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REDEFINING “NORMAL”: IU’S KOMEN TISSUE BANK SHOWS HOW RACE AND ABNORMALITIES CORRELATE WITH DEVELOPMENT OF DISEASE

By Matthew Bin Han Ong

When two women—a patient advocate and a scientist—embarked on a mission to collect “normal” breast tissue for comparative purposes, colleagues in oncology dismissed their idea as wild.

In the early 2000s, Connie Rufenbarger, a breast cancer patient advocate, and Anna Maria Storniolo, a professor of clinical medicine at the Indiana University School of Medicine and a member of the [Vera Bradley Foundation for Breast Cancer Research Laboratories](#), were attending a meeting in Indianapolis when they realized that oncologists had no source of “true normal” breast tissue to use as control in studies.

“We were at a translational meeting where clinicians and basic scientists from the major universities in Indiana—Notre Dame, Purdue, IU Bloomington, IU Indianapolis—meet and exchange ideas,” Storniolo said to *The Cancer Letter*. “The keynote speaker was from NCI that year.”

It was during that gathering that Rufenbarger experienced a light bulb moment: How can we know the abnormal if we don’t know what’s normal? Why isn’t there a repository of normal breast tissue?

Storniolo, now executive director of the [Susan G. Komen Tissue Bank](#) at the [Indiana University Melvin and Bren Simon Cancer Center](#), was skeptical. It would be impossible to set up a resource built on the extraction of tissue from healthy women, she thought.

“You don’t get it,” Storniolo said to Rufenbarger. “There’s no way that anyone is going to let us set up to collect breast tissue, and put it up in a bank for unspecified future use. Think about

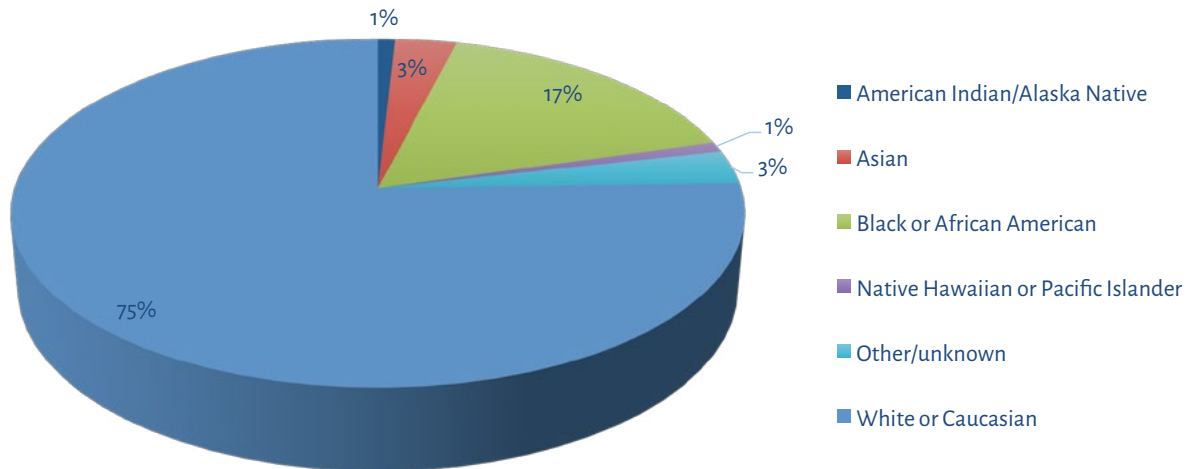
the legal issues, and the regulatory issues, and the ethical issues.”

“That’s ridiculous,” Rufenbarger said.

The dialogue continued, and over time Storniolo started to come around. The two started collecting samples in 2005, and then, in 2007, they asked Komen for funding. The bank has an annual budget of about \$1 million.

A decade later, thanks to Storniolo and Rufenbarger’s efforts and the tissue they have collected, researchers are coming to a consensus that previous measures for defining normal tissue were not reliable, and that the definition of “normal” is more complex than previously believed.

Racial composition of tissue donors (1/2017)



To date, more than 30 manuscripts have been published using samples from the Komen Tissue Bank, which contains DNA and blood samples from over 10,000 women and tissues samples from 5,000 women. Of the 5,000 tissue donors, for 1,000 samples, the bank has taken one of their tissue aliquots and created three cryopreserved aliquots.

Most importantly, there is no other bank like it.

“Patience is not a virtue I have in huge quantities, and it’s been very difficult to observe how long it has taken us to get this far,” Storniolo said. “We’re finally on a steep curve of recognition and use, but it has been a long time coming.”

The Komen bank is facilitating a scientific investigation using tissues that are much more meaningful than samples from mice or reduction mammoplasties, said Patricia Steeg, senior investigator and deputy chief of the Women’s Malignancies Branch at the NCI’s Center for Cancer Research.

“I think if we get to an atlas of what the normal breast is, what the molecular pathways are in all these different states and in white women, African American women, Asian women, we’re going to have the database to say, ‘This looks like a pathway that could be causing breast cancer,’” Steeg said to *The Cancer Letter*. “Right now, one in eight women gets breast cancer, and we truly—other than the fact that it

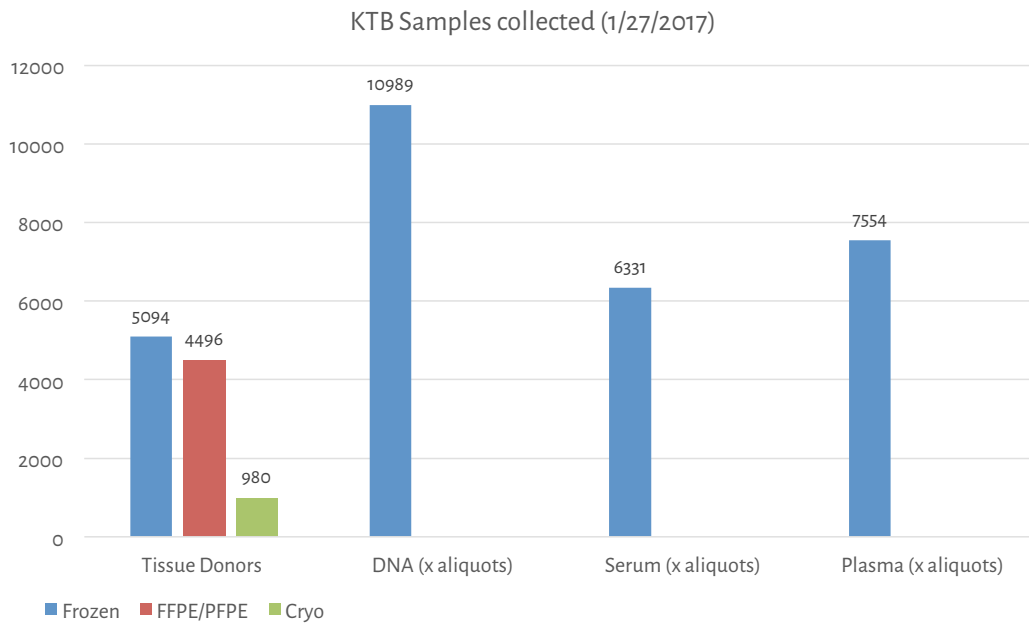
is at its base a genetic disease—don’t know what causes it.”

So, what constitutes “normal” in breast tissue, and what does it have to do with cancer?

Normal tissue may hold clues that could help researchers understand how malignancies arise, said Carlos Arteaga, director of the Harold C. Simmons Comprehensive Cancer Center and The Lisa K. Simmons Distinguished Chair in Comprehensive Oncology at UT Southwestern Medical Center.

“The ‘normal’ breast tissue in a patient with cancer or who is destined to have breast cancer, may already harbor gene alterations that will eventually lead to

Samples Collected as of January 2017



the cancer,” Arteaga said to The Cancer Letter. “So, this tissue provides a source of human material that can be interrogated for presence of molecules associated with the generation of the cancer which, one day, could be targeted with new drugs.”

At the time Rufenbarger and Storniolo were debating the feasibility of setting up a tissue bank, scientists relied primarily on two collection methods to compare normal vs. abnormal tissue:

- Reduction mammoplasty, a procedure in which a volumetric reduction of the breast is done, and
- “Adjacent normal” tissue, which refers to the tissue—near a cancer—that looks histologically normal.

As work continued, these tissues were shown to be neither histologically nor molecularly normal. In fact, tissue collected via reduction mammoplasty has been shown to be less “normal” than samples from the Komen bank.

Using normal donor tissues from the Komen bank, researchers concluded in a 2012 study that breast tissue samples from normal donors have significantly fewer histologic abnormalities and a higher frequency of more complete lobular involution.

“Breast tissue samples from normal donors represent a unique tissue resource with histologic features consistent with lower breast cancer risk,” the authors of the study wrote.

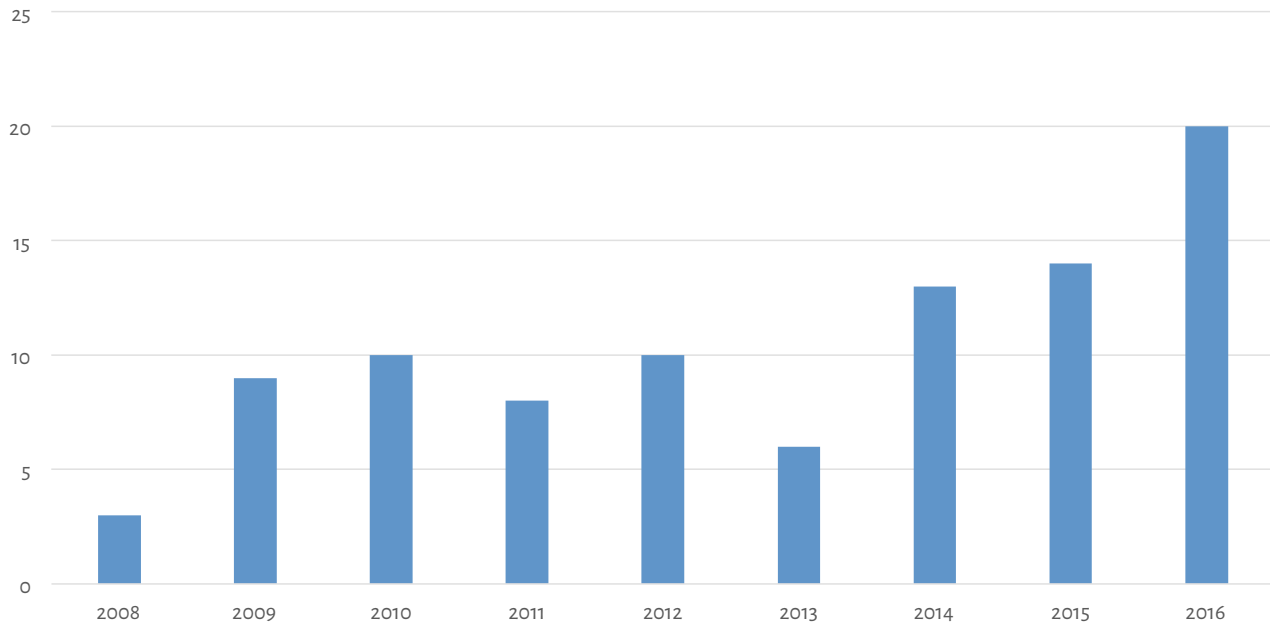
When researchers learned that reduction mammoplasties weren’t reliable, they focused on “adjacent normal” tissue.

“Taking the adjacent ‘normal tissue’ in a cancerous breast is problematic since although it appears normal to the pathologist, it may already contain mutations or other changes associated with the nearby cancer,” said Kent Osborne, director of the Dan L Duncan Comprehensive Cancer Center and the Tina and Dudley Sharp Chair in Oncology, and professor of medicine and molecular and cellular biology at Baylor College of Medicine.

Sampling errors and definitions of normal—i.e. no obvious cancer or genetic or epigenetic changes—may also af-

KTB Proposals since 2008

KTB Proposals by Year



fect how researchers understand adjacent normal tissue, said Susan Love, chief visionary officer of Dr. Susan Love Research Foundation.

“This could also be applied to contralateral breast where there may be some precancerous changes that are under the radar,” Love, a surgeon and author, said to *The Cancer Letter*.

Adjacent normal tissue is at a higher risk of containing mutations, NCI’s Steeg said.

“There is something called a ‘field effect’ in cancer, and so the tissue that is adjacent to tumor may not be the most normal,” Steeg said. “Remember that a woman who gets a breast cancer is at

10 percent risk of getting a contralateral breast cancer, breast cancer on the other side.

“I still can’t tell you why that is, but the idea that you could just take something adjacent to that tumor and say, ‘We’ve got the answer,’ isn’t going to work.”

In the past, investigators have also attempted to define “normal” breast tissue using mice, which undergo mammary development processes that differ from those in humans.

These approaches were inadequate, Steeg said.

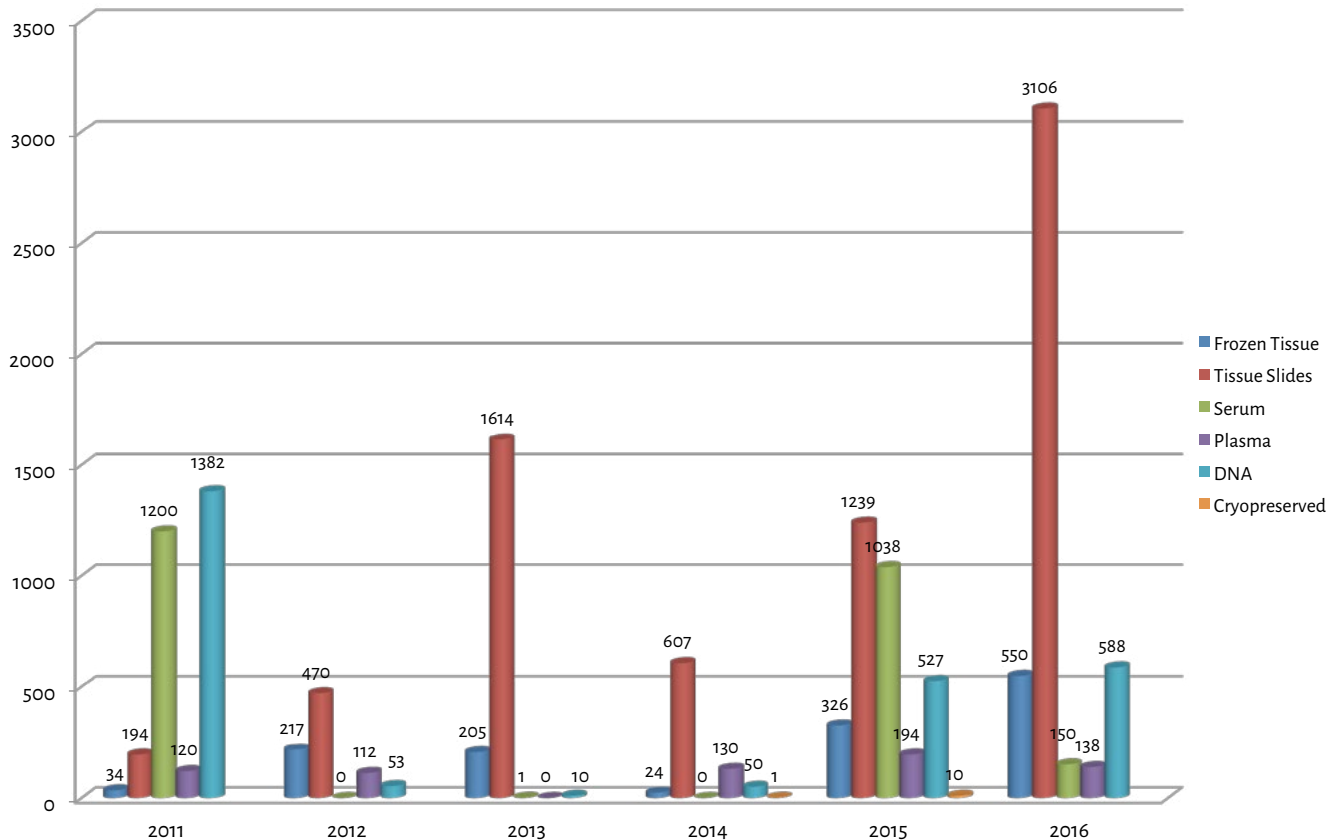
“There is no one ‘normal’ when you talk about breast development, because

there’s development through childhood,” she said. “It changes at puberty. It changes through the menstrual cycle. It changes at menopause. It changes with pregnancy. So, you have a very complex picture, and we need to understand all of those.”

The Komen bank is contributing to a more complete understanding of normal, which can help define what is abnormal in the cancer, Osborne said.

“Normal breast tissue is breast tissue taken from a woman who has no clinically evident breast problem like a lump, prior biopsy showing a benign condition (the fact that the patient had to have a biopsy is probably an indication that the breast tissue is not

Sample usage 2011- 2016



totally normal even though cancer or a precancerous condition was not identified) or malignant pathology, an abnormal mammogram, etc.,” Osborne said. “The abnormalities in the cancer, relative to normal breast, might also reveal clues to the risk of breast cancer, the causes of breast cancer, and the pathways causing it to progress.”

Storniolo: This is not rocket science

“To understand abnormal, you have to understand normal,” Storniolo said.

In the years leading up to the inception of the bank, Storniolo was reticent to ask healthy women to donate tissue.

“The medical establishment, as you’re well aware, can put many, many roadblocks in the way,” she said. “Even I couldn’t see it happening. This was an era where even data could not be collected without specific use in mind. You could not establish a database for future use. There were all kinds of regulations against that.”

Rufenbarger persisted. “Have you actually asked the ladies whether they would do it? God forbid, if the ladies actually are willing to come for no other reason, and have a breast biopsy, don’t

you think any other barrier is overcomeable?” she asked Storniolo.

Storniolo said she couldn’t come up with a reason to disagree.

“One Saturday—I was a soccer mom at the time—I went out to the fields and I asked probably 20 random women that I didn’t know,” she said. “I explained this idea.

“They got the idea. I said, ‘If you were asked, would you be willing to have a breast biopsy for research?’ I think, with the exception of one lady among 20 or 25 women, they all said yes, and they didn’t know me from Adam.

“That was that. I said, ‘Okay, if the women are willing to do it, I’m willing to do it.’”

In 2005, Storniolo organized a blood collection event in conjunction with a Race for the Cure. She and her team collected 500 samples in three hours from healthy volunteers at the race.

“Almost 100 percent of the women were willing to have it banked,” Storniolo said. “That gave us the ammunition to say to the regulators, ‘Women are willing to do this. Women do not have a problem with giving their specimens for unspecified future use.’ That got us going.”



My take is that after years of doing things the easy way, this is the way to go. There’s going to be no magic bullet, no one pathway, and here is the answer, I don’t think. But we’re mostly just poised for those discoveries in my estimation. They’re now doable.

– Patricia Steeg



The availability of a normal breast tissue bank is important for identifying the “normal” genomic, proteomic, and metabolomic profiles to compare with precancerous or malignant tissue and to better understand the normal variation present in the population.

“The bank has been a very important resource in helping us understand what normal most likely looks like and the variations among women depending on their reproductive history etc.,” Love said.

Osborne agrees.

“Comparing ‘normal’ among different age, menstrual status, parity, ethnic, or racial groups can also help to define differences that may help to explain differences in breast cancer risk among various groups,” Osborne said. “In short, scientists must understand what is considered normal before they can completely understand what is abnormal.”

The Komen bank could play a complementary role to NCI’s tissue repositories, scientists say. For instance, The Cancer Genome Atlas, the institute’s catalogue of genetic mutations responsible for cancer, mostly contains primary tumors.

“If you’re going to investigate how we get from normal to breast cancer—that is an endpoint—but the TCGA is not going to be able to tell you what change has happened along the way to getting to that endpoint,” Steeg said. “It’s a great resource when you want to look at what happened when you have breast cancer, but it’s really not going to give you a lot of information on the pathway to getting there, because you don’t have the normal controls.”

The bank is one of the better avenues to figure out the pathways whereby women are getting breast cancer, Steeg said.

“My take is that after years of doing things the easy way, this is the way to go,” Steeg said. “We don’t have smoking guns or clear answers after looking at mice and reduction mammoplasties. That’s hopefully going to lead to preventive strategies and preventive trials, and hopefully some movement of the dial back toward less breast cancer.

“I think [the Komen bank is], at this point, very poised to change the understanding. I mean, they have now collected so many tissues from women in so many different stages of their lives and are now giving these out to investigators for their molecular investigations.

“There’s going to be no magic bullet, no one pathway, and here is the answer, I don’t think. I think you’re going to get reports of, ‘Well, this may be contributory or that may be contributory.’ But we’re mostly just poised for those discoveries in my estimation. They’re now doable.”

Understanding “normal”

With its unique resources, the Komen Tissue Bank is likely closer than any other repository to figuring out what “normal” might truly look like.

“We fill the gap,” Storniolo said. “Samples are available to anyone who wants them at a very low carrying cost. There’s no reason to reproduce it somewhere else. We meet all of the international guidelines for bio repositories. The samples are pristinely preserved. We work within very tight SOPs.”

Does “true normal” exist?

“I guess the answer is there probably is not a ‘true normal,’” Love said. “Even the Komen normal tissue bank, which is probably the most likely to be normal, is only a core biopsy from a breast which may or may not be totally normal.”

In any case, the bank is proving that “normal” is, at best, a loaded term.

Early data published from the bank has shown that normal cells and stem cell populations grown in culture differ by race. This information is fascinating, Storniolo said.

“For example, the African-American population of women develops a disproportionate amount of triple-negative basal-like breast cancer—very aggressive, poorly differentiated,” Storniolo said. “When you look at their normal cells in culture, they are enriched for a population of cells with stem-like activity.

“Whereas, if you look at the Caucasian population, which develops a much more well-behaved, if you will, and indolent kind of breast cancer in the majority, estrogen receptor-positive, etc., and then, you look at their primary cell populations, it reflects again the type of breast cancer they develop.”

This means that, potentially, women are developing different breast cancers because they have different breast cells to begin with, not because their tissue isn’t “true normal.”

Also, this information may change how opinion leaders in oncology understand cancer prevention and health disparities.

“We may be looking at a situation where preventing breast cancer is going to have to be different for different races and ethnicities,” Storniolo said. “That’s huge. We would never have known that otherwise.”

Socioeconomic factors contribute to biological differences in breast cancer, said Otis Brawley, chief medical and scientific officer of the American Cancer Society.

“That is for sure, and we have to remember that,” Brawley said to *The Cancer Letter*. “Keep in mind the an-

thropological community has made some very clear statements that race is not a biological categorization of populations. Race is a socioeconomic categorization of populations.

“I think collecting normal breast tissue and studying normal breast tissue is really important if we’re going to look at the etiology of breast cancer. But I think that we need to look at etiological factors like diet, weight gain, age of menstruation—these patterns differ by ethnicity and race—and not focus too much on race itself.”

Other preliminary work is showing that women who donated breast tissue and then developed breast cancer a few years later may already differ from other women who do not go on to develop breast cancer.

“Basically, when you think about it, that original biopsy, ‘pre-obvious breast cancer,’ was not really normal because that breast biologically was already in the ‘cancerous process,’” Storniolo said. “We are calling that ‘susceptible normal,’ and we have approximately 15 of those.

“We are doing a one-to-three comparison of those susceptible normals to age and race matched normal from the bank, looking at differences in RNA expression, in DNA, and proteins. At first blush, there do appear to be differences.

“Again, without a resource like this, you would never in a million years be able to do that. What this work is going to end up doing is actually allow us to hopefully look at the very, very earliest changes in breast carcinogenesis—the very earliest changes in the steps of how breast cancer first develops.”

Without normal breast tissue to use as a baseline, researchers and women can never understand the normal breast, Love said.

“For example, recent studies have suggested that it is the stroma, not the ductal tissue, that is key,” Love said. “The Komen bank gives access to both—in healthy women with full annotation of risk factors and family history—so that we can start to understand what makes women’s breasts unique and why they develop breast cancer.”

Steeg applauded the bank’s perseverance.

“Collecting this has been a monumental task and it’s been collected in primo condition,” she said. “There are women who have given sequential biopsies, there are women who then went on to get cancer and have come back for biopsies. Besides the general collection of tissue cores, there are these number of cases now where there’s some very interesting clinical history to associate with these biopsies, and that’s where they’re really going to be able to make some progress.”

Going forward, the bank will be focusing less on increasing the overall number of samples and more on targeted collections from certain populations and cohorts, Storniolo said.

On Nov. 11, in collaboration with the New York-Presbyterian/Columbia University Medical Center, the bank will be collecting tissue in New York. The goal is to obtain samples from about 200 Asian and Hispanic women.

“I would love to see the bank itself used as a national and international resource in a much broader sense,” Storniolo said. “I would love to see us used as the ‘controls’ for something like the TCGA breast, or a major NCI effort, or one of the huge co-operative groups.

“Hopefully, scientists will see the value of the Komen Tissue Bank, and use the samples and data it provides to accelerate the path to a cure for breast cancer.”

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The Cancer Letter.

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CONVERSATION WITH
THE CANCER LETTER

Storniolo: The Komen Tissue Bank fills the gap in understanding of “normal”

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Anna Maria Storniolo
Executive Director, Susan G. Komen Tissue Bank

Ten years ago, the formation of the Komen Tissue Bank at the Indiana University Melvin and Bren Simon Cancer Center was met with skepticism.

Critics questioned the ethics of collecting “normal” breast tissue from healthy women who otherwise would have no other reason to undergo biopsies.

Anna Maria Storniolo, a founder of the tissue bank and now its director, was one of those skeptics—before she started work on the bank in 2005.

But women were willing to donate. Now, the bank has tissue samples from over 5,000 women, blood and DNA samples from over 10,000 women, and 1,000 cryopreserved samples.

Today, researchers are learning that the definition of “normal” breast tissue can vary, depending on factors such as eventual development of malignancies and racial groups.

“We’re finally on a steep curve of recognition and use, but it has been a long time coming,” Storniolo said. “Hopefully scientists will see the value of the Komen Tissue Bank, and use the samples and data it provides to accelerate the path to a cure for breast cancer.”

Storniolo spoke with Matthew Ong, a reporter with The Cancer Letter.

How did the Komen Tissue Bank come about?

Anna Maria Storniolo: In the early 2000s, we were at a meeting based in Indianapolis that happens annually. We were at a translational meeting where clinicians and basic scientists from the major universities in Indiana—Notre Dame, Purdue, IU Bloomington, IU Indianapolis—meet and exchange ideas.

The keynote speaker was from the NCI that year. It became obvious in the discussion that there was no source of true normal breast tissue for comparative purposes, for control.

What was being used was reduction mammoplasty and “adjacent normal.” Neither one of those are normal. Neither one has been shown to be either histologically or molecularly normal.

Anyway, having heard this, Connie Rufenbarger—a nationally known advocate who happens to be from Indiana and who helped sponsor the meeting—and I were a little surprised. She especially just could not figure out why this was so hard.

The medical establishment, as you’re well aware, can put many, many roadblocks in the way. Even I couldn’t see it happening. This was an era where even data could not be collected without specific use in mind. You could not establish a database for future use. There were all kinds of regulations against that.

And you were getting the same feedback from other people as well?

AMS: Correct. I said, “You don’t get it. There’s no way that anyone is going to let us set up to collect breast tissue, and put it up in a bank for unspecified future use. Think about the legal issues, and the regulatory issues, and the ethical issues.”

And Connie kept saying, “That’s ridiculous.”

The thing that finally convinced me was the most obvious reason. She finally just stopped me dead in my tracks and said, “Have you actually asked the ladies whether they would do it?” She said, “God forbid, if the ladies actually are willing to come for no other reason, and have a breast biopsy,

don’t you think any other barrier is overcomeable?”

I couldn’t argue with her. One Saturday—I was a soccer mom at the time—I went out to the fields and I asked probably 20 random women that I didn’t know. I explained this idea.

The beauty of this is it’s a straightforward idea: to understand abnormal, you have to understand normal.

And it made immediate sense to them?

AMS: Correct. This is not rocket science. They got the idea. I said, “If you were asked, would you be willing to have a breast biopsy for research?” I think, with the exception of one lady among 20 or 25 women, they all said yes, and they didn’t know me from Adam.

That was that. I said, “Okay, if the women are willing to do it, I’m willing to do it.” That was probably in 2005.

We started with a huge blood collection event coordinated with a Race for the Cure. One of my colleagues needed samples from 500 women to do a SNP analysis as comparators. He had budgeted three years for this to be able to collect that in the clinic from relatives and friends of patients that were coming in. We accomplished it in three hours from healthy volunteers that were at the Race for the Cure.

The key to that was not only that we did it, but that in the consent there was a paragraph that said, “If there is blood left over, after the specific experiment, I will, or will not, allow you to bank it for future breast cancer research.”

Almost 100 percent of the women were willing to have it banked. That gave us the ammunition to say to the regulators, “Women are willing to do this.

Women do not have a problem with giving their specimens for unspecified future use.” That got us going.

We started small with basically very small pots of philanthropic money. Then in 2007 we approached Susan G. Komen in Dallas with what some people are still saying is a crazy idea 10 years later: We asked them for operational support. They said yes.

They have been our primary infrastructure funder ever since, which is why we bear their name. So, to answer your initial question about “Why here?” we just had a crazy idea, and here we are.

The normal tissue bank is nowhere else. I think it would be difficult to reproduce anywhere else.

Samples are available to anyone who wants them at a very low carrying cost. There’s no reason to reproduce it somewhere else. We meet all of the international guidelines for bio repositories. The samples are pristinely preserved. We work within very tight SOPs.

There’s really no reason, as I said, to make another one unless there are international barriers somewhere. We’ve shipped things internationally, as well.

How many individual samples are now part of the bank? Are they cryopreserved?

AMS: We have tissue samples from over 5,000 women. We have DNA, and blood—because, remember, we started with blood—from over 10,000 women. All of those 5,000 samples are snap-frozen. Then approximately two years ago, we did start cryopreserving as well, so that those can be grown in culture, because that’s become more and more important. One thousand

samples have been cryopreserved. All samples have been ancestry mapped.

Are there other tissue banks that do what you do?

AMS: I don’t think so. Obviously, there are tumor banks. There are several banks of benign breast tissue, the best known of which is at Mayo.

Basically, these are samples done at the time of breast biopsy for people who have had abnormal mammograms and end up having a biopsy, and then those samples have been saved. These banks also contain tissues from reduction mammoplasty. There’s the spectrum of basically benign breast disease—not quite normal, but not malignant.

What have we learned from the bank about normal breast tissue? Does “normal” exist?

AMS: Well, it’s really, really interesting. So far, more than 30 manuscripts have been published using samples from the bank. I’ll give you what I think is fascinating, which is there is some very early data now published that has shown that basically when you grow normal cells in culture from different racial groups—Hispanics, African Americans, and Caucasians—and you analyze them, the earliest stem cell populations in culture are different.

If you think about the implications of that, the stem cell populations—and this is early data—appear to reflect the predominant populations of breast cancer that develop in those racial groups.

For example, the African American population of women develops a disproportionate amount of triple-negative basal-like breast cancer—very ag-

gressive, poorly differentiated. When you look at their normal cells in culture, they are enriched for a population of cells with stem-like activity.

Whereas, if you look at the Caucasian population, which develops a much more well-behaved, if you will, and indolent kind of breast cancer in the majority, estrogen receptor positive, etc., and then, you look at their primary cell populations, it reflects again the type of breast cancer they develop.

Now, what are the implications of that? Well, the implications of that potentially are that women develop different breast cancers because they have different breast cells, which, on the one hand, may seem kind of obvious, but it really wasn’t well known if it’s borne out. Thus, you can look at health disparity from a completely different angle.

The second thing is, importantly, if it’s borne out, we have our work cut out for us, because on a prevention front, one size is not going to fit all. On a prevention front, we may be looking at a situation where preventing breast cancer is going to have to be different for different races and ethnicities. That’s huge. We would never have known that, otherwise.

The other work that’s being done, again, is very preliminary. We have women who donated breast tissue and then developed breast cancer in that same breast two or three years later. We learned of this because they told us.

Basically, when you think about it, that original biopsy, “pre-obvious breast cancer,” was not really normal because that breast biologically was already in the “cancerous process.” We are calling that “susceptible normal,” and we have approximately 15 of those.

We are doing a one to three comparison of those susceptible normals to age and race matched normal from the bank, looking at differences in

RNA expression, in DNA, and proteins. At first blush, there do appear to be differences.

Again, without a resource like this, you would never in a million years be able to do that. What this work is going to end up doing is actually allow us to hopefully look at the very, very earliest changes in breast carcinogenesis—the very earliest changes in the steps of how breast cancer first develops.

If we do that, hopefully we can find some biomarker signals that will either give us a clue to early detection or a target for prevention.

What were some of the other important findings?

AMS: Right now, a lot of people, believe it or not, are looking at things you would never put together, but that are fascinating. We collect a lot of data on women, including clues about how early changes in early life affect breast cancer risk.

We do collect digital mammograms on women who are over 40. Several investigators are looking at the relationships between breast density and risk. Other people have seen a link between events during pregnancy and breast cancer risk.

The interesting thing is, when you have a huge number of patients or donors, you have all of this data, you really can begin to ask all sorts of different questions.

We also are beginning to look at our bank as a longitudinal study. We are collecting follow-up data on an annual basis and we will be trying to collect samples every five years.

In fact, now, the majority of our collections are going to be outside of Indiana and Indianapolis to improve the

diversity of the samples. On November 11, we'll be in New York, and partnering with New York-Presbyterian/Columbia University Medical Center to do a tissue collection. We hope to get samples from about 200 women concentrating on the Asian population and the Hispanic population in that area.

Who has access to the data in the bank?

AMS: Basically anyone, anywhere. It's a password-accessed database, but all you have to do is register. If you get samples from us, you are required to return the data to us, so that, with time, the database grows, so you learn more and more, research is accelerated, and redundancy is kept to a minimum, we hope.

There is data in the database currently that's cross-referenced by sample number, etc. One work that's already been done with the samples—if RNA-Seq work has been done, or if any genomic data is available on a given sample, or whatever has been done with the sample—as soon as we get the data back, we put it back into the database. Our dream is that some work can be done in silico.

If you look at the database and the website, and login as a researcher, all you have to do is set up a password. You can see individual H&E slides of the sample itself and look at the clinical data that's associated. Everything's de-identified, obviously.

It really is a beautiful resource. You also can do searches, and find out if we have what you need. We have permission to re-contact, so that if we don't have the information you need, we could probably get it from the donor.

What is the tissue bank's annual budget?

AMS: The annual budget is approximately \$1 million. Most of that comes from Komen; some of it comes from The Breast Cancer Research Foundation. We also receive funding from (luggage and handbag design company) Vera Bradley Foundation, which supports a huge amount of breast cancer research at Indiana University.

Does the bank charge for access to samples?

AMS: We do. There's a small fee for receiving the samples. We recycle that back into the operating budget. It doesn't even come close to covering our costs.

Going forward, how do you foresee the bank changing how the cancer community understands breast tissue and malignancies?

AMS: I see us focusing less on increasing the overall number and more on focused collections. In other words, collections focused on certain key populations and certain cohorts.

I see us more focused on collaborative efforts, so that, if a given consortium or a given investigator needs a special cohort, we can arrange logistically to take care of that. We can basically bring ourselves to them, and collaborate with them to get that done.

Also, in terms of, if you take even the collection out of it, I would love to see the bank itself used as a national and in-

ternational resource in a much broader sense. I would love to see us used as the “controls” for something like the TCGA breast, or a major NCI effort, or one of the huge co-operative groups.

We’re sitting on an enormous resource. In that situation, obviously, it would be a collaborative thing, and there would be no cost to the other partner involved, but that’s not even the issue. The resource is there to be used. My dream is that somebody taps us on the shoulder, and says, “We would love to have you be our controls.” That would be the major use of the bank. I would love that.

The other major dream is that someone would fund genomic characterization of all of our samples. That would be wonderful. I don’t have the money for that.

Finally, my third dream is just to be able to keep up with technology so that we can always be able to change our procedures so that we can provide samples in the form that is appropriate and useful to the people that need it.

Those are my dreams as someone who runs a bank.

My dream as a scientist is that a lot of the cancer susceptibility work happening in my lab bears fruit and that we’re able to find the earliest signs of breast cancer and able to identify some early biomarkers.

Patience is not a virtue I have in huge quantities, and it’s been very difficult to observe how long it has taken us to get this far. We’re finally on a steep curve of recognition and use, but it has been a long time coming. Hopefully scientists will see the value of the Komen Tissue Bank, and use the samples and data it provides to accelerate the path to a cure for breast cancer.

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ACS: Access and socioeconomic factors affect racial disparities in breast cancer mortality rates

By Matthew Bin Han Ong



The disparity in survival outcomes between black and white women with breast cancer—the result of a complex interaction of biologic and nonbiologic factors—can be reduced by increasing access to health care in all U.S. states, researchers from the American Cancer Society concluded in a recent study.

The paper, “Breast Cancer Statistics, 2017, Racial Disparity in Mortality by State,” was published in *CA: A Cancer Journal for Clinicians*. The article provides an overview of female breast cancer statistics in the U.S. and compares breast cancer death rates between black and white women for all 50 states.

The researchers used population-based cancer incidence data collected by the NCI Surveillance, Epidemiology, and End Results program and the Centers for Disease Control and Prevention National Program of Cancer Registries.

From 2006 through 2015, death rates decreased in all racial and ethnic

groups. However, higher breast cancer death rates continued in non-Hispanic black women, compared to non-Hispanic white women. Mortality rates were 39 percent higher in black women in 2015. By state, excess death rates in black women ranged from 20 percent in Nevada to 66 percent in Louisiana.

Importantly, breast cancer death rates were not significantly different in black and white women in seven states: Massachusetts, Connecticut, Iowa, Nevada, Delaware, Minnesota, and Washington. This, perhaps, reflects an elimination of disparities or, possibly, a lack of statistical power, researchers concluded.

It is worth noting that Massachusetts, with the lowest mortality rate ratio of 1.08, was the first state to provide health care insurance coverage to a majority of its residents in 2006.

“Improving access to care for all populations could eliminate the racial disparity in breast cancer mortality and accelerate the reduction in deaths from this malignancy nationwide,” the study’s authors wrote.

Overall breast cancer death rates increased by 0.4 percent per year from 1975 to 1989, but have since decreased rapidly, for a total decline of 39 percent through 2015. As a result of this decline,

322,600 breast cancer deaths have been averted in U.S. women through 2015, the authors concluded. The decrease occurred in both younger and older women but has slowed among women younger than 50 years since 2007.

Declines in breast cancer mortality rates have been attributed to both improvements in treatment—for instance, adjuvant chemotherapy and hormonal therapy in the 1980s and targeted therapies in the 1990s—and early detection by mammography.

“Not all women have benefited equally from these improvements, as evidence by variation in mortality trends by race and ethnicity,” the authors wrote. “A striking divergence in long-term breast cancer mortality trends between black and white women emerged in the early 1980s and continued to widen over the last several decades, but recent data suggest that the racial disparity may be stabilizing.

“The mortality gap that developed more than 30 years ago may reflect the unmasking of differences in tumor phenotype distribution between blacks and whites.”

While black women are disproportionately afflicted by triple-negative breast cancer, the substantial geographic variation in breast cancer death rates and trends confirms the contribution of social and structural factors, the authors wrote.

Nonbiologic factors that affect disparity in this context include differences in stage at diagnosis, tumor characteristics, obesity, and comorbidities as well as access, adherence, and response to treatments.

Socioeconomic factors may play a larger role in the development of triple-negative disease than previously thought, said Otis Brawley, chief medical and scientific officer of the American Cancer Society.

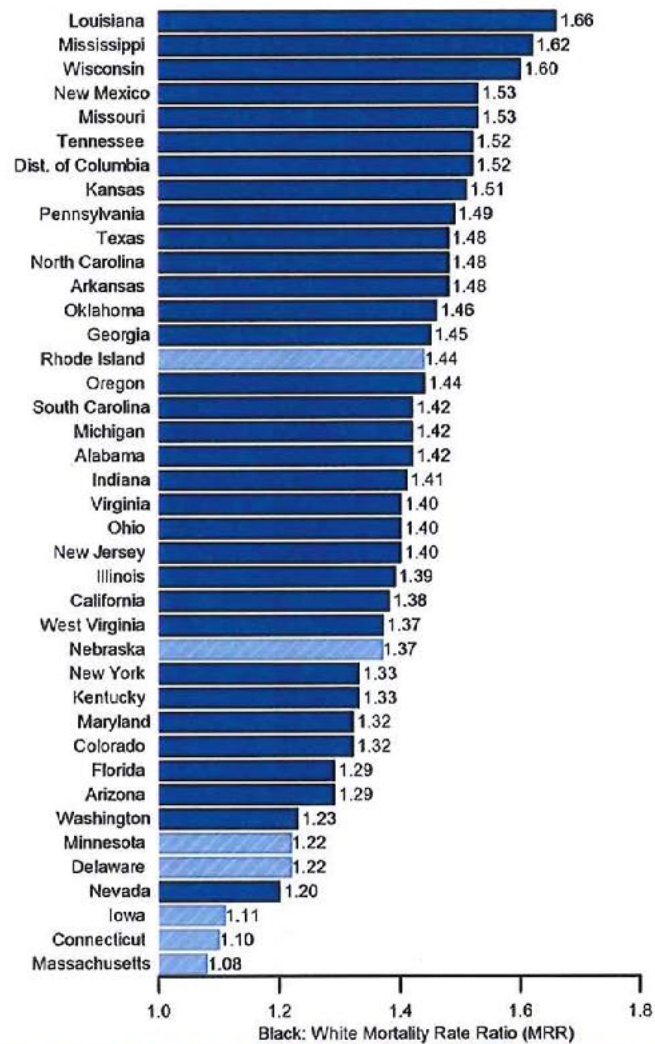
“We have data that show that poor white women in Scotland have more

triple-negative breast cancer than non-poor white women in Scotland,” Brawley said to *The Cancer Letter*. “In Scotland—where they don’t have this race thing to deal with—it turns out that poor white women, when they were children, have higher calorie diets and they gained weight faster than middle-class kids.

“And the result of that is, they start menstruating on average two years before the middle-class kids. Age of menstruation is a risk factor for breast cancer—it happens to be a risk fac-

tor for certain specific types of breast cancer. Then they looked at how poor kids have more babies that breast-feed, whereas middle-class women have fewer babies that breast-feed.

“Some of the middle-class women delay having children until late in life because of career, and that actually increases risk of estrogen receptor-positive non-triple negative breast cancer. And so, when we look at 30 percent of black women and 20 percent of white women have triple-negative disease—that’s the difference, by the way, 30 and 20.”



MORTALITY RATE RATIOS COMPARING BREAST CANCER DEATHS RATES IN BLACK WOMEN VERSUS WHITE WOMEN BY STATE, 2011 TO 2015

Note: Lighter shaded bars indicate that mortality rates between black and white women are not statistically different ($P < .05$). Source: National Center for Health Statistics, Centers for Disease Control and Prevention, 2017.



Dmitrovsky named president of Leidos Biomedical and director of Frederick Lab

By Paul Goldberg

Ethan Dmitrovsky was appointed president of Leidos Biomedical Research, Inc. and Laboratory Director of the Frederick National Laboratory for Cancer Research.

Dmitrovsky will succeed the current president, David Heimbrook, who will retire.

FNLCR is operated by Leidos Biomedical under an operations and technical support contract from NCI worth up to \$400 million-a-year.

In Frederick, Dmitrovsky will lead a team of 2,200 scientists, health professionals, and supporting staff members basic, translational, and clinical science with a focus on cancer, AIDS, and infectious diseases.

“It is a privilege to serve the Frederick National Laboratory for Cancer Research and give back to the National Institutes of Health, where my career began as a physician-scientist,” Dmitrovsky said to *The Cancer Letter*.

Dmitrovsky is the former provost and executive vice president of MD Ander-

son Cancer Center. He was brought in to MD Anderson by the institution’s former president Ronald DePinho, who resigned last March (*The Cancer Letter*, [March 9](#)).

Dmitrovsky remained in his administrative positions at MD Anderson through last June, when the cancer center simplified its power structure, eliminating the three executive vice president positions.

At that time, he was moved to on MD Anderson’s Cancer Center Support Grant and returned to his scientific work (*The Cancer Letter*, [June 30](#)).

Dmitrovsky most recently served as the Olga Keith and Harry Carothers Wiess Distinguished University Chair and American Cancer Society Professor at MD Anderson.

Prior to moving to MD Anderson, Dmitrovsky served as a professor and chair of the Department of Pharmacology and Toxicology at the Geisel School of Medicine at Dartmouth.

Heimbrook served as President of Leidos Biomedical Research and Laboratory Director of FNLCR for the past six years. He was involved in establishing the Frederick National Lab as a formal U.S. national laboratory, taking on projects that include the RAS Initiative, Genomic Data Commons, and the National Cryo-Electron Microscopy Facility.

Heimbrook is expected to serve as a consultant to Leidos and continue his service on the Leidos Biomed board of directors.

The Frederick contract was expected to be re-competed, but the process was delayed because of the laborato-

ry's potential role in the Moonshot Program and development of vaccines for the Zika and Ebola viruses (The Cancer Letter, [Sept. 30, 2016](#)).

The current contract, which was awarded in 2008, is scheduled to end in September 2018 (The Cancer Letter, [June 12, 2015](#)). In January, Leidos was awarded a [bridge contract](#) to keep operating the laboratory.

Leidos received \$400.2 million to run the lab in fiscal 2014. According to a recent job posting, Leidos said it employs about 1,900 staff and manages a \$450 million annual operating budget.

The lab was designated a national laboratory in February 2012, two years after Harold Varmus became the NCI director. To align the contractor with the institute, Varmus created the Frederick National Laboratory Advisory Committee. (The Cancer Letter, [Feb. 28, 2014](#)).

The lab, located on a 68-acre campus in Frederick, Md., is one of 41 Federally Funded Research and Development Centers. FFRDCs receive 70 percent or more of their financial support from the federal government. The lab also includes the 330,000 square foot Advanced Technology Research Facility, also in Frederick. Also, FNLCR is involved on the Bethesda campus, where it performs animal care and supplies nurses to the Clinical Center.

FNLCR is the only national laboratory dedicated solely to biomedical research.

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Help Wanted: MD Anderson seeks chief academic officer; Draetta named to the job in the interim

By Paul Goldberg

MD Anderson has begun a search for a chief academic officer.

Giulio Draetta will serve as CAO ad interim. Draetta is the Sewell Family Chair of Genomic Medicine, senior vice president, discovery and platforms and co-leader of the MD Anderson Moon Shots Program. Until now, Stephen Hahn, deputy president and chief operating officer, also served as interim chief academic officer.

MD Anderson officials are continuing to tweak the institution's box diagram. The changes are being made ahead of arrival of the new president, Peter Pisters.

Pisters has addressed the faculty and staff at a town hall meeting at MD Anderson recently (*The Cancer Letter*, [Sept. 29](#)), but his first day on the job is Dec. 1.

In the other personnel and organizational changes that were announced earlier this month:

- Helen Piwnica-Worms is out as vice president, deputy chief academic officer and division head of science. The basic science chairs will report

to Mike Brown, president and CEO of MD Anderson Physician Network, who will be responsible for all business functions of the MD Anderson Cancer Network. The position of the SVP of Network Development, held by Amy Hay will be eliminated.

- Oliver Bogler will no longer serve as vice president of academic affairs and associate dean of the graduate school. He will continue his service to MD Anderson as Professor, Department of Neurosurgery – Research. Academic Affairs responsibilities will be shared by Diane Bodurka, vice president of clinical education, and Maureen Cagley, vice president of Academic Operations. The oversight of Faculty Promotion and Tenure functions and committees will be assumed by Diane Bodurka and Mien-Chie Hung.

The text of Hahn's Oct. 27 email announcing the search for the chief academic officer follows:

I wanted to update you on recent decisions related to our institutional commitment to academics and research.

Chief Academic Officer Search Launching

The decision has been made to launch a national search for a Chief Academic Officer (CAO). We will allow time to carefully select a broadly representative faculty search committee, which will play an integral role in the process. An external recruiting firm will be engaged and MD Anderson's Executive Recruitment office will oversee the process to ensure consistency, impartiality, behavioral interviewing and confidentiality.

The search committee will identify the finalists for selection by the Deputy President and Chief Operating Officer in consultation with the President.

Giulio Draetta, M.D., Ph.D., named CAO ad interim

I am pleased to announce that while the search is conducted, Giulio Draetta, M.D., Ph.D., has agreed to serve as Chief Academic Officer ad interim effective immediately. Dr. Draetta is the Sewell Family Chair of Genomic Medicine and will continue to serve as Senior Vice President, Discovery and Platforms and co-leader of our Moon Shots Program.

Partnering closely with Dr. Draetta will be Maureen Cagley, Vice President for Academic Operations, Office of the Chief Academic Officer, and Julie Izzo, M.D., Executive Director, Faculty and Academic Integration, Office of the Deputy President and Chief Operating Officer.

Dr. Draetta joined MD Anderson in 2011. He is a physician scientist with long standing experience in cancer genetics and drug discovery in both academia and industry.

For more information on Dr. Draetta, view his faculty profile.

Research representation

MD Anderson remains firmly committed to scientific excellence and the pursuit of laboratory and clinical research. We want to ensure our science community is represented in our governing bodies and with our leaders.

The following measures have therefore been implemented:

- Jim Allison, Ph.D., will serve as Chief Scientific Advisor ad interim, effective immediately. In this role, Dr. Allison will serve as a key advisor to senior leaders. He continues in his roles as Chair of Immunology, Executive Director of the Immunotherapy Platform, Director, Parker Institute for Cancer Immunotherapy, and Deputy Director, David H.

Koch Center for Applied Research of Genitourinary Cancers

- Sharon Dent, Ph.D., Chair, Epigenetics and Molecular Carcinogenesis, and Raghu Kalluri, M.D., Ph.D., Chair, Cancer Biology, will represent laboratory science in the Shared Governance Committee
- Drs. Allison and Dent will also be science chair representatives to the Chief Academic Officer ad interim

Learn more and ask questions

You're invited to learn more about these efforts and ask questions at this Nov. 8 Town Hall:

Basic Sciences Town Hall and Q&A
Wed., Nov. 8, 5:00 – 6:00 p.m.
Onstead Auditorium, Mitchell Building, Floor 3, S3.8012

Other personnel changes were announced in an Oct. 16 email from Hahn:

The following leadership changes are effective today.

Senior Vice President of Network Development

The executive leadership team supporting MD Anderson Cancer Network™ has been restructured to further refine our leadership structure and better promote functional alignment with roles and responsibilities. The changes include the elimination of the SVP of Network Development position. We thank Amy Hay for her service and contributions to MD Anderson over the years.

Mike Brown, president and CEO of MD Anderson Physician Network, will have leadership responsibility for all business functions of the network. Mike now reports to Chris McKee, SVP of Strategy and Business Development.

Dr. Michael Kupferman, SVP of Clinical and Academic Network Development, will continue with clinical and academic oversight of the network and will lead the operations of our Global Academic Program. Dr. Kupferman will continue to report to me. Dr. Maggie Row will continue to serve as vice president of Clinical Operations, and will report to Dr. Kupferman.

Vice President Academic Affairs

Dr. Oliver Bogler will no longer serve in the administrative appointment of Vice President of Academic Affairs and Associate Dean of the Graduate School. He will continue his service to MD Anderson as Professor, Department of Neurosurgery - Research, Division of Surgery, and we appreciate his many contributions over the years. In the interim, Academic Affairs responsibilities will be shared by Dr. Diane Bodurka, vice president of Clinical Education, and Maureen Cagley, vice president of Academic Operations. The oversight of Faculty Promotion and Tenure functions and committees will be assumed by Drs. Diane Bodurka and Mien-Chie Hung.

Vice President, Deputy Chief Academic Officer and Division Head of Science

Dr. Helen Piwnica-Worms will no longer serve in the administrative appointment of Vice President, Deputy Chief Academic Officer and Division Head of Science. She will retain oversight of her lab and continue serving as Professor, Department of Experimental Radiation Oncology, Division of Radiation Oncology. We are grateful for Helen's leadership throughout the years. For now, the Basic Science Chairs will report to me in my role as interim Chief Academic Officer. Dr. Mien-Chie Hung also will work closely with Dr. Bodurka in handling academic issues with the basic science community.

Additional details on the new reporting structure for all of these areas will be available on the intranet soon.

IN BRIEF



Pat Coyne and Meg Gaines receive NCCS Stovall Award for advancing patient-centered care



Left to right: Dr. Julia Rowland, Martha “Meg” Gaines, NCCS CEO Shelley Fuld Nasso, Patrick Coyne, and Dr. Thomas Smith at the 2017 Stovall Award Reception.

The National Coalition for Cancer Survivorship presented its second annual Ellen L. Stovall Award for Innovation in Patient-Centered Cancer Care.

After a nationwide competition, the selection committee chose Pat Coyne of the Medical University of South Carolina and Meg Gaines of the University of Wisconsin at Madison.

Coyne was nominated by Thomas Smith of Johns Hopkins University School of Medicine. Gaines was nominated by Julia Rowland, the recently retired director of the Office of Cancer Survivorship at the National Cancer Institute.

Named for longtime CEO of NCCS and three-time cancer survivor Ellen Stovall, who died in 2016, the award aims to honor her memory and advocacy by annually recognizing individuals, organizations, or other entities that are innovators in improving cancer care.

Applications for the 2018 Stovall Award will be accepted beginning Feb. 1, 2018.

Coyne, an advanced practice nurse, has devoted his career to the advancement of the field of palliative care. He is one of the founders of the End-of-Life Nurs-

ing Education Consortium, which has educated more than 21,000 nurses in over 90 countries, and he has published over 100 papers on a variety of symptom management and policy issues.

Gaines is a lawyer by training, a cancer survivor, and one of the founders of the Center for Patient Partnerships at the University of Wisconsin. The Center trains students in the fields of law, medicine, nursing, pharmacy, and social work to provide advocacy to cancer patients. Interdisciplinary teams help cancer patients understand their diagnoses, get the information necessary to make critical treatment decisions, and support patients’ efforts to get the treatment they need.

SU2C launches four teams on “cancer interception” to detect and treat cancer

Stand Up To Cancer, joined by the Lustgarten Foundation for Pancreatic Cancer Research, LUNGevity, and the American Lung Association, announced four teams of researchers who will focus on on cancers of the lung and pancreas using the new approach of “interception” of cancers at very early stages.

The announcement was made at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, sponsored by the American Association for Cancer Research, the National Cancer Institute, and the European Organization for Research and Treatment of Cancer.

AACR is the Scientific Partner of SU2C.

SU2C was joined by the Lustgarten Foundation for Pancreatic Cancer Research, LUNGevity, and the American Lung Association and its LUNG FORCE initiative in funding four research teams, two each on cancers of the pancreas and lung, to a total of \$16.6 million.

The teams are:

- **SU2C-Lustgarten Foundation Pancreatic Cancer Interception Dream Team: Intercepting Pancreatic Cancer in High-Risk Cohorts.**

Funding: \$7 million.

Leader: Anirban Maitra, scientific director of the Sheikh Ahmed Pancreatic Cancer Research Center, MD Anderson Cancer Center.

Co-leaders: Michael Goggins, professor of pathology, medicine and oncology, Johns Hopkins University, Baltimore; and Scott Lippman, director of Moores Cancer Center, University of California San Diego Health.

- **SU2C-Lustgarten Foundation Pancreatic Cancer Interception Translational**

Research Team: Developing Novel Approaches to Treat and Evaluate Early Pancreatic Cancer.

Funding: \$2.6 million.

Leader: David Ryan, chief of the division of hematology and oncology at Massachusetts General Hospital Cancer Center.

Co-leader: Alec Kimmelman, chair of radiation oncology at Perlmutter Cancer Center at NYU Langone.

- **SU2C-LUNGeity-American Lung Association Lung Cancer Interception Dream Team: Intercept Lung Cancer Through Immune, Imaging, and Molecular Evaluation (InTIME).**

Funding: \$5 million.

Leader: Avrum Spira, professor of medicine, pathology, and bioinformatics, and director of the Boston University-Boston Medical Center Cancer Center.

Co-leader: Steven Dubinett, associate vice chancellor for research at

the University of California, Los Angeles and director of the lung cancer research program at the UCLA Jonsson Comprehensive Cancer Center.

- **SU2C-LUNGeity-American Lung Association Lung Cancer Interception Translational Research Team: Blood-based Early Interception of Lung Cancer.**

Funding: \$2 million.

Leader: Lecia V. Sequist, associate professor of medicine, and director of the Center for Innovation in Early Cancer Detection at Massachusetts General Hospital Cancer Center.

Co-leader: Maximilian Diehn, assistant professor of radiation oncology, Stanford University School of Medicine.

The four teams cover a range of approaches to the very early detection and treatment of cancer.

The SU2C-Lustgarten Foundation Pancreatic Cancer Interception Dream Team will perform genetic screening on family members of 2,000 people who already have pancreatic cancer for their own risk of developing it. Positive mutation carriers will then be tested with highly sophisticated and sensitive imaging techniques to detect smaller cancers missed by the human eye.

A smaller group of people with pre-cancerous lesions in the pancreas will be given a vaccine intended to induce the body's own immune system to attack the cancer. Finally, the team aims to develop a blood test for pancreatic cancer that can be used for people at high risk, such as those with new-onset diabetes.

The SU2C-LUNGeity-American Lung Association Lung Cancer Interception Dream Team will develop diagnostic tools, such as nasal swabs, blood tests, and radiological imaging, to confirm whether lung abnormalities

found on chest imaging are benign lung disease or lung cancer. To protect against recurrence of disease that has already been successfully treated, new blood tests will help identify patients at the earliest stages of recurrence, enabling timely interventions such as immunotherapy.

The SU2C-Lustgarten Foundation Pancreatic Cancer Interception Translational Research Team will test new and intensive preoperative treatments to allow more patients to achieve a complete resection and eradicate micrometastatic disease.

The team will conduct a clinical trial to evaluate the addition of losartan, a drug that may enhance the efficacy of the chemotherapy FOLFIRINOX in pancreatic cancer patients by altering the tumor microenvironment. The team will also evaluate the addition of immunotherapy to FOLFIRINOX and losartan. It will also use organoids to determine if they can be used to predict patient response to FOLFIRINOX and other therapies.

The SU2C-LUNGeity-American Lung Association Lung Cancer Interception Translational Research Team will develop Lung Cancer Interception Assay that can be used in conjunction with low-dose CT scans, based on blood-based assays that examine circulating tumor cells and circulating tumor DNA. After completing pilot testing as part of this Translational Research Grant, the team plans to move the LCIA forward to larger, prospective clinical trials.

The lung and pancreas Interception Dream Teams bring to 22 the number of Dream Teams launched by SU2C since the first Dream Teams were awarded in 2009. The new Translational Teams bring the number in that category to nine.

SU2C has also awarded 46 Innovative Research Grants to individual scientists, and a host of other grants and

awards to encourage innovative and collaborative cancer research, with funds committed by philanthropic, organizational, corporate, and individual donors, as well as nonprofit groups working with SU2C.

SU2C launches 10 clinical trial projects combining cancer treatments

Stand Up To Cancer has awarded 10 SU2C Catalyst clinical trial projects in which researchers from more than 30 institutions collaborate across academic and corporate borders on clinical trials across a variety of cancers, in a program supported by industry.

The inaugural SU2C Catalyst projects will explore new uses for an array of powerful medicines, from the three SU2C Catalyst Charter Supporters and six other pharmaceutical companies, the American Association for Cancer Research, SU2C's Scientific Partner, announced Oct. 12.

Grants to support the trials, as well as access to medicines, are being provided by the three Charter Supporters: founding collaborator Merck, as well as Bristol-Myers Squibb Company, and Genentech, a member of the Roche Group.

These Charter Supporters offered compounds to be used by the academic cancer research community, singly or in combination with products from the Charter Supporters or other companies.

The use of these treatments and combinations with compounds from additional companies were proposed by the academic research community in response to competitive Requests for Proposals. The proposals were evaluated and selected by industry-specific sub-committees, predominantly composed of leading academic scientists.

SU2C Catalyst establishes a mechanism through which industry and academic scientists in the cancer community conduct SU2C collaborative research projects to deliver benefits for patients and society.

In addition to creating these opportunities for innovative collaboration, SU2C Catalyst significantly expedites the process of going from ideas to contracts to trials, compared to traditional investigator-initiated studies.

The 10 inaugural clinical trials seek to address a wide variety of cancers, including breast, lung, melanoma, multiple myeloma, ovarian, pancreatic, hypermutant pediatric cancers, sarcoma, and urothelial cancer.

The focus of SU2C Catalyst clinical trials is to study those treatments in combinations with other pharmaceutical company medicines, devices, and therapies as well as standard-of-care treatments. The additional pharmaceutical companies providing compounds to be studied in combination, or financial support, include AbbVie, Astex Pharmaceuticals, Iovance Biotherapeutics, Mirati Therapeutics, Prometheus Laboratories, and TESARO.

SU2C Catalyst is overseen by an Executive Committee chaired by Phillip Sharp, chairman of the SU2C Scientific Advisory Committee and composed of academic investigators. Raymond DuBois, dean of the College of Medicine, Medical University of South Carolina, is chair of the donor-specific SU2C Catalyst Steering Subcommittees.

The Executive Committee selects proposals for funding based on recommendations from the Steering Subcommittees. The program is administered by the AACR. SU2C Catalyst projects also investigate why the combinations work, not just if the combinations work.

Below are the following clinical trials, listed with title, names of team leaders, amount provided through SU2C Catalyst, and the participating companies and the agents the research teams proposed for study:

- **Combined epigenetic therapy and pembrolizumab for advanced non-small-cell lung cancer.**

Stephen Baylin, Van Andel Research Institute; \$2.5 million.

Combinations: Merck: pembrolizumab (Keytruda); Astex Pharmaceuticals: guadecitabine; Mirati Therapeutics: mocetinostat.

- **Targeting VDR to make pancreatic cancer competent for immunotherapy.**

Daniel Von Hoff, MD, Translational Genomics Institute; \$2.5 million.

Combinations: Merck: pembrolizumab (Keytruda); AbbVie: paricalcitol (Zemlar).

- **DNA repair therapies for ovarian cancer.**

Alan D'Andrea, Dana-Farber Cancer Institute, and Elizabeth Swisher, University of Washington; \$1 million.

Combinations: Merck: pembrolizumab (Keytruda); TESARO: niraparib (Zejula).

- **Pembrolizumab and radiation therapy to improve outcome in high-risk sarcoma.**

David Kirsch, Duke University Medical Center; \$2.5 million.

Combinations: Merck: pembrolizumab (Keytruda); radiation therapy.

- **Tumor-infiltrating lymphocyte adoptive T cell therapy for NSCLC.**

Scott J. Antonia, H. Lee Moffitt Cancer Center; \$2.67 million.

Combinations: Bristol-Myers Squibb: nivolumab; lovance Biotherapeutics: financial support for tumor-infiltrating lymphocytes (TILs); Prometheus Laboratories, Inc.: IL-2.

- **Combined approaches by immune checkpoint inhibition for hypermutant cancers.**

Uri Tabori, The Hospital for Sick Children (Toronto); \$2.99 million.

Combinations: Bristol-Myers Squibb: nivolumab, ipilimumab.

- **Reversing primary anti-PD-1 resistance with ipilimumab and nivolumab.**

Antoni Ribas, University of California Los Angeles; \$3 million.

Combinations: Bristol-Myers Squibb: nivolumab, ipilimumab.

- **Immunotherapy to prevent progression in multiple myeloma.**

Irene Ghobrial, MD, Dana-Farber Cancer Institute; \$3 million.

Combinations: Bristol-Myers Squibb: nivolumab; lenalidomide.

- **Overcoming atezolizumab resistance with epigenetic therapy in urothelial cancer.**

Peter Jones, Van Andel Research Institute; \$2.99 million.

Combinations: Genentech: atezolizumab (Tecentriq); Astex Pharmaceuticals: guadecitabine.

- **Immunotherapy combination strategies in ER-positive metastatic breast cancer.**

Ingrid Mayer, Vanderbilt University Medical Center; \$2.3 million.

Combinations: Genentech: atezolizumab (Tecentriq), cobimetinib (Cotellic), idasanutlin.

Barbara McAneny receives ACCC award



Barbara McAneny received the Annual Achievement Award of the Association of Community Cancer Centers.

Her work in developing the grant-funded COME HOME oncology medical home initiative demonstrated reduced costs and improved care; helped to inform Medicare's current Oncology Care Model pilot; and supported physician practices in process changes critical to participation in value-based payment models, including those created under the Medicare Access and CHIP Reauthorization Act.

McAneny, a board-certified medical oncologist/hematologist from Albu-

querque, became the first oncologist to be voted president-elect of the American Medical Association. She will assume the AMA presidency in June 2018.

The ACCC Annual Achievement Award recognizes individuals who have made outstanding contributions, nationally and/or internationally, to cancer care and patients.

McAneny received the award at the ACCC National Oncology Conference, Oct. 18-20.

NCCN has one million registered users accessing the guidelines and related content

The National Comprehensive Cancer Network said its registration count has grown to more than one million users. By registering on the NCCN website, users are able to view and download all of the NCCN Clinical Practice Guidelines in Oncology free of charge for non-commercial use. According to the latest count, the number of registered users has grown to 1,013,449.

NCCN Guidelines have been downloaded approximately 50 million times since 2006, with the annual download rate doubling over the past five years. In order to keep up with user habits and facilitate easy access, NCCN Guidelines are available not only through NCCN.org, but also via the Virtual Library of NCCN Guidelines mobile app for smartphones and tablets, which launched in December 2013.

In 2017, so far, mobile downloads have accounted for more than 1.6 million additional Guidelines downloads.

NCCN's efforts to increase accessibility also include the translation of NCCN Content into 15 languages, as well as

resource-stratified guidelines tailored to low- and mid- resource regions throughout the world. International adaptations and translations of NCCN Guidelines have been downloaded more than 60,000 times, worldwide.

Among other projects, NCCN is working with the American Cancer Society, Clinton Health Access Initiative, IBM, and the African Cancer Coalition to create cancer care resources for use in Africa. The initial versions of NCCN's new guidelines for Africa will be released at the upcoming African Organisation for Research and Training in Cancer conference in Kigali, Rwanda this November. They focus on strategies for optimizing cancer care under a variety of circumstances and resource levels.

Fox Chase Cancer Center Opens Satellite Office in East Norriton



Fox Chase Cancer Center has partnered with Suburban Community Hospital to open the Fox Chase Cancer Center East Artist Rendering. The center will open in 2018 and offer access to Fox Chase's multidisciplinary care, plus radiation oncology with a linear accelerator and an infusion center.

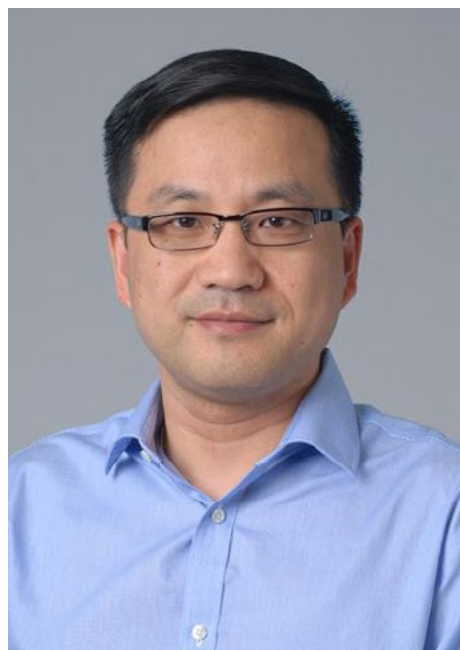
Norriton Hospital Outpatient Center.

The center will open in 2018 and will offer access to Fox Chase's multidisciplinary care by surgical oncologists, hematologists/oncologists, radiation oncologists, and support staff including onsite radiation and infusion treatments. Fox Chase's nurse navigation

system will ensure patients receive care appropriate to their type of cancer. Limited breast surgery consultations and radiation oncology will begin this fall.

The Fox Chase Cancer Center East Norriton Hospital Outpatient Center will be located adjacent to Suburban Community Hospital.

Xiongbin Lu named Vera Bradley Foundation professor of breast cancer innovation at IU



Xiongbin Lu was named the Vera Bradley Foundation Professor of Breast Cancer Innovation at Indiana University School of Medicine. He is also professor of medical and molecular genetics at IU School of Medicine and a member of the Experimental and Developmental Therapeutics research program at the Indiana University Melvin and Bren Simon Cancer Center.

Lu focuses on cancer genomics and targeted therapies. He searches for genetic flaws in and around breast

tumors that can be exploited for new ways to treat breast cancer. He also studies the root causes of why chemotherapy stops working and collaborates with other researchers to develop nano-therapies that target microscopic and resistant cancer.

Lu studies the cellular pathways that correct DNA damage, dysregulation of which can lead to cancer initiation and growth. This process, known as DNA damage response, was his focus when he identified a key protein regulator, Wip1, responsible for controlling DNA damage caused by toxic agents such as chemotherapy or radiotherapy. He also has identified several other important proteins that control tumor growth.

The GW Cancer Center announces new mobile mammography van



The George Washington University Cancer Center announced a new state-of-the-art mobile mammography van, known as the GW Mammovan.

The new GW Mammovan will stay true its mission of making early detection accessible to underserved women, regardless of their ability to pay.

The new GW Mammovan has the most comprehensive mammography system available today—the Genius 3D mammography technology with the Hologic Selenia Dimensions Mammography System.

DRUGS & TARGETS



FDA accepts Genentech's application for Avastin for advanced ovarian cancer

Genentech announced FDA has accepted the company's supplemental Biologics License Application for Avastin (bevacizumab) in combination with chemotherapy (carboplatin and paclitaxel), followed by Avastin alone, for the front-line treatment of advanced ovarian cancer.

This sBLA for Avastin for the front-line treatment of people with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer is based on data from the pivotal phase III GOG-0218 trial.

FDA is expected to make a decision on approval by June 25, 2018.

Avastin is approved for treating two different forms of advanced disease that recurred after platinum-based chemotherapy. In addition, Genentech is evaluating Avastin in combination with Tecentriq (atezolizumab) and chemotherapy for the treatment of newly diagnosed advanced ovarian

cancer in the phase III IMagyno50 trial (NCT03038100).

GOG-0218 (NCT00262847) is a multi-center, randomized, double-blind, placebo-controlled phase III study in 1,873 women with previously untreated advanced epithelial ovarian, primary peritoneal, or fallopian tube carcinoma who already had surgery to remove as much of the tumor as possible.

Participants were randomized into one of three treatment arms: chemotherapy alone (carboplatin and paclitaxel), Avastin (15 mg/kg) plus chemotherapy followed by placebo alone, or Avastin plus chemotherapy followed by Avastin alone.

Women who received Avastin in combination with chemotherapy, and continued use of Avastin alone for a total duration of 22 cycles, had a median progression-free survival of 18.2 months compared to 12.0 months in women who received chemotherapy alone (HR=0.64; 95% CI 0.54 - 0.77, $p < 0.0001$). Secondary endpoints of the study included overall survival and objective response rate. Adverse events were consistent with those seen in previous trials of Avastin across tumor types for approved indications.

The study was conducted by the Gynecologic Oncology Group and their initial results were previously published in the *New England Journal of Medicine*.

G100 receives Orphan Drug Designation from EMA for follicular non-Hodgkin's lymphoma

Immune Design said the European Medicines Agency has granted Orphan Drug Designation for G100 for the treatment of follicular non-Hod-

gkin's lymphoma. G100 has also been granted orphan drug designation by the FDA for the treatment of follicular non-Hodgkin's lymphoma.

G100 activates innate and adaptive immunity in the tumor microenvironment to generate an immune response against the tumor's preexisting diverse set of antigens.

A growing set of clinical and preclinical data have demonstrated the ability of G100 to activate tumor-infiltrating lymphocytes, macrophages, and dendritic cells, and promote antigen-presentation and the recruitment of T cells to the tumor.

The induction of local and systemic immune responses has been shown in preclinical studies to result in local and abscopal (shrinking of tumors outside the scope of the localized treatment) tumor control.

Currently, G100 is being evaluated as both a monotherapy (with local radiation) and in combination with Merck's anti-PD-1 agent, pembrolizumab, pursuant to a clinical collaboration with Merck, in a randomized Phase 1/2 clinical trial in patients with follicular non-Hodgkin's lymphoma.

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