THE CANCER LETTER

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SPECIAL ISSUE

Conversation with The Cancer Letter

Trump: Roswell Park Prepares for Sequestration

The Cancer Letter asked Donald Trump, president and CEO of Roswell Park Cancer Institute, to discuss the impact automatic cuts in federal spending would have on his institution.

The cuts, which are scheduled to take effect on March 1, could decrease the NIH budget by about 5.1 percent, or about $265 million for NCI during the current fiscal year (The Cancer Letter, Feb. 15).

Trump spoke with Paul Goldberg, editor of The Cancer Letter. An audio recording of the conversation is posted on The Cancer Letter website.

PG: *What do you think your world will look like on March 1? What's your assumption?*

DT: I think that's one of the challenges, Paul. It's hard to know exactly what's going to happen. You can ask four experts and get five opinions about what the outlook is. And, in truth—and I'm not trying to be coy—we have been dealing with economic uncertainty and the downturn in NIH budgets for several years.

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Guest Editorial

As Sequestration Becomes More Likely, Health Groups Must Make Themselves Heard

By Jon Retzlaff

Almost a year ago, the board of directors of the American Association for Cancer Research declared that the ability of cancer researchers to bring the promise of science to improve the outcomes for cancer patients is in peril, due to a decade of declining NIH budgets for medical research.

At the time, we couldn't have imagined that the overall funding situation

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In Brief

Giaccone Joins Georgetown Lombardi Center

GIUSEPPE GIACCONE joined the **Georgetown Lombardi Comprehensive Cancer Center** and will serve as associate director for clinical research, co-leader of its experimental therapeutics program, and director of the lung cancer program.

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Roswell Park Prepares for Cuts

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We spent a long time in 2007-2008 developing a strategic plan, and I think that was time well spent, because it really has allowed us to look forward. And with some planning, we have looked at ways we can modify our projected growth and investments to deal with downturns in the economy or interruptions in funding.

PG: *I've just talked to four or five experts here in town, and all of them are basically saying the same thing, which is, "Expect sequestration."*

DT: A month ago, the experts that we talked to, at least my impression was that they thought something was going to happen.

I spent Tuesday and Wednesday [Feb. 12-13] in D.C., in a couple of different meetings, and a lot of the experts this week are saying sequestration is likely to happen. But still, what exactly does that mean? How are funds sequestered, and what are the direct impacts on a cancer center?

We have planned for the two-percent reduction in Medicare reimbursement, and we have planned for an overall eight-percent reduction in NCI funding.

We were told at our pre-submission conference with the NCI program staff—our grant is due in May of this year—we were told that they were planning a 10 percent cut in the centers' budget. Those are the numbers we have been operating under the possibility of existing, and what we will do if these numbers come to pass?

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We probably will have some investigators who have very good grants [not get funded]. I think the poster child of this is a grant that Dr. [Deborah] Erwin has in with colleagues at the University of Buffalo and Mount Sinai in New York City, and this is their second submission.

They have a ninth-percentile grant to look at colorectal cancer screening in community-based African-American populations, and if sequestration happens that probably won't be funded—so that investigator will do something else.

There was an article in The Washington Post in the last couple of days in which [NIH Director] Dr. [Francis] Collins was bemoaning the fact that times have never been more exciting in science and opportunity and it's a terrific concern for all of us of what we won't be able to do because of the economic realities and the economic manipulations would happen if sequestration occurred.

"A lot of the experts this week are saying sequestration is likely to happen. But still, what exactly does that mean?"

PG: *What would a two-percent Medicare cut do to you?*

DT: Well, it's a couple million dollars. It's a significant amount of money, but I guess the thing that we are fortunate to be able to say is that we've been dealing with challenging economic times.

We've known that healthcare reform was not going to create—that a spigot wouldn't open with money flowing into to provide increased support for cancer centers.

We've been looking for ways to increase our patient-associated revenues by developing collaborations in our region and across the state.

We've also worked hard on scientific collaboration that's offered new granting opportunities and philanthropic opportunities.

We have a nice collaboration that we've executed in the last couple of years with the University of Rochester, wherein new philanthropic dollars have come in from the Rochester community, and we've

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complemented those dollars as well to support joint projects led by an investigator at Roswell Park and an investigator at the University of Rochester.

PG: *So you will remain upright with the Medicare cuts?*

DT: Yes. No question. We are a $550-million operation, so $2 million hurts, but we will go forward.

I'm cautiously optimistic, because there's a lot of good people working very hard looking at the problem from a number of angles, both increased revenue on all on fronts as well as being as judicious in our expenses as we can that we will continue to execute our mission and provide outstanding patient care and do first rate cancer research.

PG: *So what would an eight-percent cut on grants do to you?*

DT: Well, that's a $5.5 million hit.

It's distributed across a number of different investigators. We've got 65 or 70 NIH projects. Everybody will take—I heard this term most recently used by [NCI Director] Dr. [Harold] Varmus—everybody will take a haircut.

Investigators will not buy that extra piece of equipment; they'll not work as hard on Aim 3 of their grant, because they are saving money.

I think everybody will tighten the belt, and we will all also work hard in our philanthropic efforts to try to develop resources that help bridge the shortfall.

We've been, in a relatively small market, terrifically successful and wonderfully supported by our community, both for scientific investment as well as capital investment. We had a meeting of our fundraising board this morning, and they are as worried as we are, but passionately committed to seeing the mission at Roswell Park continue to flourish.

PG: *I guess the way Dr. Varmus used the word "haircut" was as opposed to an amputation. So you are not expecting amputations?*

DT: No sir. I don't think any cancer center or medical center's going to be facing amputations.

It's challenging, and you can't absorb cuts of this magnitude without careful planning, but you also have to recognize that we don't want to throw the baby out with the bathwater if we do draconian exercises that will compromise the mission—and that's just not an option as far as I'm concerned.

PG: *It works in Washington, but not in any responsible place like a cancer center. What about the 10 percent cut in the center's funding from NCI?*

DT: That's about $400,000—it's not trivial.

It will have the same impact, broadly speaking, that the individual investigator grants have. The other challenge it poses for us is that we go in for our competitive renewal in May, and the base budget in which we can project our next five years is the budget that we have at the time we go in for renewal.

So our NCI budget for the core grant was cut by five percent this year, in the current year. If it is cut 10 percent next year, there's no chance. Our CCSG budget will be anything less than the 8 or 10 or 12 percent less than we had three years ago, when we were coming off the best site visit we ever had, and the most productive science in Roswell Park's history.

"We are a $550-million operation, so $2 million hurts, but we will go forward."

It's a shame and it's a challenge. We've been planning for it as best we can, and we'll continue to try to husband resources that we have so we can do the highest quality science and provide great care to patients.

PG: *But as a half-a-billion-dollar operation, you are okay?*

DT: We are not circling the wagons or planning fire sales, by any means.

These are challenging times, but the last four to five years have been challenging to everybody in every sector of the economy.

The difficulty for us, I think, is, in addition to this being economically challenging—and we'll have to husband our resources as I said—this comes at a particularly unpleasant time, given the wonderful opportunities that exist in science.

And the other thing that other folks can't forget is that the training of the next generation of cancer care specialists and cancer scientists is going to be compromised by this.

Teaching and education—what are paid for by, at least in our center, resources that we developed from philanthropy and patient care work.

To the extent that other scientific work is compromised, we'll have to contract our education mission as well. Hopefully temporarily, but you will recognize, I'm sure, that if a young person is looking around for a career path, and sees one path that is very rocky and challenging—we will have folks that decide to do something else.

I worry about that, and to the extent that happens it's regrettable.

PG: *But it's not necessarily going to happen;*

right?

DT: I'm sure. The last five years, most of the experts—and I certainly don't consider myself an expert in this arena—but most of the experts maintain that there has been a reduction in the number of the individuals going into science and pursuing academic careers.

With the funding environment of 9 or 10 or 11 percent optimistically, it's easy to see how folks would rather try to develop their own independent career, they go into industry—and there is nothing wrong with going into industry—but most of the original discoveries in cancer happen at the cancer centers, so we don't want to lose the cadre of individuals that will make that happen in the next generation.

"We are not circling the wagons or planning fire sales, by any means."

PG: *When you superimpose sequestration on top of the Affordable Care Act, what's the impact?*

DT: Well, they are additive. The Affordable Care Act has many positive attributes to it, in terms of access of patients to care, access of patients to clinical trials, but part of the motivation for the affordable care act was to try to contain healthcare expenditures.

So we are looking at a likelihood of our reimbursements continuing to be challenged, and what we're doing internally and in our region is trying to work closely with our payer community, emphasizing the importance of care at a cancer center, and working with the payers to try to develop the programs that most benefit the their members and still bring the care of a comprehensive cancer center to each of those members in an affordable way.

And there are some novel projects developing that I hope will be able to demonstrate what can be done with partnerships that I think can be very productive, but it's going to take some work.

But we have to do the work because the healthcare dollar is getting a little bit smaller every year, and we have to work hard to maintain our contribution to the care of patients and do it in a way that's economically viable.

PG: *But do you see any places where there could be some offsets from affordable care act money that you don't have now but could be coming in?*

DT: No I don't see any of those offsets right at the moment. [Consider] the device tax. At one level, that sounds like a nice idea, it gets the companies to pay for the cost of medical care, but we all should recognize that the companies are going to pass that cost on to the consumer as soon as they can.

I don't see any new sources of revenue.

There will be some opportunities where the—I'm trying to remember the acronym—where the patient centered outcomes research, and [comparative effectiveness research], but those large population bases, there is money for those kinds of studies, and that's an advantage, and will be facilitatory of some work, but that's not the driving work in most cancer centers.

It's important work and can be developed. But for the moment, those of us who don't have large programs in that arena are not going to invest in trying to create them, but rather try to work hard to maintain the programs that we have.

PG: *So, overall, you are still seeing being able to navigate this.*

DT: If I didn't, I wouldn't keep doing this. It's going to be challenging, but as I've said we've been dealing with challenges for several years.

We are fortunate to have stepped back and tried to plan strategically, and we have invested, and sometimes slowed investment in certain areas to deal with the economic winds and snowstorms. I think we are going to do okay, but we have to keep our eyes open, and it will be challenging.

PG: *Let me present you with this hypothetical situation: Sequestration goes into effect on March 1. Then people in Washington come to their senses on let's say March 14 or 28. Will there be permanent harm done to your institution?*

DT: No. I think if the sequestration goes into effect and they don't come to their senses until June and put in some fixes, there will be challenges, but I won't accept a hypothesis there will be permanent harm.

"These are challenging times, but the last four to five years have been challenging to everybody in every sector of the economy."

We are doing pretty well, and I'm confident we will continue to do pretty well, as long as we keep our eye on the ball.

PG: *So there is still time then to work it out.*

DT: They are going to work it out some way, somehow. Exactly what it looks like is certainly not clear to me.

"We are fortunate to have stepped back and tried to plan strategically, and we have invested, and sometimes slowed investment in certain areas to deal with the economic winds and snowstorms."

But my intuition, for what that's worth—probably not much—is that there will be sequestration and then there will be an adaptation to sequestration that will reduce the pain a little bit, but we are all going to have to tighten our belts and continue to deal with the fact that the granting environment will be more and more competitive.

We will have to invest our money wisely, and we'll have to take every opportunity to develop synergistic programs, working with new partners, doing things in new ways, that will help us achieve our mission—because ultimately the mission is what has to drive what we are doing. And I'm pleased with how our institution has responded over the last few years to the economic pressures. I think nobody likes it, but we're doing okay.

PG: *Do you think NCI should do something differently?*

"I think if the sequestration goes into effect and they don't come to their senses until June and put in some fixes, there will be challenges, but I won't accept a hypothesis there will be permanent harm."

DT: I'm not sure what else they can do differently. I think there is recognition that almost every economic operation in the country can do things better, whether it's in industry or science or education, and so there are opportunities for saving and new ways of doing things, but I think the leaders at the NCI and the NIH are making a strong case—Dr. Collins interview in The Washington Post is an example.

He is pointing out that, to the extent that we don't invest in research, we are compromising the future of our citizens and the economic vitality of many sectors of our economy.

And we have to keep making that case to the legislators, and the legislators have their own challenges, given the fact that money isn't growing on trees now. But I think the NIH and NCI folks are doing a good job given the fact that they are dealing with a difficult situation.

Guest Editorial

Health Groups Must Be Heard During Sequestration Talks

(Continued from page 1)

for cancer research could decline so much more in a year, and that this would occur right before the AACR's 2013 annual meeting takes place in Washington.

Case in point is sequestration, the deep and arbitrary across-the-board federal budget cuts that are scheduled to take effect March 1.

These automatic cuts, originally put in place as a result of the 2011 deal that raised the debt ceiling, were intended to be so awful to both Democrats and Republicans that they would be driven and motivated to come together to work out a much more common-sense approach to reducing the nation's deficit.

If the sequester goes into effect, the impact on biomedical research could be devastating.

In fact, if Congress does not reach an agreement to halt or renegotiate the $85 billion in spending cuts for defense and non-defense discretionary programs by March 1, the budget for the NIH will be cut by $1.5 billion (a reduction of 5.1 percent) in fiscal year 2013, with NCI suffering a similar decline.

The cuts to NIH would come on top of the 20 percent decline in the agency's purchasing power since 2003, when inflation is taken into account.

It's difficult to assess the exact impact the cuts will have on research, because the NIH institutes and centers will have some flexibility over how to apply them.

Nonetheless, no matter how the cuts are doled out, they will put a strain on our nation's research enterprise, and specifically will jeopardize our ability to accelerate advances in cancer research for the benefit of all cancer patients.

NIH Director Francis Collins pointed out that the sequester could result in a 25 percent reduction in the number of new grants the NIH will be able to support in FY 2013, because of the fact that much of NIH's annual funding allocation is already committed to supporting grants that are typically distributed over four to five years.

Highly meritorious grant proposals will likely go unfunded, and promising research projects could grind to a halt. Sequestration could also mean less funding for cancer centers, fewer training grants, and a lack of funds to support laboratory personnel.

Limited funding opportunities and bleak prospects for the future could turn talented young people away from careers in research.

Fortunately, the cuts wouldn't have to take effect immediately.

The medical research community is hopeful that this "delay" will provide Congress with the wherewithal to replace them as part of a broader deal to fund government operations for the rest of the year.

Complicating things is a temporary funding measure (a continuing resolution) for FY 2013 that expires March 27. A failure to renew or replace it would lead to a partial government shutdown. Meanwhile, there are many members of Congress calling for still more reductions in federal funding when the CR expires.

Regardless, the bottom line is that if sequestration takes effect, which is becoming increasingly likely by the day, one of the consequences is that it could deal a devastating blow to medical research by delaying the research necessary to prevent, detect, and treat cancer.

And even if sequestration is averted, the medical research community will continue to face calls from Congress for lower overall funding levels in FY 2013 and beyond.

What's especially frustrating is that there is a consensus from all parties that sequestration is actually bad public policy, and that there are so many more sensible ways to achieving deficit reduction.

However, neither side appears willing to re-open the debate; for fear that any potential compromise runs the risk of including issues that the respective parties are especially trying to protect.

For example, Republicans appear to be content with letting sequestration happen even though many are extremely concerned about the defense cuts, because Democrats are insisting that raising revenue (through tax increases) be part of any new package.

Democrats also appear to be content with allowing sequestration to occur, even though many in their party are also extremely concerned about the discretionary programs that will be cut, because Republicans are demanding that they consider entitlement reforms that are far beyond what Democrats are willing to agree to in any compromise package.

Therefore, in some respects, it seems that both sides regard the across-the-board cuts on defense and non-defense discretionary programs as the lesser of the two evils—the greater of the two evils being raising taxes for Republicans, and agreeing to major entitlement reforms for Democrats.

The overall funding outlook for medical research is all the more reason why there has never been a more important time for all of us to make our voices heard on Capitol Hill, and directly in the offices of our nation's policymakers. Whether it is calls or emails to members of Congress, or visits to their district or state offices, it's vital that the people who are making these decisions on medical research hear directly from us, our family members, and our friends and work colleagues.

We also intend to amplify our voices and message in an unprecedented way Monday, April 8, from 11:00 a.m. to 12:15 p.m., on the steps of the Carnegie Library, across the street from the Washington Convention Center. The entire medical research community is coming together to conduct a Rally for Medical Research.

The purpose of the rally is to unite millions of Americans to call on the general public and our nation's policymakers to make funding for the NIH a national priority, and raise awareness about the importance of continued investment in scientific research that ultimately leads to more progress, more hope and more lives saved.

Survivors, scientists, health care providers, medical research advocates, and representatives from the biotechnology and pharmaceutical industry will all participate. Satellite events are being planned all over the country for those who can't be in Washington, but want to demonstrate their support for medical research.

The Rally for Medical Research presents a historic opportunity for the NIH advocacy community to join together to push for sustainable investments in medical research that will benefit patients. As Dr. Collins recently pointed out, "We're in this amazing revolution. The faster promising leads are funded, the more lives are saved."

The author is the managing director of science policy and government affairs of the American Association for Cancer Research.

In Brief

Giaccone Moves to Georgetown Lombardi Cancer Center

(Continued from page 1)

He will also serve as director of clinical research for the MedStar Georgetown Cancer Network, a clinical affiliation between MedStar Health and Georgetown Lombardi.

Previously, Giaccone was chief of NCI's Center for Cancer Research's Medical Oncology Branch.

GEORGE RAPTIS joined the **North Shore-LIJ Cancer Institute** as vice president of the system's oncology network.

In addition to the newly created position, Raptis will also serve as associate chief of oncology and attending physician in the Department of Medicine's Division of Hematology-Oncology at North Shore University Hospital and LIJ Medical Center

Previously, he was director of the Dubin Breast Center at Mount Sinai Medical Center. He has held numerous leadership roles at Mount Sinai, including associate chief for clinical affairs, associate chief of solid tumor oncology and director of the Ruttenberg Treatment Center.

YALE-NEW HAVEN'S SMILOW CANCER HOSPITAL opened a campus at **Greenwich Hospital**.

The campus will allow Yale Cancer Center specialists to work with oncologists and specialists from Greenwich in the hospital's newly renovated facilities.

Yale specialists in prostate and genitourinary, head and neck, gynecologic, and brain cancers will be available for patient appointments immediately. Additional specialists will follow later this year.

THE OREGON HEALTH & SCIENCE UNIVERSITY Knight Cancer Institute and **Organovo Holdings Inc.** formed a collaboration to develop more clinically predictive in vitro three-dimensional cancer models.

Using bioprinting technology, Organovo develops three-dimensional, architecturally correct, human disease models to improve the understanding of drug toxicity and efficacy earlier in the drug development process.

"A major challenge in oncology research today is that animal models cannot accurately represent human physiology, and cell lines do not provide information on how cells act in a three-dimensional, native architecture," said Joe Gray, director of the OHSU Center for Spatial Systems Biomedicine, the Gordon Moore Chair of Biomedical Engineering, and associate director for translational research.

"Using Organovo's bioprinting technologies, we plan to create new models to understand cancer disease mechanisms and metastatic progression, which can be used to discover and test new, targeted therapies."

UNIVERSITY OF CALIFORNIA LOS ANGELES and **NanoSmart Pharmaceuticals** entered into a research collaboration agreement to develop NanoSmart's drug delivery platform for the treatment of cancer and other diseases.

"We are very excited to work closely with Dr. Noah Federman and his colleagues at UCLA, as they will provide access to an extraordinary level of research, development and clinical resources," said James Smith, president of NanoSmart. "Their expertise in the development of nanotechnology-based drugs will enable us to continue making efficient progress towards commercializing these products."

NanoSmart's delivery system utilizes human autoimmune antibodies that target many different types of tumors, and can be combined with FDA-approved cancer drugs.

"Despite the extensive research into new drug formulations, the pace of advancing benefit to this patient population is unfortunately slowing," said Federman, director of the Pediatric Bone and Soft Tissue Sarcoma Program at UCLA, a part of the UCLA Sarcoma Program and UCLA's Jonsson Comprehensive Cancer Center; and assistant professor of pediatrics, hematology/oncology at Mattel Children's Hospital at UCLA.

THE ASSOCIATION OF COMMUNITY CANCER CENTERS released its **2013 Patient Assistance and Reimbursement Guide**, compiling information on pharmaceutical and non-pharmaceutical patient assistance programs and reimbursement resources.

Results of the association's 2012 Cancer Care Trends in Community Cancer Centers survey reveal an enduring trend toward increasing numbers of patients

struggling to afford their anticancer treatments. Among ACCC member hospitals participating in the survey, 95 percent reported that their cancer programs see patients who needed help with co-payments or co-insurance.

The guide is available in two formats. In the digital edition, members can link directly to the forms patients need, post sticky-notes directly onto the guide, and email information to colleagues and patients. The guide is also available as a PDF.

UPMC CANCERCENTER received accreditation by the **American College of Radiation Oncology**, making it the largest comprehensive cancer network in the country to be accredited in radiation oncology.

Twenty of the center's 21 sites in western Pennsylvania were accredited. The 21st site, located at the newly opened UPMC East, will be eligible for accreditation after being opened for one year.

ACRO developed its accreditation program to help promote standards for radiation oncology. The accreditation process is voluntary.

MICHAEL SEIDEN will resign as president and CEO of **Fox Chase Cancer Center** effective Feb. 28 "to seek other opportunities," an executive of Temple University said in a recent letter to the staff.

Seiden, who has been running Fox Chase since 2007, oversaw the center's merger with Temple.

His decision to step down was announced in a "dear colleague" letter from **Larry Kaiser**, dean of Temple University School of Medicine and president of the Temple University Heath System.

The text of the letter follows:

Six months ago, when Fox Chase Cancer Center (FCCC) became part of Temple's healthcare enterprise, we initiated a process to create an integrated Fox Chase/Jeanes Hospital Campus that would enable us to enrich our clinical offerings to all cancer patients, significantly advance our research efforts into the causes and cures of this challenging disease, and streamline campus-wide operations to further enhance patient-care at both hospitals.

Critical aspects of the organizational and operational changes required in this new era of expanded cancer care and research at FCCC and Temple were conceived and implemented under the leadership of Michael V. Seiden, MD, PhD, President and CEO of Fox Chase Cancer Center, who skillfully has guided the evolution of the NCI-designated comprehensive cancer center since June of 2007.

As the organizational and operational changes continue to unfold, Dr. Seiden has decided to step down as President and CEO of Fox Chase Cancer Center, effective February 28, 2013, to seek other opportunities.

To ensure continuity of the progress we have achieved throughout the Fox Chase/Jeanes Hospital Campus, I am appointing Verdi J. DiSesa, MD, MBA, Chief Operating Officer of Temple University Health System and Vice Dean for Clinical Affairs at Temple University School of Medicine, as the Interim President & CEO of Fox Chase Cancer Center, effective March 1, 2013.

As part of his current roles, Dr. DiSesa has an understanding and awareness of Fox Chase's current and future requirements (for both its clinical and research portfolios). His temporary appointment as Interim President & CEO of FCCC will ensure a seamless transition in leadership for the cancer center. Verdi will work closely with Dr. Richard Fisher upon Dr. Fisher's arrival in early March as Physician-in-Chief and Executive Vice President.

Linda Grass will continue to lead Jeanes Hospital as President & CEO, reporting directly to Verdi DiSesa in his role as Chief Operating Officer of Temple University Health System.

Finally, I am pleased to announce that Judith Lynn Bachman, most recently Managing Director/Partner of Chicago-based Huron Healthcare Consulting, will join Temple's healthcare enterprise as Chief Operating Officer for Fox Chase Cancer Center and Jeanes Hospital, effective January 14, 2013. In that capacity, she will report to the CEOs of FCCC and Jeanes Hospital.

As Chief Operating Officer of both providers on the Fox Chase / Jeanes Hospital Campus, Ms. Bachman will have administrative responsibility for their clinical and operational integration. Ms. Bachman is a seasoned healthcare administrator in both academic medical centers and large healthcare systems, with experience

in healthcare management, performance improvement, complex project management, and strategic planning. She is familiar with the Philadelphia healthcare market, having served for seven years as Senior Vice President of Strategic Initiatives for Thomas Jefferson University and Health System.

Gary Weyhmuller, SVP and Chief Operating Officer at FCCC, and Rob Davis, AVP for Integration at FCCC, will be stepping down from their roles and leaving the organization. Gary has served FCCC for over 35 years, providing leadership and administrative services. Rob has been instrumental in our integration efforts to date. I want to thank Gary and Rob for their years of service at FCCC and wish them well in their future endeavors.

On behalf of the FCCC Board of Directors, faculty, and staff, I want to express my gratitude and appreciation to Dr. Seiden for his leadership and many contributions to FCCC. In the near future, we plan to host a reception to thank Dr. Seiden for his substantial service and leadership of the organization.

We look forward to significant future opportunities for Fox Chase Cancer Center, Jeanes Hospital, and Temple's healthcare enterprise to serve those patients who entrust their lives to us. I am confident of your support for those efforts and of Verdi DiSesa, Linda Grass, and Judy Bachman in their new FCCC and Jeanes Hospital leadership roles.

Thank you very much.

Sincerely,

Larry R. Kaiser, MD, FACS

FDA News

FDA Approves Kadcyla, Fourth Drug Targeting HER2

FDA approved **Kadcyla** (ado-trastuzumab emtansine) for the treatment of people with HER2-positive metastatic breast cancer who have received prior treatment with Herceptin (trastuzumab) and a taxane chemotherapy.

Approval of Kadcyla is based on results from EMILIA (TDM4370g/BO21977), a phase III trial comparing Kadcyla with lapatinib in combination with Xeloda (capecitabine).

The study met both co-primary endpoints of overall survival and progression-free survival.

Patients receiving Kadcyla lived a median of 5.8 months longer than those who received the combination of lapatinib and Xeloda, (median overall survival: 30.9 months vs. 25.1 months).

Patients receiving Kadcyla achieved a median progression-free survival of 9.6 months compared to 6.4 months, (HR=0.65, $p<0.0001$).

Kadcyla is the first FDA-approved antibody-drug conjugate for HER2-positive metastatic breast cancer.

"Kadcyla is trastuzumab connected to a drug called DM1 that interferes with cancer cell growth," said Richard Pazdur, director of the FDA's Office of Hematology and Oncology Products. "It is the fourth approved drug that targets the HER2 protein."

Kadcyla combines the mechanisms of action of both trastuzumab and DM1.

Kadcyla is sponsored by Genentech.