this indiscriminate disease, we must also reaffirm our national commitment to preventing cancer, improving treatments and the delivery of care, and finding a cure.**



—President Joe Biden

## IN BRIEF



## Five cancer researchers receive 2021 New Discoveries Young Investigator Awards from BCAN

Five researchers have received the 2021 New Discoveries Young Investigator Awards from the Bladder Cancer Advocacy Network.

This is the first year BCAN has presented five awards.

- The 2021 New Discoveries Young Investigator Awards went to Brendan Guercio, a Hematology/Oncology fellow at Memorial Sloan Kettering Cancer Center, and Eugene Pietzak, assistant attending surgeon (urologic oncology) at Memorial Sloan Kettering Cancer Center. Guercio's project title is "Associations of Patient Diet and Benefit from Immunotherapy in Urothelial Carcinoma" and Pietzak's is titled "Defining the Clinical Impact and Molecular Drivers of 'Secondary' Muscle-Invasive Bladder Cancer."

Each Young Investigator Award provides a \$50,000 grant that supports one year of early career bladder cancer research. Since 2009, BCAN has awarded more than \$5.5 million to promising scientists and research investigators across the country and these awards demonstrate that the important work to improve the understanding of bladder cancer and its impact on patients and families continues.

- The two 2021 Palm Beach New Discoveries Young Investigator awardees are Filipe De Carvalho, urologic oncology fellow at Brigham and Women's Hospital, and Benjamin Miron, medical oncology fellow at Fox Chase Cancer Center. The title of Carvalho's awarded project is "Clonal Architecture and Tumor Microenvironment of Cisplatin Resistant Localized Muscle Invasive Bladder Cancer" and Miron's is "Relationship of Circulating Tumor DNA in Patients with Muscle Invasive Bladder Cancer to Pathologic Staging and Disease Prognosis."
- The 2021 New Discoveries Young Investigator Award for Patient Centered Research was awarded to Svetlana Avulova, urologic oncology fellow at Mayo Clinic. Avulova's project is titled "Sexual Function in Women Undergoing Radical Cystectomy."

## Roswell Park establishes Neurofibromatosis Clinic

Roswell Park Comprehensive Cancer Center has launched a dedicated neurofibromatosis care program.

While common among genetic conditions, neurofibromatosis is still relatively rare. It affects the nervous system as tumors that can manifest anywhere in the

body. Most NF tumors are noncancerous but can cause issues like pain, scoliosis, vision and hearing loss and skin growths.

Some nerve tumors, however, can become malignant, including those found along the spine, which can develop into a type of sarcoma known as malignant peripheral nerve sheath tumors. NF also puts individuals at an elevated risk for other types of cancers, including breast and gastrointestinal stromal tumors.

The Neurofibromatosis Clinic provides a multidisciplinary, coordinated approach to patient care, uniting the skill and expertise of providers in many different areas:

- Experienced diagnostic radiologists to provide prompt, accurate diagnosis,
- Comprehensive clinical care from medical oncologists, surgical oncologists, neurosurgeons and neuro-oncologists,
- Clinical geneticists to confirm diagnosis, plan treatment and guide testing of other family members,
- Plastic and reconstructive surgeons to offer options for tumor removal and improved appearance,
- Supportive care from specialists in pain management, social work and young adult health,
- Cancer screening and surveillance for ongoing monitoring; and
- The clinic is one of the few centers in the U.S. to provide coordinated, comprehensive care for adults with NF. Because the condition is inherited, Roswell Park offers Clinical Genetics counseling and testing, often extending services to family members in what's known as cascade genetic testing.

"Studies have shown that there is a benefit to neurofibromatosis patients who



receive care through a specialty clinic like the one we've established at Roswell Park," Lindsay Lipinski, a neurosurgeon at Roswell Park, said in a statement.

## FUNDING OPPORTUNITIES



## DoD Rare Cancers Research Program funding opportunities for FY21

The FY21 RCRP program announcements and General Application Instructions for the FY21 Department of Defense Rare Cancers Research Program to support research of exceptional scientific merit in the area of rare cancers research the following award mechanisms are posted on the Grants.gov website.

More information can be found [here](#).

A pre-application is required and must be submitted through the electronic Biomedical Research Application Portal (eBRAP) at <https://eBRAP.org> prior to the pre-application deadline. All applications must conform to the final program announcements and General Application Instructions available for electronic downloading from the Grants.gov website.

The application package containing the required forms for each award mechanism will also be found on Grants.gov. A listing of all CDMRP and other USAM-RDC extramural funding opportunities can be obtained on the Grants.gov website by performing a basic search using CFDA Number 12.420.

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# THE CLINICAL CANCER LETTER

## CLINICAL ROUNDUP



## ACCC report: COVID-19 took a heavy toll on cancer care staff and providers

COVID-19 took a heavy toll on cancer care staff and providers, a report from the Association of Community Cancer Centers finds.

The findings were released in *Trending Now in Cancer Care 2020*, an [annual report](#) that identifies current and emerging trends in cancer programs across the country.

The detailed report presents findings from focus groups that illuminate the short- and long-term impact of COVID-19 on cancer care programs and professionals.

Major findings of *Trending Now in Cancer Care 2020* are:

- COVID-19 took a heavy toll on cancer care staff and providers.

Many contracted COVID-19 or experienced financial hardship due to furloughs and layoffs. Those working reported burnout, exhaustion, fatigue, and stress. Physical distancing contributed to social and emotional isolation for cancer care staff and patients; providing support for staff became a full-time occupation for many managers and leaders.

- Cancer screening dropped sharply and has yet to resume pre-pandemic levels. During the height of the pandemic, screening sites closed, and primary care providers did not offer screening appointments. Patients canceled regular exams and avoided the ER, reducing the potential for incidental findings of cancer. Many providers believe that the dramatic reductions in screening and preventive appointments may lead to cancers being diagnosed at later stages. ACCC focus group participants shared that tumor registries will likely record more advanced cancers in 2021 and even beyond.
- The U.S. healthcare system took a financial hit. Some health systems stopped outpatient or scheduled appointments and suspended entire service lines. Reductions in overall patient volume and elective procedures adversely impacted revenue. Because cancer patients in active treatment kept their clinic visits, oncology programs often shored up health system revenue.
- Cancer programs adopted telehealth virtually overnight. In spring 2020, virtual visits accounted for

about 40% of patient volume, increasing to almost 50% during the fall. While telehealth has shown the potential to improve access to those in rural areas, a very real digital divide meant that telehealth did not benefit all patients equally. Many patients in rural or impoverished areas lacked cell phone minutes, cell phone service, connectivity, and privacy.

- The pandemic stimulated a nationwide discussion to address health inequities. COVID-19 exacerbated existing disparities in oncology along socioeconomic, racial and ethnic, age, gender, and geography divides. Cancer programs responded by scheduling flexible clinic and treatment hours for working patients; increasing transportation support for treatment visits; addressing food insecurity and childcare needs; and partnering with community organizations to reach at-risk individuals. ACCC also reported that new-found flexibilities in clinical research during the pandemic may have long-term potential to reshape the design and conduct of clinical trials and address health inequities.

Since 2009, ACCC has fielded an annual *Trending Now in Cancer Care* survey. This year, due to demands on the healthcare team during the pandemic, ACCC chose instead to conduct focus groups to better capture the lived experiences of the most urgent issues impacting oncology practice and care delivery.

Topics discussed included staffing and operational integrity, service line delivery and revenue optimization, telehealth and supportive technology,

clinical research, and health equity. Participants were candid in how the global pandemic tested operational, professional, and personal resilience and transformed clinical and personal communication.

## UVA develops tools to advance genomics, cancer research

University of Virginia School of Medicine scientists have developed resources to advance genomics and cancer research.

UVA's Chongzhi Zang and his colleagues and students have developed a computational method to map the folding patterns of our chromosomes in three dimensions from experimental data.

Using their new approaches, Zang and his colleagues and students have discovered useful data, and they are making their techniques and findings available to their fellow scientists. To advance cancer research, they built an interactive website that brings together their findings with data from other resources.

The website is [bartcancer.org](http://bartcancer.org).

"The folding pattern of the genome is highly dynamic; it changes frequently and differs from cell to cell. Our new method aims to link this dynamic pattern to the control of gene activities," Zang, a computational biologist with UVA's Center for Public Health Genomics and UVA Cancer Center, said in a statement. "A better understanding of this link can help unravel the genetic cause of cancer and other diseases and can guide future drug development for precision medicine."

Zang's new approach to mapping the folding of our genome is called BART3D. Essentially, it compares available three-dimensional configuration data

about one region of a chromosome with many of its neighbors.

It can then extrapolate from this comparison to fill in blanks in the blueprints of genetic material using "Binding Analysis for Regulation of Transcription", or BART, a novel algorithm they recently developed. The result is a map that offers unprecedented insights into how our genes interact with the "transcriptional regulators" that control their activity. Identifying these regulators helps scientists understand what turns particular genes on and off.

The researchers have built a web server, BARTweb, to offer the BART tool to their fellow scientists. It's available, for free, at <http://bartweb.org>. The source code is available at <https://github.com/zanglab/bart2>.

Test runs demonstrated that the server outperformed several existing tools for identifying the transcriptional regulators that control particular sets of genes, the researchers report.

The UVA team also built the BART Cancer database to advance research into 15 different types of cancer, including breast, lung, colorectal and prostate cancer. Scientists can search the interactive database to see which regulators are more active and which are less active in each cancer.

"While a cancer researcher can browse our database to screen potential drug targets, any biomedical scientist can use our web server to analyze their own genetic data," Zang said. "We hope that the tools and resources we develop can benefit the whole biomedical research community by accelerating scientific discoveries and future therapeutic development."

The researchers have published their findings in a trio of new scientific papers: They describe BART3D in *Bioinformatics* in an article by Zhenjia Wang,

Yifan Zhang and Chongzhi Zang; they describe BARTweb in *NAR Genomics and Bioinformatics* in an article by Wenjing Ma, Zhenjia Wang, Yifan Zhang, Neal E. Magee, Yayi Feng, Ruoyao Shi, Yang Chen and Chongzhi Zang; and they describe BART Cancer in *NAR Cancer* in a paper by Zachary V. Thomas, Zhenjia Wang and Chongzhi Zang.

Chongzhi Zang is a member of the School of Medicine's Department of Public Health Sciences and Department of Biochemistry and Molecular Genetics. He is also part of UVA's Department of Biomedical Engineering, a collaboration of the School of Medicine and the School of Engineering.

## DRUGS & TARGETS



## Rybrevant receives FDA approval as first targeted therapy for subset of NSCLC

FDA has approved Rybrevant (amivantamab-vmjw) as the first treatment for adult patients with non-small cell lung cancer whose tumors have specific types of genetic mutations: epidermal growth factor receptor (EGFR) exon 20 insertion mutations.

Rybrevant is sponsored by Janssen Pharmaceutical Companies of Johnson & Johnson.

The FDA also approved the Guardant360 CDx (Guardant Health Inc.) as a companion diagnostic for Rybrevant today.

“Advances in precision oncology continue to facilitate drug development, allowing diseases like lung cancer to be subset into biomarker-defined populations appropriate for targeted therapies,” Julia Beaver, chief of medical oncology in the FDA’s Oncology Center of Excellence and acting deputy director of the Office of Oncologic Diseases in the FDA’s Center for Drug Evaluation and Research, said in a statement. “With today’s approval, for the first time, patients with non-small cell lung cancer with EGFR exon 20 insertion mutations will have a targeted treatment option.”

Approximately 2% to 3% of patients with non-small cell lung cancer will have EGFR exon 20 insertion mutations, which are a group of mutations on a protein that causes rapid cell growth, and consequently, helps cancer spread. EGFR exon 20 insertion mutations are the third most common type of EGFR mutation.

Researchers evaluated Rybrevant’s efficacy in a study of 81 patients with non-small cell lung cancer and EGFR exon 20 insertion mutations whose disease had progressed on or after platinum-based chemotherapy.

The main outcome measured was overall response rate (proportion of patients whose tumor is destroyed or reduced by a drug). In the trial population in which all patients received Rybrevant, the overall response rate was 40%. The median duration of response was 11.1 months, with 63% of patients having a duration of response of 6 months or more.

## **Pylarify receives FDA approval as first and only commercially available PSMA PET imaging agent for prostate cancer**

FDA has approved Pylarify, an F 18-labeled prostate-specific membrane antigen targeted positron emission tomography imaging agent to identify suspected metastasis or recurrence of prostate cancer.

Pylarify is sponsored by Lantheus Holdings Inc.

Pylarify is the first and only commercially available approved PSMA PET imaging agent for prostate cancer. The product will be immediately available in parts of the mid-Atlantic and southern regions and availability is expected to rapidly expand over the next six months with broad availability across the U.S. anticipated by year end.

Identification of suspected metastatic disease in men considering initial definitive therapy is important to optimize treatment planning and to avoid futile interventions.

Of men with localized prostate cancer who undergo initial curative intent/management, up to 50% may experience recurrence of their disease within ten years of treatment.

Recurrent disease is often detected by a rise in serum prostate-specific antigen (PSA) levels; however, conventional imaging, especially at low PSA levels, is not able to identify the location and extent of the disease in the majority of cases.

Pylarify was developed to target PSMA, a protein that is overexpressed on the

surface of more than 90% of primary and metastatic prostate cancer cells. Pylarify binds to the target, enabling the reader of the PET scan to detect and locate the disease.

Cyclotron production of F 18 offers high batch capacity and high image resolution, and F 18’s 110-minute half-life allows for wide geographic distribution.

The approval of Pylarify is based on data from two Company-sponsored pivotal studies (OSPNEY and CONDOR) designed to establish the safety and diagnostic performance of PYLARIFY across the prostate cancer disease continuum.

Results from OSPNEY (Cohort A) demonstrated improvement in specificity and positive predictive value (PPV) of Pylarify PET imaging over conventional imaging in men at risk for metastatic prostate cancer prior to initial therapy. CONDOR studied men with biochemical recurrent prostate cancer. In patients with biochemical recurrent prostate cancer and non-informative baseline imaging, Pylarify demonstrated high correct localization and detection rates, including in patients with low PSA values (median PSA 0.8 ng/mL).

In the clinical trials, PYLARIFY was well tolerated. In OSPNEY and CONDOR, 593 patients with various states of prostate cancer were exposed to a single dose of PYLARIFY.

## **Opdivo + Yervoy receives Positive CHMP Opinion for colorectal cancer**

The Committee for Medicinal Products for Human Use of the European Medicines Agency recommended approval of Opdivo (nivolumab) in combination with Yervoy (ipilimumab) for the treat-

ment of adult patients with mismatch repair deficient or microsatellite instability-high metastatic colorectal cancer after prior fluoropyrimidine-based combination chemotherapy.

The opinion was based on data from the phase II CheckMate -142 trial. The European Commission, which is authorized to approve medicines for the European Union, will now review the CHMP recommendation.

Opdivo and Yervoy are sponsored by Bristol Myers Squibb.

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## **Keytruda receives Positive EU CHMP Opinion in combination with chemotherapy as first-line treatment for certain patients with esophageal cancer or HER2- GEJ adenocarcinoma**

The Committee for Medicinal Products for Human Use of the European Medicines Agency as adopted a positive opinion recommending approval of Keytruda in combination with platinum- and fluoropyrimidine-based chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus or human epidermal growth factor receptor 2 (HER2)-negative gastroesophageal junction adenocarcinoma in adults whose tumors express PD-L1 (Combined Positive Score [CPS]  $\geq 10$ ).

The CHMP's recommendation will now be reviewed by the European Commission for marketing authorization in the

European Union, and a final decision is expected in the second quarter of 2021.

Keytruda is sponsored by Merck.

The positive CHMP opinion is based on results from the pivotal phase III KEYNOTE-590 trial, in which Keytruda plus 5-fluorouracil (5-FU) and cisplatin demonstrated significant improvements in overall survival and progression-free survival compared with 5-FU and cisplatin alone in patients regardless of histology or PD-L1 expression status.

Keytruda plus 5-FU and cisplatin reduced the risk of death by 27% (HR=0.73 [95% CI, 0.62-0.86];  $p < 0.0001$ ) and reduced the risk of disease progression or death by 35% (HR=0.65 [95% CI, 0.55-0.76];  $p < 0.0001$ ) versus 5-FU and cisplatin alone.

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## **Venclyxto receives EC approval in combination with a hypomethylating agent for patients with newly diagnosed aml who are ineligible for intensive chemotherapy**

The European Commission has approved Venclyxto (venetoclax) in combination with a hypomethylating agent, azacitidine or decitabine, for the treatment of adult patients with newly diagnosed acute myeloid leukemia who are ineligible for intensive chemotherapy.

The approval is valid in all 27 member states of the EU, as well as Iceland, Liechtenstein, and Norway.

Venclyxto is being developed by AbbVie and Roche. It is jointly commercialized by AbbVie and Genentech, a member of the Roche Group, in the U.S. and by AbbVie outside of the U.S.

This is the third extension of indications for VENClyXTO, a first-in-class B-cell lymphoma-2 (BCL-2) inhibitor. BCL-2 is a protein that prevents cancer cells from undergoing apoptosis, the process that leads to the natural death or self-destruction of cancer cells.<sup>1</sup>

This most recent approval is based on results from the phase III double-blind, placebo-controlled VIALE-A (M15-656) and the phase Ib open-label, nonrandomized, multicenter M14-358 clinical trials.

The VIALE-A trial demonstrated patients who received VENClyXTO in combination with azacitidine showed statistically significantly greater median overall survival (OS) than patients receiving azacitidine alone ( $p < 0.001$ ).

The phase Ib M14-358 trial evaluating venetoclax in combination with hypomethylating agents, azacitidine or decitabine, exhibited an overall safety profile that was generally consistent with the known safety profiles of venetoclax combined with azacitidine and the two medications alone.

In the VIALE-A trial, the most frequently reported serious adverse events in the Venclyxto plus azacitidine arm and placebo plus azacitidine arm were febrile neutropenia, pneumonia, sepsis, and haemorrhage. In the M14-358 trial, the most frequently reported serious AEs in patients receiving Venclyxto in combination with decitabine were febrile neutropenia, pneumonia, bacteraemia and sepsis.

## Quest Diagnostics, Paige collaborate to advance AI-generated pathology insights to improve cancer diagnosis and care

Quest Diagnostics and Paige are collaborating to use artificial intelligence to improve and speed the diagnosis of cancer and other diseases that rely on pathologic assessment.

The collaboration involves analysis using Paige's proprietary machine learning expertise of pathology diagnostic data and digitized slides from Quest Diagnostics and its AmeriPath and Derm-path businesses to uncover markers of cancer and other diseases.

Using these insights, the parties intend to develop new software products which, following regulatory approval, will be marketed to pathologists, oncologists and other providers to support disease diagnosis.

Near term, the parties also intend to license the insights to biopharmaceutical and research organizations to aid biomarker discovery, drug research and development and companion diagnostics.

The collaboration will initially focus on solid tumor cancers, such as prostate, breast, colorectal and lung. The agreement involves shared revenue for achieving certain product and commercial milestones and, assuming regulatory approval, arrangements for Quest to use approved software products in its pathology operations as well as joint marketing and research. In addition, Quest's pathologists will aid in defining pathol-

ogy workflows for using the products to support diagnostic decision-making. Additional terms were not disclosed.

Quest and its specialty pathology businesses bring subspecialty expertise based largely from serving community cancer centers, which provide 80% of cancer care nationally, complementing insights from Paige's academic center expertise.

AI-enabled computational pathology can identify known patterns in tissue that characterize disease as well as identify new markers, including those that are not necessarily detected by the naked eye. Because AI systems improve with exposure to new data, the data from Quest's deep subspecialized expertise is poised to enhance Paige's efforts to discern new insights that may improve cancer diagnosis and patient care.

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