THE CANCER LETTER

May 6, 2016 • www.cancerletter.com • Vol. 42 No. 18

Virtual is Not Enough

FDA's Critics Call for Full Integration of Oncology Center Under Biden's Moonshot

By Matthew Bin Han Ong

The White House moonshot to accelerate progress in cancer research directs FDA to consolidate its oncology portfolio.

However, oncology insiders say the manner in which the presidential initiative will be implemented could make the difference between political balderdash and genuine improvement in FDA regulation of cancer therapies.

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Moonshot Task Force Director Addresses FDA-Sponsored AAADV Workshop

Greg Simon, executive director of the cancer moonshot task force, addressed the FDA-sponsored workshop for Accelerating Anticancer Agent Development and Validation in North Bethesda, Md., May 4.

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Slamming the Door

Part XI: Gilman's Teachable Moment

By Paul Goldberg

During our first conversation in the spring of 2012, Gilman said that he would go public unless he received assurances that CPRIT would retain its integrity after his departure.

He wanted guarantees that the structure he built would not be turned into a political pigsty. With guarantees being hard to come by, it was obvious that he would end up slamming the door hard. Publicly.

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Critics Call For Full Integration Of Moonshot Oncology Center

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The entire controversy boils down to the interpretation of one word: Virtual.

According to a fact sheet that accompanies President Barack Obama's memorandum on the moonshot, "the FDA will develop a virtual Oncology Center of Excellence to leverage the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices." (The Cancer Letter, Feb. 5.)

This directive comes with $75 million in new mandatory funds for FDA in fiscal 2017.

For the past three months, agency insiders and outside observers have been pondering the meaning of the word "virtual."

Oncology professional societies and several advocacy groups want the FDA cancer center to be organized to include the agency's entire cancer portfolio: drugs, biologics, immunotherapies, cellular therapies, diagnostics and other devices.

Ideally, the new center would be placed under the same physical—as opposed to virtual—roof and under the same chain of command, proponents say (The Cancer Letter, Feb. 26). This plan has the support of the American Society of Clinical Oncology, the American Association for Cancer Research, Friends of Cancer Research and other groups.

This level of consolidation appears to be running into internal opposition at FDA, particularly in units that stand to lose authority, staff and budget in a reorganization.

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Subscription $420 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.

One example is the Center for Devices and Radiological Health, which has a broad purview over diagnostics, which are an essential component of precision oncology. Would some cancer diagnostics work be moved to another administrative unit?

Another entity that stands to lose clout is the Center for Biologics Evaluation and Research, which regulates cellular and immunotherapy, using its own set of procedures and relying on the Oncologic Drugs Advisory Committee and its own advisory committee. CBER appears to apply standards that differ from those of the Office of Hematology and Oncology Drug Products, located within the Center for Drug Evaluation and Research (The Cancer Letter, Feb. 19).

What does the White House mean by virtual, and how does FDA intend to approach implementation of the moonshot?

Speaking at a recent FDA-sponsored workshop by a group called Accelerating Anticancer Agent Development and Validation, Gregory Simon, executive director of the White House Cancer Moonshot Task Force, said that virtual is "not a bad word." Moving desks at FDA may not be necessary to achieve the moonshot's goals, Simon said.

FDA officials said the structure and staffing for the virtual cancer center will be established in fiscal 2017.

"Specifically, in FY 2017 (October 1, 2016 to September 30, 2017), the FDA will establish the structure and staffing for the Oncology Center of Excellence, create the required virtual regulatory environment and coordinate with the NIH National Cancer Institute," FDA officials said to The Cancer Letter.

Oncology advocates and professional societies say a virtual reorganization is not enough. Desks and the chain of command should shift as well. Moreover, FDA leadership needs to present a detailed blueprint of its plans for the cancer center much sooner than the next fiscal year, these groups say.

"This is about patient need. We need to hear from the FDA on what they think the structure of an Oncology Center of Excellence should be," said Ellen Sigal, founder and chair of Friends of Cancer Research, a group playing a central role in creating the legislative language for the cancer center. "We look forward to working with FDA leadership, with input from all stakeholders, on creating meaningful integration through the centers of excellence.

"We have to integrate that in a way that is meaningful, so we can have diseases where oncologists really make these decisions," Sigal said to The Cancer Letter. "Of course, the skillsets in all these divisions are

really important, and I wouldn't for one moment suggest that the skillset in CDRH or in CBER isn't important, but they have to be integrated in a way with disease experts who are working together and where decisions are made."

The existing centers already work collaboratively, agency officials said in response to questions from The Cancer Letter about whether FDA oncologists in the drug and biologics divisions are being consulted in plans for the center of excellence.

"Currently, the reviews for cancer products exist in separate FDA 'centers'—CDER, CBER, and CDRH," FDA said in a statement May 5. "However, there are already examples of these centers working collaboratively across review divisions, such as for drugs or biologics (CDER/CBER) that are approved with a companion diagnostic (CDRH).

"We also have an Office of Combination Products with the distinct and important role of serving as a focal point for combination product issues for agency reviewers and industry. This office helps provide guidance and clarity on the differing regulations that may come up with products that combine a drug/biologic and device, and helps ensure consistency with premarket review and postmarket regulation."

The full text of FDA's response appears below.

Legislation to create the FDA Intercenter Institutes is underway in Congress.

The FDA and NIH Workforce Authorities Modernization Act was introduced in the Senate March 17, and a similar version will be introduced in the House next week.

Aimed at improving coordination of FDA activities, the bill would establish one or more institutes according to major disease areas no later than one year after the measure is enacted.

This means that it will fall on another administration and another Congress to implement this directive.

Moonshot Chief Executive: It's Up to FDA

More time should be spent on creating collaborations than moving offices, said Simon, formerly a senior vice president for patient engagement at Pfizer and CEO of Poliwogg, a financial services company investing in the life sciences, prior to joining the White House Cancer Moonshot Task Force.

"First off, we agree with the need for this, and I know FDA does, too," Simon said, responding to a question from The Cancer Letter. "And the FDA has come a long, long way in oncology in my 30 years in Washington, and 20 years since I was last in the government.

"By 'virtual,' I think if we spend a lot of time when we try to physically move things around and we try to put people in contiguous offices and go through all the official stuff, when what we really want is an obligation for them to work together from the beginning in a joint way, regardless of whether it's a device or biological or small molecule. So to me, virtual is not a bad word, it means that there's a common obligation to work together, so we're not going to spend a whole lot of time banging the office and relabeling things."

Simon said that any internal disputes should be settled by the agency within the agency, without external interference.

"Now, there is support for this in both sides of Congress, I know the leadership supports this, I know that the patient community supports this," Simon said. "I'm not going to prejudge exactly how they set it up, since I've been doing this [for] six weeks, and before I really wasn't thinking about the FDA's Oncology Center of Excellence to tell you the truth, I was thinking more about how we're going to help fund companies in the Valley of Death.

"But I think that with the leadership we have right now at the FDA with [Commissioner] Robert Califf and Richard Pazdur [director of the Office of Hematology and Oncology Products], that any management issues don't need to be dictated from outside, but can be managed from the inside. The moment you take control outside of the office, you lose control, and it becomes much harder to change anything. I guess what I'm saying is I'm holding off judgment about how specific the legislation has to be for it to be successful, but I'm sure I'm going to be hearing more about it."

The text of Simon's remarks at the AAADV workshop appears on page 1.

ASCO, AACR Call for Full Integration

Nancy Goodman, executive director and founder of Kids v Cancer, said that a virtual center would fall short of scientific and patient need.

"I don't know what 'virtual' means. Is that going to mean something?" Goodman said to The Cancer Letter. "Are we going to be able to actually build a separate unit with a budget and lines of responsibility and a bottom line? Is this going to be a real change? Or are we just going to put lipstick on it?

"I think this is a tipping point moment in the history of oncology, drug development and the FDA. It's critically important that we get a center of excellence that actually means something," said Goodman, who successfully advocated for the creation of priority

review vouchers to incentivize development of drugs for rare pediatric diseases. "That means that there will be reporting right up to the top, that it has its own budget, that it has everything you need. It will be really shameful if we missed this opportunity and made it virtual."

Earlier last month, at a meeting of the Alliance for a Stronger FDA, Califf said he plans to create the cancer center, according to the Pink Sheet, a pharmaceutical industry publication.

"The only thing I'll say is that it's not going to be purely virtual," Califf said April 19. "The rest of it we're working on. The big deal for the FDA here is a lot of public pressure to create a center of excellence in oncology, and we're going to do that whether it's part of legislation or not."

A "fully integrated" cancer center is the way to go, said Richard Schilsky, chief medical officer of the American Society of Clinical Oncology.

"ASCO supports the plan to establish an FDA Oncology Center of Excellence because it is in the best interests of cancer patients," Schilsky said to The Cancer Letter. "We also recognize that this is a large-scale agency reorganization that requires deliberate thought and planning by the FDA in how to best organize the staff, resources and lines of authority so that the new center fully achieves its goals of bringing safe and effective oncology products to market more efficiently. ASCO stands ready to work with the FDA to achieve the vision of the new center.

"As the number of oncology products continues to grow and diagnostic tests become a more important aspect of selecting the right treatment for the right patient, a fully integrated oncology center will improve regulatory efficiency and create a larger community of scientists and clinicians at the FDA deeply understand cancer biology and treatment. The FDA has done a tremendous job regulating oncology products and this reorganization will only improve on what is already a high level of excellence."

Patients, FDA physician-scientists, modern science, and industry need an actual cancer center, not a virtual one, said Jon Retzlaff, managing director of the Office of Science Policy and Government Affairs at the American Association for Cancer Research.

"We are extremely pleased that Commissioner Califf has publicly stated that the FDA plans to establish a center of excellence in oncology, which is in our view a key part of Vice President Biden's 'Moonshot" initiative," Retzlaff said to The Cancer Letter.

"We believe that the innovation that has occurred as a result of Dr. Pazdur's leadership, as well as his entire team's commitment to cancer patients within the OHOP, would both be magnified and strengthened through the establishment of an actual FDA Center of Excellence in Oncology. This is exactly the kind of new and strategic idea and approach that Vice President Biden is asking federal agencies to undertake and for the broader cancer advocacy community to support.

"Establishing an FDA Center of Excellence in Oncology would allow for a more disease-specific review approach to cancer therapies, and would bring FDA staff from all of the important areas of the cancer drug development process together and under one roof to ensure the rapid and timely approval of safe and effective treatments for cancer patients.

"For example, the physician-scientists at the FDA who are continuing to treat cancer patients while also analyzing and reviewing cancer drug applications, would work directly with those who have expertise in understanding how biologics, such as vaccines and gene-therapy, are evaluated and approved for patients, as well as with those who have proficiency in the area of diagnostics, and specifically those who understand the importance of reliable and effective diagnostics to accelerating personalized and precision medicine for cancer patients.

"The importance of this center is underscored by the significant increase in the number targeted therapies approved for cancer patients that rely on a diagnostic tool. In fact, some of the most exciting scientific advances of our time, genomics, proteomics and other large scale 'omics' approaches and technologies, are propelling the development of novel, rapid, sensitive, less invasive and more accurate molecular diagnostic tests, which in turn are enabling physicians to make more informed treatment decisions by tailoring cancer treatments based on each cancer patient's unique molecular profile.

"An independent FDA Center of Excellence in Oncology that includes expertise from these particular areas, along with a corresponding management reporting structure and clear and concrete authorities, would fuel the progress we are seeing today in preventing, detecting, and treating cancer. In fact, this new kind of management structure at the FDA would likely be a model to be replicated across many other disease areas.

"Therefore, we strongly support the FDA Center of Excellence in Oncology, which will enable the FDA to respond even better and in a much more coordinated way to the needs of cancer patients, the interests and goals of cancer drug and test developers and manufacturers, and the rapidly changing and ever

more complex scientific environment, such as what we are seeing in the areas of companion diagnostics and next-generation sequencing tests."

The text of FDA's statement follows:

The FDA is honored and excited to be an integral part of the National Cancer Moonshot initiative being led by the Vice President. Supporting the development and ensuring the timely review of innovative cancer therapies and diagnostics is a priority for the agency across centers for drugs, biologics and devices.

We have seen an increase in development of innovative cancer drugs in a variety of disease types, marked by the highest number of new drugs approved in 2015 in recent history. Currently, the reviews for cancer products exist in separate FDA "centers" – the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and Center for Devices and Radiological Health (CDRH).

However, there are already examples of these centers working collaboratively across review divisions, such as for drugs or biologics (CDER/CBER) that are approved with a companion diagnostic (CDRH). We also have an Office of Combination Products with the distinct and important role of serving as a focal point for combination product issues for agency reviewers and industry. This office helps provide guidance and clarity on the differing regulations that may come up with products that combine a drug/biologic and device, and helps ensure consistency with premarket review and postmarket regulation.

The Cancer Moonshot initiative takes this collaborative work a step further by calling for the creation of a virtual Oncology Center of Excellence that will leverage the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices (including diagnostics). This Center of Excellence will help expedite the development of oncology-related medical products and support an integrated approach in:

• evaluating products for the prevention, screening, diagnosis, and treatment of cancer;

• reviewing and overseeing the life cycle process for oncology-related products;

• supporting the continued development of companion diagnostic tests, and the use of combinations of drugs, biologics and devices to treat cancer; and

• developing and promoting the use of methods created through the science of precision medicine.

Planning meetings have already begun internally at the FDA for the Oncology Center of Excellence involving the Commissioner, the Associate Deputy Commissioner for the Office of Medical Products and Tobacco, along with directors of CDER, CBER and CDRH, and the FDA plans to hold listening sessions to gain input from health care professional and patient advocacy groups, as well as industry, to inform our approach.

Specifically, in FY 2017 (October 1, 2016 to September 30, 2017), the FDA will establish the structure and staffing for the Oncology Center of Excellence, create the required virtual regulatory environment and coordinate with the NIH National Cancer Institute (NCI).

While the details of the specific framework of this virtual Oncology Center of Excellence are still in the process of being developed, the FDA is actively and expediently moving forward in this important work and will share more information when possible. The FDA looks forward to working across FDA centers, the federal government and the private sector to tackle this devastating disease that touches so many American families.

Moonshot Task Force Director Addresses AAADV Workshop

(Continued from page 1)

He discussed the goals for the moonshot initiative, how the program could fit into the next presidential administration, and how to take the project international.

Simon was a former aide to Vice President Al Gore, and later helped start FasterCures, a center at the Milken Institute. In 2009, he left to become senior vice president for patient engagement at Pfizer. Since 2012, he has been working as CEO of Poliwogg, a financial services company focused on life sciences. He was named executive director of the moonshot task force in March.

An excerpt of Simon's remarks follows:

As you know, Vice President Biden lost his son to glioblastoma after a valiant fight and said he wanted to devote the rest of his life to the fight to cure cancer. Now, you know when people say they want to cure cancer, it's not that simple. There's not a cancer, it's hundreds of cancers, and cures takes many forms. We know that to cure cancer, you first have to do a much better job at preventing it. We know we have to do a better job of finding it and treating it, and making sure that everybody has the same opportunity for all of those

things as everybody else. And those are the issues we will be addressing.

So the president issued a presidential memorandum announcing the White House Cancer Moonshot Task Force, and "moonshot" was in the presidential memorandum, creating the position I hold now, the executive director of the task force.

Technically, the task force is a group of government agencies, about 20 of them—including, of course, NIH, NCI, DOD, VA, DOE—even the Patent Office has some great ideas for how they can accelerate the fight against cancer.

So I was minding my own business running a business in New York when I got a call from Biden's chief of staff [Steve Riccheti], whom I've known for many years. As I was talking to him on the phone, this little Venn diagram converges right over my head and he said, "We need somebody who's been in the science world and somebody who knows cancer politics and somebody who's worked in the White House before." And I thought, that sounds like me, and then he explains what it was and I told him I actually had cancer, which he didn't know, and after that it was a done deal. I met the vice president, with whom I had not spent any time, and realized that this was a great vision.

When a reporter asked me, "Why would you take a job that's only about 10 months long?" I said, "Well, number one, you must be talking to my wife. Number two, that's about all I can take." Working in the White House has its moments, and there's no doubt about that—we were in the Vatican on Friday and got to see the pope, that was exciting. For the entire 12 hours that we were in Rome—you do get to fly on Air Force Two. But more than the honor of working in the White House, it's a lot of pressure, because there's so much to do, and not a minute to waste—so much incoming from people who want to help. I meet half a dozen people who want to volunteer every day—from inside the building, cancer survivors, as well as people all over the country. People all over the world who want to just show up and work for me in the White House—and I kind of explained that there's a fence around it, you can't really just do that. The passion that is out there is just unparalleled, in my experience.

So why the moonshot? Well, it just so happened that I had spent a lot of time on the space program. I was on the Science, Space and Technology Committee, so I have spent a lot of time at NASA and worked with Al Gore and President Bill Clinton to cut the deal with Russia on the International Space Station. So when people complain to me about the moonshot, I go, "Okay, okay, I know it's an overused phrase, but let me tell you a few things about the similarities between what we're doing and what the moonshot did."

Kennedy didn't say, "We're going to study moonology for the next 10 years." He didn't say, "We're going to create new programs of rocketry or the Journal of Rocket News." He said, "We are going to put a human being on the moon and bring him back safely." He put a human being at the center of our national effort, and that's what made it so dramatic.

We'd already hit the moon. There were all kinds of rockets. We were like Dennis the Menace—we were throwing rockets at the moon, and they would take picture just before they crashed. So we knew how to hit the moon. The problem was how to land on the moon. So everything NASA did was around the human being.

That's true of this as well. This is not about technology development, it is not about computing, it is not about medical records; it's about keeping people alive without the scourge of cancer as long as we can, and all of those other things help us do it. The center of what we are doing is a human being.

The second thing that is totally analogous is that we built the biggest engine in the history of the world. And if you've never seen the Saturn V at the Air and Space Museum, go see it. It is massive. And you look at all the pipes and you look at all the curves and you think, "Lord, have mercy. They designed this without a computer, really? And it looks like my basement when the plumber shows up and changes everything?" But you had to have the world's biggest engine to get off the gravity of the Earth. If you watch the Apollo Saturn V launch, you could walk faster than it left the launch pad. It leaves the launch pad so slowly you feel like you can just walk up to it and hang on, because it had a long way to go, it can afford to start slowly. And then it lifted this enormous mass that had to go all the way to the moon.

Well, we have to do the same thing. We have to build, with your help, a new engine that can escape the bureaucratic gravity that's been holding you back since World War II. I'm born in the 1950s—most of you were probably born after that—but no matter when you were born, everything in your life and the way you do it, and the speed at which you do it in your private life, has changed dramatically in the last 30 years, but most dramatically in the last five to 10 years.

In your professional life, if you're getting an NIH grant, or getting an NCI grant; if you're working in your lab, it's not changed that much. We're still using the same system to review your ideas and give you money that we did after WWII. Everything else around you has

become much faster, much more efficient.

The cancer moonshot has a straightforward goal to achieve in five years what we otherwise think would take a decade to do. If you look back 10 years ago, how many of you thought that today, we would have CRISPR technology that would make gene editing as easy as building LEGOs? How many of you thought we would have massive computers at our thumbs that can do everything that we used to have separate hardware to do? Now it's ubiquitous, but at the time it was amazing. When you look back, whatever we thought was wrong. Now that we have incredibly fast computers and massive data and instant communication for the first time in human history, we have no idea what we can get done in 10 years.

So we might as well predict what we're going to get done in 10 years by laying out what we want to do, and which cancers we want to cure, and which ones we want to try and turn into chronic disease, because they'd be too hard to cure, and which preventions we think can actually stick. And then when we get that dream list put together based on the technologies we have today, we need to figure out, "Well, if I can dream that in 10 years, how can I make it happen in five? What do I really need? Is it just more money?"

It's never just more money. It's really all about getting more people involved and learning more about people, sharing data about people, doing clinical trials with more people, treating more people and reaching more people. This is how we organize what we're doing; keep in mind I've been there six weeks.

We have several levels of efforts. First is the government task force itself, which is looking at two things. First, what can we do this year through collaboration among the government agencies and government and private sector to move things faster that are already in our plan and/or things we can start right now if we work together with other people? That's a huge focus of what we're doing.

The second thing is, we know that a lot of things can't happen that fast, so we need to look at what can happen, which means, per the president's requirement, that we give him a report by the end of the year about the blueprint for next several years to make this happen. So once we've identified what we want to get done in five years, we owe the president a description of what that is and how we're going to do it. The other question I get asked the most is, "What's going to happen at the end of the year?"

Well, there are basically three possibilities: 1) Nothing. The next administration says, "Thank you very much, the White House moonshot office is over." 2) It gets integrated into the next administration, either as a vice presidential or presidential initiative. 3) Or it becomes legislatively established, like the White House Office on HIV and AIDS or the White House National Drug Control Policy Office. All of those are possibilities, and you don't have to wait long to find out, because once the election happens in November, whoever is president will have a transition team and they're start figuring it out.

Now the government piece of this is trying to be a catalyst for the private sector piece of this. So we, and I, realize that the government can lead and can point a direction that the private sector has to do a lot of the execution, and make things happen by bringing private capital to the effort. We are actively reaching out to patient foundations, to universities, venture capital, banks, drug companies, biotech companies, technology companies, cloud companies, medical record companies, and just point-blank asking them, "What are you going to do to help us, and how can you do it now, and who are you going to do it with?" Because we want to focus as much as possible on collaboration, because that's the key.

As an example, and as you know, there are data registries all over the place, and usually they are unique to the institution where they were created. They may have patient records; they may have genomic testing and outcomes information. They may have lifestyle information, clinical trial data and it may be that they're just at the hospital where it was collected, or research institution and cancer center, and it may be that people in a given region get together and create a way to share all that information. And it may be that the big dogs, value leaders, the Division I schools get together and create a national thing where three, four or five of them share the data.

That's not the way we're going to do it. We'll never going to get there from here if that's the way we do it. How many of you would go to a bank that says, "You can pay any bill online you want, as long as it's in your ZIP code." Right? Who would do that? Or you go to an airline and they say, "You can fly anywhere you want, as long as it's Chicago." That's not how any other part of our life works. So what's required?

Well, money is required. But keep in mind that the government put $35 billion dollars in the Economic Recovery Act at the beginning of the Obama administration for the creation and the use and adoption of electronic medical records. When we said we're going to spend $35 billion on medical records, we didn't mean

each person gets to create their own system and their own language—it's a Tower of Babel nationally. That was not the plan.

The plan was to have an interconnected, intergalactic network of medical data so we can understand ourselves as a people, faster, better, cheaper, and more impactful. But instead, my online information in Sloan Kettering, and I have online information now at GW where my care has been transferred to—they had to fax my records from Sloan Kettering to GW, and they're both online. Wow. And those are big institutions.

We know what the problem is with medical records. Yes, we know it's going to cost you more money to share your information ubiquitously. But guess what, all these major centers, they make money. The reason you need to spend money, it's not your data. It's our data. It's patient data. It belongs to the people you got it from. I'm a big proponent of, when you donate your tissue for research, you don't get piece of the action 10 years later or somebody develops a product from that. Until we put us all together and see patterns of how we react to cancer, how we start cancer, and how we are treated for cancer. We know we have to get universities and medical centers to share their data.

My dream, which I know can be done in five years, and the vice president's dream, is a national network in the cloud of all the data about patients that you can get, generated in the best way possible, whether it's medical records, tissue, characterization, genomic information, so that we can start using analytical tools and artificial intelligence to turn that data into information, and then use that information to gain knowledge. So we have to make that system ubiquitous and as easy to get to for everybody as it is for anybody.

Another thing we have to do is prevention. The problem with prevention is this: you develop a cure or a therapy for something, it's a cure or therapy forever. You do prevention today, you've done prevention today. It's a renewable problem, so you have to have a renewable resource, which is people. Smoking cessation is the only thing that has really brought down mass numbers of cancer, and yet, even though smoking is lower today than it's ever been, we know that every generation is tempted to go back up that hill and start smoking. So we've got to deal with tobacco cessation.

We've got to deal with obesity, nutrition, and the fact that there are nutrition ghettos all over the country where people don't have easy access to good food. And we have to deal with disparities. It is not race that causes disparities, it's place—it's being in the wrong part of town, it's being in the wrong part of the county, it's being too far from any medical center. We have to make sure we're not losing people to cancers we know how to treat, that is the most tragic of all.

I forgot to mention the most important about any kind of effort like the moonshot and that is, you have to believe this is possible. If you don't believe it's possible, how do you get out of bed every day? How do you, in particular, who are working on all these wonderful programs, how do you get out of bed if you don't think things can be better? So from the beginning, we have to have a national belief that this is possible, and if we think it's possible, then we have a responsibility, even a moral obligation, to make it happen. And that means that we have to deal with the biggest problem in the system, and that's us.

When I say it's us, it's because the system that slows things down by us a long time ago, and we're still living with it, and we need you to raise your hand and say you're volunteering for a new system. So what do I mean? We need to change the system to give younger people grants, to give everybody faster grants, to shorten review cycles, to redo the peer review system to be more daring, to be more diverse. Have you noticed that all the new foundations never model their grant program after the NIH? I'm saying we're wasting time, we're wasting people, because we're not letting young people with bold ideas try stuff, and that's the origin of most of the big ideas in the world. I'm an old man now, so I can say this. It's not people my age that come up with game-changing ideas. We've got to fix that.

The last thing is, it's got to be international. Cancer is a human problem. It's not an American problem, it's not an international problem. It's a human problem, it's everywhere. More people die in Kenya of cancer than HIV/AIDS. We have to treat it with the same urgency as we do infectious diseases; we have to standardize the way we generate the data to make it valuable all over the world. And you say, "Golly, how do we do that all over the world? That's so complicated." When you travel, can you get money anywhere in the world through an ATM with your card, in your local currency? Yes, you can. And it goes right to your bank, no matter where you are, and you get a phone call, "Are you really in Azerbaijan?"

But when it comes to medical information, we go, "Oh it's too complicated!" It's not too complicated, it's ones and zeros at the end of the day. So, standardized ways to generate the data, ubiquitous sharing of data

without any excuses anymore, more funding around the world, not just the U.S., treating it with urgency, and making it available to all people. That has to be our mantra internationally and it's certainly the mantra for our moonshot.

So you will be hearing from us. We will be doing a summit later this summer we'll announce pretty soon that will focus on people who are doing collaborations in any of those areas I just mentioned. There are a lot of things out there already like data spheres and different ways of sharing data that we can grow and connect to a lot of other things.

Everybody is on "let's go" for this. So if there were ever a time that you wanted to raise your hand to change the system and examine the way you do your work, now's the time. There's never been a better time. We have a vision, we have a leader in Vice President Biden who's devoted to this for the rest of his life. We have technology as we've never had before, we have money to get it started at least, and we hope to get more and Congress has been very open to it.

And we have you. We have a marching army of people who know how to do what you do. I'm trying to get the government out of your way, and out of the way of everybody who has a great idea. We can do it. And if we don't think we can do it, then we need to go into another line of job, because this is the most exciting and the most difficult area of human endeavor. I would like to see all of this succeed and surprise ourselves by being able to do in the next five years what we could only have imagined we could've done in ten.

Slamming the Door
Part XI: A Teachable Moment

(Continued from page 1)

Gilman was the exact opposite of a narcissistic scientist in search of the next tantrum opportunity. Rather, he had considered the politics and the principles involved, and examined all the options with the inner circle of his scientific advisors. To Gilman, seeking advice of scientific colleagues was a formal process honed over a lifetime in the academia. Being well plugged into the Texas political circles, he brought the stories of Texas backroom shenanigans to the attention of his scientific peers and weighed their advice.

It was clear that he would turn his departure into a teachable moment. There was also a chance—albeit a small one—that he would prevail. Let's define "prevail."

No, Gilman didn't want to stay in the job beyond the deadline. He wanted to get rid of the oversight committee appointed largely by then-Texas governor Rick Perry. His other goal was to oust Bill Gimson, the CPRIT executive director.

As he went public, Gilman's first step was to explain the principles in play.

He did this in an op-ed piece, which he co-wrote with Phillip Sharp, chairman of the CPRIT scientific oversight group, an institute professor at the Koch Institute for Integrative Cancer Research at MIT, and a fellow Nobel laureate.

After the principles were described, members of his inner circle of advisors would resign one by one.

Gilman circulated the piece to a small circle of people he trusted. Though he lived and worked in Dallas, he chose to give the piece to the Houston Chronicle. This was mainly because over the years he had developed a better relationship with the Chronicle. The fact the biotech incubator that started the entire debacle was at MD Anderson, a Houston institution, added to the overall impact.

The draft of the op-ed piece, which was circulated to a small circle of advisors, connects the CPRIT controversy with the MD Anderson incubator.

Killing CPRIT was not the goal. Gilman's goal was to lead America's most important cancer scientists in a public reaffirmation of support for peer review. The lesson: platitudes don't cure cancer, and neither does breast-beating.

The plan was akin to a scientific experiment, with the outcome that remained to be seen. If the message got through, all the top CPRIT bureaucrats and the institute's politically-appointed oversight committee would be given the boot. Of course, Gilman realized that this was too much to ask for.

On Oct. 12, 2012, Gilman's last day at CPRIT, it was clear that great forces had been unleashed and there was no way to predict how the game would play out. Politics and science were at equipoise.

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"Reliance on peer review to identify the best science must continue to guide CPRIT in the future," Gilman and Sharp wrote in their op-ed piece, "Of course, there are other ways to distribute public funds, but they are worse.

"Their side effects include infamy and they end in irrelevance."

The piece connects the events at CPRIT with the MD Anderson incubator:

"The past eight months were difficult [for CPRIT]. Controversy flared when several well-regarded, multi-investigator, multi-institutional collaborative research projects were put in the freezer for months—not brought to the Oversight Committee for funding after strong recommendation by the Scientific Review Council.

"This delay was at least partially based on the concern that several of these projects came from one institution. CPRIT's executive director has offered different and conflicting explanations for this action.

"Simultaneously, an expensive 'commercialization' proposal, constructed and submitted in unorthodox ways that circumvented CPRIT's rules, was rushed to the Oversight Committee and approved for $20 million for its initial year of operations, despite the absence of description or scientific review of its drug development program. This was ultimately corrected, albeit with great effort."

The piece echoed a hubristic quote from Charles Tate, the Texas financier who played a role in engineering the MD Anderson-Rice incubator. In a press release announcing the funding of the project six months earlier, Tate said: "One of the biggest obstacles to getting life-saving treatments to patients is not a lack of good ideas or good science, but a lack of business expertise. CPRIT is proud to support a center that will ensure the best cancer-fighting technologies can make it to market and into the hands of the people who need them the most."

Actually, no, the biggest obstacle is getting the science right, Gilman and Sharp wrote.

"Science must come first; commercialization is essential but comes second. Businesses hunger for great insights to turn into great products…

"Texans deserve to hear the truth about cancer. They must understand that miracles will not happen in a short time. Progress will not be made by those who simply proclaim without explanation that they can do better than hundreds of skillfully staffed and well-financed pharmaceutical and biotechnology companies.

"Real progress requires the concerted high-quality efforts of basic, translational and clinical investigators from the academic community collaborating with counterparts from the private sector when appropriate.

"There is no single 'cure' for cancer. Cancer is hundreds of diseases, and victories will come one or a few at a time. CPRIT will have an enormously positive impact on society over time, both in terms of the health of its citizens and its economy. Texans must understand this and demand that CPRIT continues to adhere to its core principles.

"Academic institutions and for-profit companies have very different cultures, and these differences must be respected. Academics strive to develop new knowledge and, usually, disseminate it widely (i.e., by teaching, broadly defined, and publishing). Companies operate much more competitively and in many cases in secret, with the goal of providing financial returns to investors by bringing useful products to society. There can and should be synergy between the two types of institutions, with academic knowledge being used to further the commercial activities of companies, and there can be links between the two. But the relationship shouldn't be excessively intimate. Secretive behavior impedes education and research training and therefore doesn't belong in academia. There are also questions of compensation, ownership, neglect of academic responsibilities, etc. CPRIT needs to understand this as it strives to facilitate commercialization of its research activities."

In the opinion piece, Gilman and Sharp call for removal of the CPRIT oversight committee:

"How can CPRIT once again become a program respected by scientists across the U.S. and the world?

"A commission should be appointed to determine whether individuals tried to violate the public trust in the actions described above. If so, they should be removed from their positions.

"CPRIT's governing board should have sufficient expertise to do its job. Only one member of this 11-person Oversight Committee has any direct knowledge of cancer, medical practice or research.

"The Oversight Committee should promote policy, provide broad oversight of personnel and operations, and ensure legal and ethical behavior. Members who meddle in day-to-day operations of the organization to further their own interests should be removed."

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Members of the CPRIT scientific review council followed Gilman out of the door.

Would CPRIT be able to survive this display of condemnation on the part of some of the world's most important cancer scientists?

I decided to call CPRIT chief executive Gimson, Gilman's nemesis. I wanted to know whether the sound of slamming door had awakened his to reality.

Gimson did not return my call, which was just as

well. Instead, CPRIT issued a public statement:

"With the departure of Dr. Gilman, CPRIT is entering a new era. It is no surprise that some of the current reviewers have chosen to leave at this time.

"We have identified several exceptional candidates to succeed Dr. Gilman as Chief Scientific Officer, and this individual's first order of business will be to recruit outstanding cancer experts to serve as peer reviewers under his or her leadership. We have every confidence that CPRIT will have a full cadre of expert peer reviewers in place for the next scientific review cycle.

"CPRIT stands by the integrity of our peer review process. Dr. Gilman was instrumental in establishing what is now considered the "gold standard" in the industry, and that process will remain intact. The process has in fact been improved over the last few years, as we have proactively seized opportunities to strengthen it.

"Any assertions that the peer review process has been compromised or that CPRIT's staff or Oversight Committee members are trying to influence the peer reviewers are false and misinformed. Since CPRIT's inception, every single grant that has been recommended to the Oversight Committee by the reviewers has been approved.

"It has been reported that CPRIT asks peer reviewers to reconsider their scores. When there are divergent scores among peer reviewers, in fairness to the applicants, the process allows for further review or discussion of the variances during panel discussions.

"Unlike the prevention and research review process, the commercialization review process includes in-person presentations by the applicants, which the scientific reviewers do not attend. If new information comes up from the in-person question and answer period, it is shared with all reviewers—including those who were not in the presentation so all reviewers have the same information.

"The final decision on whether to revise scores rests with the individual reviewer.

"We are proud of our many accomplishments to date and many more to come. Through our Future Directions initiative, we have received a great deal of input from diverse stakeholders across the state.

"This process is ongoing and no decisions have been made; this valuable feedback will inform the Oversight Committee's direction for CPRIT over the next seven years. Above all, we hold fast to our mission of reducing the burden of cancer in Texas.

"Texans' lives are at stake, and in honor of those affected by this heinous disease, we won't back down."

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It was uplifting to see the members of Gilman's scientific council follow him out the door. They explained why they were leaving, using the slamming of the door as a teachable moment.

Here are the letters of resignation from six members of the CPRIT Scientific Review Council:

Phillip Sharp, *institute professor at the Massachusetts Institute of Technology David H. Koch Institute for Integrative Cancer Research:*

I write to submit my resignation as Chairman of the Council of CPRIT effective Oct. 12, which coincides with the effective date of the resignation of Dr. Al Gilman.

I agreed to chair the Council to advance cancer research and cancer care in Texas after the State's wonderful decision to commit $3 billion to this purpose.

A strong and objective peer review process is essential to achieve this end and the Council members and panelists assembled by Dr. Gilman were the best in the country. They all shared the same objectives for CPRIT and executed their duties in an exemplary fashion and free of conflicts of interests. It has been an honor to chair this group and work with Dr. Gilman.

However, this past Spring the peer review system of CPRIT was dishonored by actions of CPRIT's administration when a set of grants were delayed in funding because of suspicion of favoritism.

Further, a proposal based on science similar to that previously reviewed by the CPRIT council was selected for funding using other criteria. These events ultimately led to the resignation of Dr. Gilman. The same events motivate my decision to resign now.

The promise of CPRIT requires an unswerving commitment to peer review. I would be willing to help future CPRIT leaders if convinced that this commitment is central to selection of cancer research to be supported.

I believe that certain changes in CPRIT leadership would be essential to demonstrate such commitment.

The past four years have greatly advanced cancer research in Texas and hopefully this record will continue.

Tyler Jacks, *the David H. Koch Professor in the department of biology and director of MIT's Koch*

Institute for Integrative Cancer Research.

I am writing to inform you that I am resigning my position as the Chair of the BCRC-1A Review Panel of the Cancer Prevention and Research Institute of Texas (CPRIT) effective immediately.

I am grateful for the opportunity to have worked with Al Gilman, Phil Sharp, and my fellow panel chairs in helping to establish a system that set the highest standard for rigorous scientific review and deliberation.

Sadly, this system was tainted by baseless accusations by members of the CPRIT Oversight Committee that our review of a series of multi-investigator grants in the spring was influenced by regional or institutional bias and the consequent failure to advance these grants for funding consideration in that cycle.

These accusations, as well as the failure to mandate scientific review of so-called incubator grants during this period, served to undermine the careful work of my committee and the sanctity of the larger CPRIT scientific review process. Under the circumstances, I feel that I have no option than to resign my position.

Over the past three years, I have been privileged to lead a group of outstanding scientists on my panel. They have work diligently to evaluate the merits of hundreds of grant applications from Texas investigators.

Through their efforts, we approved the funding of many outstanding grants, which collectively hold the promise of important breakthroughs in our understanding of cancer development and new opportunities for treatment and prevention.

I believe that the CPRIT program—and current and future cancer patients— benefited significantly by the efforts of this group. To date, three of my panelists have indicated that they are stepping down.

I will communicate my decision to the entire panel shortly.

They will decide for themselves as to whether to continue on, assuming they are welcome to do so.

The citizens of Texas deserve tremendous credit for choosing to fund the CPRIT program and doing their part to support the discoveries that will lead to improvements in cancer care and prevention in the future.

In turn, they should expect administrative and review systems that ensure that their tax dollars are used appropriately, without bias, political influence or conflict of interest.

I believe that the actions of the Oversight Committee over the past several months corrupted this process. For the sake of the program and for all of those cancer patients who stand to benefit from the proper use of these funds, I hope that CPRIT manages to regain what it has lost.

William Kaelin, *professor of medicine in the department of medical oncology at Harvard University and the Dana-Farber Cancer Institute:*

As I indicated in my letter of May 14, I was willing to devote my time to CPRIT, despite having a wife who was recently diagnosed with a brain tumor, because I believed CPRIT could transform biomedical research in Texas and ultimately improve the diagnosis and treatment of cancer patients.

CPRIT was a brilliant idea and both the Texas legislature and the people of Texas are to be commended for it. In that same letter, however, I expressed my concerns regarding the events that eventually led to Al Gilman's resignation.

These events included the circumvention of the peer review process by the MD Anderson/Rice "commercialization" proposal and the suggestion that Dr. Gilman (and by extension, myself and the members of my study section) was giving preferential treatment to grants submitted by UTSW investigators.

I also indicated that the eyes of the scientific community were now on Texas to see which course CPRIT would take moving forward (as borne out by subsequent pieces in Nature, Science, and The Cancer Letter).

Neither you nor any member of your staff responded to my letter to address my concerns.

Moreover, it has become increasingly clear that the potential for "commercialization" is going to take on greater importance moving forward.

For example, I recently learned that at least two scientific reviewers who had given non-fundable scores to a commercialization project were asked by CPRIT to "reconsider" their scores so that they would be in harmony with those given by the commercial reviewers, who were far more favorable (both of the scientific reviewers are very sophisticated with respect to the needs of industry and correctly responded that trying to commercialize flawed science is a prescription for failure and waste).

The recent posting on the CPRIT website lauding the MD Anderson "moonshot" initiative also creates the impression that the future "winners" have already been chosen and that there will be increased focus on perceived short-term deliverables.

In this environment, I am not confident that scientific quality and rigor will triumph over grandiose promises and hucksterism.

For these reasons I have chosen to resign from CPRIT effective Oct. 12, 2012. I would be happy to discuss serving in the future but only if you succeed in replacing Dr. Al Gilman with a person who, like Dr. Gilman himself, embodies scientific excellence and personal integrity and I can be convinced, through structural changes at CPRIT, that my concerns have been adequately addressed.

Charles Sherr, *chair of tumor cell biology, co-director of the Molecular Oncology Program, and Herrick Foundation Chair at St. Jude Children's Research Hospital:*

The purpose of this letter is to tender my resignation as the Chair of the CPRIT Basic Science Cancer Research Committee-3 (BCRC-3) and as a member of the CPRIT review Council chaired by Dr. Sharp, effective immediately.

In a separate email addressed directly to you on May 3, to which you did not directly respond, I communicated my personal displeasure regarding events that would soon lead to Al Gilman's resignation.

Briefly stated, my previous letter concerned the manner by which Dr. Gilman had been inappropriately pressured to step down as CPRIT's Chief Scientific Officer and my dissatisfaction with the then emerging notion that a political agenda would subvert decisions about supporting only the very best medical science deemed most likely to accelerate prevention and effective treatment of cancer.

These matters were soon echoed in a separate joint letter from the CPRIT Council addressed to members of the Oversight Committee and widely quoted in the press.

Despite my unease, I thought it prudent to remain with CPRIT through the round of review just completed in September 2012, thereby allowing those investigators in Texas who had formulated new proposals in the last months to receive careful consideration of their scientific initiatives by the BCRC-3 group.

Having now completed these efforts, I feel free to step down. I had already alerted you to the fact that many other members of BCRC-3 were equally offended by the events of recent months, and I suspect that you may be hearing from others in this regard.

There have been a series of widely publicized incidents that have been visibly documented, in particular by reporters at the Houston Chronicle and in issues of The Cancer Letter broadly circulated to cancer centers throughout the country. In my personal judgment, one of the most problematic events concerned the proposed funding of the Institute for Applied Cancer Science (IACS) at the MD Anderson Cancer Center.

Their short proposal of less than seven pages was reviewed solely as a commercial "incubator" project, but without rigorous scientific oversight by any of the more than 100 out-of-state experts already employed by CPRIT who could have offered informed opinions.

The IACS proposal was approved within several weeks of its receipt, overriding Dr. Gilman's strong objections and even disregarding caveats offered by some of the persons who were asked to participate in its "commercial" review. The level of funding of the IACS greatly exceeded that of proposals that had been previously adjudicated by our Council and review groups, underscoring preferential treatment given to this one application.

As reported publicly, the IACS proposal's budget was not reviewed by the MDACC provost, Dr. DuBois, who recently resigned his post at MDACC. Despite your proclaimed enthusiasm and that of other CPRIT Overseers, but given widespread press coverage and criticism, the IACS proposal has been withdrawn pending re-review.

New guidelines for Requests for Applications (RFAs) for "incubators" which were to be drawn up have yet to appear, and I wonder whether some persons believe that forward movement in funding the IACS would be facilitated by Dr. Gilman's departure and the possible elimination of other naysayers, myself included.

When you [CPRIT executive director Gimson] phoned me last week, I reiterated that it has been an honor and a privilege to serve CPRIT under Dr. Gilman's aegis, to participate in the deliberations of the CPRIT Council in recruiting top quality investigators to institutions in Texas (including Drs. Chin, Allison, and others to the MDACC), and above all, in leading a committee of highly distinguished scientists from outside the state who have worked diligently and with keen collective insight in adjudicating applications referred to our review panel. Indeed, the opportunity to work with esteemed colleagues on the Council and the BCRC-3 Committee has been the best such panel review experience of my scientific career, bar none.

Our singular collective concern was that we would attempt to fund the very best transformative

cancer science, whether clinical, translational, or basic.

Investigators at different institutions throughout Texas were given a fair and balanced hearing by a coterie of national referees – our deliberations paid no attention to geography or political pressures within Texas, and we had no hidden agendas or conflicts of interest.

I fully accept that it is the purview of the Overseers and, ultimately, the citizens of Texas to decide how their funds should be best spent. Under current circumstances, however, I cannot lend my approbation to the changing of the guard.

Sanjiv Sam Gambhir, *the Virginia and D.K. Ludwig Professor in the department of radiology and bioengineering, chair of the department of radiology, director of the Molecular Imaging Program, and director of the Canary Center for Cancer Early Detection at Stanford University:*

I am writing to inform you that I am resigning my position as the Chair of the Interfaces Review Committee (IRC) Review Panel of the Cancer Prevention and Research Institute of Texas (CPRIT) effective immediately.

I will be available to help in the upcoming transition in any way that I can so that cancer researchers in the state of Texas as well as patients who have already been diagnosed and those yet to be diagnosed are not harmed due to my resignation.

It has been great to help in a small way by reviewing grants and to help the state of Texas attract the best minds from all over the country to the great Universities and medical centers throughout the state.

I am highly thankful to my review committee of outstanding scientists and physician-scientists from all over the country who have carefully reviewed many grants over the last three years.

Their hard work and dedication is matched only by that of the Texas cancer researchers. I only wish even more highly meritorious grants could have been funded. It is a highly challenging time for biomedical researchers everywhere, and I am so happy the Texas taxpayers have helped to support excellent biomedical research for such a deadly disease.

The citizens of Texas are to be commended for their investments that will benefit cancer patients worldwide.

I am also very thankful for the opportunity to have learned from Drs. Al Gilman, Phil Sharp, and my fellow panel chairs. They have always worked with the highest principles to make decisions that are unbiased and at times quite difficult. I want to particularly thank Dr. Gilman for taking a firm stand against the CPRIT oversight committee for their actions that undermine the rigorous scientific review process that was championed by Dr. Gilman. Politics and science at times must mix, but at other times such as this, they should clearly not.

Everett Vokes, *the John E. Ultmann Professor, chairman of the department of medicine, and physician-in-chief at the University of Chicago Medical Center:*

This note is to indicate my intention to resign from my position as co-chair of the Translational and Clinical Review Committee 1A/2A of the Cancer Prevention and Research Institute of Texas effective immediately.

CPRIT has been a powerful and highly impactful institution that has succeeded at funding innovative research and attracting scientific leaders in cancer research to the state of Texas.

I have been highly honored to be a member of this process and to serve under the scientific leadership of Drs. Al Gilman and Phillip Sharp and work with the many exceptional reviewers on our committee.

CPRIT is in a state of transition following the events of the last several months. I hope that the disruption and distraction that has resulted from this transition can soon be ended and that new credible leadership be appointed. Should at that time my services be of interest, I would be willing to consider future interactions.

FDA to Regulate All Tobacco Products, Including E-Cigs, In Historic Expansion

By Conor Hale

FDA issued final regulations for all tobacco products, including electronic cigarettes, cigars and hookah. The rules, with provisions aimed at restricting youth access and requiring premarket clearance for new products, will take effect Aug. 8.

The federal regulations include: not allowing tobacco products to be sold to persons under the age of 18, both in person and online; requiring age verification by photo ID; not allowing the selling of covered tobacco products in vending machines, unless in an adult-only facility; and not allowing the distribution of free samples.

According to FDA, before these regulations there

was no federal law prohibiting retailers from selling e-cigarettes, hookah tobacco or cigars to people under age 18.

"We have more to do to help protect Americans from the dangers of tobacco and nicotine, especially our youth," said HHS Secretary Sylvia Burwell. "As cigarette smoking among those under 18 has fallen, the use of other nicotine products, including e-cigarettes, has taken a drastic leap. All of this is creating a new generation of Americans who are at risk of addiction."

"Today's announcement is an important step in the fight for a tobacco-free generation—it will help us catch up with changes in the marketplace, put into place rules that protect our kids and give adults information they need to make informed decisions," Burwell said.

A survey supported by the FDA and the Centers for Disease Control and Prevention showed current e-cigarette use among high school students jumped from 1.5 percent in 2011 to 16 percent in 2015.

In 2015, three million middle and high school students were current e-cigarette users, and data showed high school boys smoked cigars at about the same rate as cigarettes, according to FDA. Additionally, a joint study by FDA and NIH showed that, in 2013-2014, nearly 80 percent of current youth tobacco users reported using a flavored tobacco product in the past 30 days.

The rules published this week also require manufacturers of all newly regulated products to show that the products receive marketing authorization from the FDA, unless the product was on the market as of Feb. 15, 2007.

"The tobacco product review process gives the agency the ability to evaluate important factors such as ingredients, product design and health risks, as well as their appeal to youth and non-users," FDA said in a statement.

The review requirements include: registering manufacturing establishments and providing product listings to the FDA; reporting ingredients and harmful and potentially harmful constituents; requiring premarket review and authorization of new tobacco products by the FDA; placing health warnings on product packages and advertisements; and not selling modified risk tobacco products, including those described as light, low or mild unless authorized.

According to FDA, the agency expects that manufacturers will continue selling their products for up to two years under staggered timelines while they submit a new product application, with an additional year while the FDA performs its review. Orders granting marketing authorization will be issued where appropriate; otherwise, the product will face enforcement, the FDA says.

"As a physician, I've seen first-hand the devastating health effects of tobacco use," said FDA Commissioner Robert Califf.

"At the FDA, we must do our job under the Tobacco Control Act to reduce the harms caused by tobacco. That includes ensuring consumers have the information they need to make informed decisions about tobacco use and making sure that new tobacco products for purchase come under comprehensive FDA review." The agency also plans to publish several other regulatory documents to provide additional clarity or instructions on issues specific to the newly-regulated products.

"While this regulation represents an important step forward, the FDA must now use the full force of its authority to maximize our potential to reduce tobacco's deadly impact," said Chris Hansen, president of the American Cancer Society Cancer Action Network.

"Now we have the opportunity to move this forward in the best interest of the public's health. The FDA should immediately take action to address flavorings attractive to youth in all products and the egregious industry marketing practices," Hansen said. "In these ensuing seven years following passage of the Tobacco Control Act, the tobacco industry has taken full advantage to exploit the lack of regulations on these issues. These tactics have included marketing small flavored cigars and targeting youth with e-cigarette advertising, promotions and flavorings that have dramatically increased their use."

The FDA regulations were announced a day after the state of California raised its minimum age for purchasing of tobacco products to 21. The state joins Hawaii, which raised its minimum age in June 2015, as well as 145 localities in 10 states, according to the Campaign for Tobacco Free Kids.

"The Obama administration today has taken a critical first step—but only a first step—to protect America's kids from a new generation of tobacco products by issuing a long-overdue rule establishing FDA oversight of electronic cigarettes, cigars, hookah and other previously unregulated tobacco products," said Matthew Myers, president of the campaign.

"On the positive side, this rule extends FDA oversight to all tobacco products, without exception, and rejects proposals to exempt so-called 'premium cigars.' It applies common-sense public health protections to all tobacco products, including health

warnings, a national prohibition on sales to minors and rules to prohibit manufacturers from making unproven health claims. The FDA also announced plans to extend the current federal ban on candy- and fruit-flavored cigarettes to include flavored cigars, although this will require additional rule-making and the FDA did not commit to a specific timetable.

"However, the rule announced today falls short in protecting kids from e-cigarettes. It does nothing to restrict the irresponsible marketing of e-cigarettes or the use of sweet e-cigarette flavors such as gummy bear and cotton candy, despite the FDA's own data showing that flavors play a major role in the skyrocketing youth use of e-cigarettes. While e-cigarette manufacturers will claim these rules impose an unfair burden on them, they allow all e-cigarettes to remain on the market for at least three years, no matter how great their appeal to kids, unless the administration moves quickly to close these gaps."

National Academy of Sciences Elects 105 New Members

The National Academy of Sciences elected 84 new members and 21 foreign associates from 14 countries in recognition of their distinguished and continuing achievements in original research.

Those elected today bring the total number of active members to 2,291 and the total number of foreign associates to 465. Foreign associates are nonvoting members of the academy.

The elected members are:

•Agol, Ian; professor of mathematics, department of mathematics, University of California, Berkeley

• Ashtekar, Abhay; Eberly Professor of Physics and director, Institute for Gravitation and the Cosmos, The Pennsylvania State University, University Park

• Bailey-Serres, Julia; director, Center for Plant Cell Biology, and professor of genetics, department of botany and plant sciences, University of California, Riverside

• Bartel, Bonnie; Ralph and Dorothy Looney Professor of Biochemistry and Cell Biology, department of biosciences, Rice University

• Blau, Helen; Donald E. and Delia B. Baxter Foundation Professor, Baxter Laboratory for Stem Cell Biology, Stanford University School of Medicine

• Boothroyd, John; Burt and Marion Avery Professor of Immunology, department of microbiology and immunology, Stanford University School of Medicine

• Brown, Myles; professor of medicine, Harvard Medical School, and director, Center for Functional Cancer Epigenetics, Dana-Farber Cancer Institute

• Bull, James; Johann Friedrich Miescher Regents Professor, department of integrative biology, The University of Texas, Austin

• Car, Roberto; Ralph W. Dornte '31 Professor in Chemistry and professor in physics, department of chemistry, Princeton University

• Cashman, Katharine; professor of volcanology, University of Bristol, Clifton, U.K.

• Chakraborty, Arup; Robert T. Haslam Professor of Chemical Engineering and director, Institute for Medical Engineering and Science, Massachusetts Institute of Technology

• Cherlin, Andrew; Griswold Professor of Public Policy and Sociology, department of sociology, John Hopkins University

• Crimmins, Eileen; AARP Professor of Gerontology, Davis School of Gerontology, Andrus Gerontology Center, University of Southern California, Los Angeles

• Dafermos, Constantine; Alumni-Alumnae University Professor, division of applied mathematics, Brown University

• Dai, Hongjie; J.G. Jackson and C.J. Wood Professor of Chemistry, department of chemistry, Stanford University

• DeRisi, Joseph; investigator, Howard Hughes Medical Institute; and professor and chair, department of biochemistry and biophysics, University of California, San Francisco

• Deshaies, Raymond; investigator, Howard Hughes Medical Institute; and professor, division of biology, California Institute of Technology

• Drinfeld, Vladimir; Harry Pratt Judson Distinguished Service Professor, department of mathematics, The University of Chicago

• Eberhardt, Jennifer; associate professor, department of psychology, Stanford University

• Ehleringer, James; distinguished professor of biology, department of biology, University of Utah

• Eiler, John; director, Caltech Microanalysis Center, and Robert P. Sharp Professor of Geology and Geochemistry, division of geological and planetary sciences, California Institute of Technology

• Evans, Steven; professor of statistics and mathematics, University of California, Berkeley

• Fejer, Martin; co-director, Stanford Photonics Research Center, and professor of applied physics, Center for Nanoscale Science and Engineering,

Ginzton Laboratory, Stanford University

• Forrest, Stephen; Peter A. Franken Distinguished University Professor of Engineering and Paul G. Goebel Professor of Engineering, College of Engineering, University of Michigan

• Friesner, Richard; professor of chemistry, department of chemistry, Columbia University

• Germain, Ronald; chief, Laboratory of Systems Biology; and distinguished investigator, National Institutes of Health

• Giovannoni, James; research molecular biologist, Agricultural Research Service, Boyce Thompson Institute, Cornell University

• Glaeser, Robert; emeritus professor, University of California-Berkeley, and senior scientist, Donner Laboratory, Lawrence Berkeley National Laboratory

• Guerinot, Mary Lou; professor, department of biological sciences, Dartmouth College

• Hart, Oliver; Andrew E. Furer Professor of Economics, department of economics, Harvard University

• Hartmann, Dennis; professor, department of atmospheric sciences, University of Washington, Seattle

• Heal, Geoffrey; Donald C. Waite Professor of Social Enterprise and professor of economics and finance, Graduate School of Business, Columbia University

• Heckman, Timothy; A. Herman Pfund Professor of Astronomy and director, Center for Astrophysical Sciences, department of physics and astronomy, Johns Hopkins University

• Heintz, Nathaniel; investigator, Howard Hughes Medical Institute; and James and Marilyn Simons Professor, Laboratory of Molecular Biology, The Rockefeller University

• Hieter, Philip; professor of medical genetics, Michael Smith Laboratories, University of British Columbia, Vancouver, Canada

• Hoekstra, Hopi; investigator, Howard Hughes Medical Institute; and Alexander Agassiz Professor of Zoology, departments of organismic and evolutionary biology and of molecular and cellular biology, Harvard University

• Hu, Wayne; Horace B. Horton Professor of Astronomy and Astrophysics and member, Kavli Institute for Cosmological Physics, The University of Chicago

• Irvine, Judith; Edward Sapir Collegiate Professor of Linguistic Anthropology, University of Michigan

• Jones, Peter; research director and chief scientific officer, Van Andel Research Institute

• Kastan, Michael; executive director, Duke Cancer Institute, and professor of pharmacology and cancer biology, Duke University

• Kingston, Robert; molecular biologist and chief, department of molecular biology, Massachussetts General Hospital; and professor and vice chair, department of genetics, Harvard Medical School

• Kinzler, Kenneth; professor of oncology and co-director,The Ludwig Center at Johns Hopkins Sydney Kimmel Comprehensive Cancer Center, Johns Hopkins University

• Klebanov, Igor; associate director, Princeton Center for Theoretical Sciences, and Eugene Higgins Professor of Physics, Princeton University

• Koonin, Eugene; senior investigator, National Center for Biotechnology Information, National Library of Medicine, National Institutes of Health

• Krumlauf, Robb; scientific director, Stowers Institute for Medical Research

• Larsen, Clark; distinguished professor of social and behavioral sciences and chair, department of anthropology, The Ohio State University

• Leibler, Stanislas; professor, Institute for Advanced Study, and professor, School of Natural Sciences, The Rockefeller University

• Lester, Marsha; Edmund J. Kahn Distinguished Professor, department of chemistry, University of Pennsylvania

• Liu, Andrea; Hepburn Professor, department of physics and astronomy, University of Pennsylvania

• Lynch, Nancy; NEC Professor of Software Science and Engineering, department of electrical engineering and computer science, Massachusetts Institute of Technology

• Markus, Hazel; Davis-Brack Professor in the Behavioral Sciences, department of psychology, Stanford University

• Marqusee, Susan; director, QB3–Berkeley (California Institute for Quantitative Biosciences), and Eveland Warren Endowed Chair Professor of Biochemistry, Biophysics, and Structural Biology, department of molecular and cell biology, University of California, Berkeley

• Meng, Xiang-Jin; professor of molecular virology, College of Veterinary Medicine; professor of internal medicine, Carilion School of Medicine; and professor, department of biomedical sciences and pathobiology, Virginia Polytechnic Institute and State University

• Mirzakhani, Maryam; professor of mathematics, Stanford University

• Monroe, Christopher; fellow, Joint Quantum Institute, NIST; and Bice Zorn Professor of Physics, department of physics, University of Maryland, College Park

• Murphy, Kenneth; investigator, Howard Hughes Medical Institute; and Eugene Opie Centennial Professor of Pathology and Immunology, Washington University School of Medicine, St. Louis

• Murphy, Susan; Herbert E. Robbins Distinguished University Professor of Statistics, department of statistics, and research professor, Institute for Social Research, University of Michigan

• Niyogi, Krishna; investigator, Howard Hughes Medical Institute; faculty scientist, physical biosciences division, DOE-Lawrence Berkeley National Laboratory; and professor, department of plant and microbial biology, University of California, Berkeley

• O'Keefe, John; inaugural director, Sainsbury Wellcome Center for Neural Circuits and Behavior, and professor of cognitive neuroscience, University College London

• Palumbi, Stephen; Jane and Marshall Steele Chair of Biology and director, Hopkins Marine Station, Stanford University

• Parkinson, Claire; climate change senior scientist, Cryospheric Sciences Laboratory, NASA Goddard Space Flight Center

• Pinker, Steven; Johnstone Family Professor of Psychology, department of psychology, Harvard University

• Ploegh, Hidde; professor of biology and member, Whitehead Institute for Biomedical Research, Massachusetts Institute of Technology

• Raymo, Maureen; Lamont Research Professor and director, Lamont-Doherty Core Repository, Lamont-Doherty Earth Observatory of Columbia University

• Rosakis, Ares; Theodore von Karman Professor of Aeronautics and chair, division of engineering and applied science, California Institute of Technology

• Sabatini, David; investigator, Howard Hughes Medical Institute; and professor of biology and member, Whitehead Institute for Biomedical Research, Massachusetts Institute of Technology

• Sanford, Melanie; Arthur F. Thurnau Professor of Chemistry, department of chemistry, University of Michigan

• Schapire, Robert; principal researcher, Microsoft Research

• Segall, Paul; professor of geophysics, department of geophysics, Stanford University

• Sehgal, Amita; investigator, Howard Hughes Medical Institute; and John Herr Musser Professor of Neuroscience, Perelman School of Medicine, University of Pennsylvania

• Seydoux, Geraldine; investigator, Howard Hughes Medical Institute; and professor, department of molecular biology and genetics, Johns Hopkins University School of Medicine

• Sigworth, Frederick; professor of cellular and molecular physiology and of biomedical engineering, department of cellular and molecular physiology, Yale University School of Medicine

• Slovic, Paul; professor, department of psychology, University of Oregon

• Soltis, Pamela; distinguished professor and curator, Florida Museum of Natural History, University of Florida, Gainesville

• Stone, Anne; professor and director, Center for Bioarchaeological Research, School of Human Evolution and Social Change, Arizona State University

• Stover, Patrick; professor and director, division of nutritional sciences, Cornell University

• Summers, Michael; investigator, Howard Hughes Medical Institute; and distinguished university professor, University of Maryland

• Urry, C. Megan; director, Yale Center for Astronomy and Astrophysics, and Israel Munson Professor of Physics and Astronomy and chair, department of physics, Yale University

• Virgin, Herbert W., IV; Edward Mallinckrodt Professor and chair, department of pathology and immunology, Washington University School of Medicine, St. Louis

• Wasserman, Larry; professor, department of statistics, Carnegie Mellon University

• Yang, Peidong; S.K. and Angela Chan Distinguished Professor of Energy and professor of chemistry, department of chemistry, University of California, Berkeley

• Young, Stephen; associate director, Star Program, and professor of medicine and human genetics, School of Medicine, University of California, Los Angeles

• Zamolodchikov, Alexander; leading researcher, Landau Institute for Theoretical Physics, Russian Academy of Sciences; and Board of Governors Professor of Physics, department of physics and astronomy, Rutgers, The State University of New

Jersey

• Zank, Gary; director, Center for Space Plasma and Aeronomic Research, and Pei-Ling Chan Professor of Physics, University of Alabama, Huntsville

Newly elected foreign associates, their affiliations at the time of election, and their country of citizenship are:

• An, Zhisheng; professor, Institute of Earth Environment, and member, Chinese Academy of Sciences, Xi'an, China

• Berns, Anton J.M.; principal investigator, Netherlands Cancer Institute, Amsterdam

• Bird, Adrian; professor and Buchanan Chair of Genetics, Wellcome Trust Centre for Cell Biology, University of Edinburgh, U.K.

• Fabian, Andrew; Royal Society Research Professor in Astronomy, Institute of Astronomy, University of Cambridge, U.K.

• Fernández, Julio; professor, department of astronomy, and dean of the school of science, University of the Republic, Montevideo, Uruguay

• Frenkel, Daan; 1968 Professor of Chemistry, department of chemistry, University of Cambridge, U.K.

• Hell, Stefan; director, department of nanobiophotonics, Max Planck Institute for Biophysical Chemistry, Göttingen, Germany

• Jouzel, Jean; research scientist, Laboratoire des Sciences du Climat et de l'Environnement, CEA-Institut Pierre Simon Laplace, Orme des Merisiers, France

• Kornai, János; honorary professor emeritus, Corvinus University of Budapest

• Lanzavecchia, Antonio; director, Institute for Research in Biomedicine, Bellinzona, Switzerland

• Lutz, Wolfgang; program director, World Population, International Institute for Applied Systems Analysis, Laxenburg, Austria

• McDonald, Arthur; professor and Gordon and Patricia Gray Chair in Particle Astrophysics, department of physics, Queen's University, Kingston, Canada

• Peres, Yuval; principal researcher in theory group, Microsoft Research, Redmond, Wash. (Israel)

• Petit, Christine; professor, Collège de France, and director, Unité de Génétique et Physiologie de l'Audition, Institut Pasteur, Paris

• Possingham, Hugh; professor of mathematics and ecology, University of Queensland, St. Lucia, Australia

• Rabinovich, Gabriel; professor of immunology, University of Buenos Aires

• Reid, Nancy; Canada Research Chair and University Professor, department of statistics, University of Toronto

• Suwa, Gen; professor, The University Museum, University of Tokyo

• Voisin, Claire; director of research, CNRS, Institut de Mathématiques de Jussieu, France

• West, Stephen; senior group leader and deputy director, Clare Hall Laboratories, Francis Crick Institute, Herts, U.K.

• Wilson, Ian; Hansen Professor of Structural Biology and chair, department of integrative structural and computational biology, The Scripps Research Institute, La Jolla, Calif. (United Kingdom)

Funding Opportunity

CureSearch Opens Competition For Pediatric Research Awards

CureSearch for Children's Cancer is taking applications for its International Grand Challenge Awards addressing three challenges in pediatric cancer treatment. The awards will be worth between $2 million and $3 million.

The three challenges are: the validation of novel biomarkers to improve clinical outcomes for highrisk pediatric cancers; novel approaches for complementary, combination therapies targeting highrisk pediatric cancers; and accelerating novel therapeutics and innovative technologies developed for adults into the pediatric cancer realm.

Applicants can submit through Proposal Central, with award notifications being released in November 2016. Funding will be provided January 2017 through December 2019. The complete Request for Applications is available on the CureSearch website.

For more information this grant opportunity or pediatric cancer research sponsored by CureSearch for Children's Cancer, contact Sarita Sastry, national director of research and programs, at sarita.sastry@curesearch.org.

In Brief

ACS and CVS Announce Antismoking Campaign

THE AMERICAN CANCER SOCIETY and **CVS Health** announced a three-year, $3.6 million initiative to provide grants to 125 institutions of higher learning to help accelerate and expand the number of 100 percent smoke- and tobacco-free college and university campuses throughout the United States.

The partnership creates the Tobacco-Free Generation Campus Initiative, part of a nationwide effort to deliver the nation's first tobacco-free generation. With funding from the CVS Health Foundation, ACS will award grants to colleges and universities in 19 states with the greatest need for stronger smoke-free campus policies to help them take a comprehensive approach to implement tobacco-free campus policies, including cessation, education and support. Twenty-five grants will be awarded in the first year and 50 will be given out in each of the second and third years.

The 19 states targeted by the program are Alabama, Arizona, California, Connecticut, Illinois, Indiana, Kentucky, Louisiana, Massachusetts, Michigan, New Jersey, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas and West Virginia.

The ACS initiative is part of Be The First, CVS Health's newly announced five-year, $50 million campaign incorporating education, advocacy, tobacco control, and promoting healthy behavior against tobacco use. In 2014, CVS Health became the first national pharmacy chain to eliminate the sale of cigarettes and tobacco products from its stores.

THE PERSHING SQUARE SOHN Cancer Research Alliance announced seven winners of the third annual Pershing Square Sohn Prize for Young Investigators in Cancer Research.

Each will receive $200,000 in funding per year for up to three years. In addition to six winners funded by the alliance, a partnership with The New York Community Trust supported the seventh prize winner.

This year's winners are:

• **Omar Abdel-Wahab**, of Memorial Sloan Kettering Cancer Center: Abdel-Wahab's research focuses on the identification of novel transcripts, pathways, and therapeutic strategies to target spliceosomal-mutant malignancies in leukemias.

• **Uttiya Basu**, of Columbia University Medical Center: Basu's research focuses on infections disease induced DNA alterations in B cell malignancies. The goal is to develop antibody mediated-therapy for B cell lymphomas.

• **Christopher Mason**, of Weill Cornell Medical College: A finalist in last year's prize, Mason's research focuses on using new computational and biochemical methods to target and re-program specific sites of epigenetic aggressiveness in AML patients.

• **Agnel Sfeir**, of NYU School of Medicine: Sfeir's research focuses on identifying the molecular players in the chromosome biology of breast cancers. The goal is to uncover the mechanistic basis of DNA double-strand pathway repairs and reduce the initiation, progression, and drug resistance of cancers.

• **Samuel Sidi**, of Icahn School of Medicine at Mount Sinai: Sidi's research focuses on genetic mutations in tumors and the creation of the first viable treatment options for patients with radioresistant cancer. He is being funded through the partnership with The New York Community Trust.

• **Christopher Vakoc**, of Cold Spring Harbor Laboratory: A finalist in last year's prize, Vakoc's research employs a novel CRISPR technique for scanning proteins that reveals the key molecular details for how they can cause a cancer, which may guide the development of next generation cancer therapies.

• **Andrea Ventura**, of Memorial Sloan Kettering Cancer Center: Ventura's research applies new genome-editing technologies to identify the molecular mechanisms underlying lung cancer initiation and progression to help model and possibly overcome acquired resistance to targeted anti-cancer therapies in multiple forms of cancer.

SEAN PARKER received the **Pontifical Key Philanthropy Award at the Vatican**, presented by Cardinal Gianfranco Ravasi, president of the Pontifical Council for Culture, and Robin Smith, president of the Stem for Life Foundation.

This recognition was announced during The Third International Conference on the Progress of Regenerative Medicine and Its Cultural Impact, held in Vatican City.

"We congratulate Sean Parker for winning the 2016 Key Philanthropy Award," said Ravasi. "Sean's unique vision for the role of cellular therapies in addressing disease, especially his work in cancer immunotherapies, as evidenced by his recent announcement of the Parker Institute, offers real hope for cancer patients everywhere."

In April, the Parker Foundation announced a $250 million grant to create the Parker Institute for Cancer Immunotherapy. The institute is an collaboration between Memorial Sloan Kettering Cancer Center, Stanford University, UCLA, UCSF, MD Anderson Cancer Center, and the University of Pennsylvania. The gift is the largest single contribution ever made to the field of immunotherapy.

RICHARD O'REILLY was named the inaugural recipient of **The Society of Memorial Sloan Kettering Prize**. This new award recognizes an individual who has made outstanding contributions to the field of pediatric oncology.

O'Reilly is chairman of the Department of Pediatrics and director of the Bone Marrow Transplantation Program at MSK. He pioneered the development of curative marrow transplantation approaches for patients who lack HLA-matched siblings and dramatically expanded treatment options for all patients.

Founded in 1946, The Society of Memorial Sloan Kettering is a volunteer-led organization within MSK dedicated to promoting the well-being of patients, supporting cancer research, and providing education on the early prevention, detection, and treatment of cancer.

O'Reilly has received numerous honors including the Lila Acheson Wallace Chair of Pediatric Research, the Louise and Allston Boyer-Young Investigator Award for Clinical Research, the Vincent Astor Chair of Clinical Research, the Distinguished Alumnus Award from MSK, the Herman Boerhaave Medal from the University of Leiden, the McGovern Award of the Houston Academy of Medicine, the Lifetime Achievement Award from the American Society of Blood and Marrow Transplantation, the Pediatric Oncology Award from the American Society of Clinical Oncology, the Bob Pinedo Cancer Care Prize of the Society for Translational Oncology and the Castle Connolly Lifetime Achievement Award,.

DAVID WEINER received the **W.W. Smith Charitable Trust Professorship for Cancer Research**. Weiner is executive vice president of The Wistar Institute and director of The Wistar Institute Vaccine Center.

The W.W. Smith Charitable Trust is a private foundation established through the will of William Wikoff Smith. The Trust provides grants in three areas: medical research in cancer, heart disease and AIDS; financial aid for college students; and basic needs for children, families and the elderly.

The Wistar Institute has been a W.W. Smith Charitable Trust grant recipient for more than 30 years.

THE CANADIAN CANCER CLINICAL TRIALS NETWORK unveiled a new national campaign to raise awareness of cancer clinical trials in Canada, ahead of International Clinical Trials Day on May 20.

The Ask Me Campaign will be introduced at more than 60 cancer centers across Canada and include hospital staff wearing "Ask Me" buttons, as well as posters and brochures placed in hospitals. These will be used to encourage patients to engage their healthcare team in a conversation about clinical trials and see if a trial may be a treatment option for them. The ultimate goal is to increase awareness about, and enrolment in, cancer clinical trials in Canada.

"We've seen a decline in enrolment in clinical trials in Canada, which is a trend that we are aiming to reverse," said Janet Dancey, scientific director of the network. "A big part of this is making sure the patients who are undergoing treatment for cancer are aware that world-class clinical trials are underway in their province, that they may be eligible to participate and that these trials may help them."

THE KARMANOS CANCER INSTITUTE raised more than $2.4 million at its 34th Annual Dinner gala.

This year's Annual Dinner Chairs were Paula and Steve Kiefer. Steve Kiefer is vice president of Global Purchasing and Supply Chain at General Motors. This is the sixth consecutive year that General Motors has been a major sponsor, with the GM Foundation making a grant of $400,000; and donating the first retail production 2017 Chevrolet Corvette Grand Sport Collector's Edition.

This vehicle was auctioned at the Barrett-Jackson Collector Car Auction in Palm Beach, Fla., earlier this month. The winning bid brought in $170,000 with 100 percent benefitting Karmanos Cancer Institute.

WINSHIP CANCER INSTITUTE raised more than $1.3 million at its fourth annual institute gala.

More than 400 people attended the black-tie event at the Piedmont Driving Club in Atlanta, with the proceeds supporting cancer research and grants.

"We are grateful for all of the generous donors who made this event a tremendous success," says Walter J. Curran, Jr., MD, executive director of

Winship. "We are especially appreciative of our hard working Gala chairs: Lou Glenn, Louisa Glenn D'Antignac and Rand Glenn Hagen as well as our honorary chair, Brenda Nease."

High level sponsors included the Ma-Ran Foundation, the Wilbur and Hilda Glenn Family Foundation, Brenda and Mac Nease, Cox Enterprises, Inc., and The Home Depot Foundation.

Drugs and Targets

Eribulin Receives EU Approval For Unresectable Liposarcoma

The European Commission approved a variation to the terms of the Marketing Authorisation of eribulin for the treatment of adult patients with unresectable liposarcomas who have received prior anthracycline containing therapy for advanced or metastatic disease.

The decision is based on the results of Study 309, which was published in The Lancet. The randomized, open-label multicenter phase III study compared the efficacy and safety of eribulin mesilate to dacarbazine in 452 patients aged 18 or over with leiomyosarcomas or liposarcomas.

Data show a median overall survival improvement of 2.6 months (13.5 months versus 11.5 months) in patients with leiomyosarcomas or liposarcomas treated with eribulin versus dacarbazine (HR=0.768, 95% CI 0.618-0.954; P=0.017). A subset of people with unresectable advanced or metastatic liposarcomas treated with eribulin lived a median 7.2 months longer than those treated with dacarbazine (15.6 months versus 8.4 months median OS, HR = 0.511; 95% CI 0.346-0.753; P=0.0006). Eribulin's toxicity profile was consistent with prior experience, with no unexpected or new safety findings.

Eribulin, developed by Eisai Co., Ltd., is a microtubule-dynamics inhibitor, structurally modified analogue of halichondrin B, originally isolated from the marine sponge Halichondria okadai. Its mode of action is distinct from other tubulin inhibitors and involves binding to specific sites on the growing positive ends of microtubules to inhibit their growth.

In January 2016, FDA approved eribulin for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen. License was granted in Japan to extend the indication of eribulin to treat patients with soft tissue sarcomas in February 2016.

Health Canada approved Lynparza (olaparib) capsules as a maintenance treatment for patients with platinum-sensitive relapsed BRCA-mutated (germline or somatic) high grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer.

Lynparza is the first poly ADP-ribose polymerase inhibitor available in Canada, and has been granted the Health Canada Notice of Compliance with Conditions, based on promising evidence of clinical efficacy and duration of response data.

PARP inhibitors disable the ability of BRCA-mutated tumor cells to repair their damaged DNA. Lynparza's approval represents a significant milestone as the first biomarker-driven targeted treatment for BRCA-mutated ovarian cancer, and this innovative and first-of-its-kind treatment has the ability to actively extend progression-free survival, according to AstraZeneca Canada, the drug's sponsor.

FDA granted Priority Review for olaratumab, a PDGFRα antagonist, in combination with doxorubicin, for the potential treatment of people with advanced soft tissue sarcoma not amenable to curative treatment with radiotherapy or surgery.

Eli Lilly and Co., the drug's sponsor, has also received Breakthrough Therapy, Fast Track and Orphan Drug designations, for olaratumab in this indication.

"We are encouraged that the FDA has granted Priority Review for olaratumab as a potential treatment for advanced soft tissue sarcoma," said Richard Gaynor, senior vice president, product development and medical affairs for Lilly Oncology. "We are hopeful that, if approved, olaratumab will provide a meaningful addition to the limited treatment options for this rare and difficult-to-treat disease."

The BLA submission for olaratumab was based upon the results from the phase II trial JGDG, an open-label, randomized study that compared olaratumab in combination with doxorubicin chemotherapy to doxorubicin alone in patients with advanced STS not amenable to curative treatment with surgery or radiotherapy. Results were presented at the 2015 American Society of Clinical Oncology annual meeting and the 2015 Connective Tissue Oncology Society annual meeting.

A phase III trial of olaratumab and doxorubicin in advanced STS is currently recruiting adult patients (trial NCT02451943).

The European Medicines Agency Committee for Medicinal Products for Human Use issued a positive opinion for Imbruvica (ibrutinib) for the

treatment of adult patients with previously-untreated chronic lymphocytic leukemia.

The positive CHMP recommendation follows the March 2016 FDA approval of Imbruvica for the first-line treatment of patients with CLL. If approved by the European Commission, this would be the fifth treatment indication for Imbruvica in the E.U.

Imbruvica is jointly developed and commercialized in the U.S. by Pharmacyclics LLC, an AbbVie company and Janssen Biotech Inc. In Europe, Janssen-Cilag International NV holds the marketing authorization and its affiliates market Imbruvica in Europe, the Middle East and Africa, as well as the rest of the world.

Imbruvica is already approved in Europe to treat adult patients with relapsed or refractory mantle cell lymphoma, adult patients with CLL who have received at least one prior therapy or who have del 17p or TP53 mutations, and adult patients with Waldenström's macroglobulinemia who have received at least one prior therapy, or as a first-line treatment for WM patients unsuitable for chemo-immunotherapy.

The EC will review the CHMP opinion and is expected to render a final decision on the use of Imbruvica for previously untreated patients with CLL later this year.

Afinitor (everolimus) received a positive opinion from the EMA Committee for Medicinal Products for Human Use for the treatment of unresectable or metastatic, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin in adults with progressive disease.

The positive opinion was based on data from the phase III RADIANT-4 study showing everolimus reduced the risk of progression in patients by 52 percent (HR=0.48; 95% CI, 0.35-0.67; $p<0.00001$) compared to placebo and that the safety profile of everolimus was consistent with what has been observed in previous studies of this drug.

In February, FDA approved Afinitor for the treatment of adult patients with progressive, well-differentiated, nonfunctional NET of GI or lung origin that are unresectable, locally advanced or metastatic. Additional worldwide regulatory filings for this indication are underway, according to Novartis, the drug's sponsor.

AstraZeneca and Foundation Medicine Inc. will collaborate to develop companion diagnostic assays to identify patients most likely to benefit from medicines within AstraZeneca's oncology pipeline.

AstraZeneca will utilize the Quality Systems Regulations-compliant version of Foundation Medicine's comprehensive genomic profiling assay for solid tumors to enroll patients into clinical trials of therapies that target genomically driven mechanisms of disease. The companion diagnostic assay assesses multiple cancer-related genes as well as all four classes of genomic alterations, and will be developed in parallel with the clinical development of AstraZeneca medicines as part of a coordinated regulatory strategy.

"We're delighted to expand our relationship with AstraZeneca to now include the development of companion diagnostics for their novel anti-cancer medicines," said Steven Kafka, president and chief operating officer for Foundation Medicine. "This collaboration agreement, the fourth we have put in place with leading oncology companies, underscores the importance and potential of utilizing our rigorously validated, comprehensive profiling approach to make available to physicians an FDA-approved universal companion diagnostic solution for use with targeted medicines. We look forward to providing further updates as individual programs are initiated."

AbbVie and **CytomX Therapeutics Inc**. entered into a collaboration to co-develop Probody Drug Conjugates against CD71, also known as transferrin receptor 1 (TfR1).

Probody therapeutics are designed to take advantage of conditions in the tumor microenvironment to enhance the tumor-targeting features of an antibody and reduce drug activity in healthy tissues.

Under the agreement, CytomX will lead pre-clinical and early clinical development and AbbVie will lead later development and commercialization, with global late-stage development costs shared between the two companies.

CytomX will receive an upfront payment of $30 million and is eligible to receive up to $470 million in development, regulatory and commercial milestones, pending the achievement of pre-determined outcomes. AbbVie will lead global commercial activities with CytomX eligible to receive a profit share in the U.S. and tiered double-digit royalties on net product sales outside of the U.S. CytomX retains an option to co-promote in the U.S.

AbbVie also receives exclusive worldwide rights to develop and commercialize Probody drug conjugates against up to two additional, undisclosed targets. Should AbbVie ultimately pursue these targets, CytomX is eligible to receive additional milestone and royalty payments per target on any resulting products.