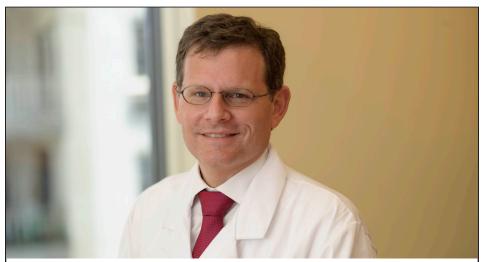
# THE CANCER LETTER

March 25, 2016

www.cancerletter.com

Vol. 42 No. 12



## <u>Conversation with The Cancer Letter</u> Clifford Hudis Named CEO of ASCO

Clifford Hudis was named CEO of the American Society of Clinical Oncology.

Hudis, who served as ASCO president in 2013 and 2014, is chief of Breast Medicine Service as well as vice president for government relations and chief advocacy officer at Memorial Sloan Kettering Cancer Center.

Hudis, 56, will start the job at the society's headquarters in Alexandria, Va., June 27. He will succeed Allen Lichter, who is retiring after having held that job for ten years.

(Continued to page 2)

## **NEJM Editors: There Will Be No Clarification For Disputed Power Morcellation Story**

### By Matthew Bin Han Ong

The New England Journal of Medicine said it stands by the story that has triggered investigations of a potential breach of patient confidentiality.

In a paper that criticized FDA's regulatory actions that effectively ended power morcellation in gynecology, Lisa Rosenbaum, an NEJM national correspondent, made a statement that some readers interpreted as suggesting that she had access to confidential patient information (The Cancer Letter, March 18).

(Continued to page 5)

## <u>Slamming the Door</u> Part IX - "Furnituregate"

#### By Paul Goldberg

I first heard something about a red sofa that cost an impressive amount of money soon after I started to cover the controversy at the Cancer Prevention and Research Institute of Texas.

(Continued to page 8)

NCCN Launches Evidence Blocks ... Page 14

... Faye 17

In Brief Maha Hussain Joins Northwestern Lurie Cancer Center . . . Page 15

Drugs and Targets FDA Approves Roche Hepatits C RNA Test . . . Page 18

© Copyright 2016 The Cancer Letter Inc. All rights reserved. Price \$420 Per Year. Visit www.cancerletter.com

## Hudis Named ASCO CEO

(Continued from page 1)

"When the board of directors began its executive search nearly a year ago, we couldn't have imagined finding a candidate more ideally suited for the position," ASCO President Julie Vose said in a statement. "Dr. Hudis is one of the most highly respected, well-regarded oncology leaders in the world."

Announcing his move to his MSKCC colleagues in an email dated March 23, Hudis wrote: "I have been extraordinarily lucky to be part of the MSKCC community for nearly three decades and I have the greatest respect and personal affection for everyone here and our shared mission. This new opportunity is in large measure a direct consequence of the experiences I have had in working with so many of you since I arrived in 1988. Indeed, I have no desire to actually leave MSK and, while I will assume this new fulltime role, I will remain a member of our community with a very limited clinical practice on the Breast Medicine Service."

Later that day, Hudis spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

# **Paul Goldberg:** Why did you decide to take this job?

**Clifford Hudis:** Because this is the most fun, exciting and invigorating thing I can imagine doing at this stage of my life. It leverages the experiences and opportunities that I've been fortunate to have for three decades in oncology, and it's a chance to influence the quality of care that people get around the world. And I don't see any better place to accomplish all of that.

**PG:** What would be the three top issues for ASCO

## Editor & Publisher: Paul Goldberg Associate Editors: Conor Hale and Matthew Bin Han Ong

Editorial, Subscriptions and Customer Service: 202-362-1809 Fax: 202-379-1787 PO Box 9905, Washington DC 20016 General Information: <u>www.cancerletter.com</u>

Subscription \$420 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Other than "fair use" as specified by U.S. copyright law, none of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, photocopying, or facsimile) without prior written permission of the publisher. Violators risk criminal penalties and damages. Founded Dec. 21, 1973, by Jerry D. Boyd. ® The Cancer Letter is a registered trademark.

### under your leadership?

**CH:** I think it might change from what I tell you today. One of the things about ASCO is that it's a flexible, responsive, vibrant organization; maybe we'll talk a little more about some of these things in a moment. But besides that caution, obviously the cost of care in the United States is a critical issue, and I think we're going to need a pretty thoughtful, considerate collaboration from all the stakeholders that allows us to preserve what's good about our system, but addresses some of its weaknesses.

At the same time, the other obvious big thing, that we will be committed to for a long time, is the use of Big Data, which is increasingly sitting in front of us from all of our electronic records, but also from other sources. With it we can bring more of medical care and research into the 21<sup>st</sup> century.

We have to match what else is going on in the broad digital economy. Finally, I think that there's an opportunity to look at how we do adult education, which is such a critical role for ASCO, specifically, but also an ongoing commitment for all of our members.

#### **PG:** *Do you mean CME?*

**CH:** Well I'm talking about how we do education; how adults learn most efficiently. I wonder about this because our educational challenges are actually growing very quickly with the exciting advances being made in molecular biology and the translation of that into clinical care. I think we have a very exciting opportunity to improve how we do education and make it more efficient and effective.

I will add a fourth thing, I know you asked for three, but I think it's worth mentioning the opportunities that are developing around the world. We may come back to this, but from a macroeconomic point of view, the proportion of people in the world who are poor has never been smaller, the number of countries that are rising solidly into middle income ranges is growing, and the number of people who are going to have middle class aspirations for everything, including their health care, is growing. I think there's a tremendous opportunity for ASCO to help seed the deployment of the everimproving quality of cancer care around the world.

These are all things that I see right away as opportunities. I humbly suggest to you that I may have all these wrong; I may have the order wrong, but I think these are where we will start.

**PG:** You recently served as president of ASCO. Who will define ASCO's priorities? Is it going to be a strong CEO or a strong president?

CH: It's really multiple players.

ASCO is a member-driven, volunteer-run organization and it's an association, specifically, of medical professionals. In ideal circumstance, this is a collaboration between a CEO who is identifying possibilities, trends, opportunities, and risks with a board of directors and a president who extend the reach and the range of the CEO tremendously and who can highlight additional opportunities.

So what we do is collaborate. I've been on one side of this as a president, and I'll be on the other side of this as a CEO, and obviously each president works a little differently, and the tone and tenor of a board can evolve over time, but this is very much a collaboration, and it has to be.

**PG:** Can ASCO continue to grow the way it has in the Lichter years? Should it?

**CH:** Allen is a tough act to follow, isn't he? He's been a really remarkable—not just as a CEO, but as one of several fantastic mentors that I've been lucky to have.

I think we may measure ASCO's future growth in different ways. I don't know that we can continue to grow the membership or the attendance of the annual meeting at the same pace as in the past. But we've made a very big commitment to CancerLinQ, for example. I'm not sure we can make as big of a programmatic bet in the immediate future.

On the other hand, some of the things we were already talking about, I think, represent tremendous opportunities—we clearly have opportunities to grow our impact and, if you will, our footprint on the world. I'm very optimistic that the changes in cancer care and technology are going to let us grow as or more dramatically as we have in the past, but we may be measuring that growth in new ways.

**PG:** *I* thought one way to measure that was money—that was really how I was asking the question—revenues continuing to grow.

CH: I see. You mean business opportunities? PG: *Of course*.

**CH:** Well no money, no mission, right? We know that.

And that's something that, again, has been a great strength of Allen's. He has been a successful financial steward of the organization, and I think the growth can certainly continue in that regard. I think there can be new products and new services that can appeal to the members, and beyond the members to new constituencies, and that's something that we've already begun to look at and will be looking at even more intensively in the years ahead.

PG: What future do you see for CancerLinQ, or

## ASCO's role in big data?

**CH:** Well, CancerLinQ is a critical initiative. It has the potential to usher in a new type of learning and care, not just for cancer patients, but also for as a model for other areas of medicine.

The opportunities are almost limitless, but a lot of it is catch-up. A lot of what we aim to accomplish in cancer care occurs in other industries; I alluded to this already. The predictive abilities of machine learning, the ability to recognize associations in behaviors and activities, all of that is going to enrich cancer care, but also, I think, all of medical care.

What's unique and critical about CancerLinQ is that it is run by physicians and its fundamental purpose is quality of care. Yes, ultimately, it has to be self-sustaining, so it has to be financially viable, but our focus, like other things we do, is different from conventional for-profit businesses. So in that regard, I think the success of CancerLinQ is critical to our field. I think this is going to continue to garner a tremendous amount of our attention. It'll be adjusted; we may change directions a little bit as we realize places where we can succeed and places where maybe it is harder to succeed. But fundamentally, there's going to be a product from CancerLinQ soon, and it's going to be a big contribution to how doctors treat patients.

**PG:** I think last time we talked was about the barriers to data sharing. Is that something that can be fixed?

**CH:** The answer to that, I think, may come from what was then an unexpected quarter. I think that the vice president and the president's commitment to what's been called the cancer moonshot - you've covered that already – includes a goal of providing resources to facilitate the use of big data. And one of the things that they've zeroed in on already is the idea of interoperability.

I can't emphasize how important this is—not just for the research aspirations that we have, but, honestly, for day-to-day care. When you walk into an emergency room across town from where you've been getting your chronic care for any illness, it really shouldn't be a project to get all of your records digitally transmitted, especially the key data points, but right now it's just too hard. So interoperability is going to be a whole lot more than how databases communicate. It's going to be about how you get your everyday care.

It's a facile example, but you know, if you walk into the hotel lobby in Budapest and slip your ATM card into a random machine, you manage to get money withdrawn from your checking account in Washington. So there's interoperability across this system, and we expect it. Why do we tolerate less in medicine?

**PG:** Well that's because a lot of it is a little more complicated than an ATM.

**CH:** But it doesn't have to be. Not this. Standards could exist and interoperability could be enabled, and to be very frank, it's my understanding that some of the underpinnings of the original legislative push to get us on EMRs was meant to bring interoperability. I think this is a place where the delivered system has failed the original intent.

**PG:** *I'm sure we will be talking about this for a long time.* 

**CH:** Yeah. We have to undo this. It's an opportunity. **PG:** *Does ASCO have a role to play in drug pricing*?

**CH:** I would just point out that although our members did not create the current system and its perverse incentives, they've clearly been players within it. We also are always going to be relied upon to select the most appropriate and effective treatments for patients. That's our ethical obligation and our expertise.

Sometimes our choices create financial hardships for patients, and that's something that's gotten more and more attention lately. Sometimes our choices increase the cost of care more generally. And that includes within the systems and the practices that employ so many of us too. Cost has many repercussions.

I think we have an obligation to lead this discussion, because we're the only people who can. We're the only people who can integrate not just the price, but also the impact, the value of various treatments in terms of the outcomes that we're trying to achieve. It's something that we can't leave to others.

**PG:** I noticed <u>something you said</u> in your presidential address at ASCO: "If we intend to achieve social justice in cancer care, we must define value in cancer care so that we are best able to optimally use society's precious resources."

*How do you see ASCO's role evolving in determining value-based reimbursement?* 

**CH:** Make no mistake about it, assessing value is hard. There can be subjectivity. And really smart, wellmeaning, well-intentioned, honorable people may not agree on how we do it. Despite those challenges, we have the Value Framework that ASCO has labored over for a long time. It will be refined, and I think we'll slowly hone in on what people can agree on—or at least what describes the basics of higher- versus lower-value care.

I think it's very related to the drug pricing question—we have to do this. If we don't, others will do it for us, and they won't declare that they're doing it overtly, they may not call it this, but it will be imposed on us and on our patients, and I'm concerned about how it would potentially restrict choice and access to care. So we have to do this.

PG: You're an academic's academic...

CH: You're flattering me.

**PG:** It's your path! And ASCO represents community doctors as well, so how will you address their needs?

**CH:** You're exactly right, ASCO represents the full spectrum of clinicians caring for patients, and by the way, that's going to extend beyond docs, to what are called mid-level providers—PAs and NPs, nurses, many others. We're all in this together and we're all trying to help patients.

So that's the first point. The second point is that you're right, I've been very fortunate to work in a really fantastic and innovative leading institution. I've had a variety of interesting research opportunities in my career within the cooperative group system, which is community-based, largely, or at least distributed to the community.

I've worked in other research networks; I've conducted industry-sponsored research. I've always maintained a busy clinical practice, in fact that's the hardest thing to cut down on as I move into this role - my clinic. Even at an academic center like Memorial, one of the things that people don't always realize that we have to run a balanced book. At the service level we have to generate enough revenue to pay everybody's salaries, staff and doctors; and we have to do it year after year. We have to deliver affable, empathic care to patients who expect and deserve no less. And I'm emphasizing this to point out that the challenges of academic practice are not so different any more from what's called community practice. And the lines get blurrier.

Many of our big centers, mine included, have built out a network of sites, geographically dispersed, and we've sought to distribute the same single standard of care to all of these sites. We've been as responsive as we can to the needs of the docs who staff those, some of whom you would call "community" docs. So with all of this, I think that's there more in common than different across the spectrum of practitioners.

At the same time I recognize the special challenges that many in traditional community practice have to meet. They have to run a business basically, and the leeway in some cases may be less than in others. But in the end I'm optimistic that our shared values and our shared goals are going to make something that ASCO and I can really help them with. **PG:** So you're noting a convergence, coming from both directions.

**CH:** I am. When you say community docs, for example, how many of our members are working in what used to be traditional small community practice? Some. Others are working in big multidisciplinary practices. Others still work for big commercial entities that are aggregating. And others still are working for academic centers even if they themselves are not pursuing traditional academic careers—meaning primary research, publication and teaching, and so forth. Again I think that we all have more in common than we have that's different.

**PG:** What priority will you place on ASCO's international work?

CH: A big one and a growing one.

I touched on this already, but the United States is of course just a small fraction of the world. We are the American Society of Clinical Oncology and we have been fortunate, as Americans, to have the resources in many cases to lead the development of so many of the therapies that benefit the world. But we also have this opportunity and obligation to share, and so we're going to be focusing more and more on the ways that we can contribute to the improving quality of care that's possible around the world.

**PG:** *As a New Yorker, will you be okay in this sleepy Southern town? Should we worry?* 

**CH:** I don't know what you're worried about, I've been commuting to Washington, honestly, for about seven years now, maybe eight. One of my children went to school there. I've been on the board of ASCO for six straight years and even in the years since then, I've been back and forth in my committee roles. And by the way, I'm originally a Philadelphian, so I grew up halfway between anyway.

**PG:** So I'll just withdraw the question.

**CH:** No, it's alright! I'm excited by the opportunity actually. I don't want to minimize it. But I'm going to be down there full time, and it's not so far from New York.

## INSTITUTIONAL PLANS

allow everyone in your organization to read The Cancer Letter and The Clinical Cancer Letter.

Find subscription plans by clicking Join Now at: <u>http://www.cancerletter.com</u>

## **NEJM Editors: No Clarification For Disputed Morcellation Story**

(Continued from page 1)

Rosenbaum is a cardiologist at Brigham & Women's Hospital, the institution where Amy Reed—a patient who brought national attention to the harm associated with the procedure—underwent her ill-fated hysterectomy.

Reed, who is now suing the hospital, also alleged that the NEJM story had breached her patient privacy. Officials at Brigham said an audit found no evidence of improper use of records and the hospital's radiology imaging archive system.

It is plausible that this explosion was sparked by an unfortunate choice of words by the author or, for that matter, editing or lawyering by NEJM. However, if that is the case, NEJM isn't willing to make a clarification.

In <u>her March 10 article</u>, titled "N-of-1 Policymaking—Tragedy, Trade-offs, and the Demise of Morcellation," Rosenbaum writes:

"Practice changed after 2013, when Amy Reed, a 40-year-old anesthesiologist and mother of six, underwent a hysterectomy with intraoperative morcellation for presumptively benign uterine fibroids at Boston's Brigham and Women's Hospital (where I have since joined the faculty). The masses turned out to contain foci of leiomyosarcoma (LMS), a rare, aggressive cancer that has a 5-year survival rate of 63% when diagnosed at stage I. Reed's LMS was stage IV, so her likelihood of surviving 5 years was only about 14%."

Was there an intermediate step that took Reed from stage I to stage IV?

Was that step power morcellation?

Or was Rosenbaum suggesting that Reed's disease was already stage IV when she received the power morcellation procedure? If that's the case, how would she know?

Michelle Meyer, an assistant professor of bioethics at Clarkson University, director of bioethics policy at the Clarkson-Icahn School of Medicine at Mt. Sinai, described Rosenbaum's phraseology as "grammatically ambiguous" and suggested some edits <u>in an article</u> for Forbes:

"It would have been better for all involved perhaps most of all for Rosenbaum herself—had she instead written something like this (changes in italics):

"Reed...underwent...morcellation for presumptively benign uterine fibroids...The masses turned out to contain...cancer that has a 5-year survival rate of 63% when diagnosed at stage I. *Following and likely as a result of—morcellation*, Reed's LMS was *diagnosed as* stage IV, so *by then* her likelihood of surviving 5 years was only about 14%."

NEJM editors aren't taking suggestions. "We do not plan to publish a clarification of Dr. Rosenbaum's article," NEJM said in a statement to The Cancer Letter. According to NEJM editors, Rosenbaum did not report unpublished, confidential health information about Reed.

"Dr. Rosenbaum was not reporting that the cancer was stage IV before the time of the initial fibroid surgery. It would be impossible to know this," NEJM officials said. "The stage of disease was widely reported in many news stories. It was reported so widely that we did not think it would be an area of dispute."

In the statement, the journal cites news stories by The Boston Globe, The Wall Street Journal, Prevention Magazine, and the Boston NPR affiliate WBUR as evidence that the staging of Reed's disease was widely reported.

NEJM initially declined to answer questions from The Cancer Letter about Rosenbaum's sourcing, citing an "ongoing investigation."

Contacted by Reed and her husband, Hooman Noorchashm, Rosenbaum said in an email that she didn't access Reed's records (The Cancer Letter, <u>March 18</u>).

#### Surgeon: A Clarification "Completely Reasonable"

Reed and Noorchashm said that the question of whether Reed had stage IV disease would likely figure in the couple's medical malpractice lawsuit against Brigham.

This consideration prompted them to file complaints with federal and state authorities.

Paul Sugarbaker, director of the Center for Gastrointestinal Malignancies and chief of the Program in Peritoneal Surface Oncology at MedStar Washington Hospital Center, also noted the lack of clarity in Rosenbaum's statement that "Reed's LMS was stage IV."

"It's not clear to me," said Sugarbaker, the surgeon who treated Reed's disseminated leiomyosarcoma in an emergency procedure Nov. 21, 2013. "If multiple people have a question, I would think it's completely reasonable that [Rosenbaum and NEJM] would clarify that issue."

Sugarbaker spoke to The Cancer Letter with Reed's permission.

"I don't understand Dr. Rosenbaum's thinking with that particular statement saying that it '*was*' stage IV," said Sugarbaker. "It doesn't hang together for me."

Sugarbaker's report doesn't specifically cite the stage of Reed's disease.

"I guess [conventional staging criteria] would apply. Five weeks after, when I saw Dr. Reed, it was established radiologically and histopathologically that there was sarcomatosis. I think that would meet the definition of stage IV.

"The evidence, based on radiologic studies done at Brigham & Women's Hospital prior to her morcellation, was that the disease was confined to the uterus," Sugarbaker said. "Now, how far had it progressed within the uterus, there's no way to know, because that evidence was morcellated. My knowledge of the case was that it was an unknown sarcoma.

"The only documentation of sarcoma implanted outside of the uterus came from the radiologic workup and then the pathology reports that were generated here [in Washington]," Sugarbaker said. "Dr. Rosenbaum would have to provide the evidence for that [stage IV claim]. It's not in any of Dr. Reed's records as far as I know."

Sugarbaker disagrees with Rosenbaum's characterization of the demise of morcellation as "N-of-1 policymaking."

"We've seen numerous patients, six patients that have had morcellation that ended up with peritoneal sarcomatosis," Sugarbaker said. "I just don't see how anyone can argue with the fact that scrambling up a malignancy within the peritoneal space is going to be an innocuous event.

"It seems to me that we should be able to do something better, that direct and conscious dissemination of a malignant process within the peritoneal space cannot be overlooked. There's got to be a better way to get at uterine fibroids."

Sugarbaker's operative report, which Reed and Noorchashm made available to The Cancer Letter, documents the local dissemination of tumor tissue in Reed's abdominal cavity:

"During the entire 90 minutes of the chemotherapy treatment, I used the curved Mayo scissors to remove several hundred small nodules from the small bowel surface, from the small bowel mesentery, from the ascending colon, and from the large bowel mesentery. I am not sure what these small nodules are. It is quite possible that some of them are sarcoma implants."

#### **Sophisticated Readers Admit Confusion**

"I think the passage was inartfully worded," tweeted Charles Ornstein, a senior reporter for ProPublica covering health care and the pharmaceutical industry. "I read it as 'before,' [Reed's surgery] but NEJM said that was not the intention or implication."

Rosenbaum's note about Reed's staging "could have been clearer in this sentence," wrote Ornstein, who won a Pulitzer Prize for Public Service in 2005 while working for the Los Angeles Times, and was a finalist in 2009.

"I admit that I misread the NEJM piece," Ornstein wrote, after he received an expanded response from NEJM. "But if others did too, should it be clarified?"

Clarity is especially important in this case because of the radioactive nature of the controversy, said Arthur Caplan, the Drs. William F. and Virginia Connolly Mitty Professor of Bioethics and director of the Division of Medical Ethics at New York University Langone Medical Center.

"You're talking about something that's dividing the surgical field and is even leading into federal action," Caplan said to The Cancer Letter. "In describing Dr. Reed's case, it is important that anyone writing on the case clearly note that she and her husband believe the morcellation caused the dissemination and subsequently the upstaging in the severity of her cancer. I think the firefight over the whole subject cries out for as much clarity as is possible."

Ivan Oransky, vice president of the Association of Health Care Journalists, highlighted NEJM's initial hesitance in explaining the meaning of Rosenbaum's writing.

"It is easy to say, <u>as some have</u>, that The Cancer Letter jumped the gun on this story, given what we now know about what NEJM says they meant," Oransky, vice president and global editorial director of MedPage Today, wrote <u>in Retraction Watch</u>. "But that would seem to ignore the fact that NEJM had several opportunities to clear up the confusion surrounding that sentence.

"The first, which in hindsight seems likely to have nipped the whole controversy in the bud, was when The Cancer Letter asked NEJM for comment sometime before the story about the essay ran Friday."

When Oransky asked NEJM whether a clarification is in order, he received a similar response.

"NEJM's other opportunity is, of course, to correct or clarify the actual piece, which they could do at any time," wrote Oransky, a Distinguished Writer In Residence at New York University's Carter Journalism Institute. "When we asked whether they would be doing so, however, a spokesperson said, 'we don't plan to change the article.""

This would not be the first time NEJM has declined to correct the record when issues were brought to the journal's attention, Oransky wrote.

"The New York Times reported on <u>one such case</u> <u>earlier this month</u>, in which the journal published a letter without realizing it omitted critical data about anti-clot drug Xarelto," Oransky wrote. Roy Poses, a clinical associate professor at the Alpert Medical School at Brown University, said that Rosenbaum's diction is vague.

"On re-reading the NEJM article, I find the sentence about cancer staging ambiguous," said Poses, president of the Foundation of Integrity and Responsibility in Medicine. "I am not sure what it means, and I can't really say whether it meant the cancer was stage IV initially, or whether the cancer became stage IV much later as is well known."

On March 20, Poses published <u>a blow-by-blow</u> <u>critique</u> of Rosenbaum's arguments on Health Care Renewal, a blog that advocates for "transparency, honesty and ethics."

"I thought there were many points made in the NEJM commentary that were interesting, but somewhat concerning," Poses said to The Cancer Letter. "That's why I attempted to discuss my concerns in the blog post."

#### The Anatomy of a Suspicion

Reed and Noorchashm said they filed complaints because Rosenbaum's statement that Reed's cancer "was" stage IV suggested that she may have had access to confidential information.

Here, it's important to consider the facts of the case:

Reed's early CT scans at Brigham revealed lung nodules that might suggest metastases at the time of morcellation in October 2013. This information was known to her Brigham physicians, Reed and Noorchashm said.

Subsequent biopsies found no evidence of malignant spread prior to the morcellation, according to Thomas Greene, the couple's attorney:

"In the First Set of Dana Farber records—on page 12/50, Dr. [Suzanne] George's Progress Note from 04/07/2014 states that Dr. Reed 'underwent pulmonary resection of two small pulmonary nodules on the right. I personally reviewed the pathology with and reviewed this with our sarcoma team at our pathology conference. There was no evidence of malignancy of the sample or clear evidence of treated tumor.""

On March 14, as a direct consequence of the NEJM story, Reed filed a complaint under the Health Insurance Portability and Accountability Act with the Office of the Massachusetts Attorney General and the HHS Office of Civil Rights.

"It is a fact that my case has been a high profile one within the BWH/DFCI system and in addition has been discussed in settings within the hospital, and in the press with my own permission," Reed wrote in the complaint. "But the simple fact remains that the content of Dr. Rosenbaum's article leads me to conclude that she, or a proxy not involved with my care, may have accessed my records illegally and in violation of HIPPA.

"This complaint is to request an immediate investigation...to determine...whether any of my immediate care team has, without my consent, exposed and misrepresented my medical information to Dr. Rosenbaum and the NEJM."

Brigham completed an audit of Reed's electronic medical record and radiology imaging archive system and determined that Rosenbaum did not access either system.

"I did not read Dr. Reed's medical records, nor did I discuss her care with any of her treating physicians," Rosenbaum wrote in a March 14 email to the couple.

Rosenbaum's article also states that Noorchashm has given up his "promising surgical career for a mission of offering comfort to people undone by illness."

Noorchashm disputed this, stating that no one at NEJM has fact-checked this statement with him. "It is simply untrue that I'm 'abandoning' my profession," Noorchashm said to The Cancer Letter. "This is a disgusting defamation of my professional reputation from a very powerful place."

Rosenbaum directed The Cancer Letter's questions to NEJM, which declined to comment.

Reed and Noorchashm launched an aggressive campaign in late 2013 against power morcellation over 300 patients and families have come forward claiming harm.

Their advocacy led to FDA restrictions and a black box label on the use of power morcellators, finding that one in 350 women undergoing hysterectomies or myomectomies have an unsuspected uterine malignancy. Hospitals banned the surgery, and the agency's final guidance largely ended insurance coverage for the procedure.

George Demetri, the director of the Center for Sarcoma and Bone Oncology at Dana-Farber Cancer Institute and a professor of medicine at Harvard Medical School, said FDA's November 2014 decision on morcellators is valid.

In early 2014, NEJM rejected a paper co-authored by Demetri on how power morcellation worsens outcomes for patients with undetected uterine sarcomas.

"I believe that we have gotten to a valid place where this practice is not routinely performed nor considered as it once was," Demetri wrote in an email that was shared with The Cancer Letter. "The [Rosenbaum] editorial should change nothing."

## <u>Slamming the Door</u> Part IX - "Furnituregate"

(Continued from page 1)

The sofa, I was told, was to be purchased with MD Anderson funds for the office of Lynda Chin. I wanted to look into it, but I want to look into many things, and some take precedence over others. This seemed to be fun, but it was undeniably trivial.

The sofa in question was intended for the same entity CPRIT was being asked to fund. Had I been able to get it through my thick skull that the furniture was a part of the same story that was causing the ungluing of CPRIT, I would have filed my freedom of information requests sooner.

When it finally appeared, my friends coined the term "furnituregate."

\*\*\*

As the first lady and a senior scientist at MD Anderson Cancer Center, Lynda Chin built an executive suite intended to make corporate executives feel at home while hammering out co-development plans or negotiating agreements for licensing anticancer compounds.

Internal documents obtained by The Cancer Letter show that the suite may have cost the state institution at least \$1.5 million, and the overall costs could be closer to \$2 million.

MD Anderson officials disputed these numbers. Total spending on the lab and office design projects was \$1,492,159 they said, but this sum also included lab equipment, such as new hoods and a ventilation system for a specialized chemistry section. Officials estimated the cost of upgrading Chin's office suite at \$547,434.

This explanation appeared to be contradicted by the budget documents, purchase orders, invoices and other materials obtained under the Texas Public Information Act. These documents do not mention lab equipment and contain no evidence of payments being made for such expenses from the budget for upgrading the suite.

I posted these documents—680 pages—on The Cancer Letter website.

Though architectural plans identify the project as "Dr. Chin Office Renovation," a renovation it was not.

The 25,000-square-foot suite, much of it southfacing, was new, located on the sixth floor of the justconstructed South Campus Research Building III.

Chin, scientific director of the Institute for

Applied Cancer Science and chair of the cancer center's Department of Genomic Medicine, was its first occupant.

\*\*\*

"Corporate" was the word MD Anderson documents used repeatedly to describe the intended feel of the suite—a departure from standard practice at MD Anderson, where office furniture styles tended toward heavy-duty functionalism and where and office space is strictly regimented in accordance with rank.

Since the suite isn't open to the public, all but a few members of the faculty and staff ever saw it.

Many of the interior walls in the new suite were replaced with translucent interior glass panels, an upgrade that was estimated to cost \$210,000 and required a variance from the UT System.

The bill for modern classic settees, lounge chairs and occasional tables for the institute's two senior leaders came up to \$27,920. In another departure from the norm, a credenza in the executive office conceals a refrigerator.

There was no donor specifically underwriting this project.

Purchase order by purchase order, the money came from MD Anderson's capital accounts, documents showed.

The story of rising costs and reconfigurations in Chin's suite did little to lift the spirits of MD Anderson faculty members, who were expected to work harder to offset the institution's rising operating costs.

MD Anderson doctors who planned to attend the annual meeting of the American Society of Clinical Oncology in 2013 had to submit plans for making up the time missed in the clinic.

In a survey conducted earlier that year, faculty members characterized DePinho and Chin as "imperious" and "dictatorial." In a recent memo to employees a bit before the ASCO annual meeting that year, DePinho announced austerity measures, which include suspending merit raises, slowing down recruitment—and suspending capital projects.

MD Anderson officials said the \$547,434 they acknowledge having spent on the office portion of the project was "similar to previous renovations made to accommodate new senior faculty."

Responding to questions, officials said that "the renovations of space for the Institute for Applied Cancer Science and Department of Genomic Medicine—both new entities for MD Anderson—transformed a traditional academic office suite to a work environment and meeting area for a science/business enterprise. "The existing space was not configured to support this new concept," the statement reads. "The 9,000-squarefoot office space was redesigned to create an open environment of communication, provide an appropriate meeting space with high-level industry decision makers and support a new suite in computational biology."

Since the project fell outside MD Anderson's rigid standards for allotting office space and furniture, officials ended up seeking variances from Kenneth Shine, the UT System's executive vice chancellor for health affairs. Though insiders say that formal variances were granted, MD Anderson officials said no such documents existed.

"The variances were approved by Dr. Shine via email, and MD Anderson is not aware of any additional variances," an official said to The Cancer Letter.

IACS appeared to be a crucial element of DePinho's vision for MD Anderson. After all, DePinho and Chin were chosen to lead MD Anderson in part because of their relationship with the pharmaceutical and biotechnology industries and their promise to make the massive academic cancer center behave more like a corporation.

IACS was the place where discovery would meet commerce.

"It is intended to be a hybrid that brings the best of what academia has and the best of industry practice, merge them together to have this new construct that allows us to execute efficiently cancer drug discovery, but do so in a scientifically-driven manner embedded in the richness of academia," Chin said as she described the institute in an MD Anderson video.

Documents show that the suite's décor was intended to reflect perceptions of accoutrements the pharmaceutical industry executives would require.

\*\*\*

For starters, Chin wanted to replace many of the interior walls with a translucent material produced by a company called DIRTT, an upgrade initially estimated at \$180,000.

The rationale:

"The suite is dark and will benefit from natural light," an MD Anderson official wrote in a request for a variance. "The glass walls also provide a feeling of transparency which fosters collaboration. The corporate feel is also enhanced by glass walls."

Subsequently, another \$30,000 worth of DIRTT

panels was used, replacing the drywall partitions that separate Chin's office from a small conference room. "Dr. Chin would like to add a glass wall and sliding door between her office and the conference room," the variance request states.

This would further enhance the "corporate feel" by "giving a connection between her office and the conference room," the variance request states. Giulio Draetta, director of IACS, also got a DIRTT wall. MD Anderson officials provided similar rationale for spending \$50,000 more than the norm to buy two desks, two non-regulation freestanding credenzas, seating and glass-top tables for Chin's and Draetta's offices:

"Their office suites will be used by institute advisory board, leadership team, and joint steering committee and high level meetings and needs furniture that reflects the institute," the variance request reads.

The DIRTT walls in Chin's and Draetta's offices are largely obscured by their high-top credenzas.

\*\*\*

Do pharmaceutical company executives expect luxurious surroundings?

Do they judge cancer centers by the Bauhaus pieces scientists display in their offices?

Are luxurious offices standard in big pharma?

I called Bruce Ross, former chairman of the board of Biogen Idec, former senior executive at Bristol-Myers Squibb, and former CEO of the National Comprehensive Cancer Network.

No, no, and no, Bruce said. "It's extraordinary to see this sort of opulence in the office suite of a senior scientist at an academic medical center, particularly one that is state-owned," he continued. "It moves into the bizarre class, because the designer and occupant of these quarters is the wife of the president of the institution. I personally would feel very uncomfortable attending a meeting in such surroundings. The trend in corporate America today is to downsize and simplify executive offices and meeting facilities."

I submitted several questions for Chin, but the institution chose to respond in a statement. The cancer center's investment in the institute has paid off, the statement read.

The institute "has generated a research collaboration and license agreement with GlaxoSmithKline that is estimated to have a potential value of \$335 million," officials said.

"In addition, IACS/GM has raised more than \$15 million in philanthropy," officials said. "In total,

IACS/GM activities have led to more than a dozen publications in leading journals.

"We believe our investment in the Institute for Applied Cancer Science and the Department of Genomic Medicine has created a world-class facility and teams that will yield benefits for patients at MD Anderson and beyond for years to come," officials said. "The MD Anderson mission is to eradicate cancer, and the work ongoing in this facility will help achieve that goal."

Spending on executive offices is a recipe for disaster in an academic institution, public or private, said Arthur Caplan, head of the Division of Medical Ethics at NYU Langone Medical Center.

"At a time of budget cuts, sequesters and cutbacks in research funding, opulent spending on space, facilities and furnishings seems at best ill-thought through and at worst callous to budget realities," Caplan said. "In my experience, lavish spending on non-scientific space and furnishings is the 'third rail' for administrators."

Donors may not be pleased, either, said Sheldon Krimsky, the Lenore Stern Professor of Humanities and Social Sciences and adjunct professor at the Department of Public Health and Family Medicine at Tufts University.

"At a time of federal sequestration and forced furloughs of dedicated public employees, the extravagance of spending at MD Anderson, a public institution, seems unconscionable," said Krimsky, co-author of "Biotechnology in Our Lives," a recently published book.

"How would those volunteers and small donors who have never seen the profligate executive suites feel about the use of their contributions?"

\*\*\*

MD Anderson documents showed that the office upgrade project began soon after she and DePinho arrived at the institution and was completed in the spring of 2011.

Sources said that the just-constructed office suite didn't require much improvement. The walls were up. Carpets were down. Light switches, plumbing and climate control functioned fine.

Raymond DuBois, the MD Anderson provost at the time, balked at issuing the initial variances. Instead, he kicked the matter to Shine, who is ultimately responsible for managing DePinho's and Chin's conflicts of interest. DuBois was the middle link in a chain of command that was like no other: Chin had to go to DuBois when she needed institutional resources, while DuBois reported to Chin's husband.

One didn't need to be an insider to see that the couple didn't trust DuBois, whose job as provost was to promote the academic mission of MD Anderson.

On Oct. 24, 2011, DuBois fired off an email to Shine:

"I am inclined to approve these variances for Dr. Lynda Chin, but wanted to make sure that you were in the loop on these requests. These are requests that are outside our normal guidelines, but some of these I think will help the institute be more competitive and provide better space for industry/academic collaborations."

An inclination to approve does not an approval make. It means nothing. The email says fundamentally: Here is some expensive stuff. You approve it.

And Shine approved. On Oct. 25, he responded with a two-word email:

"Approved. Ken."

\*\*\*

"It is not uncommon for MD Anderson to seek variances to renovate work spaces, offices and laboratories of new senior faculty recruited to the institution," MD Anderson officials said in response to questions from The Cancer Letter.

Altogether, the following variances were sought:

• Glass walls: \$180,000. "The suite is dark and will benefit from natural light," the variance request reads. "The glass walls also provide a feeling of transparency which fosters collaboration. The corporate feel is also enhanced by glass walls."

• More glass walls and a glass sliding door: \$30,000. "Replace existing standard dry wall along South wall office corridor and interior entrance suite with glass walls has been previously approved," a variance request states. "However, Dr. Chin would like to add a glass wall and sliding door between her office and the conference room." The justification asserts that this would further enhance the "corporate feel" by "giving a connection between her office and the conference room."

• Free-standing desks with credenzas and seating with glass end tables and coffee tables for Chin's and Draetta's office suites: \$50,000. "Their office suites will be used by institute executive advisory board, leadership team, and joint steering committee at high level meetings and needs furniture that reflects the institute," a request states.

• Build executive boardroom "with a corporate feel" that would include "one large conference table to accommodate 15-20 people" and "full audio-visual capabilities, including teleconferencing:" \$147,800. This is necessary because "the boardroom will be used for the institute executive advisory board, leadership team, joint steering committee and VIP meetings," the justification reads.

• A boardroom table that has power and telecommunications capabilities: \$14,700. "The boardroom will be used for institute executive advisory board, leadership team, and joint steering committee and VIP meetings and needs a table with tele/data capabilities that can house microphones for videoconferencing needs," the request states.

• Cushion-top seating and storage spaces in open environments, in the area occupied by post-docs and computation staff: \$34,906. "These spaces don't have sufficient space for additional folding chairs or lateral file cabinets," the request states. "The cushion-top pedestal can be used as additional storage and seating, and can be stored under desk, providing ample room for working."

• Glass panels for partitions in computational area: \$400 per partition. "This is the computational area and furniture needs to be open, but semi-private environment since they work at their desk the majority of the day," the justification reads. "They also want to foster collaboration between workstations, so frosted panels will give privacy, but openness as well."

• Wood veneer for partition panels: \$60,000. The veneer accents would be on the lower sections of partition panels (as opposed to standard fabric panels). The rationale: "Wood panels will add accents to the space since these are research faculty working in open environment."

DuBois, who resigned from MD Anderson in August 2012, declined to discuss the project.

"I am no longer employed by MD Anderson and cannot comment on specific purchasing decisions or office renovation practices," he said at the time. "All such questions should be directed to Dr. Kenneth Shine, to whom Dr. Chin reported, and who had the ultimate authority over approval of purchases and provision of resources, including office space."

\*\*\*

An official tally called the Funding Authorization Transmittal, reports the project's total cost at \$1,542,802—almost 60 percent above the original budget of \$919,200.

This amounts to \$61.71 per square foot, though most of the high-priced items are concentrated in the executive section of the suite, documents show.

Construction costs came up to \$905,000. Furniture cost reflected in the budget added up to \$175,000. (The original estimate was \$100,000.)

MD Anderson officials said budgets can be misinterpreted. "The Funding Authorization Transmittal is a high-level estimate that gives staff a starting point for budgeting," officials said.

"Figures for line-item components frequently change as the project becomes more defined, but MD Anderson manages the project to the overall bottom line. Line items should not be considered as a true baseline for budget comparisons."

Just adding up the invoices suggests that the actual furniture bill was \$464,306, though this appears to include furnishing the institute's facilities on the fifth floor of the same building.

Overall, furniture chosen for the suite tends toward darker, reddish hues.

The table in the big conference room is a 20foot "Saber," produced by a company called Nucraft. (Purchasing price: \$12,151).

The two credenzas in the suite cost \$4,743 and \$5,141. One of them conceals a refrigerator (\$2,704).

In their offices, Chin and Draetta gravitated toward modern classics. Chin chose a red leather Florence Knoll settee with a polished chrome base (\$7,754) and a matching lounge chair (\$5,012). Draetta chose the same group, but in black (\$6,961 for the settee, \$4,481 for the lounge.)

Other classic pieces in the executive suites include a Ludwig Mies van der Rohe clear glass MR table (\$1,669), a Florence Knoll coffee table (\$604), a Knoll end table (\$583) and Marcel Breuer coffee and side tables (\$500 and \$353).

Data processing and communications equipment was originally estimated at \$10,000, but ultimately came up to \$160,000 in the budget. When the invoices are added up, the IT spending rises to \$282,522.

Experts said the IT purchases are standard equipment for high-speed data throughput.

With additional furniture and IT equipment added to the FAT, the cost of the project jumps to \$1,954,630.

On Sept. 9, 2011, when the project was getting set up in the MD Anderson bill-paying system, an official suggested that it should be treated as an "unbudgeted 'high priority' space renovation request" funded from the provost's budget for space renovation.

However, officials determined to tap capital funds instead, and documents show that a large number of such funds were charged as the office was being built. MD Anderson officials confirmed that longterm capital project funds were used. Such funds are "derived from investment income, philanthropy and patient revenue," officials said in a statement.

\*\*\*

The project's growing price appears to reflect its expanding scope.

Records show two "change orders," the result of the client saying that the job was performed well enough, but changes need to be made anyway. A change order, essentially a change of mind, is an unusual occurrence in state construction projects.

The first change order, dated April 13, 2012, cost MD Anderson \$98,276.33. "This change order includes the additional electrical scope developed after the furniture and boardroom plan was developed," an explanation reads. "The funds are also needed for additional scope including millwork, dishwasher, and fire safety."

The second change order, on May 22, 2012, cost \$55,489.22. It included "fire alarm, electrical, HVAC, architectural, furniture wall system, teleshades due to office and boardroom reconfiguration," the explanation reads. "Plumbing changes due to unforeseen conditions when installing the dishwasher. Relocation of sprinkler heads due to reconfiguration of office space. Modification of the door to except [sic] the card reader."

As costs increased, officials started to wonder whether Shine needed to be consulted again.

In October 2011, when several officials raised questions about the need for additional variances, Chris McKee, associate vice president, business affairs, cut off the debate:

"It is our understanding that these approvals fall into operational decisions category that Dr. Shine gave the campus authority to manage when he approved the overall business plan," he wrote in an email.

\*\*\*

Soon after The Cancer Letter published the Furnituregate story, Draetta, the gentleman with the black Florence Knoll suite, clarified to senior MD Anderson senior faculty members that he and Lynda deserved good furniture because they were from Harvard.

The email was forwarded to me minutes after Draetta hit send:

Lynda and I were both extremely concerned about moving to Texas, having never lived here and being heavily influenced by the Harvard community.

The administration then, Dr Shine, Dr DuBois, put together attractive recruitment packages and Lynda and I negotiated for the best deals we could get: salaries, infrastructure, office space. Lynda took the lead in negotiating as the new department chair.

We had beautiful offices at Dana Farber, which we had just moved into. We asked for offices that resembled those we had in Boston and we got them. Never knew that we had broken any rules.

Lynda and I are bringing here exactly what many of you have been asking for: expertise in genomic science and translation. Every one of the flagships projects asks

for expanded "omics" capabilities and drug discovery and development efforts. We are here for this and with your support will achieve this.

Thanks very much,

Giulio

\*\*\*

Later, the Houston Chronicle columnist Lisa Falkenberg wrote a hilarious piece about MD Anderson's new-found appreciation of finer things. The headline was a hoot: "Are \$7,700 Couches Needed to Cure Cancer?"

"Rest assured, donors and patients, your money was well-spent," Falkenberg wrote. "It's important to point out that...Dr. Giulio Draetta, director of the institute...fully explained his reasons for wanting a nice office in a letter he wrote to friends and colleagues that was obtained by the Chronicle.

"Lynda and I were both extremely concerned about moving to Texas, having never lived here and being heavily influenced by the Harvard community," he wrote. "Bless his heart. He thought we'd set him up with trailer curtains and an outhouse. We can't expect a Harvard recruit to slum at a state-funded nonprofit hospital without offering him a little incentive."

\*\*\*

On April 6, 2015, Chin vacated her jobs as founding head of genomic medicine and IACS scientific director to join the UT System as an associate vice chancellor for health transformation and chief innovation officer for health affairs.

In her new UT System role, Chin would create and lead the new Institute for Health Transformation that will seek to "leverage, develop and deploy innovative, technology-enabled solutions to improve access to and affordability of quality health care," officials said.

"If we want to transform the way health care is delivered, then we need bold and innovative solutions," UT System Chancellor McRaven said in a statement. "Dr. Chin is a very talented physician scientist who has the vision and the ability to get it done."

McRaven made it his top priority to fix the morale problems at MD Anderson. On a visit to MD Anderson a month before change was announced he declared that trust at the cancer center had been broken and called for shared governance at the institution. This new structure is being implemented.

The UT System said its new Institute for Health Transformation initially will focus on Project DOC, for Diabetes Obesity Control, which was funded by the Board of Regents in 2014 to improve diabetes care and management in South Texas through the use of big data and technology.

"The current health care model is based on providing acute care to sick patients; that is very ineffective in management of chronic diseases like diabetes," Chin said in a statement. "A system redesign is needed. Today's social, mobile and cloud technology along with big data and cognitive analytics can be the keys to a much-needed transformation."

UT System officials said to the Houston Chronicle that Chin had been working on the diabetes issues since last year. In June, she was named a health fellow on the project, which received the first-phase funding of \$5 million in November 2014.

Chin's departure eliminated even appearances of conflict, potentially strengthening DePinho's position as MD Anderson's president. MD Anderson scientist Andrew Futreal became chair ad interim for Genomic Medicine.

The day before Chin's departure from MD Anderson was announced, the Houston Chronicle ran the following editorial:

Early detection of a problem can often prevent the spread of cancer, at least according to the physicians at the crown jewel of the Texas Medical Center, the University of Texas M.D. Anderson Cancer Center...

The one dangerous symptom that shouldn't be ignored is faculty dissatisfaction. The faculty has spoken in four negative surveys as well as in a recent faculty senate resolution sent to UT System leaders, where members cited a 'climate of fear' and 'pervasive dissatisfaction' at M.D. Anderson...

Lives are at stake in the important work done at M.D. Anderson. The chancellor and the board of regents should treat this management problem with the same urgency as physicians do when treating their patients.

\*\*\*

In a recent interview, I asked Dan Fontaine, MD Anderson's executive chief of staff, whether Chin has been replaced at IACS.

"I don't think that position has been replaced, and the reason is she moved and spent a whole lot more of her time in the digital world, with IBM and Watson technology," he said. "Frankly, I think, it's not to say that Lynda wasn't an important contributor from a scientific standpoint at the inception, but Giulio Draetta and the other folks that he brought on board with [IACS] are making great progress.

"I'm not sure there's a specific scientific director anymore, because they're getting a lot of their scientific direction both from the work that we're doing for other platforms for the Moon Shots, as well as from our own faculty, having worked with them on the development of certain things. To my knowledge, the scientific director for IACS I do not believe has been refilled. I asked whether any plans are afoot to refill the position.

"I don't know that it's actively under recruitment," Fontaine said. "I think how things evolved with Giulio and the rest of the scientific team there, I think that a lot of the work that they're doing is with other scientific leaders on some of our moon shots and some of our platforms.

"But generally I think Giulio and the rest of the team there is basically kind of doing it themselves."

I asked Fontaine to explain the metrics of IACS's performance.

"I think we've got some pretty pleasing ones," he said. "It's interesting because IACS was able to shift from small molecules to some small molecules and immunotherapeutics. And there were some things that were here when IACS was being formulated that they were doing work on and it definitely accelerated it.

"I think we've got one of our first ones that are either in clinical trials or on the verge of starting in phase I clinical trials that came out of one of our inventions here.

"I think that also because with a lot of these biologicals, it's also pairing them with other things. And it's opened opportunities to pair some of the things that we've done with other drug companies' products. Some of this is proprietary, so I'm not going to be able to go into much more detail.

"But I think if you look at the alliances we've built with industry some of the things that are coming through the developmental pipeline with the institute for applied cancer science, some of the credence of the science that is coming out of here is given, and the discoveries that are coming out of here are given and the opportunities to join those things with what pharma is doing I think speaks very well for the [IACS].

"This isn't just me saying this, I think that there's never been this degree of outside external advisory input that's been provided by people from other institutions, and it has been consistently bullish on what we're trying to do here.

"That's the subject of a different story."

## NCCN Launches Evidence Blocks as Part of its Guidelines

The National Comprehensive Cancer Network launched its value tool, NCCN Evidence Blocks, which will be presented at its annual conference, March 31 to April 2.

NCCN has published two additional resources since its 2015 meeting: the NCCN Framework and the NCCN Quick Guide Series for patients.

#### NCCN Guidelines with NCCN Evidence Blocks

Originally presented at the NCCN's 10<sup>th</sup> Annual Congress: Hematologic Malignancies in October 2015, the Evidence Blocks represent five measures of specific recommendations found in the NCCN Clinical Practice Guidelines:

- Efficacy of Regimen/Agent
- Safety of Regimen/Agent
- Quality of Evidence
- Consistency of Evidence
- Affordability of Regimen/Agent

The goal is to provide health care providers and patients the information to make choices when selecting systemic therapies based upon measures related to treatment, supporting data and cost.

These measures may be used to understand

the clinical and scientific rationale for specific recommendations and estimates of the economic impact of the recommendations. These measures may also be used to educate providers and patients, and to be a starting point for shared decision-making considering the patient's own value system.

To date, NCCN has published guidelines with evidence blocks for cancers of the breast, colon, kidney, non-small cell lung, prostate and rectum; as well as chronic myelogenous leukemia, melanoma, multiple myeloma, and non-Hodgkin's lymphomas.

More information is available <u>on the NCCN</u> <u>website</u>.

# NCCN Framework for Resource Stratification of NCCN Guidelines

Announced in March 2015, NCCN Framework guides evidence-based adaptation to available clinical treatment resources. The goal of the framework is to define appropriate treatment pathways at four resource levels—Basic, Limited, Enhanced, and NCCN Guidelines—and deliver a tool for health care providers to identify treatment options that will provide the best possible outcomes given specific resource constraints.

The four levels of NCCN Framework resources are defined as:

• Basic: Essential services needed to provide basic minimal standard of care

• Limited: Services from the Basic Level and additional services that provide major improvements in disease outcomes, e.g. survival, that are not cost prohibitive

• Enhanced: Services from the Limited Level and additional services that provide lesser improvements in disease outcomes and/or services that provide major improvements in disease outcomes but are cost prohibitive at lower resource levels

• NCCN Guidelines: The parent NCCN Guidelines are evidence-based, consensus-driven recommendations made by the NCCN Guidelines panels. They include services from the Enhanced Level and additional services that provide minor improvements in disease outcomes, interventions that are cost prohibitive at lower resource levels, and/or services that do not provide improvement in disease outcomes but are desirable services.

To date, <u>versions of NCCN Framework</u> are available for the following: breast, cervical, gastric, hepatobiliary, non-small cell lung, and prostate cancers.

#### **NCCN Quick Guide Series**

Launched in 2015, the NCCN Quick Guide sheets are educational tools for use by patients and their caregivers in conjunction with the NCCN Guidelines for Patients.

The NCCN Quick Guide Series summarizes key points and recommendations of the complete NCCN Guidelines for Patients and feature links to the appropriate information within the NCCN Guidelines for Patients.

The NCCN Quick Guides can be found <u>on the</u> <u>NCCN website</u>.

## <u>In Brief</u> Hussain Joins Northwestern; Douillard Named ESMO CMO

**MAHA HUSSAIN** will join the Robert H. Lurie Comprehensive Cancer Center of **Northwestern University** as associate director for clinical sciences research, effective Sept. 1.

Hussain will also serve as co-director of the Lurie Cancer Center's Genitourinary Oncology Program, along with Edward Schaeffer, chair of the Department of Urology at Northwestern University Feinberg School of Medicine. Hussain is currently Cis-Maisel Professor of Oncology, and professor of medicine and urology at the University of Michigan.

She has served in many scientific and leadership roles at the University of Michigan including associate director for clinical research and co-leader of the Prostate Cancer/GU Oncology Program at the UMComprehensive Cancer Center, as well as associate chief for clinical research in the Division of Hematology/Oncology.

Hussain's research focuses on the development of therapeutics for prostate and bladder cancer. At Northwestern, Hussain will oversee the clinical sciences research programs and working groups, and foster interdisciplinary and inter-programmatic collaborations.

"We are thrilled to welcome Maha to the Lurie Cancer Center," said Director Leonidas Platanias. "She is one of the world's leading researchers in the field of prostate cancer and her presence will strengthen our clinical research efforts immensely."

Hussain's national scientific leadership roles include serving as co-chair of the Prostate Cancer Subcommittee/Genitourinary Cancer Committee of SWOG; as a member and chair of the integration panel of the U.S. Army Medical Research and Materiel Command Prostate Cancer Research Program; and as a member and chair of the FDA Oncology Drug Advisory Committee.

Hussain has held leadership roles within the American Society of Clinical Oncology and was recently elected to ASCO's board of directors. She currently serves on ASCO's Clinical Practice Guidelines Committee, as a member of the National Comprehensive Cancer Network International Committee and the Advanced Prostate Cancer Panel of the American Urological Association.

JEAN-YVES DOUILLARD was appointed the first chief medical officer of the European Society for Medical Oncology. A senior staff position based at the Society's headquarters in Lugano, Switzerland for a fixed two-year term, the CMO will lead the development of ESMO's scientific strategy and activities.

Douillard's appointment follows a six-month selection process open to all ESMO members with the necessary high-level qualifications and experience for the role. Candidates were also required to have held senior ESMO leadership positions.

In a career spanning more than 30 years, Douillard has achieved international recognition as a leading expert in lung cancer and gastrointestinal oncology, holding a number of leadership positions.

At the University of Nantes, he was professor in medical oncology, while at the Integrated Centers of Oncology Rene Gauducheau, also in Nantes, he was head of the Medical Oncology Department and later director of clinical and translational research. In addition, he spent a total of four years working in the U.S., initially at the NCI and later at the FDA Center for Drug Evaluation and Research.

Douillard has led clinical trials in relation to lung cancer and GI tumors and investigated targeted therapies, publishing his work in leading scientific journals. He has also served as chair of the ESMO Educational Committee and as a member of the society's executive board.

THE KARMANOS CANCER INSTITUTE recently promoted five scientific staff members: Jennifer Beebe-Dimmer, Michele Cote, Justin Klamerus, Larry Matherly, and Hayley Thompson.

Beebe-Dimmer was appointed co-leader of the Population Studies and Disparities Research Program at Karmanos Cancer Institute and Wayne State University School of Medicine. She is an associate professor in the Department of Oncology. Her research focuses on the epidemiology of genitourinary cancers with a special interest in hereditary prostate cancer and familial aggregation of prostate with other cancers. She also serves as the scientific director of the Epidemiology Research Core at Karmanos.

Cote was named associate center director for Education at Karmanos Cancer Institute. She is also an associate professor in the Department of Oncology at Wayne State University School of Medicine. In this newly created position, Cote will coordinate educational activities across the Institute, overseeing the integration of research-focused education into the scientific research programs.

Cote joined the staff of Karmanos and Wayne State University in 2005 as assistant professor. Her research focuses on the intersection of molecular epidemiology and health disparities with a special interest in examining genetic and molecular factors in lung and female cancers that impact disease occurrence or prognosis in underserved populations.

Klamerus was appointed to the new position of associate center director for Community Oncology at Karmanos Cancer Institute and Wayne State University School of Medicine. He is also an assistant professor in the Department of Oncology, as well as vice president of Community-Based Programs and chief quality officer for Karmanos. Additionally, he serves as medical director for Clinical Oncology Research for McLaren Health Care. Klamerus joined the staff of Karmanos in 2014, and currently oversees operations at 12 community-based centers in the network.

Klamerus's independent research has focused on upper aerodigestive cancers, health policy and health care disparities. He currently serves as program director of the Pathways initiative of Blue Cross Blue Shield of Michigan and also serves on committees and work groups within the American Society of Clinical Oncology.

Matherly was appointed as associate center director for Basic Sciences at Karmanos Cancer Institute. He also serves as the leader of the Molecular Therapeutics Program and as is a professor in the Department of Oncology at Wayne State University School of Medicine. His research focuses on the basic biology of membrane transporters and the biology and therapeutic applications of folates and related analogs. Additionally, he leads studies aimed towards drug discovery and translational studies of chemotherapy response and resistance. Matherly joined the staff at assistant member of the Michigan Cancer Foundation in 1987, which is now known as Karmanos Cancer institute. He oversees the Basic Science Core Cluster, which includes the Animal Model and Therapeutics Evaluation; Microscopy, Imaging and Cytometry Resources; and Proteomics Cores. He promotes and facilitates intra- and interprogrammatic collaborations, recruits new faculty, mentors junior faculty and advocates for the interests of basic science research at Karmanos.

Thompson was named leader of the Population Studies and Disparities Research Program at Karmanos Cancer Institute and Wayne State University School of Medicine. Thompson is also an associate professor in the Department of Oncology. Her research has primarily focused on the development and testing of culturally targeted interventions at all phases of the cancer care continuum, including community-based research implementation. She also works in the area of cancer survivorship, eHealth and the use of personal technologies in cancer care. Thompson joined the faculty of Karmanos and Wayne State University in 2011. She is also the director of the Witness Project of Detroit.

JENNIFER PIETENPOL was honored with the Medical Research Advancement Award during the T.J. Martell Foundation Nashville Honors Gala. Pietenpol is the B.F. Byrd Jr. Professor of Oncology and director of Vanderbilt-Ingram Cancer Center.

The award is in recognition of Pietenpol's career as a cancer researcher. She focuses on the p53 family of proteins and breast cancer, especially triple-negative breast cancer.

Pietenpol joined the Vanderbilt faculty in 1994 and was named director of VICC in 2007. In addition, she has been named to the Institute of Medicine's National Cancer Policy Forum and is a previous presidential appointee on the National Cancer Advisory Board.

Previously, Pietenpol has received the Burroughs Wellcome New Investigator Award, the Excellence in Teaching Award at Vanderbilt University and the Carleton College Distinguished Alumni Achievement Award. She was inducted into the Johns Hopkins Society of Scholars, and is an elected fellow of the American Association for the Advancement of Science, for work including advances in the understanding of signaling networks in breast and other cancers. She has authored or co-authored over 125 articles published in peer-reviewed scientific literature.

#### **DENNIS PATRICK MEEHAN HUGHES**, a

former pediatric oncologist at MD Anderson Cancer Center, pleaded guilty in federal court to collecting child pornography. Sentencing is set for June 1.

Hughes, 49, resigned from MD Anderson after being arrested in June 2015, and later turned in his license to the Texas Medical Board, <u>according to the</u> <u>Houston Chronicle</u>. He faces up to 40 years in prison.

MD Anderson has contacted the families of approximately 300 young cancer patients, the Chronicle reported.

THE AMERICAN CANCER SOCIETY received a \$1.58 million, four-year grant from The Merck Foundation to implement a comprehensive Patient Navigation Program in three U.S. communities where substantial cancer care disparities exist.

Sites selected to participate in the communitybased program include the Queens Hospital Center in Queens, N.Y.; the Phoenix Cancer Center/ Maricopa Integrated Health System in Phoenix; and the University of New Mexico Cancer Center in Albuquerque. The organizations were selected because they provide services to diverse, low-income and often underserved patient populations.

"Many people don't know how to access the health care system. They don't have insurance, they're afraid or they have personal beliefs that lead them to ignore their health and avoid the health care system altogether," said Katherine Sharpe, senior vice president of Patient and Caregiver Support for the American Cancer Society. "The Patient Navigation Program addresses these issues and helps people get the care they need even under very difficult cultural, economic, educational and financial circumstances. We are grateful to the Merck Foundation for providing this grant to bring much-needed support to cancer patients in vulnerable communities in Arizona, New Mexico and New York."

**MD ANDERSON CANCER CENTER** submitted its plan to comply with Senate Bill 11, a state law commonly known as Campus Carry, to the University of Texas System and its Board of Regents, as a public institution of higher education.

Under the bill, any individual holding a valid concealed handgun license will be allowed to carry concealed handguns on some parts of MD Anderson's campus. The UT Board of Regents will review and vote on MD Anderson's plan in May. The law goes into effect Aug. 1. The plan was developed by a working group composed of a cross section of more than 30 faculty, patients, staff, administrators, trainees and students, MD Anderson said in a statement, and was approved by Ronald DePinho, president of MD Anderson.

"Our primary goal at MD Anderson is to ensure the safety of our patients, visitors, faculty, staff and students while complying with Texas law," said DePinho. "Our working group listened to many passionate opinions expressed about this issue and considered all feedback in putting together our plan. I am confident it addresses our goal."

The plan recommended that concealed handguns not be allowed in patient care areas; research laboratories; animal care facilities and vivaria; child care facilities, pediatric activity areas, pediatric school areas, and areas where activities are conducted for children who are not registered at MD Anderson; chapels and prayer rooms; and areas required to be excluded by state or federal law.

According to MD Anderson, concealed handgun license holders will be allowed to carry concealed handguns in all parts of the Jesse H. Jones Rotary House and MD Anderson's administrative building, the Fannin Holcombe Building. In addition, most of the Mid Campus Building 1 will be a carry area as well, except in the offices of Employee Health and Well-being and the Employee Assistance Program.

Other carry areas include a number of MD Anderson landscaping and storage warehouses, Mid Campus Garage A, Braeswood Garage and garages adjacent to the Fannin Holcombe Building and Mays Clinic.

## Drugs and Targets FDA Approves Roche Hepatits C RNA Test

**FDA approved a hepatitis C virus quantitative RNA test** to be used as an aid in the diagnosis of HCV infection for certain patient populations.

Results from the COBAS AmpliPrep/COBAS TaqMan HCV Test v2.0, developed by Roche, can now be used to confirm an active hepatitis infection, in addition to providing an accurate measurement of how much virus is in a patient's blood, to help a physician determine the best course of treatment.

The test is the first quantitative HCV RNA test to be approved for use as an aid in diagnosis for active HCV infection. This expanded indication is in addition to its approved use as a viral load test to help physicians assess a patient's response to antiviral therapy. Roche HCV viral load tests have also been used to establish the treatment efficacy of direct-acting antiviral treatment regimens recently approved by the FDA.

The dual-probe PCR assay is intended for use in the management of patients with chronic HCV, in conjunction with clinical and laboratory markers of infection, and as an aid in diagnosis for individuals with antibody evidence of HCV infection with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection.

The test is an in vitro nucleic acid amplification test for the detection and quantitation of hepatitis C virus RNA genotypes 1 to 6 in human EDTA plasma or serum. It can be used to predict the probability of sustained virologic response early during a course of antiviral therapy and to assess viral response to antiviral treatment, as measured by changes of HCV RNA levels.

The University of Pennsylvania and Genisphere LLC formed a collaborative research agreement to study targeted nanotherapeutics. The collaboration between Genisphere, provider of the 3DNA drug delivery platform, and UPenn's Theresa Busch, will utilize a breast cancer model to study photodynamic therapy.

Photosensitizing drugs are administered to patients prior to surgery, and then activated by visible light after the tumor tissue is removed, to destroy cancerous cells left behind. The delivery of PDT to the entire surgical field is essential, thus selective photosensitizer accumulation in diseased cells is necessary to avoid therapy-limiting damage to normal tissues.

"When used in the intraoperative setting, PDT provides for local treatment at the site of surgery and can be effective in eradicating undetected or unresectable tumor," said Busch, a research associate professor of radiation oncology. "This concept is suggested by patient outcomes in our previous clinical trials of intraoperative PDT for malignant pleural mesothelioma, and we are currently conducting a randomized phase II clinical trial for this indication.

"This approach can be adapted for intraoperative PDT of breast cancer; however, the addition of a photosensitizer that is targeted to breast cancer cells could broaden the therapeutic window and selectively increase cytotoxic effect."