ST. JUDE COMMITS $100 MILLION TO IMPROVE PEDIATRIC CANCER CARE AMID WAR ZONES, ECONOMIC CRISSES, AND POVERTY

St. Jude Children's Research Hospital is expanding its international outreach program with an initial investment of $100 million to improve childhood cancer survival rates worldwide.

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ST. JUDE COMMITS $100 MILLION TO IMPROVE PEDIATRIC CANCER CARE AMID WAR ZONES, ECONOMIC CRISES, AND POVERTY

By Matthew Bin Han Ong

St. Jude Children’s Research Hospital is expanding its international outreach program with an initial investment of $100 million to improve childhood cancer survival rates worldwide.
The initiative, St. Jude Global, aims to improve access to care for children with life-threatening diseases as well as influence the care of 30 percent of children with cancer worldwide within the next decade, especially in low to middle-income countries.

“It was my feeling that we could do more, that we really needed to do more,” James Downing, president and CEO of St. Jude, said to The Cancer Letter. “It was really our moral imperative to do more, based on the way St. Jude is structured, and the way we raise money across the United States.”

St. Jude Global builds on existing partnerships established by the Memphis, Tenn., hospital’s International Outreach Program since 1993. In 2016, St. Jude formed the Department of Global Pediatric Medicine to accelerate its work to ensure that children have access to quality care and treatment—no matter where they live.

“We had a long history of our International Outreach Program; it had been in existence over two decades, and really had done fantastic work,” Downing said. “We had great success across Central America, South America, the Middle East, in China and regions of Southeast Asia and had set up 24 programs in 17 countries.

“When I became CEO in 2014, we reflected on that program. While were we very proud of it, we realized it couldn’t be scaled any larger. At its current capacity, it was reaching about 3 percent of the children with cancer around the globe.”

The St. Jude Global initiative creates a network of interactive programs and institutions, forming a global alliance focused on enhancing the quality of care children receive.

“St. Jude was founded under the premise that no child should die in the dawn of life, and so, there was no geographical limitation to that,” said Carlos Rodriguez-Galindo, executive vice president, chair of the Department of Global Pediatric Medicine, and director of St. Jude Global. “We have been able to show that we can cure childhood cancer through excellent care, research, education. Can we now explore that at a global level?

“That’s not something we’ll do in five or ten years, that’s something we’ll do in probably the next five or ten decades. What we are setting is basically the next chapter of St. Jude.”

A conversation with Rodriguez-Galindo appears on page 8.

“Pediatric cancer knows no boundaries,” Downing said. “Children come down with pediatric cancer irrespective of where they are living—whether it be an incredibly poor country or a middle-income country or a developed country.

“Childhood cancer is a global problem and one that is increasing in scale and in scope—so it needs a global effort. St. Jude is in a unique position to step up, to lead this effort and to bring countries together across the world to learn from each other and advance our ability to care for these children.”

St. Jude Global will focus on three core areas:

1. **Education:** Training the clinical workforce needed to treat childhood cancer worldwide. Educational programs are being made available at the St. Jude campus in Memphis, Tennessee; at regional sites worldwide; and through online platforms.

2. **Capacity building:** Strengthening health systems and patient-centered initiatives across the continuum of care. Through the development of regional networks and a global alliance, St. Jude Global leaders are working with partners internationally to develop patient-centered initiatives that strengthen health systems and policies and establish standards and guidelines to improve patient care.

3. **Research:** Advancing knowledge of global pediatric oncology and hematology to sustain a continuous improvement in the level and quality of care delivered around the globe. St. Jude faculty will share their expertise and serve as mentors for St. Jude Global collaborative sites. The goal is to help facilitate research on a global scale, enabling members to perform high-quality and successful research projects, as well as implement some of the therapeutic protocols available at St. Jude.

The initiative is building on the relationships that St. Jude has established in other countries, including Brazil, Chile, China, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Jordan, Lebanon, Mexico, Morocco, Nicaragua, Philippines, and Venezuela, and emerging relationships in regions that include Russia, Myanmar, Cambodia, and sub-Saharan Africa to establish regional networks to promote self-sufficiency and the sharing of knowledge, skills and best practices.

In Beirut, a 16-year collaboration between St. Jude and the Children’s Cancer Center of Lebanon at the American University of Beirut Medical Center has resulted in childhood cancer remission and survival rates that approximate outcomes in the developed West.

In a long-term study published in the journal Cancer, AUB researchers showed that childhood cancer is highly curable and, through collaboration, effective treatment is possible, even in an area affected by a humanitarian crisis.

For St. Jude, the Lebanon partnership is a template for addressing cancer and
other non-communicable diseases in other regions in the world.

Since the war in Syria began in 2011, more than 1.5 million refugees have poured into Lebanon. With refugees making up more than 25 percent of the population, Lebanon has the highest per capita number of refugees anywhere.

A conversation with Saab appears on page 14.

“Most children with cancer across the globe aren’t being treated. They’re dying of their disease. So, how do we change that statistic?” Downing said. “We are looking at opportunities right now that will bring additional investments into this, and we’ll be announc-
gy to radiation oncology, to diagnostic imaging, to pathology, to epidemiology and cancer control, to psychology.

"It expands beyond the contexts of just the program, but really creates a mindset across the campus where many people are thinking how their efforts can contribute to the greater good around the globe."

St. Jude’s success in Lebanon prompted the hospital to open a “twinning site” in Jordan, which is now part of a collaboration called the Pediatric Oncology East and Mediterranean Group, which includes physicians from about 72 centers in 23 countries.

“We help teach at those meetings. We bring physicians from those centers to St. Jude as part of our visitor program so they can learn and hear what we do here,” Downing said. “That program has really expanded the transfer of knowledge and the generation of new knowledge across that region.

"Then they were struck with the crisis in Syria and the influx of many refugees from Syria and surrounding regions into Lebanon. That put a major strain on the health care systems in Lebanon to treat those children who were coming across the border into Lebanon.

“We reached out and helped the clinic in Lebanon to cover the costs of care for some of the refugees. That was done as part of our overall global effort, but also for us to learn from the experience.”

St. Jude’s collaboration with the American University of Beirut grew the cancer program from a 10-bed inpatient floor and a limited outpatient department to a cancer center that provides comprehensive services.

“When I first came in 2002, this was really the first center of excellence at AUB. It was really thanks to a tripartite agreement between AUB, the local foundation that is the fundraising and the administrative body equivalent to ALSAC at St. Jude, and St. Jude,” said Miguel Abboud, chair of pediatrics at AUB and an oncologist at the Children’s Cancer Center of Lebanon. “At that point in time, there was pediatric cancer care in Lebanon, but it was really not very sophisticated. There were no pediatric bone marrow transplants, no autologous transplants.”

Sixteen years ago, the fledgling cancer center counted on significant financial support from St. Jude, up to about 50 percent of the budget, Abboud said.

“Among the innovative things that we brought in, just to name a few—it sounds ridiculous right now—but placing central lines for all the kids, doing all the procedures under sedation, allowing nurses to actually transfuse blood products,” Abboud said to The Cancer Letter. “We used to have almost weekly or monthly teleconferences with St. Jude to discuss difficult cases, particularly solid tumor cases and retinoblastoma cases, and we had a lot of technical backup from St. Jude.

“The important thing is this idea of having a major cancer center in the U.S., and St. Jude is unique in that respect, providing technical backup and support to centers in the developing world is critical, because really, even if we could do it on our own, it would take a much longer time. The technology that we have here and the methodology that we have adopted have a lot to do with direct input from St. Jude and the St. Jude physicians way back then.”

The survival rate of patients with leukemia in Lebanon went from 30 percent in 2002 to close to 90 percent in 2018, said Samar Muwakkit, professor of clinical pediatrics at the American University of Beirut and director of clinical affairs at the CCCL.

“After the Children’s Cancer Center of Lebanon opened, all medications became available, and patients were treated free-of-charge,” Muwakkit said to The Cancer Letter. “Our population, more than one-third of them are below the poverty line, so you need to support these patients. The improvement in survival skyrocketed.”

The biggest benefit that the St. Jude Global initiative will bring to health care systems around the world is the track record of sustainability demonstrated by the programs that St. Jude invests in, and the development of networks—a domino effect in improving regional standards of care for children, Muwakkit said.

“Collaboration is very important. Although we were pioneers in applying the St. Jude TOTAL XV acute lymphoblastic leukemia protocol in Lebanon and publishing our local results, the important thing is sharing and collaboration with others in the region,” Muwakkit said. “I first was part of a group called Middle East Childhood Cancer Alliance, and now I’m part of the POEM group—it’s not only to apply things in your country.

“It’s to collaborate with your neighbors and countries in the region, because what applies to me most probably applies to my neighbor, and we are more close and similar than we are to somebody in North America. We have the same genetic background.

“I think the most important thing that we did is that we shared our experience with our neighbors in the region, and we are part of these groups. We hope that we will grow bigger and hope that we will apply what we learn to other countries.”
Rodriguez-Galindo spoke with Matthew Ong, a reporter with The Cancer Letter.
St. Jude’s Rodriguez-Galindo: Someday, all children will have the same chances for cure

“...Our generation has been part of the one of the most remarkable feats in medicine in the last few decades, the cure of children with cancer. Taking these advances to a global level is the next frontier in pediatric oncology. Can we do it? This is the ultimate challenge; one that will measure the success of our generation.

Carlos Rodriguez-Galindo, Executive vice president, chair of the Department of Global Pediatric Medicine, and director of St. Jude Global at St. Jude Children’s Research Hospital.
St. Jude Global will spend $100 million to improve care for kids with cancer and catastrophic blood disorders in low to middle-income countries, including those in the midst of conflicts, said Carlos Rodriguez-Galindo, executive vice president, chair of the Department of Global Pediatric Medicine, and director of St. Jude Global at St. Jude Children's Research Hospital.

“We understand that the success in our initiatives and the sustainability of our interventions will require a major focus on educating and growing the workforce,” Rodriguez-Galindo said. “Reducing global disparities has always been the mission of St. Jude. We see St. Jude Global as the second chapter in the history of St. Jude.

“Taking these advances to a global level is the next frontier in pediatric oncology. Can we do it? This is the ultimate challenge; one that will measure the success of our generation. We understand that this is not something that we will do in five or ten years; it will take many decades of work, commitment, and persistence.”

Rodriguez-Galindo spoke with Matthew Ong, a reporter with The Cancer Letter.

**Matthew Ong: How long have you been at St. Jude, and how did you become the lead for St. Jude Global?**

**Carlos Rodriguez-Galindo:** I am a pediatric oncologist; I trained here at St. Jude in the late 90s, and I remained on its staff as a clinician and clinical and translational investigator for another ten years. While my work and responsibilities where on those fields, I always helped with what at that time was called the International Outreach Program, which was our first attempt at reducing global disparities through a philanthropic, humanitarian approach.

In 2009 I moved to Boston, where I was the director of the Solid Tumor Program and Medical Director of the Clinical and Translational Investigations Program at the Dana-Farber/Boston Children's Cancer and Blood Disorders Center. When Dr. James Downing assumed the leadership of St. Jude, he immediately incorporated a global vision into the new strategic plan, and he recruited me back to St. Jude to help with this initiative two years ago.

**When did St. Jude come up with this initiative? And how long has it been in the works before you were ready to launch it?**

**CRG:** St. Jude has been working on international medicine since the 90s with a program that was called International Outreach Program that opened in 1993, and which had a very humanitarian and generous focus. Our model was based on twinning partnerships to build capacity and educate, to facilitate the transfer of technology, and build sustainable programs through advocacy and strengthening local fundraising mechanisms; this is a very standard model of global partnership in many specialties. Over two decades, the IOP helped build 24 programs in 17 countries, mostly in Latin America, but also in the Middle East, China and the Philippines.

Four years ago, St. Jude started a new strategic planning process after Dr. Downing took over as president and CEO. As part of this new process we asked ourselves “What should we be doing globally? What are we doing right now? Is this enough, or should we be trying to take a more comprehensive approach that would allow us to reach out to more children?”

We tried to transform our global health program in a couple of ways. First, by creating an academic department, the Department of Global Pediatric Medicine, to integrate our work within the academic fabric of the institution and build a scientifically rigorous framework to support our global health initiatives.

As a new department, we had to create the entire academic, organizational, and administrative structure, and develop a recruitment strategy to sustain growth. We wanted to transform our global presence to be more effective, more efficient, and broader in scope and reach. We now have 10 faculty members and have lines of work in implementation science, molecular epidemiology, health services and health systems research, burden estimation and simulation analysis, and cost-effectiveness.

We then created St. Jude Global, a program that comes to represent the vision of our institution in its goal to continue to advance in the care of children with cancer and life-threatening blood disorders globally. That’s what St. Jude Global means—it’s St. Jude going global. Overall, completing this process has taken about two-years.

Reducing global disparities has always been the mission of St. Jude. St. Jude was founded under the premise that no child should die in the dawn of life; there was no geographical limitation to that dream. We see St. Jude Global as the second chapter in the history of St. Jude.

Our generation has been part of the one of the most remarkable feats in medicine in the last few decades, the cure of children with cancer. Taking these advances to a global level is the next frontier in pediatric oncology. Can we do it? This is the ultimate challenge;
We understand that the success in our initiatives and the sustainability of our interventions will require a major focus on educating and growing the workforce. Toward that end, we have created the St. Jude Global Academy, a comprehensive educational initiative that will include certificate and competency-based training at St. Jude, fellowship training programs in the different regions, a robust distance learning platform, and a Master in Global Child Health degree, the St. Jude Global Scholars Program, in collaboration with the St. Jude Graduate School of Biomedical Sciences.

We are particularly excited with this graduate program; we hope to recruit 10 to 20 promising young health care providers from all over the world to complete the masters degree, which will provide them with the transformative training and leadership skills that are so necessary to implement and sustain change.

Together with capacity-building and education, we will be placing a significant emphasis on research. We understand that it is only through a judicious integration of the research principles that we will be able to advance and generate the knowledge for continued and sustained growth.

As we discussed earlier, the Department of Global Pediatric Medicine will host a cadre of research faculty that will focus on global health science. Research will be implemented gradually at all sites, under the leadership and with the mentorship of St. Jude faculty, and local and regional research capacity will be built through the St. Jude Global Scholars program and the St. Jude Global Academy.

The regional networks described above will grow to adopt consortium-like functionality to support research. These regional networks will be provided with a solid clinical research infrastructure, including a global research database, support personnel, and training, for the development of regional clinical research studies and implementation science.

We have prioritized the creation of a global clinical research support unit and we are in the process of defining the operating procedures to regulate and oversee the research operations and the scientific quality of the initiatives proposed by the members of the Department of Global Pediatric Medicine and St. Jude Global Alliance.

As you see, these three main pillars, capacity-building, education, and research, will require major investments in the future and a long-term institutional commitment for many more years; the $100M figure is probably the tip of the iceberg, as you say. But we also invest time and resources to train local foundations in resource mobilization and advocacy in collaboration with the American Lebanese Syrian Associated Charities, our foundation; this is a critical component of our model to work towards building sustainable programs.

CRG: Yes, definitely. I would not like to focus on $100 million; this is just the figure we have estimated to fulfill the objectives set forth by the strategic plan through 2021. We have already invested a significant amount to support programs over the last two decades, and we expect to increase significantly our financial commitment beyond the current strategic plan period.

Our approach has always been to work with the public systems to grow and strengthen the existing structures and processes at the regional, national, and program levels. We are now working on six regional programs: Mexico, Central and South America, Eastern Mediterranean, Southeast Asia and China. And we have set the base for two new regional initiatives in Eurasia and Sub-Saharan Africa. These regional initiatives are integrated within St. Jude Global’s operational structure, the St. Jude Global Alliance.

In our capacity-building programs, we try to encompass the entire continuum of care, from strengthening health systems to training and growing the workforce, and improving the quality and reach of the care delivered. Since March this year we are a WHO Collaborating Centre for Childhood Cancer, and we are looking forward to synergizing our efforts with PAHO and WHO.

CRG: No, there is no business model associated with that in the sense of generating profit for our institution; this would be against our mission. St. Jude Global is an entirely philanthropic effort integrated within the strategic plan of St. Jude, consistent with our vision, and in fulfillment of our mission.

You might’ve addressed this, but to be sure, St. Jude Global is a strictly philanthropic initiative, right? There’s no business model?
“There is an increasing interest in global oncology, and many academic centers, including NCI-designated cancer centers are involved in the development of global initiatives. And more importantly, in many cases these initiatives are being incorporated into the programmatic goals of those institutions, which brings more rigorous, long-term, and sustainable interventions.

What are your primary goals for St. Jude Global? Can you briefly describe how you will improve care and access to care for up to 30 percent of children around the world?

**CRG:** The vision of St. Jude Global is that all children with cancer or catastrophic blood disorders will have access to quality care. And as we discussed, our overarching goals are to train the clinical workforce required to meet the vision, to develop and strengthen health systems- and patient-centered initiatives that encompass the entire continuum of care required for children with cancer and blood disorders, and to advance knowledge in global pediatric oncology and hematology through research. We hope that the operational structure, with initiatives at regional, national, and program-levels will facilitate the fulfillment of those goals and increase our reach exponentially.

Is part of the budget going to a peer-reviewed research grant process or is all of it going straight into policy work, practitioner training, education, direct care and other clinical efforts?

**CRG:** Most of the funding will be dedicated to the support of the program and the capacity-building and educational initiatives, and the research infrastructure described earlier; however, new programs and initiatives will be constantly developed within the St. Jude Global Alliance. While we are not a granting institution, all these new initiatives will go through a rigorous review process.

You mentioned 17 countries at some point—have the number of countries you’re working with grown since then?

**CRG:** Yes, our reach has grown significantly. We started with 17 countries two years ago; these are the countries with which we had agreements through our International Outreach Program. With our new structure and model, we have already more than doubled the number of countries with which we are currently working, and we hope to continue to expand our reach.

Would you be able to accommodate more countries if, say, every other nation that isn’t already part of your program reached out tomorrow and said, “I’d love to partner with you”?

**CRG:** I hope yes, but not immediately. The plan is that the St. Jude Global Alliance will develop the structure and mechanisms to grow and facilitate the incorporation of new programs and new country structures. Also, our work with PAHO and WHO will increase our capacity, and we are hoping to join efforts with other institutions and organizations and maximize the impact.

You talked about agreements and letters of intent—are government health agencies in other countries involved?

**CRG:** Yes; we work with public entities; all our agreements and relation-
It sounds like St. Jude Global is poised to become, if it isn’t already, the most comprehensive program in global pediatric oncology coming from the U.S.; right? What can you do that others cannot?

CRG: We have a 20-year history in global pediatric oncology, and with St. Jude Global we just want to create a more comprehensive and expansive initiative that can reach out to more children. I think that what makes the difference with other programs is that addressing the global burden of pediatric cancer is part of St. Jude’s mission; this makes a big difference.

It starts with Jim Downing, who has prioritized the development of an institution-wide initiative to address the global disparities in childhood cancer; this has expanded St. Jude’s vision and created the basis for building the most comprehensive program to address the global burden of pediatric cancer.

Decades from now, what do you think will be the single most tangible outcome or improvement in health care for children worldwide as a result of your work?

CRG: I hope that through building alliances and joining forces with other institutions and global agencies and organizations, the next generations will see a major reduction in the global disparities in access to quality care for children with cancer, and that at some point, someday, all children with cancer in the world will have the same chances for cure, wherever they are. This is the challenge, and we will not stop until we conquer it.

Do you foresee this initiative continuing indefinitely, even after you reach most of your goals?

CRG: Through St. Jude Global, we are taking on the ultimate challenge of tackling childhood cancer and other life-threatening diseases at a new level, and by incorporating this initiative into the institution’s strategic goals we declare a long-term commitment. We know that it may take 20, 30, 40 years, or probably more, to achieve most of our goals, but we are ready to take on this challenge. This may very well define St. Jude’s legacy.

CRG: Each case is different. We work in partnership with local institutions and foundations, and we develop the strategies and plans for resource allocation together. The key issue is how to build sustainable programs; it takes time, and we understand that we are in for the long run. We work with local foundations to strengthen their capacity for resource mobilization and advocacy, and try to develop cost-effective analyses of different interventions to help hospital administrators allocate resources more wisely.

Will your international partners and their networks be committing resources to this initiative? Or is it all over the board, depending on who can give what?

CRG: There is an increasing interest in global oncology, and many academic centers, including NCI-designated cancer centers are involved in the development of global initiatives. And more importantly, in many cases these initiatives are being incorporated into the programmatic goals of those institutions, which brings more rigorous, long-term, and sustainable interventions. Also, the WHO Cancer Resolution of May 2017 is a call to address the global burden of cancer that initiates the dialogue at many levels in our cancer research community.

Will your international partners and their networks be committing resources to this initiative? Or is it all over the board, depending on who can give what?

Do you know of anyone else with a similar plan?

CRG: There is an increasing interest in global oncology, and many academic centers, including NCI-designated cancer centers are involved in the development of global initiatives. And more importantly, in many cases these initiatives are being incorporated into the programmatic goals of those institutions, which brings more rigorous, long-term, and sustainable interventions. Also, the WHO Cancer Resolution of May 2017 is a call to address the global burden of cancer that initiates the dialogue at many levels in our cancer research community.
Saab spoke with Matthew Ong, a reporter with The Cancer Letter.
AU Beirut’s Saab: Kids in the region now have access to treatment similar to Western countries

"No family would pay out-of-pocket expenses, and the same applies, whether the child is Lebanese or non-Lebanese, irrespective of their nationality, social status, or third-party payer, or the availability of insurance or governmental coverage."

Raya Saab
Acting director of the Children’s Cancer Institute, and director of the Pediatric Cancer Research Program at the American University of Beirut Medical Center
Patients who come to the American University of Beirut Medical Center and the Children’s Cancer Center of Lebanon now have the same chances of cure, thanks to systematic program building over the years, said Raya Saab, acting director of the Children’s Cancer Institute, and director of the Pediatric Cancer Research Program at the American University of Beirut Medical Center.

“Since the start of the refugee crisis since 2011, we started having an influx of patients, refugees who have moved into Lebanon—kids from Syria who lack access to the correct treatments or to available treatments,” Saab said. “We also have been getting more and more patients from Iraq, because of the lack of available treatment for children with cancer.

“It’s quite exciting now in the next phase of the plans for St. Jude with the global health program to really extend the collaboration to the whole region, rather than just Lebanon and a few others, in order to impact the largest number of patients.”

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

Matthew Ong: What’s your role at the Children’s Cancer Center of Lebanon?

Raya Saab: I’m currently the acting director of the Children’s Cancer Institute and the director of the pediatric research program.

I’m a graduate of the American University of Beirut. I did my undergraduate studies and medical school there, so it’s my alma mater, and then I came to the States. I did my residency at Duke University and then my fellowship at St. Jude Children’s Research Hospital.

When I started my fellowship, the Children’s Cancer Institute was just starting up. I was in fellowship during the early years of the institute in Lebanon. I traveled back and forth and it's very tough to not want to be a part of that, especially since the idea of being able to treat kids while also being at a center where you can alleviate the cost of care from the families and just focus on that—that’s additionally attractive.

Also, being a pediatric oncologist practicing standard-of-care medicine in my hometown and my alma mater is a dream come true. That’s when I decided to go back, and since then, we’ve really been growing quite fast. We have recently, since 2012, started a regional collaboration with St. Jude as part of their global mission as well to improve access to care and improve the pediatric oncology treatment in the whole region.

We started a regional network, called POEM, Pediatric Oncology East and Mediterranean Group, which includes doctors from around 72 centers in 23 countries that span from Morocco to India and includes the Middle East and North Africa.

Together, we are forming a platform through the POEM group to be able to improve the standards of care in the region in pediatric oncology, and we’re partnering very closely with St. Jude to do that. The central office of the POEM group is at the Children’s Cancer Center in Lebanon and it’s really been growing very nicely.

We have several projects to train nurses in pediatric oncology in the region, educate health care providers and we’re currently developing a project to improve access to diagnostics, imaging, and pathology. There are a lot of exciting developments.

What’s the situation in Beirut like right now for your cancer center, in terms of the refugee crisis?

RS: The cancer center was started in 2002, and at that time, the majority of patients that we saw were primarily Lebanese. We saw a few patients from the region, Palestinians, Iraqis, Syrians, and others.

Now, since the start of the refugee crisis since 2011, we started having an influx of patients, refugees who have moved into Lebanon—kids from Syria who lack access to the correct treatments or to available treatments. We also have been getting more and more patients from Iraq, because of the lack of available treatment for children with cancer.

Since 2012, we started this initiative with St. Jude as a humanitarian response to the crisis in the region and we allocated separate funds for displaced kids with cancer. We just recently published our review of the steps that we put in place, the cost of care, and the magnitude of the crisis over the past few years.

We have been able to, in collaboration with St. Jude and the Children’s Cancer Center of Lebanon Foundation to help probably around 40 percent of kids who come to us who are displaced—whether Syrian or Iraqi. We have had to prioritize so that we can treat only patients with new diseases rather than recurrences or previously treated patients.

And we have tried to focus on treating the largest number of patients. We have been trying to avoid accepting patients for things like bone marrow...
transplant—the really expensive treat-
ments with a lower rate of cure.

So, this has been going on since 2012,
we have so far have had three success-
ful funds for those kids, and currently,
the number of patients that we see at
our cancer center, almost 25 to 30 per-
cent are currently non-Lebanese, be-
cause of the regional crisis.

This has caused us to have to expand
our infrastructure, both in the out-
patient and the inpatient setting to
keep up with the influx of additional
patients.

RS: You can really imagine, the families
have a lot to deal with other than the
child with cancer as well. A lot of these
families do not have the means—the
majority of these families live in the
outskirts of Lebanon, in the peripheral
areas, and the transportation can be
expensive for them.

They usually have very limited social
support, because they don’t have a lot
of extended family members who can
help take care of the other kids, for ex-
ample, if the kid is at the hospital or be-
ing treated for cancer.

Since the Children’s Cancer Center
started, we’ve had very low rates of
abandonment, and we’ve had to put a
lot of effort and extra social resources
to prevent abandonment in this popu-
lation, because you have so many oth-
er stressors, and sometimes you hear
patients’ parents make that decision,
how much resources to put into treat-
ing this one kid, when they have sib-
lings who are at home and they need
parents who are working so they can
provide for them.

It’s a difficult situation. We’re lucky at
our cancer center—with the support
of the Children’s Cancer Center Foun-
dation, social work services, Child Life
Services, for those families, sometimes
you can have accommodations as well
close to the hospital for a specific peri-
od of time.

But, there’s definitely many more bar-
riers, more stressors to those families,
because of the displaced status, the
lack of support, the lack of other fam-
ily members around, and the lack of a
stable social situation and stable jobs.

RS: Actually, the founder of St. Jude,
Danny Thomas, is of Lebanese descent,
and it was always his dream to have
something similar to St. Jude in Leb-
anon. After he passed, the American
Lebanese Syrian Associated Charities
board decided to honor his wish and
look into this possibility of something
similar to St. Jude in Lebanon, and
that’s when they came in 2000 to look
at the possibility of having a hospital
like that.

That resulted in the partnership be-
tween St. Jude, ALSAC, the American
University of Beirut, and the creation
of the Children’s Cancer Center Foun-
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ter. These four parties together then
formed the Children’s Cancer Institute,
which I’m the director of currently.

Ever since it started, the institute itself
is a collaboration among the four enti-
ties. St. Jude’s input is an integral part
of the Children’s Cancer Institute, which
is located and run by the American
University of Beirut.

RS: Yes. The Children’s Cancer Center
of Lebanon, when it was initially estab-
lished, it was set up after the example
of St. Jude Children’s Research Hospital
in Memphis, Tenn. The idea was that
no family would pay out-of-pocket ex-
penses, and the same applies, whether
the child is Lebanese or non-Lebanese,
irrespective of their nationality, so-
cial status, or third-party payer, or the
availability of insurance or governmen-
tal coverage.

Our Children’s Cancer Center Founda-
tion covers financial costs of treatment
for all accepted patients through fund-
raising. Since the refugee crisis, addi-
tional funds were allocated through
a collaboration by St. Jude for the hu-
manitarian response. We cover all the
treatment expenses as well as out-
patient medication—anything that’s
related to cancer care. Because we do
that, we have had to create the criteria
for acceptance for newly-diagnosed
diseases at a limited number per year.
We have been able to help around al-
most half of the kids who come to us.

RS: You can really imagine, the families
have a lot to deal with other than the
child with cancer as well. A lot of these
families do not have the means—the
majority of these families live in the
outskirts of Lebanon, in the peripheral
areas, and the transportation can be
expensive for them.

They usually have very limited social
support, because they don’t have a lot
of extended family members who can
help take care of the other kids, for ex-
ample, if the kid is at the hospital or be-
ing treated for cancer.

Since the Children’s Cancer Center
started, we’ve had very low rates of
abandonment, and we’ve had to put a
lot of effort and extra social resources
to prevent abandonment in this popu-
lation, because you have so many oth-
er stressors, and sometimes you hear
patients’ parents make that decision,
how much resources to put into treat-
ing this one kid, when they have sib-
lings who are at home and they need
parents who are working so they can
provide for them.

It’s a difficult situation. We’re lucky at
our cancer center—with the support
of the Children’s Cancer Center Foun-
dation, social work services, Child Life
Services, for those families, sometimes
you can have accommodations as well
close to the hospital for a specific peri-
od of time.

But, there’s definitely many more bar-
riers, more stressors to those families,
because of the displaced status, the
lack of support, the lack of other fam-
ily members around, and the lack of a
stable social situation and stable jobs.

RS: Actually, the founder of St. Jude,
Danny Thomas, is of Lebanese descent,
and it was always his dream to have
something similar to St. Jude in Leb-
anon. After he passed, the American
Lebanese Syrian Associated Charities
board decided to honor his wish and
look into this possibility of something
similar to St. Jude in Lebanon, and
that’s when they came in 2000 to look
at the possibility of having a hospital
like that.

That resulted in the partnership be-
tween St. Jude, ALSAC, the American
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University of Beirut.
RS: It depends. The partnership with St. Jude is programmatic. We have multiple programs, including patient care and humanitarian response, and the POEM group. Each one has its own separate budget, so the budget varies from year to year, but generally the contribution from St. Jude probably falls around 20 percent or so of the total budget for specific programs.

The rest comes from local fundraising by the Children's Cancer Center of Lebanon.

RS: For the general programs, we did not have a separation. Because of the magnitude of the humanitarian crisis, we realized that we had to have a separate fund for non-Lebanese children for two reasons:

First, to make sure that we have earmarked funds that we can actually utilize to best serve this particular population, and second, so that we do not, at the same time, affect the mission of treating the kids with cancer in Lebanon. This is so we can maintain the same relative amount of treatment for Lebanese kids, because that's our area of catchment, and at the same give the needed support for the non-Lebanese kids with cancer.

So in summary, since the start of the humanitarian crisis, we have earmarked some funds, but for particular disease-specific programs, those are still accessible to all kids irrespective of nationality.

RS: Our collaboration with St. Jude started since right from the beginning of the establishment of the cancer center. Before that, children with cancer were treated in the general pediatric ward, the medical services were all there, but they were not in a multidisciplinary cancer center setting. That's really the major difference as a result of the collaboration with St. Jude and the establishment of the Children's Cancer Institute as a separate physical structure and the creation of a multidisciplinary patient-centered service.

Since then, the different initiatives that have been developed in collaboration with St. Jude Global have served to strengthen multiple components of the program. We recently started the first pediatric neuro-oncology program in the Middle East region. We have multiple disease-specific programs that were also developed throughout the years through the collaboration with St. Jude through the outreach global department with training of personnel and the transfer of technology.

More recently with the global outreach programs, the regional impact of the children's cancer center has also increased to be able to transfer the expertise to areas in the region that need that as well.

All through the development of the Children's Cancer Institute, there has been continuous milestones that have been achieved through the collaboration with St. Jude.

RS: Prior to the Children's Cancer Institute, the care for kids with cancer was very fragmented. We did not have any data or information on what was being done right, what needed improvement, and what were the outcome numbers. And now, kids in the region can get access to treatment similar to what they would in the Western developed countries with similar cure rates, for the most part.

It has definitely made all the difference through the collaboration, and through this systematic program building over the years, we have reached a point where a family who has a child with cancer can be comfortable that their kid has the same rates or same chances of cure irrespective of where they are in the world, because they have access to the correct treatment modalities.

The hope is that a similar pattern of transfer of expertise will occur in the region as well, and fundraising and the ability to cover the cost of care through private NGOs, because I think that's a model that will be adopted in a lot of the developing countries and the countries in the region due to the lack of appropriate government-led health plans for cancer.
You and your colleagues recently completed a study, finding that over six years, a majority, in fact, 58 percent of your patients who are displaced children have completed treatment and are in remission. Is this unprecedented, especially in the region?

**RS:** Correct. That’s in addition to the number of patients who were already on therapy and in remission. For displaced kids with cancer who were treated at our center, the numbers who went into remission and ones who achieved remission at the end of treatment is very similar to those of Lebanese kids, which very closely approximates the numbers that are reached in the Western world.

Now, we don’t have a lot of follow-up for these displaced children after they finished treatment, because due to the limited earmarked funds, we have decided to just cover the initial treatment for the children, so we have not been following up after end of treatment.

Now, you would anticipate that if somebody had recurrence or relapse, they would come back to us to let us know and for the planning, but we cannot be sure what happens to those kids after they finish treatment. But, at the end of treatment, the response rates have been very similar to what we see in Lebanese kids, and the major reason for that is, despite the social situation and the displaced status, they have been able to continue all through treatment, we have very low abandonment rates, and a good support structure, at least within the center.

What’s your average day like at CCCL? You mentioned having to expand the infrastructure to accommodate the influx, but are your clinics still generally at capacity because of the refugee crisis? And do you ever have to turn away patients?

**RS:** So we have increased our capacity from around 70 patients a year to currently about 120 new patients a year. That’s really increased quite a bit, and this is since 2012. And to do that, we have had to increase the capacity in the outpatient and inpatient facilities.

We definitely do have to turn away patients due to a lack of capacity to treat them, both physical capacity as well as financial. This is the reason why we probably turn away about half of the patients that we see, for the displaced population.

Patients who need BMT, for instance?

**RS:** Exactly. Or those who have received prior treatment somewhere else or who have recurrence disease after therapy. Occasionally, we also have to turn away patients with newly diagnosed tumors, even if they are curable, just because of the lack of capacity or projected funding.

So, we’re definitely still not able to meet all the needs. If you look at the number of refugees in Lebanon, I think the published numbers by the UN are a little bit of an underestimate. We do go into that in our paper, because there was a point after 2015 where there was no more registration, so the UN was not registering refugees anymore. And then, you have all the new children who are being born in Lebanon—a lot of those are not registered either.

It’s estimated that the number of displaced kids in Lebanon approximates the number of Lebanese kids, because it’s skewed towards the younger population. So, we expect that there’s a large proportion of kids with cancer that we are not capturing, and I’m not sure where those people are going.

What would you say is the most important takeaway from this collaboration over the past seven years?

**RS:** I think it’s very clear that you can achieve a lot of impact at the individual level of a child with cancer as well as at the general population level, by having the correct and committed partnership between academic medical centers, NGOs, and leading medical centers in the Western world.

That impact is really quantifiable, it is possible, and it is something that can be exported to other areas and other regions. But, it does require commitment, it does require a plan, and it requires metrics and quantification so that you can set up a model or a pathway and reassess periodically to figure out what’s working and what’s not, and where you need to put in more resources.

But, this can probably also be applied to other diseases other than cancer, and it’s always a good bet to focus on pediatric condition, especially those that are curable, because at the end of the day, this is the future of the popula-
tion, and you will gain so much even at the population level in terms of years of productivity, and at the same time, giving a chance to those families to access care that they would not be able to access otherwise.

I see that St. Jude and ALSAC have launched a similar effort in Jordan—are they seeing similar results there, so far?

RS: I know that in Jordan, they have focused also on addressing the humanitarian crisis. I have not seen numbers regarding results there, but I do know that without that partnership with St. Jude, it would be difficult to address a lot of difficulties that they are facing that are similar to those in Lebanon.

Did we miss anything?

RS: No, I think that’s it. It’s quite exciting now in the next phase of the plans for St. Jude with the global health program to really extend the collaboration to the whole region, rather than just Lebanon and a few others, in order to impact the largest number of patients.

We’re looking forward to being a part of that, specifically through the POEM platform, to try to get people together and leverage the change that is possible in the region.
The cuts began on April 1, 2013, and are expected to continue through 2027.

COA, which represents oncology practices across the US, filed the lawsuit in the US District Court for the District of Columbia on May 30.

The complaint names HHS as well as the Office of Management and Budget. COA seeks injunctive relief to specifically stop the Centers for Medicare and Medicaid Services from applying the sequester cut to Part B drug reimbursement.

On the same day, COA sent a letter to HHS Secretary Alex Azar. HHS is preparing change in the Part B program as part of the Trump administration plan for lowering drug prices.

“We are dismayed that the Administration did not consult with community oncologists to understand what is, and is not, working with the payment for cancer drugs and services before making grand pronouncements,” COA President Jeff Vacirca and Executive Director Ted Okon wrote in their letter to Azar.

"Patients' lives are at stake with policy changes and practicing medical professionals on the front lines must be involved. COA is working very diligently on several important initiatives aimed at payment reform for cancer drugs and services, but feel that the proverbial rug is being pulled out from under us with some of the Administration's proposals, starting with moving Medicare Part B cancer drugs to Part D," Vacirca and Okon wrote.

COA's constitutional argument, abridged from the lawsuit, follows:

OMB or HHS does not have the authority to effectively amend through sequestration the legislatively sanctioned formula by which providers or suppliers are paid or reimbursed for Part B Drugs. The application of the 2 percent sequestration cut against Part B drugs is a constitutional violation of the separation-of-powers doctrine.


The Presentment Clause provides that before becoming a law, a bill must pass through both the House and Senate and "be presented to the President," and "[i]f he approve he
shall sign it, but if not he shall return it . . . “ U.S. Const. Art. I, § 7.

The presentment requirement was considered so important to the Founders that they took effort to make sure the requirements could not be circumvented. As a result, the President is entrusted with only the limited authority in the lawmaking process to nullify proposed legislation. Under the Presentment Clause’s mandate, the President (or other parts of the Executive Branch) has no authority to nullify, alter, or amend existing legislation.

Applied here, the Executive Branch could not alter the MMA’s statutory ASP plus 6% formula even if Congress intended it to do so. It is clear, though, Congress did not intend to do so, because the BCA does not contain any express language indicating that the sequestration applied to the MMA’s statutory formula.

Moreover, the letters from Congress to CMS immediately after the sequestration effective date further corroborate that the statutory formula was not intended to be altered. In other words, even if reimbursement for Medicare Part B drugs could somehow be considered “services,” that still does not demonstrate that the MMA’s statutory ASP plus 6 percent formula was meant to be altered. The Balanced Budget Act does not specifically amend or modify the separate statutory ASP plus 6 percent reimbursement formula contained in the MMA.

OMB’s recommendation to the President to make the 2 percent cut to Medicare (and HHS/CMS’ implementation), including the cut to Part B drug reimbursement, is analogous to an Executive Branch line-item veto, which has been ruled an unconstitutional invasion into the legislative sphere. By reducing the payment formula contained in the MMA, Defendants effectively amended the Medicare Part B payment provisions.

The MMA’s statutory formula can only be amended or repealed through a duly approved bill in Congress that the President then signs into law. It cannot be amended or repealed through OMB’s (or HHS/CMS’) purported execution of the separate BCA, especially where the BCA itself does not address the MMA’s statutory formula, and Congressional members specifically urged CMS not to apply the sequestration cut to Medicare Part B drugs.
Rejoice or despair: Right to Try becomes law

By Matthew Bin Han Ong and Paul Goldberg

President Donald Trump May 30 signed the “Right to Try” bill into law, making it possible for terminally ill patients to bypass FDA to gain access to experimental drugs.

The legislation removes FDA’s mandate to determine whether individual patients can receive investigational drugs. The agency’s expanded access program remains intact as an option for patients and physicians who desire expert FDA review.

The long path toward passage of this law began in 2013, and during those five years pretty much everything that could be said has been said, and said again (The Cancer Letter, March 23).

Supporters said that the new law will speed lifesaving treatments to dying patients by removing bureaucratic FDA red tape (The Cancer Letter, March 23).

Meanwhile, critics said the measure will not improve access, but instead will legitimize medical quackery and erode patient protections that come with FDA’s expanded access program (The Cancer Letter, March 23, 2018; Aug. 4, 2017; April 14, 2017).

Trump, a vocal proponent of the measure, said he liked its name:

“Right to Try. That’s such a great name. Some bills, they don’t have a good name. Really. But this is such a great name, from the first day I heard it. Right to Try. And a lot of the trying is going to be successful. I really believe that. I really believe it.”

FDA Commissioner Scott Gottlieb said the agency would implement the new law.

“Our implementation of the Right to Try Act will build on our long-standing efforts to help patients and families who are facing life-threatening diseases or conditions, in a way that seeks to protect their autonomy, their safety, and the safety of others following in their paths,” Gottlieb said in a statement. “The decisions we reach related to products that can serve as an effective treatment for a terminal illness, or that can arrest a devastating and debilitating condition, are among the most important and carefully considered judgments that we make.

“We recognize the important balance between making sure patients have the assurances Congress intends, while enabling timely access to promising treatments in these devastating circumstances. And we’ll implement this new law consistent with these long-standing values.

“This new law amends the Federal Food, Drug, and Cosmetic Act to establish a new pathway aimed at increasing access to unapproved, investigational treatments for patients diagnosed with life-threatening diseases or conditions who have exhausted approved treatment options and who are unable to participate in a clinical trial.

“For patients with serious or immediately life-threatening diseases, the FDA remains committed to enhancing access to promising investigational medicines for those unable to access products through clinical trials.

“This is the mission of our expanded access program. The agency is dedicated to these purposes, and it has been for more than three decades.”
Awards to be presented at ASCO annual meeting

The American Society of Clinical Oncology and ASCO’s Conquer Cancer Foundation announced the winners of ASCO’s Special Awards, the Society’s highest honors, and Conquer Cancer’s Women Who Conquer Cancer Mentorship Awards.

The 2018 Special Awards Recipients are:

Ralph Weichselbaum—David A. Karnofsky Memorial Award and Lecture

Weichselbaum is professor and chairman of the department of radiation and cellular oncology and co-director of the Ludwig Center for Metastasis Research at the University of Chicago.

Weichselbaum made discoveries in basic mechanisms of signal transduction and gene expression following radiation exposure that led to translational investigations of radio-inducible gene therapy and the integration of chemotherapy and radiotherapy.

Weichselbaum and Samuel Hellman proposed the spectrum theory of metastasis, predicting that some patients will develop only limited metastatic disease, termed “oligometastasis.” This concept resulted in the administration of curative regional therapy to those patients with oligometastatic disease.

Weichselbaum and colleagues are currently investigating the relationship between radiotherapy and immunotherapy, a logical extension of investigations into local and systemic effects of radiation.

Gabriel Hortobagyi—Gianni Bonadonna Breast Cancer Award and Lecture

Hortobagyi is professor in the Department of Breast Medical Oncology at MD Anderson Cancer Center.

Hortobagyi has developed important clinical trial concepts, identified patient populations on which to test such concepts, and designed innovative translational medicine concepts within each clinical trial.

For the past several years, Hortobagyi has focused his research on the clinical development of CDK4/6 inhibitors. He developed, implemented, and chaired the MONALEESA-2 phase III trial, assessing the efficacy and safety of ribociclib in combination with letrozole in patients with hormone receptor-positive metastatic breast cancer.

Douglas Lowy—Science of Oncology Award and Lecture

Lowy is the NCI deputy director. As chief of the Laboratory of Cellular Oncology in the Center for Cancer Research at the NCI, Lowy’s research includes the biology of papilloma viruses and the regulation of normal and neoplastic cell growth.

His laboratory, in close collaboration with John Schiller was involved in the initial development, characterization, and clinical testing of preventive virus-like particle-based HPV vaccines that are now used in the three FDA-approved HPV vaccines.
Along with Schiller, Lowy received the National Medal of Technology and Innovation from President Obama in 2014, and the 2017 Lasker-DeBakey Clinical Medical Research Award. Lowy is a member of the National Academy of Sciences, as well as the National Academy of Medicine.

Karen Lu—ASCO-American Cancer Society Award and Lecture

Lu is senior vice president and chief medical officer ad interim, at MD Anderson Cancer Center. She is professor in the Department of Gynecologic Oncology and Reproductive Medicine and holds the J. Taylor Wharton Distinguished Chair in Gynecologic Oncology.

Lu’s main clinical interests include treating women with ovarian and endometrial cancers, as well as managing women at high-risk for these diseases. She is a national leader in the cancer genetics field and has published seminal articles on hereditary gynecologic cancers.

She serves as principal investigator of the NCI-sponsored Uterine Cancer Specialized Program of Research Excellence and currently receives support for her research from the NCI and Stand Up to Cancer. She is an elected member of the American Society of Clinical Investigation. She serves on the ASCO Cancer Prevention Committee and is currently the past chair. In addition, she takes pride in having mentored many clinical fellows and trainees and has been awarded an MD Anderson Outstanding Educator Award.

Nancy Davidson—Allen S. Lichter Visionary Leader Award and Lecture

Davidson is a breast cancer researcher who serves as senior vice president and director of the clinical research division at the Fred Hutchinson Cancer Research Center, president and executive director of the Seattle Cancer Care Alliance, and head of the division of oncology at the University of Washington.

As a physician-scientist Davidson has published key findings on the role of hormone response and epigenetics in breast cancer and helped to guide several important national clinical trials of new therapies for breast cancer.

A member of the National Academy of Medicine, Davidson has served in several leadership positions, including 2007-2008 President of ASCO, 2015-2016 president of the American Association for Cancer Research, and director of the University of Pittsburgh Cancer Institute from 2009 to 2016.

Gregory Reaman—Pediatric Oncology Award and Lecture

Reaman is known for his extensive work in the biology and treatment of childhood acute leukemia and new drug development for pediatric cancers. Reaman is the associate director for oncology sciences in the office of hematology and oncology products in the FDA Center for Drug Evaluation and Research, as well as the associate director for Pediatric Oncology in the FDA Oncology Center of Excellence.

He is a professor of pediatrics at the George Washington University School of Medicine and Health Sciences. Reaman has been a long-standing member of the division of hematology-oncology at the Children’s National Medical Center in Washington, DC, which he directed for more than 17 years prior to becoming the first chair of the Children’s Oncology Group, and is executive director emeritus of the Center for Cancer and Blood Disorders.

Reaman has recently served on a number of NCI ad hoc review committees of the NCTN, NCORP and the ETNCTN. At the FDA Reaman has consistently sought to maximally use the regulatory authority provided by the Best Pharmaceuticals for Children Act to expe-
Gregory Kalemkerian—Excellence in Teaching Award

Kalemkerian is professor of medicine in the Division of Hematology/Oncology, associate division chief for faculty development and education, associate director of the Hematology/Oncology Fellowship Program, and disease group lead for the Upper Aerodigestive Cancer Team in the University of Michigan Comprehensive Cancer Center.

He has devoted his professional career to oncology as a clinician, an investigator, and a leader, serving as President of MD Anderson from 1996 to 2011. His research in the laboratory and in the clinic, including the development of the targeted therapy cetuximab, led to the development of an entirely new class of agents that have transformed cancer treatment by targeting tumors based on their genetic and molecular aberrations.

Supriya Gupta Mohile—B.J. Kennedy Award and Lecture for Scientific Excellence in Geriatric Oncology

Mohile is a professor of medicine in the division of hematology/oncology at the University of Rochester Medical Center. A board-certified geriatrician and medical oncologist with clinical expertise in gastrointestinal and genitourinary cancers, Mohile’s research interests include the evaluation of patterns of care, health outcomes, and quality of life related to cancer treatment in older patients.

In 2013, she was awarded a Patient Centered Outcomes Research Institute Award and an NCI R01 to evaluate whether geriatric assessment can improve outcomes of older patients with cancer.

She directs the Specialized Oncology Care & Research in the Elderly geriatric oncology clinic at the University of Rochester/Highland Hospital and is an integral member of the University of Rochester NCI Community Oncology Research Program Research Base which is directed by Gary Morrow. She currently is on the editorial board of the Journal of Clinical Oncology, is editor in chief of the Journal of Geriatric Oncology, and she previously served as Chair of the ASCO Geriatric Oncology Course Planning Committee.

John Mendelsohn—Distinguished Achievement Award

Mendelsohn is the L.E. & Virginia Simmons Senior Fellow in the Division of Health and Technology Policy at Rice University’s Baker Institute, as well as director of the Zayed Institute for Personalized Cancer Therapy and professor of genomic medicine at MD Anderson Cancer Center.

He has devoted his professional career to oncology as a clinician, an investigator, and a leader, serving as President of MD Anderson from 1996 to 2011. His research in the laboratory and in the clinic, including the development of the targeted therapy cetuximab, led to the development of an entirely new class of agents that have transformed cancer treatment by targeting tumors based on their genetic and molecular aberrations.
Danielle Leach—Partners in Progress Award

Leach is the senior director of advocacy and government relations of St. Baldrick's Foundation, an organization committed to funding promising research to find cures for childhood cancers and give survivors long, healthy lives.

Leach brought to St. Baldrick's over 20 years of experience in the health nonprofit industry. She has worked in leadership positions at the American Cancer Society, Ovarian Cancer National Alliance and Strang Cancer Prevention Center in cancer control program development and implementation.

Leach founded the Mason Leach Superstar Fund at Children’s National Medical Center and the American Childhood Cancer Organization in memory of her son Mason, who died of pediatric brain cancer in 2007.

Leach currently serves as the co-chair of the Alliance for Childhood Cancer, a national coalition of patient advocacy groups and professional organizations working collaboratively to advance childhood cancer research, treatment, and policies.

Gideon Blumenthal—Public Service Award

Blumenthal is acting deputy office director of the office of hematology and oncology products and the associate director for precision oncology in the FDA Oncology Center of Excellence.

Blumenthal previously worked as a medical officer and clinical team leader in thoracic oncology and head and neck cancer, where he led a team of oncologists during an unprecedented time for new drug and biologics approvals of treatments for lung cancer.

He has been instrumental in coordinating the efficient review and subsequent approval of several breakthrough targeted therapies and immunotherapies for cancer patients and has led several key policy initiatives to advance the fields of precision oncology and targeted drug development, including initiatives on co-development of drugs with companion diagnostics, the use of novel endpoints and real-world evidence, and the development of liquid biopsy technologies.

Julie Gralow—Humanitarian Award

Gralow is the Jill Bennett Endowed Professor of Breast Medical Oncology and professor of global health at the University of Washington School of Medicine, a member of the clinical research division at the Fred Hutchinson Cancer Research Center, and director of breast medical oncology at the Seattle Cancer Care Alliance.

Gralow is medical director and team physician for Team Survivor Northwest, a non-profit focused on helping female cancer survivors improve their health through exercise; founder of the Women’s Empowerment Cancer Advocacy Network, a group dedicated to empowering patient advocates in low- and middle-income countries; and she co-chair of the Breast Cancer Initiative 2.5, a global campaign to reduce disparities in breast cancer care.
benefit ASCO, the specialty of oncology, and, most importantly, the patients at risk for or with cancer. The 2018 recipients of this distinction are:

- Clement Adebayo Adebamow
- David Adelstein
- Alex Adjei
- Jaffer Ajani
- Kenneth Carl Anderson
- Christopher Azzoli
- Jordan Berlin
- Smita Bhatia
- J. Sybil Biermann
- Michael Russell Bishop
- A. William Blackstock
- Paul Celano
- Walter John Curran
- Don Dizon
- Nagi El Saghir
- Laura Esserman
- Christopher Flowers
- Giuseppe Giaccone
- Jill Gilbert
- Susan Halabi
- Lyndsay Harris
- James Hayman
- Carolyn Hendricks
- Martee Leigh Hensley
- Roy Herbst
- Sundar Jagannath
- Mohammad Jahanzeb
- Hagop Kantarjian
- Beth Karlan
- James Khatcheressian
- Alok Khorana
- Hedy Kindler
- Andrew Ko
- Natasha Leighl
- Andrew Loblaw
- Jennifer Malin
- Bruce Minsky
- Beverly Moy
- Craig Nichols
- Kenneth Offit
- Mark Pascal
- Jyoti Patel

Lori Pierce is a tenured professor of radiation oncology and vice provost for academic and faculty affairs at the University of Michigan School of Medicine. Her research focuses on the use of radiotherapy in the multi-modality treatment of breast cancer with emphasis on cardiac-sparing in treatment planning, pre-clinical and clinical studies of radiation sensitizers with RT, and outcomes following radiation in women with breast cancer who carry a BRCA1/2 susceptibility gene.

Pierce was an ASCO Board of Directors member from 2010 to 2014. She is currently chair of the Conquer Cancer Foundation Nominating Committee and past chair of the ASCO Leadership Development Program.

Kebudi is a professor in pediatric hematology-oncology at the Istanbul University, Cerrahpasa Faculty of Medicine and the Istanbul University, Oncology Institute. She served on the board of the Istanbul University, Oncology Institute and as the director of the Pediatric Hematology-Oncology Division.

She is a past president of the Turkish Pediatric Oncology Group and current chair of the International Society of Pediatric Oncology Supportive Care Working Group. She has been actively involved in the scientific activities of the Middle East Cancer Consortium. Kebudi has successfully mentored residents, fellows, and junior faculty over the last 25 years and has ensured that they make progress in their career.

**Fellows of the American Society of Clinical Oncology:**

The Fellow of the American Society of Clinical Oncology distinction recognizes ASCO members for their extraordinary volunteer service, dedication, and commitment to ASCO. Their efforts...
ASCO Conquer Cancer Foundation gives out $7.3 million in grants

The Conquer Cancer Foundation of the American Society of Clinical Oncology has announced the recipients of this year’s Advanced Clinical Research Award, Career Development Awards, Young Investigator Awards, Global Oncology Young Investigator Awards, and Gianni Bonadonna Breast Cancer Research Fellowship.

These awards support young researchers with projects spanning all aspects of cancer care, including immunotherapy, carcinoma, lung cancer, and palliative care.

The Advanced Clinical Research Award in Breast Cancer—Mariana Chavez MacGregor

The award funds original breast cancer research in an area that is currently not funded. The 2018 Conquer Cancer Foundation of ASCO/Breast Cancer Research Foundation MacGregor, of MD Anderson Cancer Center, will receive $450,000 over the next three years to further her research project, “Understanding barriers and decreasing the time to chemotherapy in a vulnerable population: Pilot study of a targeted intervention.”

This a three-year grant that funds clinical investigators who have received their initial faculty appointment and are working to establish an independent, patient-focused, clinical cancer research program.

This year, Conquer Cancer will award 15 Career Development Awards. The list of winners can be found here.

The Young Investigator Award is a grant supporting early-career researchers to begin and establish the direction of their research. The award supports pre-clinical and clinical cancer research projects by oncologists who are undergoing a career transition from a fellowship program to a faculty appointment.

Seventy-two investigators will receive YIAs this year. The full list of Young Investigator Award winners can be found here.

This year, Conquer Cancer acknowledges four new endowed YIAs, sponsored by Boehringer Ingelheim International GmbH; Bristol-Myers Squibb Company; Thomas Roberts, Jr., and Susan DaSilva; and the Generous Supporters of the Women Who Conquer Cancer.

The Boehringer Ingelheim Endowed Young Investigator Award in Gastrointestinal Cancers mirrors Boehringer Ingelheim International GmbH’s investment in challenging but impactful areas of cancer research.

The inaugural award is granted to Ankur Nagaraja of Dana-Farber Cancer Institute to identify new therapies for gastroesophageal cancer.

The Bristol-Myers Squibb’s award, which was established to support research by young female investigators, will go to Rachael Rowswell-Turner of University of Rochester Medical Center to study a novel immunotherapy target in ovarian cancer.

The inaugural Endowed Young Investigator Award in honor of Grant and Victoria Merryman is granted to Adam Waxman of the University of Pennsylvania to study comparative cardiac toxicities of novel therapies for multiple myeloma.

The Generous Supporters of the Women Who Conquer Cancer have endowed a YIA to support young female investigators’ research for years to come. The inaugural recipient of the Endowed Women Who Conquer Cancer Young Investigator Award is Jessica Yang of New York-Presbyterian and Columbia University Medical Center to study a novel approach to treating metastatic uveal melanoma.

For the first time, Conquer Cancer is awarding the Global Oncology Young Investigator Award to support early-career researchers with projects focused on addressing global health needs when it comes to cancer. In its inaugural year, seven researchers will be awarded with Global Oncology YIAs.

The list of Global Oncology Young Investigator Award winners can be found here.

The Gianni Bonadonna Breast Cancer Research Fellowship, which provides funding to an early-career investigator for their unique work in breast cancer research. The recipient of this year’s fellowship is Clinton Yam of MD Anderson Cancer Center.
Berlin is an Ingram Professor of Cancer Research, and co-leader of the Gastrointestinal Cancer Research Program and director of the phase I Clinical Trials Program at VICC.

In his new role, Berlin will work closely with Vicki Keedy, medical director of the CTSR, Marta Crispens, chair of the Scientific Review Committee, Ingrid Mayer, chair of the Data and Safety Monitoring Committee, and the operational leaders of the CTSR to optimize operations and facilitate clinical trial services for the VICC membership.

Berlin joined the faculty at Vanderbilt in 1999. He specializes in treating GI cancers.

At VICC, Berlin is the principal investigator of Project 2 and co-director of the Administrative Core for the GI Specialized Program of Research Excellence, a prestigious research grant program funded by the National Cancer Institute.

He also is principal investigator of the Vanderbilt Lead Academic Participating Site Grant with the National Clinical Trials Network and of the UM1 to conduct early-phase trials with the Early Therapeutics Clinical Trials Network.

The organizations will combine expertise in drug development and research support services, which will expand the menu of clinical trials to patients across the Delaware Valley and beyond. Additionally, Sarah Cannon will provide SKCC-designed clinical trials in sites within their national network.

“By combining the strengths of SKCC and Sarah Cannon’s robust cancer programs, we are bringing together experts who share a mission to advance cancer research so that patients will have greater access to the latest treatment options that focus on personalized care,” Karen Knudsen, director of Sidney Kimmel Cancer Center – Jefferson Health, said in a statement. “We are excited to form a strategic partnership that will accelerate drug development both nationally and globally, with the goal of impacting a larger population of patients seeking new therapies.”

“At Sarah Cannon, we are focused on offering patients cutting edge cancer therapies closer to home — a commitment shared by our esteemed colleagues at SKCC,” Howard “Skip” Burris, president and chief medical officer at Sarah Cannon, said in a statement. “Together, this collaboration will make a greater impact on the field of cancer research through the synergy of our scientific and operational expertise.”

Burris is also the incoming president-elect of the American Society of Clinical Oncology.

In addition to the collaboration in clinical research, SKCC and Sarah Cannon will work together to advance blood cancer care through Sarah Cannon’s Blood Cancer Network. Sarah Cannon is one of the world’s largest providers of hematopoietic cell transplantation, performing more than 1,000 transplants per year.

Jordan Berlin was named associate director of Clinical Investigation Strategy and Shared Resources at the Vanderbilt-Ingram Cancer Center.

In his new role, he will chair the Resource Allocation Committee and continue as chair of the Clinical Trials Shared Resource Steering Committee.

Sidney Kimmel—Jefferson and Sarah Cannon form drug development collaboration

Sidney Kimmel Cancer Center–Jefferson Health and Sarah Cannon Research Institute announced a collaboration to advance clinical research through an expanded early phase drug development program and investigator-initiated trials.
Wasik joins Fox Chase Cancer Center as chair of pathology

Mariusz Wasik was appointed chair of the Department of Pathology at Fox Chase Cancer Center and Jeanes Hospital.

He will also serve as associate director of the Cancer Center.

Wasik joins Fox Chase from the University of Pennsylvania, where he served in various positions in the department of pathology and laboratory medicine, including director of experimental hematology, director of the Hematology Fellowship Training Program, and director of hematology. Most recently, he was the principal investigator and scientific leader of the Translational Center of Excellence for Lymphoma at Abramson Cancer Center.

Wasik’s research focuses primarily on aberrant cell signaling, the underlying genetic and epigenetic mechanisms in lymphomas, the development of new diagnostic and monitoring tools, and the identification of novel treatment approaches based on the unique biology of malignant cells. He will continue scholarly activities of this kind at Fox Chase.

George W. Bush headlines $26 million fundraiser for Inova

Former President George W. Bush and former White House advisor Karl Rove helped raise more than $26 million for the Inova Schar Cancer Institute, setting a new record for a single-event non-profit fundraiser in the Washington, D.C., region.

The donations will help support a new highly personalized cancer research and treatment center on a 117-acre campus.

The fundraising dinner, held at the Inova Center for Personalized Health and chaired by NVR, Inc. president and chief executive officer Paul SAVille and his wife Linda, drew more than 225 guests.

Former President Bush, who was interviewed by his former advisor at the event, has made the fight against cancer one of the priorities of his post-presidential activities.

The Inova Schar Cancer Institute got its start in 2015, when Dwight Schar, Chairman of the Board of NRV Inc., and his wife Martha, made a $50 million gift to Inova, the largest in the health system’s history. The institute will move into a new facility on the campus of the Inova Center for Personalized Health in Falls Church, Virginia, in April 2019.

Wistar receives grant to further research by Wistar scientists Rauscher and Chen

The Jayne Koskinas Ted Giovanis Foundation for Health and Policy awarded The Wistar Institute a $840,000 grant over three years, to support the Jayne Koskinas Ted Giovanis Breast Cancer Research Consortium at Wistar.

The award furthers the multidisciplinary research projects of two Wistar scientists, Frank Rauscher, the principal investigator of the award, and Qing Chen, whose integrated research targets breast cancer and specifically how cancer cells migrate from the primary tumor to form an often-deadly metastasis.
meostasis and how disruption of these mechanisms affects tumor initiation and metastatic progression.

Chen, assistant professor in Wistar’s Immunology, Microenvironment and Metastasis Program, focuses on the molecular mechanisms of brain metastasis originating from primary tumors like breast cancer.

Working in collaboration, the scientists will focus their breast cancer research at the mechanisms used by the tumor at the very onset of the metastatic process, and how the primary tumor burden promotes and activates metastasis to distant organs—specifically in the brain. They hope to understand and define the biochemical mechanisms specific to cancer cells that promote metastasis and to find druggable targets to block tumor spread.
In its just-published guideline on screening for colorectal cancer, the American Cancer Society revised its 2008 CRC screening guidelines, recommending that screening begin at age 45 instead of 50.

This may turn out to be quite reasonable, but, as ACS noted, it is a “qualified recommendation,” one that deserves further scrutiny before being widely implemented.

Starting at age 45 was considered—but not adopted—by the US Preventive Services Task Force in the modeling the NCI Cancer Intervention and Surveillance Modeling Network (CISNET) performed in development of the task force’s 2016 revision of CRC screening guidelines.

It would be instructive to patients, providers, and payers to have further discussion among the principals—modelers and guideline-makers—to more clearly understand the reasons different guideline decisions were reached as well as the tradeoffs involved in starting at the lower age.

Organizations with fixed populations like HMOs and the VA may face difficult tradeoffs if colonoscopy and other testing resources must be reallocated for more primary screening.

By David Ransohoff
Professor of medicine and clinical professor of epidemiology at the University of North Carolina at Chapel Hill
ACS is to be commended for using quantitative assessment of outcomes including benefits and harms in development of these guidelines, even if the rules for how quantity was used in decision-making are not pre-specified and clear.

Indeed, over the years ACS has utilized very varied processes for making guidelines. Such variability—a lack of foundation—can itself cause problems.

In the previous iteration of the CRC guidelines, in 2008, ACS developed the “rules of evidence” for guideline-making during the course of deliberations, not beforehand. And the two rules created were qualitative and did not consider long-term outcomes. Decades earlier, the ACS had used detailed quantitative models developed by David Eddy.

In contrast, the USPSTF has, over decades, developed and extensively published a set of rules about how to synthesize evidence and judge its quality, including a quantitative conceptual framework to assess consequences of different decision choices, that the task force has strived to adhere to.

ACS should be encouraged to develop detailed pre-stated “rules of evidence” to use in all its assessments, and to map their decision-making to those rules—as all guidelines-makers should.

In 2018, the dangers of having rules that are unwritten or too flexible is that guideline-makers may be tempted to “work backwards” from conclusions that they feel pressured to reach.

In contrast, having transparent, quantitative, logical, and fair criteria and rules, agreed-on upfront, will help ensure “trust” in guidelines by the public, providers, and payers, as discussed by the Institute of Medicine (now National Academy of Medicine) in its 2011 report on “Clinical Practice Guidelines We Can Trust”.

Publications of guidelines could be strengthened by expecting major organizations, when they disagree, to routinely explain in detail how differences occur and why—related to changes in evidence or changes in rules.

Last, guidelines could be improved by external peer-review by appropriate arms-length reviewers in the same way as scientific papers are, for clarity, logic, transparency, and adherence to quality standards.

“

It would be instructive to patients, providers, and payers to have further discussion among the principals—modelers and guideline-makers—to more clearly understand the reasons different guideline decisions were reached as well as the tradeoffs involved in starting at the lower age.

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Tecentriq plus chemo helped metastatic non-squamous NSCLC live longer vs. chemo alone

Genentech said the phase III IMpower130 study met its co-primary endpoints of overall survival and progression-free survival.

Genentech is a member of the Roche Group.

The combination of Tecentriq (atezolizumab) plus chemotherapy (carboplatin and Abraxane [albumin-bound paclitaxel; nab-paclitaxel]) helped people live significantly longer compared to chemotherapy alone in the initial treatment of advanced non-squamous non-small cell lung cancer.

In addition, the Tecentriq combination reduced the risk of disease worsening or death compared with chemotherapy alone. Safety for the Tecentriq and chemotherapy combination appeared consistent with the known safety profile of the individual medicines, and no new safety signals were identified with the combination. These data will be presented at an upcoming oncology congress.

Currently, Genentech has eight phase III lung cancer studies underway evaluating Tecentriq alone or in combination with other medicines. This is the third positive Phase III study evaluating TECENTRIQ alone or in combination to demonstrate an OS benefit for people with Tecentriq.

IMpower130 is a phase III, multicenter, open-label, randomized study evaluating the efficacy and safety of Tecentriq in combination with carboplatin and nab-paclitaxel versus chemotherapy (carboplatin and nab-paclitaxel) alone for chemotherapy-naïve patients with stage IV non-squamous NSCLC. The study enrolled 724 people who were randomized equally (1:1) to receive:

- TECENTRIQ plus carboplatin and nab-paclitaxel (Arm A), or
- Carboplatin and nab-paclitaxel (Arm B, control arm)

During the treatment-induction phase, people in Arm A received Tecentriq and carboplatin on day 1 of each 21-day cycle, and nab-paclitaxel on days 1, 8 and 15 of each 21-day cycle for 4 or 6 cycles or until loss of clinical benefit, whichever occurs first.

People received Tecentriq during the maintenance treatment phase until loss of clinical benefit was observed.

During the treatment-induction phase, people in Arm B received carboplatin on day 1 and nab-paclitaxel on days 1, 8 and 15 of each 21-day cycle for 4 or 6 cycles or until disease progression, whichever occurs first.

People received best supportive care during the maintenance treatment phase. Switch maintenance to pemetrexed was also permitted. People who were consented prior to a protocol revision were given the option to cross-over to receive Tecentriq as monotherapy until disease progression.

The co-primary endpoints were:
- PFS as determined by the investigator using RECIST v1.1 in all randomized people without an EGFR or ALK mutation (intention-to-treat wild-type)
- OS in the ITT-WT population
- IMpower130 met its OS and PFS co-primary endpoints.

Lung cancer risk drops substantially within five years of quitting smoking

The main findings of a new analysis of the landmark Framingham Heart Study by researchers at Vanderbilt University Medical Center published May 16 by the Journal of the National Cancer Institute shows that the risk of lung cancer drops substantially within five years of quitting.

First author Hilary Tindle, the William Anderson Spickard Jr., MD Professor of Medicine at the Vanderbilt University School of Medicine and director of the Vanderbilt Center for Tobacco, Addiction and Lifestyle, and her colleagues examined the health records of residents of Framingham, Massachusetts, who have been followed for decades by the Framingham Heart Study.

The study, which is supported by the National Heart, Lung, and Blood Institute, helped establish high blood pressure and high cholesterol as key risk factors for cardiovascular disease. But it also tracked cancer outcomes.

The current study looked at 8,907 participants who had been followed for 25 to 34 years. During this period, 284
lung cancers were diagnosed, nearly 93 percent of which occurred among heavy smokers, those who had smoked at least a pack of cigarettes a day for 21 years or more.

Five years after quitting, the risk of developing lung cancer in former heavy smokers dropped by 39 percent compared to current smokers, and continued to fall as time went on. Yet even 25 years after quitting, their lung-cancer risk remained over threefold higher compared to people who had never smoked.

The Framingham study is unique because it asked people about their smoking every two to four years, and could account for increases or decreases in smoking over time.

Current federal guidelines, which mandate insurance coverage of lung cancer screening for current and former smokers, exclude those who haven’t smoked for 15 years or more. Yet four of 10 cancers in heavy smokers in the current study occurred more than 15 years after they quit.

Further study is warranted to determine whether extending the cut-off point for mandated screening would be cost-effective and save lives, the researchers concluded.

The senior author is Matthew Freiberg professor of Medicine and founding director of the Vanderbilt Center for Clinical Cardiovascular Outcomes Research and Trials Evaluation.

Other Vanderbilt co-authors were Pierre Massion, Cornelius Vanderbilt Professor of Medicine; Robert Grevey, associate professor of Biostatistics; Meredith Stevenson Duncan, V-CREATE database administrator; and Suman Kundu, associate database administrator in the Division of Cardiovascular Medicine and V-CREATE.

Vasan Ramachandran, principal investigator of the Framingham Heart Study and professor of Medicine at Boston University, also contributed to the study.

Loxo Oncology and Bayer are in a collaboration for the development and commercialization of larotrectinib. Bayer plans to submit a Marketing Authorization Application in the European Union in 2018.

In an analysis of 55 RECIST-evaluable adult and pediatric patients with NTRK gene fusions, larotrectinib demonstrated a 75 percent centrally-assessed confirmed overall response rate and an 80 percent investigator-assessed confirmed ORR, across many different types of solid tumors. The majority of all adverse events were grade I or II.

Larotrectinib has been granted Priority Review, Breakthrough Therapy Designation, Rare Pediatric Disease Designation and Orphan Drug Designation.

In November 2017, Loxo Oncology and Bayer entered into an exclusive global collaboration for the development and commercialization of larotrectinib and LOXO-195, a next-generation TRK inhibitor.

Bayer and Loxo Oncology will jointly develop the two products, with Loxo Oncology leading the ongoing clinical studies as well as the filing in the U.S., and Bayer leading ex-U.S. regulatory activities and worldwide commercial activities. In the U.S., Loxo Oncology and Bayer will co-promote the products.