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THE CANCER LETTER
Inside information on cancer research and drug development
Vol. 48 No. 27
JULY 8, 2022
www.cancerletter.com

KAREN KNUDSEN: LESSONS LEARNED WHILE REBUILDING THE AMERICAN CANCER SOCIETY

Karen E. Knudsen has spent the past year bringing the American Cancer Society into the 21st century.

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Karen E. Knudsen, PhD, MBA
Chief executive officer, American Cancer Society, American Cancer Society Cancer Action Network

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CONVERSATION WITH THE CANCER LETTER

> We've gone through what a textbook business school would call true transformation—taking the things that are exceptional about the organization, and aligning them so that we can accelerate even further on our mission to improve the lives of cancer patients and families.

Karen E. Knudsen has spent the past year bringing the American Cancer Society into the 21st century.

Knudsen is the first woman CEO to lead the 109-year-old organization. She is also the first basic scientist and the first director of a cancer center to hold this job. Before moving to ACS, she was the executive vice president of Oncology Services and enterprise director for Sidney Kimmel Cancer Center at Jefferson Health. She continues to serve on the NCI Board of Scientific Advisors.

In a recent interview, Knudsen said she has redesigned the society to follow a four-pillar blueprint.

"We are now organized into those units that we talked about last year: Advocacy, Patient Support, and Discovery," Knudsen said to *The Cancer Letter.* She started the reorganization on Day One of the job (*The Cancer Letter,* Sept. 3, 2021)

"Those units each have a component of the strategic plan that they own, and all of it laying on the foundation of our commitment to health equity. So, every component of our strategic plan, irrespective of the pillar, is aligned to reducing a particular cancer disparity, and our overall goal to enhance cancer equity and health equity," Knudsen said.

The fourth pillar on Knudsen blueprint—Development—is about money.

In an interview, Knudsen refrained from citing actual numbers, but said that fundraising is up. More information will be released in the next few weeks, after the meeting of the audit committee of the board.

Total public support for ACS has been sliding every year since 2007, with an especially steep drop—caused primarily by COVID—occurring in 2019 and 2020.

"We beat our plan by about 30% last year. We're having a really good year this year, but the most important part about that is that the dollars are going back out the door," Knudsen said. "We're putting more dollars into mission than have happened in the last many years. And in terms of what we were able to do last year, we realized toward the end of the year, when we were doing very well, we had more dollars that we could put out into mission. So, we did.

"We, again, thought deeply as an executive team: 'All right, if we've got more money to go out the door, what is the highest and best use of funds? What's the thing that right now is really going to help a patient or family?' And because of the pandemic, and because so many individuals were behind on either cancer care or cancer screening, those dollars largely went into patient transportation and lodging toward the end of the year, so that we could get more patients to care. And it was across the country.

"I hope we have the same problem this year, that at the end of the year, we're able to say, 'Okay, what can we do for Advocacy, Discovery, and for Patient Support at the end of the year that's above and beyond what we had been able to plan?'"

Knudsen spoke with Paul Goldberg, editor and publisher of *The Cancer Letter.* A video of the conversation is posted here.

Paul Goldberg: I can't believe it's been a year. We met and discussed your plans at the Hope Lodge in Burlington, which was just coming online after COVID. So, we know what you were planning to do.

Karen E. Knudsen: It has been a little more than a year—a year and a few days. So, we're right on the mark. I'm just thrilled with what we've been able to accomplish in this last year.

I would say that we've gone through what a textbook business school would call true transformation—taking the things that are exceptional about the organization, and aligning them so that we can accelerate even further on our mission to improve the lives of cancer patients and families.

We know where we want to go. We are speeding in that direction and are just delighted by the impact, mostly, that we've been able to make across the country.

But is it going along on schedule? Is it proceeding as planned?

KK: I'm so glad you asked that. No one loves a strategic plan more than I do, and that's something that we commenced developing early on. Actually, months before I got in the door, I started working nights and weekends with the executive team to stand up what our plan would be.

It's terrific that we have the goal to improve the lives of cancer patients and their families, but that has to be measurable, and there has to be a business structure as a way to get there. The first part of the strategic plan was to stand up that structure.

We are now organized into those units that we talked about last year: Advocacy, Patient Support, and Discovery.

Those units each have a component of the strategic plan that they own, and all of it laying on the foundation of our commitment to health equity. So, every component of our strategic plan, irrespective of the pillar, is aligned to reducing a particular cancer disparity, and our overall goal to enhance cancer equity and health equity.

I've been covering ACS for more than 30 years, and I've never really understood it. Until about now.

KK: My goal is to make that easier.

Yes.

KK: Well, I mean, I think the way I would describe it is by the following—again, because I believe things need to be measured.

Our Discovery team continues to be a foundation of the American Cancer Society. The intramural program is the one that sets the single book of truth for the nation on cancer incidence, cancer mortality, and cancer trends. That's just one of the things that happens in the extramural program.

Of course, there are other gems, such as the cohorts that identify new factors that are contributing to cancer risk. The intramural program remains the mainstay of ACS, and that lives within the Discovery pillar.

But our extramural program, wherein we are the largest nonprofit funder of cancer research outside the U.S. government, is now starting to think differently under our new chief science officer about the kind of science that ACS could and should be funding, the kind of science that NCI can't do, or doesn't have the bandwidth to do, given the small or the relatively low payline.

What are the things that will be the most impactful across the cancer continuum? That we've defined as our scope of work: prevention and screening through detection, through treatment, and through survivorship, which as we continue to improve outcomes for cancer, we've got to shift to [survivorship], but also through bereavement, because the caregiver is one of our key stakeholders—the patient and their family.

So, across that cancer continuum, what are the things that we at the American Cancer Society are uniquely positioned to fund?

That's where we've shifted our line of sight. Expect different things from the American Cancer Society. We want to fund the most impactful breakthroughs that we are uniquely positioned to do. All underneath Discovery.

But discoveries, we know, are not enough. There has to be access to care, and our access to care comes through advocacy.

The Advocacy pillar under Lisa Lacasse and team, which is ACS CAN, and it's our 501(c)(4), is informed by all the things that are happening in our Discovery pillar, things that we fund or things that we've become aware of that others have funded, and leads to strategies across the nation that are uniquely intended to enhance access to these new breakthroughs.

For example, biomarker testing, which we were very thankful that you wrote an article about.

Going state by state to ensure that Medicaid plans include coverage for biomarker testing happening now, knowing that so many of these new therapeutics that we just heard about at ASCO require or recommend biomarker testing. Yet, only single digit percentages of individuals are getting access to these in many states. Advocacy sets its priorities based on what we learn from Discovery.

That's the intertwine.

Then, the third and final pillar (of our mission execution pillars) comes in the

form of Patient Support. This is simply borne out of our impatience in the cancer continuum that too many patients fall through the gaps.

We see ourselves there as filling the voids in the cancer continuum that no one else will, by setting up prevention and screening plans for patients in 5,000 communities across the country, but also for those patients who have been diagnosed with cancer, ensuring that they can complete their care to the best of ability through transportation, through lodging at our 31 Hope Lodges and beyond, and through education.

We firmly believe that empowering patients to be their own best advocate can help them get the care they need. But also through new programs that we stood up through our new patient support officer, like navigation. We know navigation is something that is so critical for improving outcomes, yet it's not reimbursed.

So, I would close in saying ACS works like this. It is the parable of navigation. We know through research we and others have funded that it makes a difference in patient outcomes, and also patient-reported outcomes. We know through our Patient Support pillar that patients aren't being navigated in many sites across the country. So, we feel compelled to go fill that void and go do it.

But at the end of the day, the answer is always going to be advocacy, because our advocacy team will learn and be informed by what happened in research, in our discovery team, and what happened when we are touching 55 million patients every year through our patient support team.

And that becomes a priority for advocacy to have navigation become a reimbursable component of healthcare.

I use that as an example, and I hope it explains ACS. It's what I call the magic of ACS. It's when all of these things work together in a way that measurably improves life. That's how we make our strategic choices.

I didn't mean for my previous question to sound snide.

KK: Oh, no. Hey, I take it all in stride. It's all good.

No, no. I'm not apologizing, either. Just I did not mean it to sound snide, because there's actually a point there, which is the American Cancer Society evolved over many, many years in its own way. The rest of the universe evolved differently.

So, there was this gap that emerged, and you were hired, I always thought, in order to bridge these gaps. So, I'm building up to a question, believe it or not. You're a scientist, and you're a science administrator, and you're a cancer center director. Have you been able to keep those identities going, both as a scientist and a center director—and center directors are your peers?

KK: It's something that actually is really important to me, and I think the answer is yes.

An example is still being highly integrated into the cancer community. So, while I no longer have my own laboratory at Jefferson—all those projects have been completed and grants handed off—I look back on those years as some of the best years of my life, of understanding how to develop science priorities based on what's happening in the clinic, because that was my style, and then to bring those problems back, and put them back into the clinic in a form of a potential answer in a clinical trial.

I'd like to think that I have an understanding of what a translational scientist is facing and can help contribute to the Discovery pillar concepts of what creates a priority.

But I stay fresh in a number of ways. I still am on the external advisory boards of 12 NCI-designated cancer centers, and I think that that's an important component of my job. It lets me know where their challenges lie. Their priorities become our priorities.

The vast majority of dollars at ACS go back out to the major centers, because that's where the research is happening. It's where the clinical trials are happening. It's where the patients are being treated. So, themselves and their related healthcare systems are the recipient of not all, but quite a lot of ACS funding. So, understanding their priorities is key, to have these formal relationships through external advisory boards.

But I've also traveled the country to see them. So, I've now seen 22 cancer centers, sitting down to talk to directors about what their priorities are for research, for advocacy, and for patient support, and also to make sure that we have the same touch points.

That's one way of staying fresh.

Another is staying engaged in the science discovery component on its own. I just came back from a very thrilling week at ASCO, learning about new discoveries, then using that to understand what patients are going to need from a three-pillar strategy, from us.

And then I guess I would finally say I was really delighted this year to be the keynote speaker at ASCO-GU—this is my meeting, right? These are my people in the GU space. This year, I endeavored to collaborate within my own team, within

the intramural program at ACS, to look through trends in cancer incidence and cancer mortality for the GU cancers.

We identified some really new, surprising features of what's happening in GU cancers across demographics, and across geographies, and we'll be writing that up. So, look for me to still be publishing, but in potentially different ways as years go on.

How many hours are in your day? Is it 24, or is it 48, or what's a day?

KK: What's a day? Oh boy. A day is long. It never ends.

In truth, last night, we were waiting on a vote in South Dakota that we had been advocating for—it's a particular amendment which we felt would get in the way of enhancing access to cancer care in that state. I was up at one o'clock in the morning, waiting for that vote to come in.

So, it depends on the day. The days are long, but they feel full of energy. It is overwhelming.

A day is early, and into late, but I have to say I'm very thankful for my family that feels like part of the ACS executive team sometimes. Even our 18-year-old son last night said to me, "Mom, when's that vote coming in in South Dakota?"

So, they know what's going on, and I'm very thankful for my home team, and I'm thankful for my ACS team, because everyone's leaned in pretty hard.

The pillars idea, when was that born? Was it during your interviewing for this job? Because, there was no reason for it to be there before. Maybe we should talk about them a little bit more and...

KK: Sure.

... how that evolved.

KK: Well, I fully believe, again, as a businessperson, that form has to follow function. We needed to decide what it is that we wanted to achieve. That started to develop in the two months that I was leaving Jefferson and coming back up to ACS, and had a lot of time, again nights and weekends, to spend with the executive team members.

So, we circled around first, what's the mission?

We want to measurably improve lives.

And then, as I started to understand how ACS lived, I realized that there were things that were already fully intact, like the Advocacy pillar. It stands almost identically to how it is today. But what was not clear to me was how some of the other activities were truly organized. Through that fact-finding, the pillar concept started to come.

I had alluded to the board during the interview process that it was unlikely that the current structure would stand, from what I knew, but that I would do due diligence and determine what the structure would be that would allow us to maximally get to where we want to go. Soon after joining ACS and having done that due diligence is when the pillar concept came together.

The Discovery pillar was an easier one to tick and tie and really streamline. It's focused on science, and what is the science that we can accelerate, we're going there.

And then soon after came the formation of the Patient Support pillar. I would say that happened a couple of months after I started, and I had the pleasure of leading. It needed someone to start to pull it together strategically, with the concept of truly understanding what are all the touch points? We did due diligence ourselves.

What are all the touch points across the country wherein we interface with a patient, with a caregiver, and with a health system? What do those look like and how do we measure it? And what are the things that we should keep doing and do more of, and what are the things that we should stop doing, because it's not as impactful as it could be?

So, I had this wonderful time period of serving as CEO and the head of Patient Support, which I think was valuable because it gave me insight into the kind of person who could lead that pillar. And so, for me, what I said to Dr. Kamal during the interview process, when he became very quickly the lead candidate—I mean, we were just all blown away by him— is that I thought this was the job of a lifetime.

At ACS, we had people who were out in the field, who are passionate about cancer control, who know how to set up a prevention and screening program, who know what it's like to shepherd a patient through a cancer journey, because they've got to get transportation, they've got to get navigation, they need to understand their care better, so they need an education strategy.

They were really hungry, I would say, for someone to come in to cherish that aspect of ACS and commit to grow it. I was the first person to do that, but Arif Kamal is the second. Dr. Kamal is really phenomenal.

So, that's the component of ACS where they're not new activities, but they're activities that have really grown in this last year, because now there's a strategy behind them and a real desire to triple the things that we know are incredibly impactful. That pillar was the last to stand up.

But again, it's not that the activities were new. I just think that it's now got this mindset of, what do patients need right now?

And, okay, if we're going to see more cell-based therapy in the cancer continuum for patients who really need it, then that need, that gap for patients to be next to the center and to be able to get there and afford to stay there, is going to grow.

> It is the parable of navigation. We know through research we and others have funded that it makes a difference in patient outcomes, and also patient-reported outcomes. We know through our Patient Support pillar that patients aren't being navigated in many sites across the country. So, we feel compelled to go fill that void.

So, what's our strategy?

Where is our next set of Hope Lodges or Hope Lodging strategies? And how can we use those Hope Lodges as a place beyond just a place to stay and to serve as a home, as a community? Which they are—it's not like a hotel.

But how can we also maximize that ability to improve lives? Can we educate about clinical trials? Can we actually run nutritional studies and physical therapy studies to enhance outcomes while they're there? Some patients stay 200 days free of charge.

That's the kind of thinking that is empowered, again by the pillar strategy, because the things that we'll decide to do for how we're touching patients is informed by what's happening with research, and was informed by what patients can and can't access.

Well, it was interesting looking at how this transformation occurred. I mean, the ACS had a choice. They could continue in its nosedive, not for very long, or they could hire a transformational leader who could make it go straight up—not straight up, but at a very nice trajectory.

And the people making the choice were the board, and I had actually never seen the board at ACS really say, "Hey, enough." Because at times, the board had been captive to the CEO. Looking back, how did this happen?

KK: Well, thank you. I appreciate that.

I wish I had more insight into what their thinking was, but I would say what I very much appreciated about the subcommittee of the board that was the search committee for the CEO was the transparency, because they allowed me the latitude to say, on the other end, on the receiving end of ACS activities, these are the things I really value.

These are the things that concern me. And there are other aspects of the organization, more internal, that I wanted to understand better and suspected that there were opportunities for improvement.

And they took that in stride, and were, I would say, very candid to say, "Yes, actually we think you're right. We think that there are these things that probably need to be focused on."

So, the next set of conversations then that followed were along the lines of, "Well, I'm not the kind of CEO that's going to come in and babysit. I'm the kind of CEO who's going to come in and be laser-focused on improving lives."

That is something that I told them before I came in, that this is where I saw the value of the American Cancer Society, and that things would align with that concept, or we would choose to no longer do some of those activities.

And they were supportive, and I have to say to their credit, now having interacted with the full board, they have been highly supportive.

It's what I would call a very good board-CEO dynamic. There's trust, there's transparency, and there is good governance. The board's described to me their role is noses in, hands out. They're going to hold me accountable, as they should, and they have fiduciary oversight of ACS. Are we executing on mission? Are we using our dollars wisely to execute our mission? Absolutely. That's their role, and it's a good role for them. And, of course, their role is to hire and fire me.

But outside that, the running of the organization is mine and my executive team's. And I also suspect that the board sees what I see. I've got an incredible executive team to a tee. Each person is serving as the CEO of their part of this

organization, and that's what I needed them to do.

Oh, that's fascinating. Just thinking back about how ACS structures worked in the past, and how it functioned, where the rubber met the road. John Seffrin at one point decided that he wanted the big headquarters in the center of Atlanta, which everyone would see, and so this thing was built. Actually, he didn't decide that. McKinsey [& Co.] told him that he needed that, and he liked that idea (*The Cancer Letter*, July 24, 2020) How does your office look?

KK: We have a very different strategy, again, because we are committed to serving cancer patients and families across the nation.

Our structure—back for form follows function. That's our structure, too. Atlanta is where our Discovery pillar is located, the intramural team, because we have a team of scientists who need a place to be—they are in Atlanta.

And our extramural leadership is in Atlanta as well. That's a mainstay, but it's not a large headquarters. It's what you would expect for a science team.

But advocacy and our Advocacy pillar has always been headquartered in Washington, D.C., but appropriately, had operations in all 50 state capitals. This is key for us. They're distributed across the country according to the activities that we need to conduct.

And Patient Support, by definition, has to be across the country. So we have cancer control or cancer support now, vice presidents across the country that lead those teams that touch the patients, touch the caregiver, and touch the health system.

They are distributed across the country, including Hawaii, and including Alaska. So, we're in the Lower 48 as well as the two that are not connected to mainland U.S., and each of them has the strategy that's right for the patients in their catchment area.

Now, they're led by our chief patient officer, who resides, and until he chooses not to, in North Carolina.

So, all of us have a role to play being out in the field.

That's what I think has been the dynamic change. I just had my entire executive team, including my chief legal risk officer, including my chief financial officer, at ASCO, because we get together once a month in person. That's the way we do it. Instead of having a brick and mortar that's someplace that we all report to, we've hired the best and brightest, and what we're committed to is coming together once a month.

We come together for about two-and-a-half days, and it's some of the most important time that we have. We, of course, connect on Zoom as an executive team every week. And, as I think we said when we talked about the first time, on Slack 24/7, but it's the case that that time together once a month really helps us with the connective tissue between the pillars that's so critical for us.

We just had a phenomenal time doing that at ASCO, with our new chief science officer. So Dr. Dahut joined us for the first time live and in person and in 3D, with the executive team at ASCO, and so we were able to just get so much more done.

So, that's the way we operate. I have an office in downtown Philadelphia. I just took a space in what was already the existing ACS office there. That's my home base, but my true home base is everywhere where we touch lives across the country.

How much travel do you end up doing? It must be a lot.

KK: It's a lot. So, I am not in Philadelphia very often, as much as I would like to be. So, yes, it's where the need is. And I think that will change over time, as we sharpen our focus of what our activities are in each of these areas and I've completed my world tour of cancer centers, of understanding how we're connecting appropriately on research, advocacy, and patient support.

I think that will ebb and flow, I hope. But I have to say I am truly inspired by things that I see across the country.

Let me just give you an example.

Navigation. This is something that we know is critically important for us to get together, and fund, and build the case to support. We see it as igniting navigation; right? We're building the case for this to be a permanent solution. So, I can only afford to fund 14 navigators across the country, and in response to our request for applications, we got just shy of 200, right?

I mean, that says something about the need for navigation.

And what did we ask?

We asked these cancer centers to tell us why they need patient navigators. How are you going to deploy them? Tell us about your catchment area. What are the cancer disparities you're trying to address by using a navigator? What is the innovative strategy that you're planning to use?

Are you bringing something new to the table for navigation?

What is your commitment to clinical trials? You yourself might not need to conduct them, but you need to at least

show us that you have a track record and history of referring someone to clinical trial, because we view assessment for clinical trial as part of advanced, acceptable quality cancer care. So, tell us all of these things.

All these applications are coming in, and that's really important, but I've also learned firsthand across the country what some of these really phenomenal strategies look like.

For example, one of the cancer centers that I had gone to was UC Irvine—and I'm sure many other centers do this as well, but UC Irvine takes a really interesting strategy on their patient navigation program, which is highly connected to their community outreach and engagement program.

They have, for example, large communities within their catchment area that are from the Pacific Islands. So, they have a navigator who is from that community who is specifically charged to connect with that community.

They have navigators from specific Latin American populations that are specifically tied to those communities. So, they've really tied patient navigation to their COE office in a way I thought was really phenomenal.

Those are the kinds of things that start to come into my mind as we start to think about a kind of model for patient navigation. The strategies that we'll fund will hopefully help to determine, what is the gold standard? What is the thing that is the most effective for patient navigation? And how can we combine that with other research that's happened in extramural community and use that in advocacy as a case for support?

But I think that my ability to go boots-on-the-ground to centers has been irreplaceable to see what is the real need and how are people, in a really creative way, addressing the needs of their catchment area? And what I find in Iowa is going to be very different than what I find in Orange County, CA, because the populations are so different.

Oh, fascinating. What kind of science are you going to do that isn't being done by others? You're looking for that opportunity right now. Have you found it?

KK: We've heard a lot. Before I left Jefferson, I actually canvased every cancer center. I think 90% of the cancer centers responded to my poll—my Survey Monkey that I wrote myself—to say what should we do more of.

And so, I have that list of information. Then I've been going around the cancer centers and talking to them about what they'd like to see differently from research. And as you can imagine, there are variances in answers. I spoke to Dr. Sharpless, when he was still the head of the NCI, about things that kept him up at night that he wanted to fund more of, but was unable to.

So, all of that information has come to Dr. Dahut, and no firm decisions have been made yet, because it would be part of our next year plan. But the kinds of things that I will tell you are rising to the top sound like this: clinical correlates for trials, the kind of trial where you have drug, no money.

You need to be able to do the clinical correlates in order to understand who responded and why. And part of that addresses something that we've heard from a lot of cancer centers, which is the pressure on physician scientists of not having enough protected time to write trials, or do trials. So, by definition, those two things could come together to give a little relief, mental relief for physician scientists to be able to write studies.

Pre-me, ACS was the first one in to recognize the plight of early-career investigators. So, we went to that space. We funded early-career investigators, and then ultimately granting agencies like the NCI also gave an extended payline.

What we've heard from many centers, and, in fact, many faculty, is the pressure on someone who's sitting on an R01. They already have one R01, but you can't run a lab these days on one R01. They need the second. So, can we think differently about that pool that gets stuck in the middle?

Another component also highly tied to our mission is diversity of the pipeline. What can we do to enhance diversity of those going into cancer research as well as cancer care?

We've already committed millions of dollars to HBCUs, to try to get earlier intervention of an exposure of individuals to what a career in cancer looks like. Those, I expect, will continue, but we've had some just really interesting conversations at ASCO with another organization, thinking about funding grants in the post-back area as well to try to get more exposure of individuals from diverse backgrounds and diverse geographies to cancer research.

I would say I would not look for something to disappear from the ACS portfolio. We'd like to grow the overall grant portfolio, and as we do, to bring in new opportunities for growth.

The final thing, I would say, is innovation.

Again, with our concept that we would like to measurably improve lives, one thing that ACS has not gone into in the past as much as it could have is the kind of implementation science that uses things like digital technologies to enhance the patient experience, or patient understanding, of their care. Things like digital navigation start to become important to us.

I would look for us to find best and brightest ideas across the cancer continuum, but also to judge whether or not we are uniquely positioned to do that, versus another agency or organization which we think would be distinct. I would also say that the commitment to health equity, also that has to rise to the top, something that could demonstrably enhance health equity if it's going to rise to the top of ACS, as guided by our chief diversity officer.

And when appropriate, I'd love to talk about her, because that's also something new about ACS that probably has not gotten enough airtime.

Oh, I'd love to hear that. Another thing that didn't get enough airtime, and I'm sorry we didn't write enough about it, but the patient information systems that you put together with ASCO. That probably took all of maybe 30 minutes of negotiations, and it was done, because you could do it. I couldn't imagine it being done before, because people would be looking for where's the knife? You know?

KK: This is something that really was quite facile to stand up. And it's because of the commitment of myself and Dr. Hudis, from ASCO.

I was just delighted—I think I hadn't even started yet at ACS, but it had been announced that I was joining the organization, and Cliff Hudis, whom I knew in the past from my life as a cancer center director and researcher, had contacted me and said, "Karen, when it's the right time, let's talk about things to do together."

I said, "Absolutely. Let me get in the door, so I can understand what I'm dealing with and then let's talk."

So, we made good on that commitment. It was just he and I, and we did what you would expect. We had a small brainstorm of what are the things that we can do together that bring value added. And this concept of empowering a wider array of individuals with information through a relatively easy data share online could bring value.

We loved the idea. We each agreed to go bring it to our teams. Our teams enjoyed the idea. We stayed on the task force, he and I, through a point to make sure that there was just no logistical barrier, no technical barrier that would keep us from doing it.

When we realized that there was not, we unleashed our teams on each other. They worked together beautifully, and out came this project.

You're right. I don't want to use the word "easy," because I wasn't the one having to do the code in the background. But it was easy, in terms of where we wanted to go. Here was our thinking. From Dr. Hudis's position, their key stakeholder is the clinical realm and physicians, everything from oncology to primary care, to give detailed information about cancer.

But they also have something that we were not as strong in, which was survivorship plans. And again, as much as we're reducing cancer mortality, we're enhancing the number of cancer survivors. But those individuals need to have guidance on what are the additional things that they're going to need to continue and contend with downstream of their last successful treatment.

On the flip side, our stakeholders are patients and families. So, our content about cancer is written in a way that is meant to be easily understood, truly by everyone, and to stand up as well the cancer continuum that starts with prevention and screening.

So, our thought process was like this:

If we could cross populate Cancer.org, our site, and Cancer.net, their site, we bring value on each end of the spectrum—prevention and screening coming from ACS, survivorship coming from ASCO.

And because we have a Venn diagram where there's an overlap of the kind of person who accesses our material, a patient or a survivor who really wants to get much more deeply into, for example, standard-of-care detail, they can find that now through this cross-populated site. And for us, to have additional information that's being viewed, especially on prevention and screening, by those that are in the care arena was a goal as well.

It was just a net win. And what it required us to do was to put aside our egos, and not get into the conversation about branding and who owns what, but rather let's do the right thing for the patient. One of the things I really love about ASCO and ACS—and it's exemplified by the leadership—is that we are driven by what is doing the right thing, period.

And as long as we can afford it, we're going to go do it. So, that was step one. It was awesome.

Yeah. The whole critical part of the conversation must have taken less than an hour.

KK: It did. It really did. Well, I also really enjoy, Dr. Hudis. He has such a terrific business mind also that, without betraying confidences, we've had a lot of times to touchpoint with each other, CEO to CEO, about variances in our organization like how do you do this, and how do you do that?

And use each other as guides, or just a sounding board, which is, frankly, I think, the way organizations should

run, I would say. I don't want to discount we have really wonderful relationships with AACI, again, because the centers become our priorities. We've had conversations with ASTRO about radiation oncology studies not being funded enough. So, we put together a grant mechanism with ASTRO.

When I sat in the White House, the day that the Moonshot reignition was being announced, and Dr. Hudis was in there, too, and President Biden talked about the need for cancer organizations to work together more deeply, I kind of thought we're there, right? We're doing this, and we believe that. So, yeah. And we'll do more.

It's easier than not.

KK: Well, it is as long as you're driven by the strategy of what's the right thing. And in our case, that thing is patients and families. So, finding those like-minded individuals to get things done, that's what we're going to do.

So, the other question, you mentioned briefly Ukraine.

KK: Yes.

I talked with Arif Kamal about when this was all beginning, and he mentioned that we are doing this as part of the program, not as part of fundraising (*The Cancer Letter*, April 22, 2022). And in the past, ACS would've run ads, if they could have stood up a campaign fast enough, saying: "Give us money so we could give it to Ukraine cancer patients." How did that come about? How did your response to Ukraine happen?

KK: Yes, it happened really quickly, actually. In the days after the invasion started, we actually had our executive team meeting in Philadelphia, in my office at Philadelphia. Dr. Kamal and I were there, and as part of our executive team meeting, I said, "Look, what can we do?"

Back to our mindset. What is it that ACS is uniquely positioned to do? And we were aware that there are about 176,000 newly-diagnosed cases every year of cancer in Ukraine.

Our minds went to—well, we have about 176,000 people who've been diagnosed in that last 12 months that are either on the precipice of starting treatment or are in the middle of treatment and are going to be displaced. We've got to do something.

What's going to be on their mind? What's going to be on their mind is. "How can I continue treatment?". Our goal was to reduce the number of individuals who had to stop care.

We realized an asset that we have is Cancer.org, where we have information, but it's all in English. So, what can we do to get key pieces of information translated and especially over to our 24/7 call center, which previously could only be assessed from the U.S., because there's a cost to opening up multiple lines. So, we made the decision quickly in the executive team that we would take dollars from the organization that were allocated to other programs and immediately put into Ukraine.

So, Dr. Kamal and I left the room. I called my previous cancer center, Sidney Kimmel Cancer Center, because we had oncologists that spoke Polish, that spoke Russian, that were from Ukraine, who knew the languages and asked them if they could immediately help us translate, including messages that were on our 24/7 line that could tell someone leave us what you need to know.

We're going to get back to you with information. So, all that got stood up within about 48 hours.

And, immediately that same day, I also called Dr. Hudis from ASCO and said, "Look, here's our intention. Our intention is to create a conduit channel where someone can talk to us, reach out to us. And we have some oncologists downstream of that, that, again, came from Jefferson, "but we need more. We need a bullpen of oncologists."

He said, "I'm going to find them." So he then started to scour at ASCO and that's how it started to come together, and then ultimately other organizations joined in this strategy as well.

So, at the end, what do we have? We have a website—we were looking at the numbers a few days ago. Since we started it, more than 35,000 people have come to the website, almost a thousand have downloaded information in different languages from the area.

So, they're taking advantage of the patient information. Through our chatline and through our 24/7 call line, now with six different call numbers, all with a high price point we're willing to pay, we've navigated about 200 patients to care, so that they're able to find a place to continue their care.

We're just delighted by the impact of what we've been able to do. I mean, the 200, we were hand-curated, but with the 800 that received the information and downloaded, and then 35,000 accessing online, we know we're making an impact.

The durability of this is such that we now have a "clinical volunteer corps" that was, again, made possible through

that relationship with ASCO. In the event there is the next world disaster that prevents someone from accessing cancer care, that we are able to pull and connect from that volunteer core and we know what their language capabilities are.

So, it's something that actually we have not gone to raise money for. Everything we do at ACS comes from funds raised. So, at some point, we're going to have to determine how we're going to sustainably keep this going. But it was a do-the-right-thing moment.

And I would say this is, well, we sat at the team said, well, is there any risk to the organization if we do this? What if someone is navigated to care and something poor happens? Do we have any legal liability? And even our chief legal and risk officer said, "This is the equivalent of people choking on a plane. We've got to do the right thing here. Let's move forward and we'll figure it out." And he did figure out the legal structures behind it.

But I give my team credit for understanding how quickly we were able to move, and having that sense of urgency, that we have to do something now. We can't wait.

I'm just mopping up the odds and ends here, but I understand you found the time capsule that Mrs. Lasker put together. What's it look like?

KK: The time capsule looks like you would expect it to look like. I invite you to Philadelphia, to have a look. I actually can send you a picture of the time capsule as well. But it's interesting. It's bigger than I thought it would be. It's several feet high, big, black, looks like a time capsule from the era. And we have no idea what's in it. So, it's definitely an object of much speculation within my team about what could possibly be inside this thing.

God, you got to have some kind of a metric for when you would open it, because it was intended to be opened when they've cured cancer, which would've been roughly 1976.

KK: Yeah. So, when they cure cancer, for sure, but now that we know cancer is at least 200 individual diseases, we're not sure what to make of that. But we started to talk about it as when we cure cancer as we know it, and we're not there yet.

Well, then we'll know it in a different way, and then it's still there. But what about money? How is that working out? Is it going up?

KK: Going up. We beat our plan by about 30% last year. We're having a really good year this year, but the most important part about that is that the dollars are going back out the door. We're putting more dollars into mission than have happened in the last many years. And in terms of what we were able to do last year, we realized toward the end of the year, when we were doing very well, we had more dollars that we could put out into mission. So, we did.

We, again, thought deeply as an executive team: "All right, if we've got more money to go out the door, what is the highest and best use of funds? What's the thing that right now is really going to help a patient or family?"

And because of the pandemic, and because so many individuals were behind on either cancer care or cancer screening, those dollars largely went into patient transportation and lodging toward the end of the year, so that we could get more patients to care. And it was across the country.

I hope we have the same problem this year, that at the end of the year, we're able to say, "Okay, what can we do for Advocacy, Discovery, and for Patient Support at the end of the year that's above and beyond what we had been able to plan?"

Please note that it took a lot of self-control for me not to ask this question first, but what are the numbers? Can you give them to me yet?

KK: I can't. I have to wait for that. Our audit committee is actually meeting later this month, and then we'll have the audited financials from last year, and then I can give them out.

But you're happy?

KK: Yes, we're very happy. As I said, we released more dollars into mission, so we had a great year.

Wow. So, actually, just having bucks follow mission is actually a functional approach.

KK: We're very clear on what it is that we do and what we want to achieve, and I think that transparency is being heard, and the impact is being heard.

Paul, before you go, can we talk about my chief diversity officer?

Oh, please, let's do this.

KK: So, I know we talked about the pillars, and the pillars as being a new construct within ACS, and each having this lead that's the strategist at the top. The foundational underneath all of that is our commitment to health equity, and that is run by our chief diversity officer, Tawana Thomas Johnson.

She is the first chief diversity officer at the American Cancer Society, and the way that she is positioned, her role on the executive team is, I would say, empowered almost to the point of mine to influence everything that we do at the American Cancer Society.

When we are going to stand up a new research program, it is her role to ensure that all of those research studies are maximizing our ability to enhance health equity, and she holds us all accountable for that. So, for each pillar decision, Tawana, in her role as chief diversity officer, is influencing what we are doing, but then she also has her own body of work.

And in fact, I guess I should back up by saying that in our strategic plan, it is notable that every metric by which we say success looks like (that we're being held accountable by the board), every one of those trues up to a known cancer disparity that we're trying to resolve. It's not that there's just this thing over here we do on the side that's reducing cancer equity. She's achieved through our strategic plan, what I think is optimal. It's woven through the fabric of everything that we do.

But then she also has her own programs that she runs above and beyond that float beyond, between the pillars. She has her program, for example, on health equity ambassadors. She's worked with community partners to develop a core of health equity ambassadors that then became trained to go work out into the community to, for example, talk about the importance of breast cancer screening in the Black American population, informed by research. Informed by our Cancer Facts and Figures for this last year, which showed that for the first time breast cancer is starting to surmount lung cancer in terms of cause of death for Black women.

Okay. So, then we've also got to get people into prevention and screenings that's the right for them.

So, being informed by research, that becomes a priority for Tawana and her team and her health equity ambassadors. This is something she continues to grow, and I would say has been just a force throughout the nation of positive that's coming behind her ability to galvanize communities through these ambassadors. She's someone that, should you ever choose, is definitely worth a conversation and getting to know. She is a hero.

Absolutely. Let's do that. Let's do the conversation with her, and let's just talk to her throughout as part of the coverage.

KK: Well, interestingly, and I think you'll find this interesting, she's been at ACS a long time. I want to say close to 15 years. She's been at the organization. She's seen it through multiple phases and iterations, even back when it was a federated model. When I met her, I think day three on the job, I thought, "Oh, this is a woman who is poised for greatness."

And so, she and I talked about it. Because this is a pretty weighty role at ACS—what does a chief diversity officer look like and how can she be just maximally empowered to influence everything that we do?

We thought deeply about that job description. And then, when she met with everybody on the executive team, before we finalized the job description for the chief diversity officer, we made sure everyone really knew this woman is really going to be empowered to influence every decision that you are making, because the right thing for patients and families. And it's just worked out beautifully.

She is amazing.

> I would look for us to find best and brightest ideas across the cancer continuum, but also to judge whether or not we are uniquely positioned to do that, versus another agency or organization which we think would be distinct. I would also say that the commitment to health equity, also that has to rise to the top.

Well, thank you so much for talking with me.

Q & A

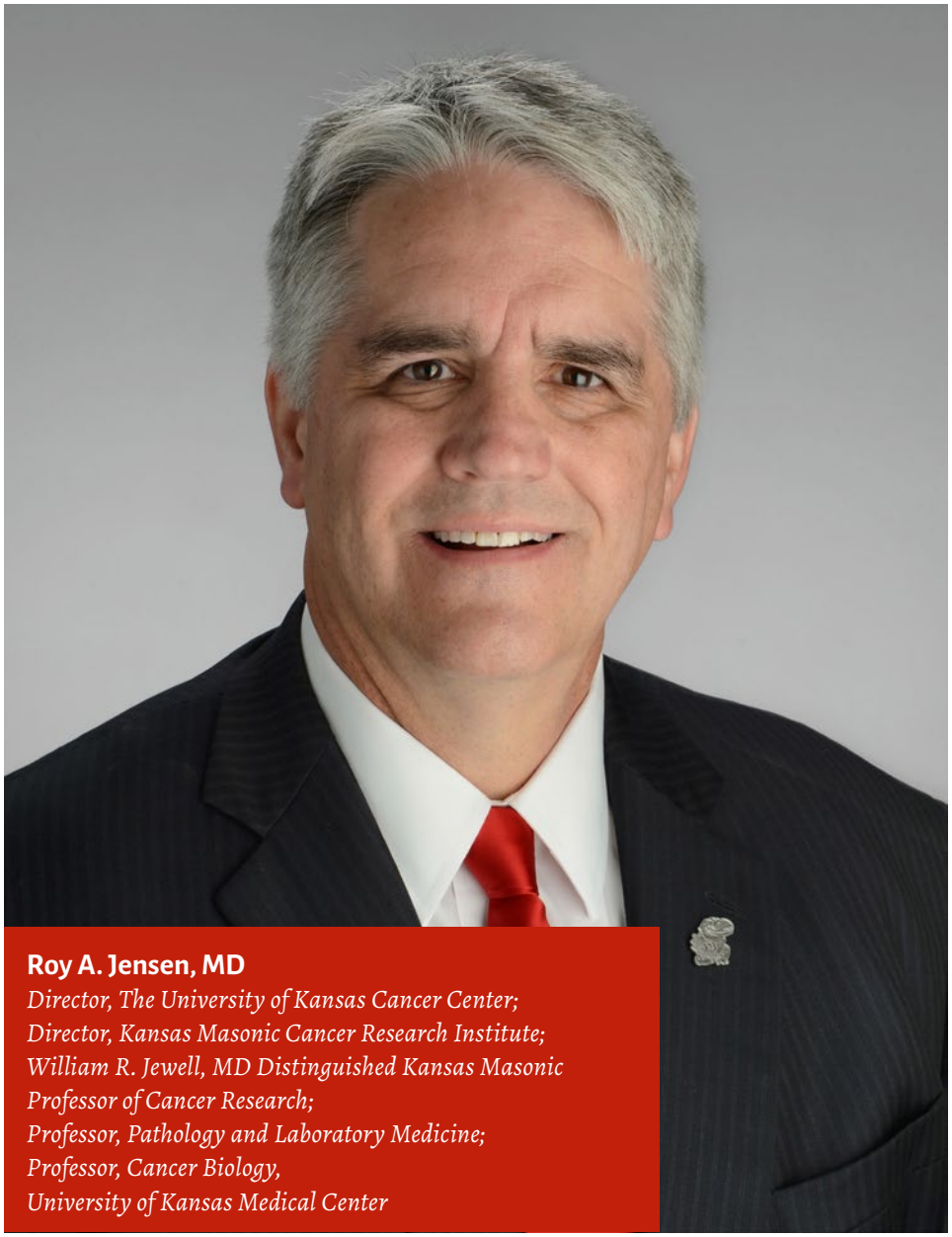
Jensen spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

THE CANCER LETTER | JULY 8, 2022 | VOL 48 | ISSUE 27

CONVERSATION WITH THE CANCER LETTER

Roy Jensen describes KU's 18-year path to Comprehensive designation

> It really is an astounding process that takes place in terms of the institution preparing themselves to be at that level, and then watching the impact that that has on the quality and the delivery of patient care.



Roy A. Jensen, MD
Director, The University of Kansas Cancer Center;
Director, Kansas Masonic Cancer Research Institute;
William R. Jewell, MD Distinguished Kansas Masonic Professor of Cancer Research;
Professor, Pathology and Laboratory Medicine;
Professor, Cancer Biology,
University of Kansas Medical Center

Some things are known to grow well in Kansas. Some things aren't.

Over the past 18 years, Roy Jensen has been told time and again that it made no sense to even try to grow an NCI-designated Comprehensive Cancer Center in Kansas. Yet, he did the only thing he could. Persist. Stubbornly.

The University of Kansas Cancer Center has received Comprehensive Cancer Center designation, joining an elite club of 53 such institutions nationwide. The center's new designation was announced July 7.

Taking a few minutes off from the celebration of his team's achievement, Jensen acknowledged that people who years ago told him to stop dreaming weren't necessarily wrong.

"A lot of people who were giving that advice back in 2004, 2005, I think they were right. I think the issue was, they couldn't see the place changing, and they couldn't envision that sufficient amount of change would happen, that it could be within the realm of possibility," Jensen said to *The Cancer Letter*. "And, if you just keep plugging, and keep plugging, and don't give up, eventually people say, 'Well, you know what, try it your way.' And, that's kind of what happened."

KU received an "outstanding" rating from NCI reviewers, as well as a five-year, $13.8 million grant to support cancer center operations.

Jensen spoke with Paul Goldberg, editor and publisher of *The Cancer Letter*. A video recording of the conversation appears here.

Paul Goldberg: Well, thank you for agreeing to talk with me, and congratulations! You know, you've been told this couldn't be done. You've been told this shouldn't be done—yet it's done! So, how does that feel?

Roy Jensen: You know what, it feels good.

Actually, I was talking with Tom Curran, who sends his regards, by the way. And, we were laughing, because in retrospect, we probably agreed with the folks that were giving us that advice.

If we'd have known everything that we had to go through—but luckily, I think we were just naive enough and stubborn enough that we, kind of like Elizabeth Warren, we persisted, and we just kept at it.

What's fascinating with all of this is that—how long did it take from the beginning to now?

RJ: So, I got here in 2004, so, roughly 18 years.

Eighteen years.

RJ: Almost exactly 18 years.

Oh, my. And, if we were to break it apart, how long did it take to get the Cancer Center designation, and how long did it take for Comprehensive?

RJ: So, it took eight years to get designation. We got started in 2004, got designated in 2012. And then, of course, we were in a situation in 2017 where they moved the goal post on us. They decided to codify the rules around moving to Comprehensive status and to require that Clinical Cancer Centers had to be designated for 10 years before they were eligible for Comprehensive.

So, you got it exactly at 10 years.

RJ: Yes.

So, that's pretty fantastic. What was the hardest thing about all of this?

RJ: I think there were a lot of great things happening in the Kansas City region when we got started, but there still was a lot of misunderstanding about NCI designation and cancer centers, and what it would really take. And a lot of cultural shifts had to take place, and recruiting people in who had been at NCI designated centers was, frankly, one of the most crucial things.

Because, you didn't have to explain a lot of things to them, and they just knew, and yeah, we got to do this, that, or the other things. So, Andy Godwin, fantastic recruit, had been at Fox Chase, knew exactly what cancer centers were all about, knew what had to be done. And, you chat with him for five minutes, and—bam!—he's off and he's doing his thing.

Danny Welch, another great recruit, helped build our basic science program—Weijing Sung, Shri Anant, all of these folks were just fantastically talented, tremendously energetic people. And of course, Scott Weir, who is the core of our philosophy around building drug discovery expertise within a cancer center.

And Scott really led that whole idea and helped get it started. And, of course,

now, that's one of our pillars of success without a question.

One of the people who did not understand what you were doing was Benno Schmidt [Jr.], who understood many things, but not that one. So, if maybe we could just...

RJ: Yeah, I missed an opportunity. I should have invited him.

Well, he's otherwise occupied.

RJ: Yeah. Well, like I said, a lot of people who were giving that advice back in 2004, 2005, I think they were right. I think the issue was, they couldn't see the place changing, and they couldn't envision that sufficient amount of change would happen, that it could be within the realm of possibility.

And, if you just keep plugging, and keep plugging, and don't give up, eventually people say, "Well, you know what, try it your way." And, that's kind of what happened.

Well, it's fantastic that we have done the Q&A for the Cancer History Project, which was very, very detailed about all of this. I hope folks click on that and see what it took—just really full of great stories. But, let's get into the politics of, excuse me, of medicine, of oncology, locally.

RJ: Yes.

What was the shift, because it was seismic?

RJ: Well, I think, KU was sort of an interesting institution in that they were not the dominant medical presence in the town. And there were a couple of other private hospitals that really ran the show around here, and there are a lot of reasons for that.

Basically, KU was coming out of a period of about 20 years of not great leadership, and the place had gone downhill significantly.

And there are all kinds of state rules and regulations that prevented them from really operating in a modern healthcare environment. And so, I think there were two catalyzing events that got things going, one of which was the hospital breaking off and being able to build a functioning, revenue-generating, margin-generating system, and with no margin, there's no mission. And that was certainly true at this place.

And then, I think another key event of course, was the Stowers Institute. And, Stowers Institute was like a rock dropping on Kansas City's head. And, they discovered that biomedical research is a great way to build an economy, and they got with the program and they started designing all kinds of programs like the Kansas Bioscience Authority, and things like that, which started injecting real money into building the biosciences here.

And, they were key to moving us forward. And so, [Gov.] Kathleen Sebelius and her administration were really key. It was more than ironic when she became secretary of HHS and came back and announced our designation in 2012. I couldn't have had a more fitting person.

Well, plus the cancer care all over Kansas and parts of Missouri has changed from community-based to really academic and community-based. So, that's an enormous achievement.

RJ: Well, I think from the very start of our cancer center, we were quite cognizant of the fact that we have this absolutely huge catchment area that spans the entire state of Kansas and the western portion of Missouri, and that we needed to build the infrastructure to reach those folks and to leverage a lot of the great work that's going on in these community hospitals and be a benefit to them, as opposed to taking market share.

How could we figure out a way to help them provide better care, provide access to clinical trials, provide access to expertise, and keep care close to home? And that's what the Masonic Cancer Alliance was focused on from day one.

And then, of course, the other thing that was really fortuitous for us was that became a focus of the community outreach and engagement component of the P30 grant. And so, we were loaded for bear on that, really starting in 2007 is when we began developing all of that.

Should there be a limit on the number of cancer centers that NCI should designate or should this be more-is-better?

RJ: I think the key thing there is being able to demonstrate a real need in the community to serve people where they are. The two articles that came out in the last year that documented the catchment areas for all of the cancer

centers across the country, and showed that there are still significant regions where there is a lack of coverage, is the best answer to that question, because I think that there are still places that don't have access, or ready access, to the great care that's provided at NCI-designated cancer centers.

But, as far as you're concerned, is there more catchment area you can take on? Is there anything more you can do that you're not doing?

RJ: There's a lot of discussion about that in the cancer center community right now. And one of the things that's holding centers back is, and I've seen this at site visits, where cancer centers expand their catchment area with the best of intentions, and then they get slammed by the reviewers for not having the full range of services extend across their entire catchment area, and specifically in the new areas of expansion.

And so, from a grantsmanship standpoint, I certainly understand the reticence of cancer center directors. I think that we should be figuring out ways to incentivize centers to take on those challenges and to expand and extend their reach into the community.

Well, Utah, just had a gigantic expansion, and Fred Hutch just had a gigantic expansion (*The Cancer Letter*, April 1, 2022).

RJ: Exactly.

Is there anything down that path? Is there any path that is good for you?

RJ: My hat's off to those two places, because I think that was a bold move, and absolutely appropriate. One of the things that we could look at is extending farther east. I think there's some potential there. I would say that we were somewhat conservative in drawing our catchment area.

It's largely based on the patients that come to our center right now. So, 95% of the patients that are in our cancer center come from the catchment area that we've drawn.

But, I think to effectively serve more folks in central Missouri, we'd have to look at trying to establish outpatient centers. And I don't know if that's a direction that our health system wants to go in right now.

What's your next challenge? What's next? You've just done this—that's not small.

RJ: The next biggest challenge for us is looking at a signature cancer center building on the medical center campus, and we have plans for that.

I think that was one of the reasons that we did pretty well in our review is because we had addressed a very significant concern that had come up at our last site visit around the fact that when you walk on our campus, it's difficult to point to the cancer center.

We're in, like, 12 different buildings. But that means that we have not been able to aggregate all of our investigators, whether they're basic scientists, population scientists, or clinicians, in reasonable proximity to one another.

And, the site visit team back in 2017 said, "This is a big problem. You guys really are leaving a lot of collaborative opportunities on the table if you're not physically together."

And so, we have been looking at how we can do just that, how can we build a building that brings that critical mass of folks from all the different disciplines together? And we have some plans on the drawing board to do that.

And now, my challenge is going to be to identify funding for that, and to settle on the exact configuration of that facility with our health system partners.

So, you need a few million, quite a few, to do that?

RJ: Yeah. It's going to be a several-hundred-million-dollar building.

It sounds like it would be quite fascinating. So how are you celebrating this? What will you do?

RJ: Well, we've got a couple of events tomorrow. We have a press conference where we're going to announce Comprehensive designation, and we've asked [Sen.] Jerry Moran [(R-KS)] to do that. And, he readily agreed. And so, we're going to have, I think probably around 250, 300 people at that event. And, we were limited by the space available there.

And then, in the afternoon, we're very excited about having a party out at the Sporting KC Stadium, which is known as Children's Mercy Park. We've been working with them on an event out there that's going to be a lot of fun, and pretty much we have space to accommodate everybody across the whole cancer center out there. It'll just be a celebration of what all these folks have been able to achieve over the last couple of decades.

Roy Jensen (right) with Sen. Jerry Moran (R-KS). *Source: The University of Kansas Cancer Center*

> We were quite cognizant of the fact that we have this absolutely huge catchment area that spans the entire state of Kansas and the western portion of Missouri, and that we needed to build the infrastructure to reach those folks and to leverage a lot of the great work that's going on in these community hospitals and be a benefit to them, as opposed to taking market share.

Well, what about you personally? Are you going to take a couple of weeks off, go someplace nice?

RJ: After the site visit, I took a week off, and we rented a Vrbo in Exuma, and that was fun. We had the whole family there, and that was the best vacation we've had in a long, long time, because between COVID and getting ready for the grant and the site visit, it had been a while since we'd been on vacation.

So, we'll probably start doing more vacation types of stuff now that this is behind us.

Is there anything we've missed, anything we forgot, any words of wisdom for other people trying to get a Comprehensive designation?

RJ: I guess I would say that I've now had the privilege of being witness to two institutions getting designation and watching the transformative effect that that had, so both here at KU, and at Vanderbilt.

It really is an astounding process that takes place in terms of the institution preparing themselves to be at that level, and then watching the impact that that has on the quality and the delivery of patient care.

You're able to attract the best of the best to your institution. And, those are the folks that your cancer patients are putting their trust in, and it's really well deserved, because they are the experts. They're the national experts, they're the world experts. And it makes a huge difference in the quality care that you can deliver.

And I think it's worth it.

Well, thank you so much for talking with me.

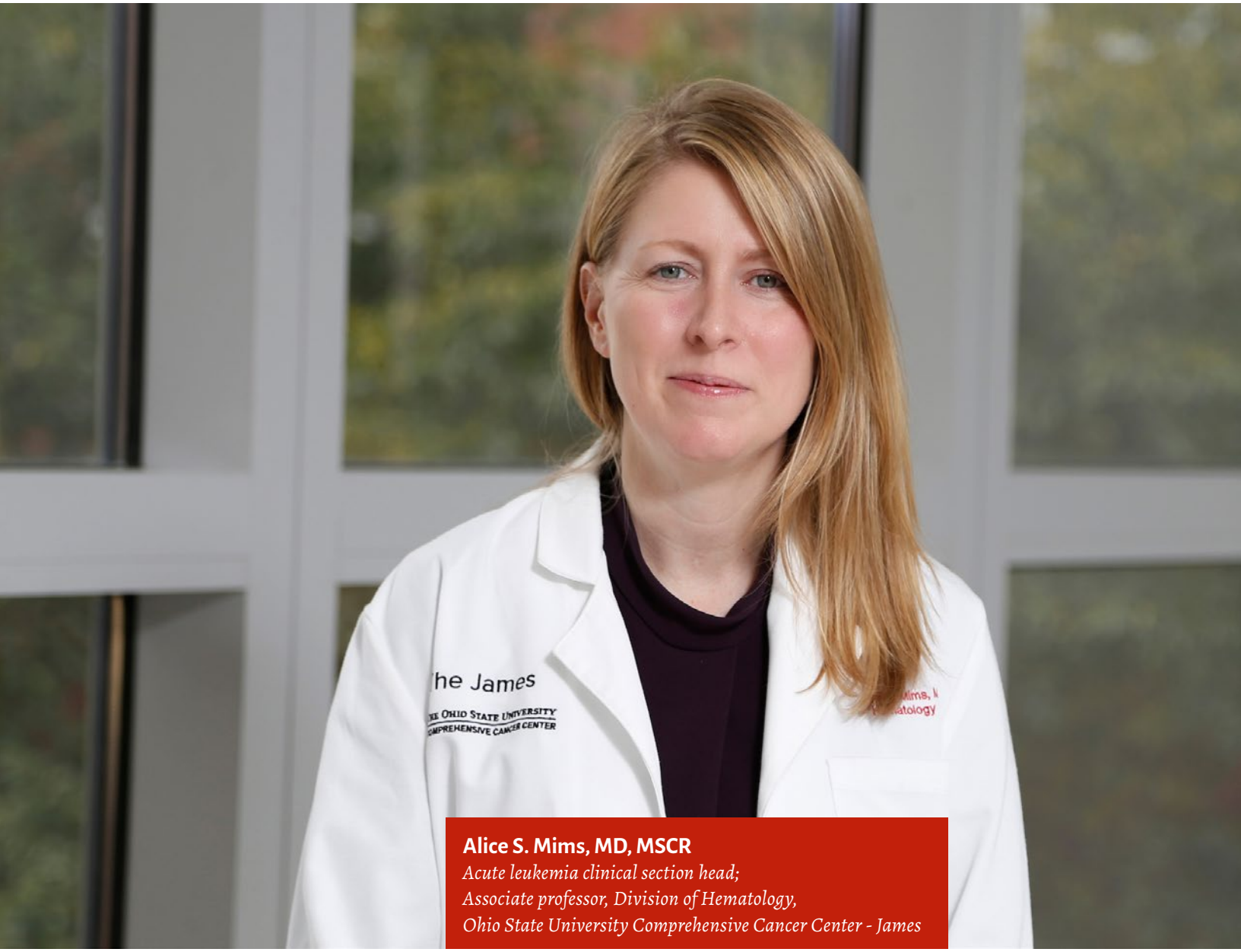
Q & A

Mims spoke with Alice Tracey, a reporter with The Cancer Letter.

THE CANCER LETTER | JULY 8, 2022 | VOL 48 | ISSUE 27

CONVERSATION WITH THE CANCER LETTER

Ohio State's Alice Mims: Six-week abortion ban places oncologists in jeopardy



Alice S. Mims, MD, MSCR
Acute leukemia clinical section head;
Associate professor, Division of Hematology,
Ohio State University Comprehensive Cancer Center - James

As conservative legislatures take the cue from the Supreme Court's overturn of *Roe v. Wade* by enacting abortion restrictions, oncologists in many states are scrambling to figure out how to best care for their pregnant patients, said Alice Mims, a hematologist-oncologist at the Ohio State University Comprehensive Cancer Center – James.

"I live in a state now—Ohio—where there's a six-week abortion ban, unless in case of a medical emergency or no heartbeat detected," Mims, the OSUCCC-James acute leukemia clinical section head and associate professor in the Division of Hematology, said to *The Cancer Letter*. "I think the concern is, do you have to wait and get permission?"

The Ohio bill prohibits abortions after six weeks, except in the case of medical emergency or necessity, or if there is no heartbeat. (Experts have pointed out that the term "fetal heartbeat" is not medically accurate—fetuses haven't yet developed heart valves at six weeks.)

"Who's making the determination about 'medical emergency'?" Mims said. "How do you feel confident you're not going to have your medical license be charged with a felony, versus doing your job to take the best care of the patient, which is more important?"

Almost half of U.S. states—including Ohio—have already banned or heavily restricted abortion. Immediately following the Supreme Court's June 24 ruling, an Ohio judge dissolved the injunction on the six-week abortion ban.

The American Civil Liberties Union of Ohio, Planned Parenthood Federation of America, and the law firm WilmerHale have filed a lawsuit against the bill—but, at least for now, the ban remains. On July 1, the Ohio Supreme Court rejected a request for an emergency stay on the bill.

"[Cancer] should equate to a medical emergency, but you just don't know, especially when you have people in the legislature who are trying to draft things—like in Ohio, they have this bill that they were trying to propose to replant ectopic pregnancies," Mims said. "Fortunately, that didn't go forward, but if you have people who don't understand and don't have a medical background who are trying to make laws, it makes things a lot more complicated in trying to do the best thing for your patients."

Pregnancy does, in many cases, threaten a cancer patient's survival. However, pregnant cancer patients undergoing treatment may face more nuanced risks—birth defects to the fetus, for example, or having to accept suboptimal treatment in order to carry the pregnancy to term—that may not qualify as a "medical emergency" (*The Cancer Letter*, July 1, 2022).

"It's hard when there are these black-and-white laws from people who don't understand the nuances of medicine and how it impacts patients," Mims said. "The people who are trying to put all these regulations in place, unless they personally go through this as human beings or know people who do, they don't understand it to that level."

If an Ohio doctor does perform an abortion, they need to provide written rationale in the patient's medical record for how the abortion will "prevent the death of the pregnant woman or to prevent a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman." The doctor must keep this written statement for seven years.

"You need to document all the rationale behind it, but who's going to make the determination that your rationale is good enough?" Mims said.

Failure to comply may result in legal action (*The Cancer Letter*, July 1, 2022). In Ohio, violating the six-week "heartbeat law" equates to a felony of the fifth degree. Doctors may also incur steep fines.

"The state medical board may assess against a person a forfeiture of not more than twenty thousand dollars for each separate violation or failure of the person to comply with any of the requirements," the bill reads.

Ohio oncologists are concerned about the consequences not only of performing abortions, but of administering treatment that threatens pregnancy, Mims said.

> "As physicians, the majority of us go into this field because we want to help people. It's hard when you feel that there are laws in place that don't allow you to give the best care possible for your patients."

"What if you treat a patient later in their pregnancy, like second or third trimester, with chemotherapy—when it should be safer, but it's still not a completely safe thing—and the patient miscarries, and that could potentially be attributed to a side effect of your chemotherapy?" Mims said.

Providing legal justification for an abortion could also take time—something pregnant cancer patients don't have a lot of, Mims said.

"Sometimes, things happen very quickly with cancer patients, and we don't have time to call a lawyer, necessarily, and talk to the attorney general in the state to decide about care for our patients," Mims said. "I think we're going to run into problems because of that."

Mims spoke with Alice Tracey, a reporter for *The Cancer Letter.*

Alice Tracey: I'd love to hear your thoughts on how abortion bans are affecting—or are going to affect—cancer patients and cancer doctors.

Alice Mims: Absolutely. So, I'll tell you a little bit about my background. I focus on acute leukemias in adults—so, blood cancers. I think that's where my perspective comes from, because I live in a state now—Ohio—where there's a six-week abortion ban, unless in case of a medical emergency or no heartbeat detected.

It's not common that we have patients who come in who are pregnant with acute leukemia, but it has happened, and I have taken care of those patients. Typically, those are medical emergencies, where they need to start treatment very soon or the patients will die.

I think the concern is, do you have to wait and get permission? Who's making the determination about "medical emergency?" How do you feel confident you're not going to have your medical license be charged with a felony, versus doing your job to take the best care of the patient, which is more important. It's very stressful to think about.

It's something that's come up with my colleagues, other people who care for these patients, because we've had these scenarios arise in the past. The response—it's been difficult.

We're not sure about this new legislation. We'll have to see—[cancer] should equate to a medical emergency, but you just don't know, especially when you have people in the legislature who are trying to draft things. Like in Ohio, they have this bill that they were trying to propose to replant ectopic pregnancies.

Oh my gosh.

AM: Fortunately, that didn't go forward, but if you have people who don't understand and don't have a medical background who are trying to make laws, it makes things a lot more complicated in trying to do the best thing for your patients.

For our patients, they come in, they have acute leukemia, they're pregnant, they have complications from their leukemia—they can present with bleeding complications—they're going to have a high white [blood cell] count and need urgent chemotherapy. Then you have to consult your OB/GYN colleagues.

Are they going to feel comfortable moving forward with the procedure? How do you document it? You need to document all the rationale behind it, but who's going to make the determination that your rationale is good enough?

Or, what if you treat a patient later in their pregnancy, like second or third trimester, with chemotherapy—when it should be safer, but it's still not a completely safe thing—and the patient miscarries, and that could potentially be attributed to a side effect of your chemotherapy? It just makes it very difficult to try to do the best thing to care for your patient, when you have that looming over your head.

Absolutely. And from my understanding, sometimes it's not a life-or-death medical emergency, but there are risks of being pregnant while having cancer or undergoing treatment. So, I'm imagining it's really hard to make that call in a state where there are these black-and-white rules about who can have an abortion.

AM: Yeah, absolutely. As physicians, the majority of us go into this field because we want to help people. It's hard when you feel that there are laws in place that don't allow you to give the best care possible for your patients.

Do you think this will affect where physicians choose to practice, or is this going to have an impact on physician burnout?

AM: Yes. Healthcare providers, in general, are so burnt out from the pandemic to begin with. Then, when you pile these rules and regulations on top of that, I absolutely do think it will impact where providers choose to practice.

If you're worried about litigation for trying to care for your patients—I think people will move. I also think people will move to places that align with their core beliefs. People may not want to raise families in places where they don't feel that it represents their background.

This all seems to stem from certain religious backgrounds. When you're trying to care for all of your patients, and there may be patients who don't agree with this, or you yourself maybe don't, that's not your core background—it's hard to be in a place where you can't practice medicine, or raise a family, and feel safe.

I understand also that women physicians have higher rates of miscarriage and pregnancy complications, for a number of reasons—so, I guess there are situations where doctors will be equally impacted by these restrictions.

AM: Oh yeah, absolutely. There's also concern that—as physicians, it can be harder to have pregnancies, like you mentioned—but also for cancer patients, where there's thoughts of legislation to regulate life at conception.

> You need to document all the rationale behind it, but who's going to make the determination that your rationale is good enough?

When you think about IVF, embryos, things like that—where, at least for patients who have chemotherapy, that can affect their fertility, and then they're trying to get pregnant later by different means than the norm—they may get in situations where their life is in danger again.

I think it's just all very complicated and, like you said, I think it's hard when there are these black-and-white laws from people who don't understand the nuances of medicine and how it impacts patients.

The people who are trying to put all these regulations in place, unless they personally go through this as human beings or know people who do, they don't understand it to that level.

So, what has been the reaction among the doctors at your cancer center? Have you been talking about this with colleagues, or are people reacting silently?

AM: I think there's both. Definitely, there are a lot of reactions—we have different groups, for hematology/oncology physicians—and as far as on social media, people discuss it.

I think people are very blown away and taken aback by this. Within my own institution, I think, people are very concerned.

That's why we're trying to preemptively understand, how does this apply to us? When these scenarios come up, can we be proactive in knowing what we can or cannot do? And how do we counsel our patients in regard to this?

There are a lot of conversations, but I also think people get concerned about talking about this more publicly, because of the repercussions. It can be a little bit unnerving to talk about things where people can have such strong reactions, and how it can impact your career—even just speaking out.

Is there anything that we have missed that you would like to share about the impacts of these abortion restrictions?

AM: I think the biggest thing that I'd like to share is that you have to remember that you have to have a mom in order to have a healthy baby.

This needs to be better thought of: How do we best take care of moms, people who are pregnant, providing them with the best care?

Not having such restrictive laws in place that don't allow physicians or healthcare providers to do their jobs.

Sometimes, things happen very quickly with cancer patients, and we don't have time to call a lawyer, necessarily, and talk to the attorney general in the state to decide about care for our patients.

I think we're going to run into problems because of that.

Yes. You don't have time to have a court decide if it's a medical emergency or not, when somebody's life is at stake.

AM: Exactly. Well, thank you.

Thank you for sharing. Lovely to meet another Alice.

GUEST EDITORIAL

Abortion care, cancer, and the fate of American physicians

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A journey through cancer treatment can be grueling, unforgiving, and treacherous for both patient and physician. But what happens when a pregnancy complicates the treatment?

With the Supreme Court's recent overturning of *Roe v. Wade* and *Planned Parenthood v. Casey*, unplanned pregnancy during cancer treatment will significantly impact the access and timeliness of adequate care for patients, create a confounding landscape of legal and ethical dilemmas for physicians, and result in consequences that may irreparably alter the landscape of medicine in this country.

The American Cancer Society has reiterated the importance of local clinics and early screening and detection of cancer, stating that they are in opposition to "any action that results in limiting the number of institutions or clinics where people can receive access to affordable screening and early diagnosis."

Public clinics like Planned Parenthood have long been accessible locations for early cancer screening and diagnosis of breast and reproductive cancers in women.

In states with restrictive abortion laws, family planning clinics have already begun to shut down, limiting access. Beyond the devastating consequences affecting pregnant persons with cancer, the loss of family planning clinics will decrease access to early cancer detection.

Early diagnosis of breast and reproductive cancers is essential for the best shot at survival.

U.S. cancer centers, advocacy groups, professional societies, and medical journals have been very direct in their concerns (*The Cancer Letter*, July 1, 2022).

Approximately one in 1,000 patients—or 6,400 people—are diagnosed with cancer while pregnant each year. The ability to provide cancer treatments like imatinib, which is associated with spontaneous abortions, will be affected by the recent SCOTUS decision. The ruling also threatens the doctor-patient relationship and informed decision-making in medical treatment (*The Cancer Letter*, July 1, 2022).

Physicians will no longer be able to provide a patient with all medically viable options; instead, the physician will be limited to methods which are in compliance with their state's legislation. According to some health law experts, it is unclear whether a physician may even discuss abortion or treatments that may have abortifacient effects with a patient without being liable for criminal charges in some states (*The Cancer Letter*, July 1, 2022).

Jack Resneck Jr., president of the American Medical Association, stated that the *Roe* decision represents a "direct attack on the practice of medicine and the patient-physician relationship" for this very reason. The hallmark of patient-centered care, including informed decision-making on evidence-based practices, is undermined and in many ways impossible.

Instead, patients have less agency, and physicians in restrictive states are left with three exceedingly uncomfortable options: remain in practice where they are and risk losing licensure or even criminal prosecution; remain and watch their patients risk increased mortality without access to certain evidence-based options for treatment; or, leave those restrictive states and practice where it is safer to do so.

A recent University of California San Francisco study illustrates that physicians are very likely to leave their restrictive states to practice elsewhere. The authors of the study wrote, "In 2020, 92% of obstetrics and gynecology residents reported having access to some level of abortion training [...] We predict that, if *Roe v. Wade* is overturned, this would plummet to at most 56%." The authors went on to note that their numbers likely underestimate the effect of the *Roe* overruling, as they did not incorporate "family medicine or other similar specialties where residents receive abortion training."

The Association of American Medical Colleges reiterated the impact of the *Roe* decision on the legality of abortion training in tandem with abortion care. *Bloomberg Law*, a news service, tracked pre-*Roe* abortion legislations, dating to the 19th century, which are currently being revisited. While the ramifications of such legislation coming back is not yet fully known, it is clear that opportunities for medical students and residents to learn life-saving procedures are being struck down.

OB/GYN residents are required by the Accreditation Council for Graduate Medical Education to have access to abortion training. However, new trigger bans and modified curriculums in several restrictive states are making that access extremely difficult. It seems reasonable that future residents will not desire to be placed in such states in which the necessary training for their specialty will not be provided.

Residents put in that position would either be unable to fulfill their accreditation requirements, or—as has already become the case in Texas—they would be forced to leave their residency to do abortion training in another state. Either option is clearly undesirable.

As Theresa Rohr-Kirchgraber stated in an earlier interview with *The Cancer Letter*, medical students with any desire to train in the OB/GYN specialty are left to pursue placements where they are able to fulfill the requirements of their specialty.

According to the AAMC, 54.2% of residents maintain practice in the state they did their residency in—and, further, there is a correlation between restrictive states and lack of comprehensive abortion training in medical schools. If there is less training in these states, and residencies in them will not fulfill the requirements to become a certified OB/GYN, it follows that patients may have reduced access to OB/GYN care in restrictive states.

Abortion care affects all medical specialities. It may not just be the obstetrics and gynecology fields that lose physicians in certain states; other specialties could follow suit. For example, if an oncology resident or physician wishes to protect their physician-patient relationships or ensure that all treatment options remain available to their patients, practicing in a restrictive state may put them at legal and moral risk. In order to protect themselves, physicians will likely move to a state in which they are safe to practice to the fullest extent of their Hippocratic Oath.

Thus begins the great dive into deeper healthcare disparity in this country, all thanks to the overruling of *Roe v. Wade*.

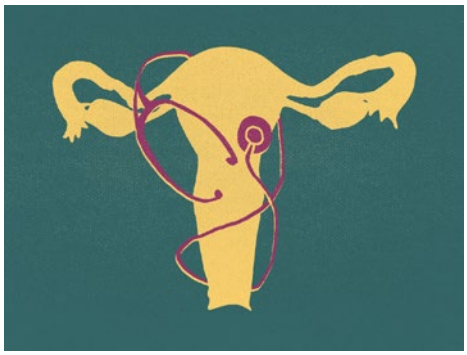
Legislatures have the power to avoid this public health crisis, however. If state governments so chose, they could bypass the devastating consequences of restrictive abortion laws by simply not enacting them.

States should seek to maintain reasonable legislation which—at the very least—protects the right to medically necessary abortions and abortions for circumstances of grave emotional or physical harm to the birthing person.

IN THE ARCHIVES

CANCER HISTORY PROJECT

The 50-year history of abortion and oncology in *The Cancer Letter* archives



Following the Supreme Court's June 24 ruling on *Dobbs v. Jackson Women's Health*, the Cancer History Project has created a timeline of the regulatory history of women's reproductive rights based on news stories from *The Cancer Letter* that track the impact of "pro-life" policies on cancer research and cancer care.

Over the past 50 years, this battle has been waged on three fronts:

- Fetal tissue and embryonic stem cell research,
- The alleged link between breast cancer and abortion, and
- State laws governing access to abortion.

A half-century ago, the debate over fetal tissue research emerged in the context of standards for human subject protection in government-funded experiments. In 1974, research using fetal tissue was mentioned alongside experimentation on prisoners and patients in mental institutions.

On several occasions, appropriations for NIH were held hostage to the issue of funding fetal tissue research. Every year since 1996, Congress amended the Labor-HHS appropriations bill to prohibit NIH funding of research "in which a human embryo [is] destroyed, discarded, or knowingly subjected to risk of injury greater than that allowed for research on fetuses in utero."

To adjust, NIH created two types of fetal tissue research—the sort that requires destruction of fetal tissue and the sort that doesn't.

For more than a decade, NCI-funded research had to be limited to 60 cell lines that were already in use. Mouse models were seen as a potential alternative to the "NCI 60." The ban on federal funding for embryonic stem cell research was ultimately lifted by then-President Barack Obama in 2009.

"This research has been a political football over the course of the last 30 years, with different administrations of the federal government taking different positions on it," I. Glenn Cohen, deputy dean and faculty director of the Petrie-Flom Center for Health Law Policy, Biotechnology & Bioethics at Harvard Law School said to *The Cancer Letter*.

Dobbs changes the rulebook. "Essentially, what Justice Alito's opinion is saying, or what I understand him to say, is that if the state were to want to ban this research entirely, to say, 'Any research involving the destruction of an embryo is banned in X state,' there's nothing in the Constitution that prohibits that," Cohen said. "That's how I read his opinion, which is to say, because it involves the destruction of potential life, and there's no right to destroy potential life."

The alleged link between abortion and breast cancer surfaced—and quickly became politicized—during the George W. Bush Administration. No evidence exists to demonstrate that women who had had abortions or miscarriages are at an increased risk of breast cancer, NCI said at the time.

The political atmosphere was so charged and pitfalls so deep that, in 2012, Susan G. Komen for the Cure, a fast-growing breast cancer charity, was dealt devastating blows from both sides of the abortion issue. Komen's attempt to stop funding breast screening at clinics operated by Planned Parenthood triggered boycotts from pro-choice advocates. As the charity reversed course, anti-abortion groups attacked.

Last year, after Texas enacted a law that restricted abortion, two scientists who coordinated peer review for Cancer Prevention and Research Institute of Texas, resigned in protest. CPRIT officials thanked the departing scientists for their service, saying that the research institute is focused on cancer, describing abortion as an describing the law in question as "unrelated to CPRIT's mission." Subsequently, 50 physicians and scientists who conduct reviews for CPRIT signed a strongly-worded letter stating:

"The state's overt attack on women's reproductive rights and its misguided and harmful COVID policies demonstrate an unwillingness by Texas lawmakers to prioritize the long-term health of citizens over short-term political gain," CPRIT's reviewers said in the statement shared with *The Cancer Letter*. "We strongly believe in the CPRIT mission and are committed to supporting it, but we must speak out against policies that are anathema to its spirit. Failure to do so would implicitly signal that we accept those policies; we do not."

Post-*Dobbs*, this debate has gone national.

Excerpts of these stories are available here.

50 years of Duke cancer care

In July, the Cancer History Project will be highlighting the founding—and founders—of oncology's institutions. Duke Cancer Institute became an NCI-designated cancer center in 1973, two years after the signing of the National Cancer Act of 1971.

- Duke Celebrates 50 Years of Cancer Care — and Looks Toward the Next 50
  By Duke Cancer Institute | July 7, 2022

When Joseph O. Moore, MD, came to Duke as a fellow in 1975, he and his mentors treated chronic myeloid leukemia (CML) with a chemotherapy regimen that was like a "wet blanket." It suppressed the cancer for a few years. "But it didn't change the trajectory of the disease," Moore said. Patients developed acute leukemia, which was almost always fatal.

By the early 1990s, younger patients could achieve a cure with a bone marrow transplant, though complications were common. By 1999, Moore was the Duke investigator for a national study of a targeted drug, imatinib, which stops leukemia cells from growing by shutting down a key protein. When imatinib was approved by the Food and Drug Administration (FDA) in 2001, it transformed CML into a disease easily treated by taking a pill.

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

The CML example provides a snapshot of just how far cancer treatment has come in the last 50 years. For many patients, "There's an expectation of success and people living normal lives," said Moore, professor emeritus of medicine.

Much of that progress can be traced to research funded by the "war on cancer," which launched in 1971 when congress passed the National Cancer Act. The act gave the National Cancer Institute (NCI) the authority and funds to create a national cancer program. The backbone is a network of comprehensive cancer centers that provide patient care and conduct rigorous research to find new and better ways to prevent, diagnose, and treat cancer.

Duke was one of the original eight such centers, designated in 1973 because of the strong research and clinical care programs it had already put into place, including one of the first brain tumor programs in the United States, said Steven Patierno, PhD, deputy director of today's Duke Cancer Institute (DCI), and professor of medicine.

In 1937, Barnes Woodhall, MD, came to Duke as its first chief of neurosurgery—(an the only neurosurgeon in North Carolina). He established at Duke one of the first brain tumor programs in the nation.

- Then, Now, Next: History of Cancer Care at Duke / Published Spring 2012 in DukeMed Magazine
  By Duke Cancer Institute | July 6, 2022

When Evelyn Morgan was hired as Duke's first oncology clinical nurse specialist in 1967, she embraced her role. "I was drawn to the field because it seemed romantic and challenging. We were going to cure people!" she says. "But often what we gave patients could prove to be no good."

In those early days, when patients often died from the side effects of new treatments rather than the cancer itself, researchers and doctors all over the country were desperate for a better way. Just a few years after Morgan started work on the wards, in the early 1970s, the government would declare "war" on the cancer menace and create the nation's first eight comprehensive cancer centers—one of which was at Duke. In the decades that followed, Duke scientists and clinicians contributed, discovery by discovery, to a growing arsenal of tactics to prevent and treat the once-unstoppable disease—offering new hope to patients in North Carolina and all over the world.

Yet while many have benefited from those advances, the dream of curing people too often remains elusive. With a vision for accelerating progress, Victor Dzau, MD, chancellor for health affairs at Duke, led the conceptualization and creation of the Duke Cancer Institute, which was ultimately launched in 2010.

The Duke Cancer Institute represents a total restructuring of clinical care and research designed to generate innovative ideas and speed the translation of scientific discoveries into advances in care. This new approach to cancer care and research was catapulted forward in February 2012 with the opening of the new Duke Cancer Center, where those treatment advances will be delivered to patients in a far more focused and patient-friendly manner than ever before.

Duke survivor spotlight: Gayle Serls, Sabrina Lewandowski

- Extraordinary: Gayle Serls, Duke's First Adult Cord-Blood Transplant Patient
  By Duke Cancer Institute | July 7, 2022

This patient story was published in 2012 in DukeMed Magazine.

Gayle Serls of Durham says her life is ordinary—and that's just fine with her. For a time, it was about as far from ordinary as a life can get.

In 1995, at 45 years old, Serls was diagnosed with a rare form of acute lymphocytic leukemia, which could not be treated with conventional chemotherapy. Her best hope was an autologous bone marrow transplant, for which she was referred to Johns Hopkins. The night before she was to leave, though, she learned that her cancer had returned, and the procedure could not be performed.

"Now I had no hope," she says.

But a new option was taking shape at Duke. Joanne Kurtzberg, MD, had pioneered the use of cord blood transplants to treat children with cancer in 1993—and in 1996, Serls became the first adult to receive the groundbreaking procedure at Duke. Today, Serls is one of the longest-surviving adult cord blood transplant patients in the world, and helps make the lifesaving procedure possible for others through her job at the Carolinas Cord Blood Bank at Duke.

Duke physician-scientists continue to pioneer advances in the field, through both the pediatric program and an adult program founded by Nelson Chao, MD, in 1996.

- First Comes Love: Sabrina Lewandowski, Duke Brain Tumor Patient
  By Duke Cancer Institute | July 7, 2022

One morning in 2002, Sabrina Lewandowski awoke with a headache that wouldn't let up. The then 30-year-old teacher eventually was diagnosed with glioblastoma multiforme, the deadliest form of brain cancer.

Duke's Peter Bronec, MD, performed surgery, and Lewandowski was referred to neuro-oncologist Henry Friedman, MD, deputy director of the Preston Robert Tisch Brain Tumor Center at Duke, where she was immediately started on chemotherapy and radiation.

In the meantime, her boyfriend, Gregory, proposed—he had purchased a ring while she was in surgery. "Later I begged him not to marry me," she says, "because I couldn't even promise him a year."

But the team at Duke had a plan. "Dr. Friedman told me the plan, and he said that if it didn't work, we had another plan," she says. She battled neutropenia and lost her hair. But the cancer never returned.

"Rather than settle for the standard of care, we used a rotation of chemotherapeutic agents following surgery and radiotherapy," says Friedman. "We believe she did well because we used multiple agents, which is not the norm in this fi eld, but she also may have had a tumor with a unique predisposition to respond to therapy. I choose to believe that our foundation of hope—which embraces more than the standard of care— made the difference."

Ten years on, Lewandowski remains cancer-free. In February 2012 she became the first patient seen in the Preston Robert Tisch Brain Tumor Center's new Duke Cancer Center clinic—and a first-time mom, welcoming daughter Layla on February 9.

This column features the latest posts to the Cancer History Project by our growing list of contributors.

The Cancer History Project is a free, web-based, collaborative resource intended to mark the 50th anniversary of the National Cancer Act and designed to continue in perpetuity. The objective is to assemble a robust collection of historical documents and make them freely available.

Access to the Cancer History Project is open to the public at CancerHistoryProject.com. You can also follow us on Twitter at @CancerHistProj, or follow our podcast.

Is your institution a contributor to the Cancer History Project? Eligible institutions include cancer centers, advocacy groups, professional societies, pharmaceutical companies, and key organizations in oncology.

To apply to become a contributor, please contact admin@cancerhistoryproject.com.

IN BRIEF

House Appropriations Committee approves FY23 $2.5B increase for NIH

The House Appropriations Committee approved a $2.5 billion increase for NIH in fiscal year 2023, as part of a June 30 markup of the Labor, Health and Human Services, Education, and Related Agencies spending bill.

The bill, which provides $242.1 billion total—including an increase of $28.5 billion, or 13% above FY22—passed with a vote of 32-24.

As part of the boost in funding for NIH, the bill includes $7.4 billion for NCI, an increase of $466 million above the FY22 enacted level, including $216 million for the Cancer Moonshot.

The bill also slates $2.75 billion for the Advanced Research Projects Agency for Health, an increase of $1.75 billion, to fund research into diseases including ALS, Alzheimer's disease, diabetes, and cancer.

President Joe Biden's proposal for FY23 would have boosted NIH base funds by $275 million—the smallest increase in the past seven years—and cut NCI funding by $199 million, while adding $4 billion to ARPA-H (*The Cancer Letter*, April 1, 2022). House appropriators voiced concerns that Biden's proposal would fund high-risk, high-reward projects at the expense of basic research (*The Cancer Letter*, May 13, 2022).

Fox Chase researchers win $1.4M DoD Prostate Cancer Health Equity Grant

A team of researchers at Fox Chase Cancer Center was awarded a Department of Defense Prostate Cancer Health Disparity Research Award for New Investigators.

The three-year, $1.4 million grant provides funding to investigate how social determinants of health, including environment and socioeconomic status, impact quality of life and treatment-related decision-making in men with advanced prostate cancer.

"For this grant, we wanted to take a comprehensive approach and look at not only a patient's own social and economic circumstances, but also the neighborhood where they live, to see how these factors work together to impact patient quality of life and satisfaction with their prostate cancer treatment decisions," Shannon Lynch, assistant professor in the Cancer Prevention and Control research program at Fox Chase, said in a statement.

Lynch is the principal investigator on this grant. Her colleague, Erin K. Tagai, assistant research professor in the Cancer Prevention and Control research program, is a co-investigator.

Lynch's research uses a "neighborhood lens" to identify social determinants that can help explain differing rates of advanced prostate cancer across populations. Tagai focuses on identifying social determinants reported by localized prostate cancer patients that affect treatment decision-making and quality of life.

Black men in particular are more likely to be diagnosed with and die of prostate cancer and are also more likely to report decreased quality of life after they receive treatment. Lynch and Tagai's study aims to identify social determinants of health that explain these disparities, to unpack the causes underlying them, and to use the findings to inform interventions that will improve patients' quality of life.

The study is designed in three phases. The first two phases will draw data and recruit eligible participants from Fox Chase and Temple Health clinics, as well as available databases, including the Temple and Fox Chase contributions

to the Pennsylvania Urologic Regional Collaborative, a statewide database of men diagnosed and treated for prostate cancer in urology practices.

In the first phase, Lynch and Tagai will identify social determinants of health that might explain differences between Black and white men diagnosed with prostate cancer when it comes to how they choose treatment and what their quality of life is after treatment.

In the second phase, the researchers will interview some of these men, as well as clinicians, including Fox Chase and Temple Health oncologists, to get their input on why the disparities might be occurring.

The final phase of the research will be translational.

"The main goal of this study is to be able to update and adapt an existing social determinants of health screening tool based on our study findings," Lynch said.

The tool would help clinicians identify men who might be at risk for regret or poorer quality of life after their treatment decisions, with the end goal of connecting these men with social programs and other resources to inform their treatment.

Fred Hutch announces 2022 Eddie Méndez Award recipients

Fred Hutchinson Cancer Center announced the 10 recipients of the 2022 Dr. Eddie Méndez award. The awards are named after a physician-scientist at Fred Hutch who focused on supporting early-career scientists underrepresented in science.

Now in its fourth year, the award has recognized a total of 28 recipients.

The 2022 recipients are postdoctoral researchers from across the U.S. with research expertise in cancer, infectious disease, and basic sciences. They will be honored at a Sept. 19-20 symposium.

"We are proud of this year's awardees, whose accomplishments to both science and diversity, equity, and inclusion efforts are truly outstanding. We look forward to welcoming them to the Hutch this September and honoring the memory of Dr. Méndez," Christopher Li, faculty director of the Office of Diversity, Equity, and Inclusion and associate director of DEI for the Fred Hutch/University of Washington Cancer Consortium, said in a statement. Li holds the Helen G. Edson Endowed Chair for Breast Cancer Research at Fred Hutch.

People interested in applying for next year's Méndez award can reach out to diversity@fredhutch.org for more information. Solicitation for the next round of applications is expected in mid-October and with applications accepted through March 2023.

The 2022 Dr. Eddie Méndez award recipients are:

- María Angélica Bravo Núñez, Harvard University
- Lesley Chapman Hannah, National Cancer Institute
- Aileen Fernandez, Yale University
- Jaye Gardiner, Fox Chase Cancer Center
- Luis Hernandez-Nunez, Harvard University
- Alexis Jaramillo Caragena, Broad Institute
- Brittany Lord, National Cancer Institute
- David Martinez, The University of North Carolina at Chapel Hill
- Aaron Moye, Boston Children's Hospital, Harvard Medical School
- Daniel Fernando Zegarra-Ruiz, Memorial Sloan Kettering Cancer Center

Noel Alaka named vice president of life sciences at COTA

Noel Alaka was named vice president of life sciences COTA Inc.

Alaka will be responsible for developing partnerships with life sciences companies that are looking to adopt real-world data and real-world evidence in cancer research.

Most recently, Alaka was senior director of business development and alliance management at Parexel, where he helped to build and expand real-world data and real-world evidence services. Prior to that, Alaka worked in clinical development at Sanofi.

THE CLINICAL CANCER LETTER

CLINICAL ROUNDUP

Sabizabulin significantly reduces deaths in high-risk hospitalized COVID-19 patients

Results from a phase III COVID-19 study showed that oral sabizabulin, a novel dual antiviral and anti-inflammatory agent, improved outcomes in hospitalized moderate-to-severe COVID-19 patients at high risk for acute respiratory distress syndrome and death.

The study was published in *The New England Journal of Medicine Evidence*. Sabizabulin is sponsored by Veru Inc.

The phase III clinical trial is a double-blind, randomized, multicenter, and global placebo-controlled study evaluating oral, once-a-day dosing of sabizabulin 9 mg versus placebo in approximately 210 hospitalized moderate to severe COVID-19 patients who were at high risk for ARDS and death.

Patients were randomized in a 2:1 ratio to the sabizabulin treatment group versus placebo. Patients in both treatment groups were allowed to receive standard of care treatment including remdesivir, dexamethasone, anti-IL6 receptor antibodies, and JAK inhibitors.

The trial was conducted in the United States, Brazil, Colombia, Argentina, Mexico, and Bulgaria. COVID-19 infections treated in the study included the delta and omicron variants. A planned interim analysis was conducted in the first 150 patients randomized into the study.

The Independent Data Safety Monitoring Committee unanimously recommended that the phase III study be halted early due to clear efficacy benefit. For the primary efficacy endpoint, which was death at or before day 60, sabizabulin treatment resulted in a clinically and statistically meaningful 55.2% relative reduction in deaths (p=0.0042) in the intent to treat population.

At day 60, the placebo group (n=52) had a 45.1% mortality rate compared to the sabizabulin-treated group (n=98), which had a 20.2% mortality rate. In the overall study of 204 randomized patients, the reduction in the all-cause mortality (ITT population) was similar to the results observed in the interim efficacy analysis patient population with sabizabulin treatment resulting in a 51.6% reduction in deaths compared to the placebo group.

The key secondary endpoints included effects of sabizabulin treatment on mortality through day 29, with a placebo mortality rate of 35.3% compared to sabizabulin treatment mortality rate of 17%, sabizabulin treatment resulted in an absolute reduction of 18.3 percentage points and a relative reduction in deaths of 51.8%.

Sabizabulin treatment also resulted in a 43% relative reduction in days in ICU (p=0.0013), 49% relative reduction in days on mechanical ventilation (p=0.0013), and 26% relative reduction in days in hospital (p=0.0277) compared to placebo group. Adverse and serious adverse events were lower in the sabizabulin group compared to the placebo group.

NCI study: COVID-19 was third leading cause of death in the U.S. in 2020 and 2021

COVID-19 was the third leading cause of death in the United States between March 2020 and October 2021, according to an analysis of national death certificate data by researchers at NCI.

The study was published in *JAMA Internal Medicine*.

During the 20-month period studied, COVID-19 accounted for 1 in 8 deaths (or 350,000 deaths) in the U.S. Heart disease was the number one cause of death, followed by cancer, with these two causes of death accounting for a total of 1.29 million deaths.

Accidents and stroke were the fourth and fifth leading causes of death. In every age group 15 years and older, COVID-19 was one of the top five causes of death during this period.

When the authors analyzed deaths in 2020 (March-December) and in 2021

(January-October) separately, they found that in 2020, COVID-19 was the fourth and fifth leading cause of death among people ages 45-54 and 35-44, respectively. But in 2021, COVID-19 became the first and second leading cause of death in these age groups. Among those 85 and older, COVID-19 was the second leading cause of death in 2020, but dropped to third in 2021, likely because of targeted vaccination efforts in this age group.

Past data have shown that deaths from other causes, including heart disease, accidents, stroke, Alzheimer's disease, and diabetes increased from 2019 to 2020, possibly because people were reluctant to seek medical care for fear of catching COVID-19.

ACS study: Patients report increased likelihood to enroll in decentralized clinical trials

In a survey of nearly 1,200 recent cancer patients and survivors conducted as part of the American Cancer Society Cancer Action Network's Survivor Views project, more than 80% of respondents said they would be willing to use remote technologies and tools in a trial.

The article was published in *JAMA Network Open*.

Willingness to enroll in a clinical trial increased—even among those who initially said they would not enroll—when told they could use remote technology and other decentralized tools to decrease the need for in-person visits and other appointments. Many patients (44%) had already begun using remote care outside of a clinical trial and reported that their health care issues and questions had been well addressed (95%) by the remote interaction.

"The pandemic necessitated mass adoption of remote technologies, and patients' positive experiences with those tools is increasingly reflected in their willingness to use technology in trials," Devon Adams, senior analyst in policy and legislative support on emerging science at ACS-CAN and author of the article, said in a statement. "Expanding who is able to enroll in trials through these tools could have a significant positive impact on the number and diversity of patients enrolled in trials. Researchers and regulators should take note and ensure these tools can continue to be used and are widely available."

The DIVERSE Trials Act (S.2706/ H.R. 5030), currently before Congress, could further help expand enrollment opportunities and improve clinical trial diversity by requiring FDA to issue permanent guidance on the use of decentralized clinical trial tools, ACS-CAN said.

"This research provides more evidence that any changes to telehealth regulations must prioritize equitable patient access, and we hope lawmakers consider the benefits to these technologies when addressing these important issues," Adams said.

Cedars-Sinai/JHU study: Three-drug combo prevents pancreatic cancer metastasis

Researchers at Cedars-Sinai Cancer and Johns Hopkins University discovered a novel three-step treatment that disrupts the pancreatic tumor microenvironment in laboratory mice.

The study was published in *Gastroenterology*.

The researchers studied a three-step strategy that combined an anti-PD-1 immunotherapy antibody and a protein known as FAKi with a novel pathway called CXCR4.

"These three drugs, used in combination in a laboratory setting, prevented disease metastasis," corresponding author Arsen Osipov, program lead in the Pancreatic Cancer Multidisciplinary Clinic and Precision Medicine Program at Cedars-Sinai Cancer, said in a statement. "By focusing on the difficult-to-treat tumor microenvironment, we were able to amplify an immune response while simultaneously attacking cancerous cells."

As a next step, Osipov, also a medical oncologist and researcher in the Gastrointestinal Research Group at the Samuel Oschin Cancer Center, and team plan to develop a clinical trial to further explore the treatment potential of the CXCR4 pathway.

Cleveland Clinic study shows role of ecological cellular interactions in targeted NSCLC therapy resistance

Cleveland Clinic researchers measured cellular interactions in a simplified tumor environment consisting of drug-resistant non-small cell lung cancer cells and drug-sensitive precursor cells, aiming to better understand how therapeutic resistance develops.

"In the study of drug resistance, researchers often try to understand the fitness of cells that have specific mutations in the presence of a drug in a laboratory setting," Jacob Scott, radiation oncologist and head of Cleveland Clinic's Theory Division in the Lerner Research Institute Department of Translational Hematology and Oncology Research, said in a statement. "But the reality is more complex, because tumor cells don't exist in a vacuum; instead, they co-exist in a complex, heterogeneous mixture of other tumor cells and normal tissues—an interacting ecology."

The study was published in *Science Advances*.

Cells resistant to the metastatic NSCLC treatment gefitinib were derived from existing lung cancer cells by continual treatment with gefitinib over six months, and grown in an in vitro co-culture experiment with their sensitive ancestors. The researchers used an assay they had previously developed to assess cellular growth dynamics with and without gefitinib.

"We cultured the two groups of cells together in different starting fractions, and we measured how their growth changed depending on how much of each group was mixed together," Jeff Maltas, postdoctoral researcher at Cleveland Clinic and co-lead author on the study, said in a statement.

The researchers found that the fitness of the resistant type of cell changed drastically depending on the composition of the mixture. The resistant population was outcompeted by the ancestral line at all studied population frequencies in the absence of therapy, pointing to complete competitive exclusion of the resistant population and a cost of resistance.

When gefitinib was added, there was a complete reversal of this effect; the resistant clone was able to outcompete the sensitive ancestor.

The changing growth dynamics between treatment-resistant and treatment-sensitive cells could not be detected by standard assays available to date, suggesting a novel mechanism by which resistant cells persist in the absence of treatment, the researchers said.

Tukysa shows durable responses in HER2+ mCRC

Results from the pivotal phase II MOUNTAINEER trial showed Tukysa (tucatinib) in combination with trastuzumab was well-tolerated with durable responses in patients with previously treated HER2-positive metastatic colorectal cancer.

Tukysa is sponsored by Seagen Inc.

These late-breaking data were presented in an oral session at the European Society for Medical Oncology World Congress on Gastrointestinal Cancer on July 2 in Barcelona, Spain.

At a median duration of follow-up of 20.7 months (interquartile range: 11.7-39.0), results of the MOUNTAINEER trial showed a 38.1% confirmed objective response rate (95% CI: 27.7-49.3) per blinded independent central review in the HER2-positive patients who were assigned to receive Tukysa in combination with trastuzumab (n=84 with a median age of 55.0 years [24-77]).

In these patients, the median duration of response per BICR was 12.4 months (95% CI: 8.5-20.5). Median progression-free survival per BICR was 8.2 months (95% CI: 4.2-10.3), and median overall survival was 24.1 months (95% CI: 20.3-36.7). At study entry, 64.3% and 70.2% of these patients had liver or lung metastases, respectively, and had received a median of 3.0 (1-6) prior lines of systemic therapy.

In a cohort of patients who received Tukysa monotherapy (n=30), the ORR per BICR by 12 weeks was 3.3% (95% CI: 0.1-17.2) and the disease control rate was 80.0%. Participants who did not respond to Tukysa monotherapy by 12 weeks or progressed at any time had the option to receive the combination of Tukysa and trastuzumab.

Data from this trial will form the basis of a planned supplemental New Drug Application to FDA for accelerated approval. Merck has exclusive rights to commercialize Tukysa in regions outside of the U.S., Canada, and Europe and plans to discuss these results with certain global health authorities.

DRUGS & TARGETS

FDA accepts BLA for mosunetuzumab in relapsed or refractory follicular lymphoma

FDA accepted the Biologics License Application and granted priority review for mosunetuzumab, a potential first-in-class CD20xCD3 T-cell engaging bispecific antibody, for the treatment of adults with relapsed or refractory follicular lymphoma who have received at least two prior systemic therapies.

Mosunetuzumab is sponsored by Genentech.

FDA is expected to make a decision on approval of the immunotherapy by Dec. 29, 2022.

The BLA is based on positive results from a pivotal phase I/II GO29781 study of mosunetuzumab. The study showed high complete response rates, with the majority of responders (57% [95% CI: 49-70]) maintaining responses for at least 18 months, and manageable tolerability in people with heavily pretreated FL.

After a median follow-up of 18.3 months, the CR rate was 60% (n=54/90) and the objective response rate was 80% (n=72/90). The median duration of response among those who responded was 22.8 months (95% CI: 9.7-not estimable).

Results were presented for the first time in December 2021 at the 63rd American Society of Hematology Annual Meeting & Exposition.

FDA granted Breakthrough Therapy Designation to mosunetuzumab for the treatment of adults with R/R FL who have received at least two prior systemic therapies in June 2020 and Orphan Drug Designation in December 2018. The European Commission granted conditional marketing authorization for mosunetuzumab for the treatment of people with R/R FL who have received at least two prior systemic therapies in June 2022.

The development program for mosunetuzumab is ongoing, including two phase III studies: CELESTIMO, investigating mosunetuzumab plus lenalidomide in second-line plus (2L+) FL, and SUNMO, investigating mosunetuzumab plus Polivy (polatuzumab vedotin) in 2L+ diffuse large B-cell lymphoma.

AstraZeneca to acquire TeneoTwo and its clinical-stage T-cell engager, TNB-486

AstraZeneca will acquire TeneoTwo Inc., including its phase I clinical-stage CD19/CD3 T-cell engager, TNB-486, currently under evaluation in relapsed and refractory B-cell non-Hodgkin lymphoma.

The acquisition of TNB-486 aims to accelerate the development of this potential new therapy for B-cell hematologic malignancies, including diffuse large B-cell lymphoma and follicular lymphoma.

AstraZeneca will acquire all outstanding equity of TeneoTwo in exchange for an upfront payment of $100 million on deal closing.

Under the agreement, AstraZeneca will make additional contingent R&D-related milestone payments of up to $805 million and additional contingent commercial-related milestone payments of up to $360 million to TeneoTwo's equity holders.

The transaction is expected to close in the third quarter of 2022, subject to customary closing conditions and regulatory clearances. The transaction does not impact AstraZeneca's financial guidance for 2022.

NCI TRIALS

NCI Trials for July 2022

The National Cancer Institute approved the following clinical research studies last month.

For further information, contact the principal investigator listed.

Phase I - 10508
A Phase 1 Study of Nivolumab in Combination with ASTX727 in B-cell Lymphoma (NHL or HL) with an Expansion Co-

hort in Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)

NY011 Laura and Isaac Perlmutter Cancer Center at NYU Langone
Diefenbach, Catherine S. Magid
(212) 731-5670

Phase I - NRG-GY027
Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Paclitaxel and Carboplatin with Ipatasertib as Initial Therapy of Ovarian Cancer PTMA 100805

NRG Oncology
Fuh, Katherine Cynthia
(314) 362-3181

Phase I - PEPN2113
A Phase 1 and Pharmacokinetic Study of Uproleselan (GMI-1271, NSC #801708) in Combination with Fludarabine and Cytarabine for Patients with Acute Myeloid Leukemia, Myelodysplastic Syndrome or Mixed Phenotype Acute Leukemia That Expresses E-selectin Ligand on the Cell Membrane and is in Second or Greater Relapse or that is Refractory to Relapse Therapy

Pediatric Early Phase Clinical Trial Network
Sulis, Maria Luisa
(212) 639-5175

Phase I/II - 10499
Phase Ib/II Study of ZEN003694 and Entinostat in Advanced and Refractory Solid Tumors and Lymphomas

Yale University Cancer Center LAO
LoRusso, Patricia Mucci
(203) 785-5944

Phase I/II - APAL2020B
A PedAL/EuPAL Phase 1/2 Trial of IMGN632 in Pediatric Patients with Relapsed or Refractory Leukemia

Children's Oncology Group
Kutny, Matthew A.
(205) 638-9285

Phase II - NRG-GU012
Randomized Phase II Stereotactic Ablative Radiation Therapy (SABR) for Metastatic Unresected Renal Cell Carcinoma (RCC) Receiving Immunotherapy (SAMURAI)

NRG Oncology
Hall, William Adrian
(414) 719-4694

Phase II - NRG-GY029
A Randomized Phase II Trial Comparing the Combination of PI3K Inhibitor Copanlisib (BAY 80-6946) and PARP Inhibitor Olaparib (AZD2281) to Standard Chemotherapy in Patients with Recurrent Platinum Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Have Progressed Through Prior PARP Inhibitor Therapy

NRG Oncology
Konstantinopoulos, Panagiotis A.
(167) 632-1914

Phase II - S2107
Randomized Phase II Trial of Encorafenib and Cetuximab with or Without Nivolumab (NSC #748726) for Patients with Previously Treated, Microsatellite Stable, BRAFV600E Metastatic and/or Unresectable Colorectal Cancer

SWOG
Morris, Van Karlyle
(713) 792-2828

Phase III - ARST2032
A Prospective Phase 3 Study of Patients with Newly Diagnosed Very Low-Risk and Low-Risk Fusion Negative Rhabdomyosarcoma

Children's Oncology Group
Haduong, Josephine Hoatuyet
(714) 509-4348