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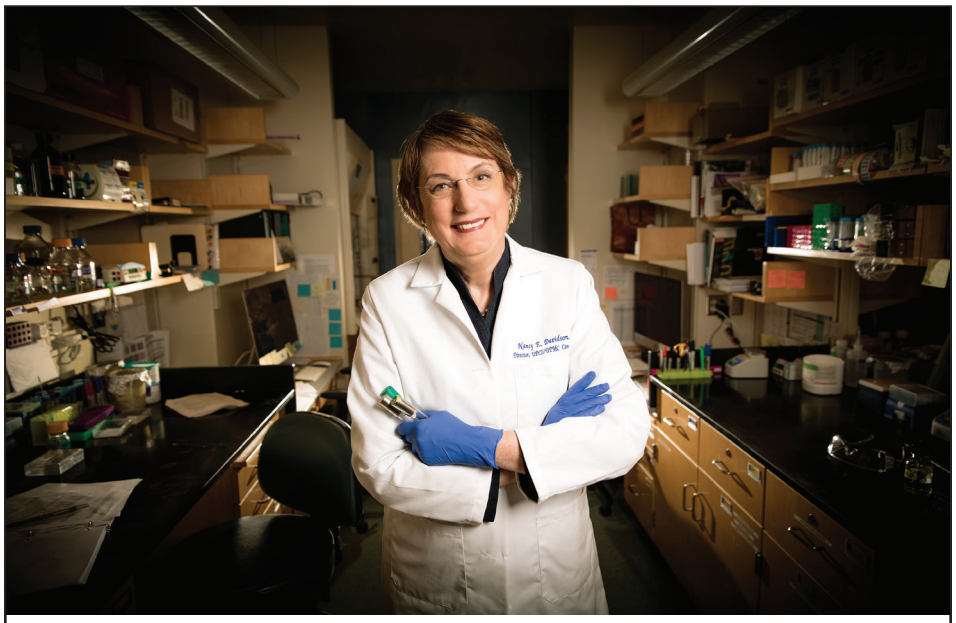

Conversation with The Cancer Letter

Davidson Moves to Seattle Cancer Consortium

By Paul Goldberg

Nancy Davidson was named executive director of the Fred Hutchinson/University of Washington Cancer Consortium effective Dec. 1. For nearly eight years, Davidson has served as director of the University of Pittsburgh Cancer Institute.

(Continued to page 2)

Where is the FY18 Bypass Budget? Cancer Groups Want to Know

By Paul Goldberg

The NCI Bypass Budget was expected to be made public on Oct. 6. Alas, this didn't happen; why didn't it?

America's top cancer groups would like to know, and theirs is not idle curiosity. The NCI Bypass Budget is an important, unique authority established by the National Cancer Act of 1971.

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Letter to the Editor

Goodman: Too Many PD-1 Trials for Adults, Too Few for Children

By Nancy Goodman

Kudos to The Cancer Letter's report on the 803 PD-1 or PD-L1 trials. As Rick Pazdur noted, that is just too many resources chasing the same idea for adult cancer studies.

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Conversation with The Cancer Letter

Davidson Moves to Seattle Cancer Consortium

(Continued from page 1)

In the new role, Davidson, will coordinate cancer treatment, clinical and translational research programs of consortium members Fred Hutch, UW School of Medicine, Seattle Children's and Seattle Cancer Care Alliance, the cancer treatment arm of Fred Hutch, UW Medicine and Seattle Children's.

"I look at myself as someone who has the great fortune to come into a group that is already functioning at the highest levels and is incredibly productive, and being able to add my previous experience at a couple of large medical schools, my interest in basic, translational and clinical research," Davidson said to The Cancer Letter.I "It's a wonderful opportunity for me to be able to contribute to a really vibrant team."

Davidson, this year's president of the American Association for Cancer Research and a past president of the American Society of Clinical Oncology, will serve in several leadership roles at the Hutch/UW consortium institutions:

• At Hutch, she will be senior vice president, member and director of the Clinical Research Division.

• At UW School of Medicine, she will be professor and head of the Division of Medical Oncology in the Department of Medicine.

• At SCCA, Davidson will serve as president and executive director and be responsible for directing and managing the organization's affairs, including planning, organizing and coordinating cancer care, clinical research and education.

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She will also care for patients with breast cancer as part of the SCCA's breast cancer team.

SCCA sees more than 25,000 patients from around the world each year. In addition to its main facilities in Seattle's South Lake Union neighborhood, it has six clinical care sites, including a medical oncology clinic at Evergreen Health in Kirkland, Wash., and medical and radiation oncology clinics at UW Medicine/Northwest Hospital & Medical Center in Seattle. In addition, it has network affiliations with hospitals in five states.

At the Hutch-UW consortium, Davidson will take on the role currently held by Fred Appelbaum as well as succeeding him as president and executive director of SCCA. Appelbaum, an expert in the research and treatment of blood cancers, who for two decades led the Clinical Research Division at Fred Hutch and was head of the UW Division of Medical Oncology, will remain executive vice president and deputy director of the Hutch and will continue to treat patients at SCCA.

Davidson will report to Gary Gilliland, president and director of Fred Hutch, and William Bremner, professor and chair of medicine at UW School of Medicine.

Davidson has been on the faculty at Pitt since 2009 and is Hillman Professor of Oncology, associate vice chancellor for cancer research, and distinguished professor of medicine, pharmacology and chemical biology.

Prior to joining the Pitt faculty, Davidson, a breast cancer expert, served as the breast cancer research professor of oncology and founding director of the Breast Cancer Program at Johns Hopkins University School of Medicine Her awards, honors and appointments include: serving as president of ASCO (2007-2008), receiving the seventh Rosalind E. Franklin Award for Women in Science from NCI (2010), election to the National Academy of Medicine (2011) and Association of American Physicians (2010) and being listed among Thomson Reuters Highly Cited Researchers (2014-2015).

Davidson spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

Paul Goldberg: First of all, congratulations. Why did you decide to take this job?

Nancy Davidson: Thank you so much. I took this position, because my colleagues from Seattle talked to me about the opportunity to take this leadership job, which allows one to think about how to continue to wed the science and the clinical and translational care with population research.

I am very excited to be able to lead the Seattle

Cancer Care Alliance and to take a leadership position at the Hutch and at the University of Washington—great organizations, great science, great translation, home of bone marrow and stem cell transplant, and, of course, a wonderful and growing city.

PG: *How is this job going to be different from what you were doing at Pitt? What's the difference between what you were doing and what you will be doing?*

ND: I had the chance at the University of Pittsburgh to serve as the director of the NCI-designated comprehensive cancer center, a large matrix cancer center that allowed us to think of basic science, population science and clinical translation in western Pennsylvania. It is a terrific job. I feel like it was a great cancer center when I walked in. I hope I made it a little bit better. I think, though, the appeal to me—the difference in the new job—is that I am going to join a different team, a team that has a different kind of basic science portfolio. It has enormous population science strength, of course. And the opportunity to help to grow the clinical mission beyond its current excellence is very real.

I am excited about being able to help this alliance of Seattle Children's, the University of Washington and the Hutch, work together even more closely so that they can continue to advance things such as stem cell therapy and immunotherapy, which is such a tremendous strength there. . There is an opportunity for me, as a person interested in epithelial cancers, to think about how to grow the area of epithelial cancers as well.

PG: *What will you do differently from what Fred Appelbaum did? Is the job exactly the same, or is it a little different?*

ND: No two jobs are the same; are they? You are right that I am stepping into the shoes of Fred Appelbaum, and those are tough shoes to fill. He has been--and will continue to be--an enormous strength at Fred Hutch and the alliance. I am honored to pick up where he has left off.

The general job description is not very different. The goal will be to maintain and advance the strengths in stem cell therapy, immunotherapy and the hematologic malignancies, and to think about how to advance work in solid tumor areas as well. There is a lot of interest in how to grow beyond Fred Hutch central, into the networks, to expand the footprint across the Pacific Northwest in an even more meaningful way.

PG: *You were on their advisory board. Is there a connection? Did they say, "Would you take this job?" How did that work?*

ND: I did have the good fortune to be on the advisory board for the Fred Hutch for about five years. I think that came about as one cancer director helping to advise another one. So I had a chance to see the evolution over the past several years.

I've had a chance to see the excitement that's been growing with the arrival of Gary Gilliland as the president of the Fred Hutch and of Jeff Sperring as the CEO of Seattle Children's Hospital, and the long-standing wonderful strength in place already with Paul Ramsey, the UW medical school dean and CEO of UW Medicine, and Bill Bremner, who is the chair of medicine at UW. So when the search committee contacted me and asked me whether I would take a look, it was pretty easy to say "Yes," because I knew of some of the excitement, and I learned even more as I became involved in the search process.

PG: *This is a massive multi-institutional alliance. Could you throw some metrics at me?*

ND: I believe that Fred Hutch has the highest portfolio of NCI funding in the country, more than any other cancer center, and I think that speaks to the quality of its research, the depth of the science and the ability of the faculty to have great ideas and to be out there competing in a very meaningful way.

PG: *How would the bioinformatics function in these institutions, systems like the electronic medical records and so forth? Is that functioning well? Is it going to change?*

ND: I think that is very much work that's in progress. EMR is being rolled out, and the OnCore clinical trials system is being put into place. One of the key recruitments that Gary Gilliland has made is Matthew Trunnell from the Broad [Institute of MIT and Harvard], who has come to the Hutch to work through the bioinformatics issues. [He is the vice president and chief information officer at Hutch.]

He recently arrived, and I look forward to being a part of the team that will think about how to move it forward. We are also fortunate to be in Seattle, and I hope that we will be able to benefit from the expertise of some of the big companies in town in this area.

PG: *That's going to be a major piece of what you will do; right?*

ND: I think that's a major piece everyplace right now; isn't it? Trying to think how we are going to take this wealth of information that we are generating and turn all of these data into knowledge.

PG: *What is your vision for how you are going to roll all of these pieces that we were discussing together?*

ND: I think that I have embraced the missions of the Hutch and of the Seattle Cancer Care Alliance.

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Ravi Salgia, M.D., Ph.D.


Steven T. Rosen, M.D.


Yuman Fong, M.D.

Pictured above, clockwise from top left: Ravi Salgia, M.D., Ph.D., Chair and Professor, Department of Medical Oncology & Therapeutics Research; Steven T. Rosen, M.D., Provost, Director, Beckman Research Institute of City of Hope and Comprehensive Cancer Center; Yuman Fong, M.D., Chair and Professor, Department of Surgery, Professor, Department of Experimental Therapeutics.

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This work has been going on for a while, Paul, and I am simply the newest member to join the team--the many, many people who are wrapped up in this--thinking about what it will take to realize the goals of precision cancer medicine that we all strive for in the Seattle area and beyond.

I look at myself as someone who has the great fortune to come into a group that is already functioning at the highest levels and is incredibly productive, and being able to add my previous experience at a couple of large medical schools, my interest in basic, translational and clinical research. It's a wonderful opportunity for me to be able to contribute to a really vibrant team.

PG: *How do you see immunotherapy evolving further at the Hutch? Do you see a need to balance it against other modalities in precision medicine?*

ND: You are right that immunotherapy has been a huge priority and a huge strength of the Hutch. Work is going on right now to enhance the clinical facilities to embrace this new modality that we are all bringing to bear.

I don't think there is going to be a need to balance immunotherapy, Paul.

Immunotherapy is going to be another pillar in the way that we think about cancer treatment. It's going to join surgery and radiotherapy, it's going to join standard chemotherapies, it's going to join targeted therapies, it's going to join supportive care.

To me, the question is, how do we integrate immunotherapy effectively into our current portfolio of modalities that are available, and particularly how do we make it one of our most effective tools?

So, as you know, we are working hard to figure out how to right-size tailored therapy, to make sure we are giving the right people the right therapy at the right time, and to understand resistance and sensitivity markers. All of these things are important across all of cancer medicine, and they are certainly important in immunotherapy right now.

PG: *I am asking you this as a breast cancer expert: By coming to the Hutch, will this open new avenues for your own research?*

ND: Absolutely. I am coming, as you point out, to take a very large leadership position, where the primary goal will be to think about the global mission, and not specifically about breast cancer. But I am never going to lose my drive to find better treatments for breast cancer, and I am extremely excited about coming to a new environment, with new breast cancer collaborators.

At the Hutch, there is a number of them in place. The Hutch has been home of one of the breast cancer SPOREs, and I hope that I will be able to embed myself in that research group. I am also excited because the Hutch has a tremendous track record of research in population health, particularly in women's health with its roles as the coordinating hub of the Women's Health Initiative. I am hoping that I will be able to contribute in meaningful ways to how we might think about population health for woman, and breast health, of course, will be part of that.

PG: *Is there anything we've overlooked? Anything you'd like to add?*

ND: This is an example of an absolutely wonderful opportunity, coming to me at a great time in my personal career, and I think at a great time in terms of the phenomenal upward trajectory of Fred Hutch, the SCCA, Seattle Children's and the University of Washington. I am glad that these things came together at the same time.

Where is the Bypass Budget? Cancer Groups Want to Know

(Continued from page 1)

That law designates the NCI director as the top official of the National Cancer Program, requiring this official to inform the U.S. President about opportunities in the cancer program. At least on paper, the document bypasses NIH and HHS, and goes directly to the White House.

The NCI document was prepared, and its summary was sent out to members of the National Cancer Advisory Board, and was obtained by The Cancer Letter. The document is posted here.

Citing his unique authority and his position as the coordinator of the National Cancer Program, NCI Acting Director Douglas Lowy is asking for $6,484 million for fiscal year 2018—an increase of $590 million over the President's FY17 Budget Proposal.

That increase consists of a $165 million inflation adjustment and $425 million in additional funding

The House and Senate appropriations bills contain no new funds for the Moonshot program. However, the 21 Century Cures Act, should it become law, does contain budgetary increases. The version of that legislation that was passed by the House proposes an $8.75 billion increase for NIH, which would be given out over five years. These funds are contingent on budgetary offsets.

With Hillary Clinton seeming likely to win the upcoming election, it appears that the moonshot program

run by Vice President Joe Biden will continue.

On Oct. 17, a report of the Moonshot Task Force will be released at a White House ceremony. With the moonshot likely to continue into the new administration, observers worry about the prospects of these new funds not making their way to NCI as well as the prospect of erosion of the NCI director's authorities.

Three major oncology organizations contacted by The Cancer Letter said they are eager to see the Bypass Budget released:

• **American Society of Clinical Oncology**: "We appreciate that NCI must take into account a wide range of factors in determining the timing of the bypass budget release," said ASCO President Daniel Hayes. "The bypass budget serves as a critical benchmark in the federal budget process that ASCO and others examine to better understand the funding requirements needed to advance critical cancer research priorities.

"ASCO continues to be encouraged by Vice President Biden's moonshot initiative and the Blue Ribbon Panel recommendations.

"We will continue to strongly advocate for funding that will supplement, not supplant, current NCI appropriations in order to realize the moonshot's vision for accelerating progress against cancer."

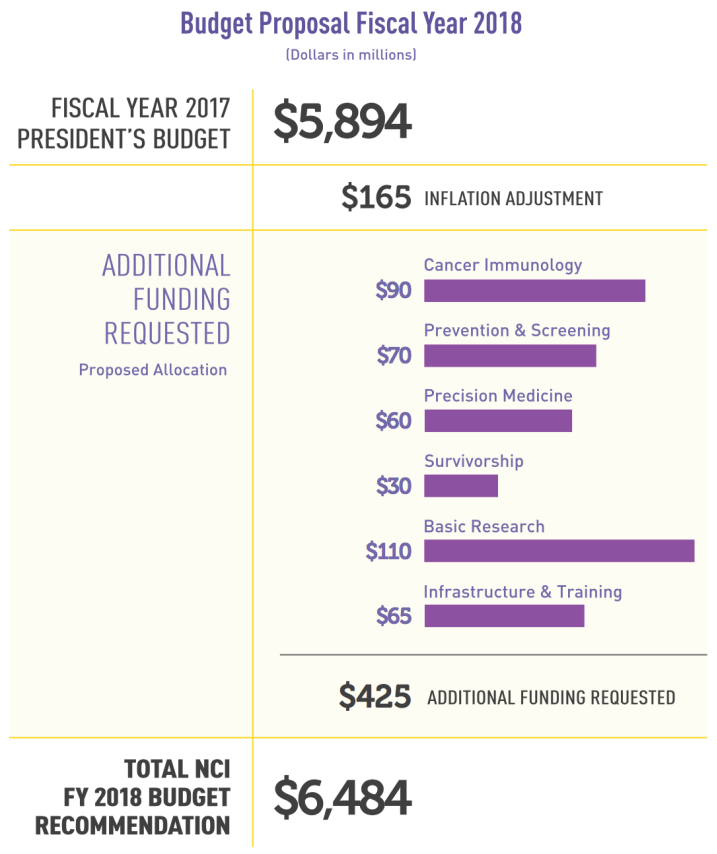
• **American Association for Cancer Research**: "We are very much looking forward to NCI releasing its FY 2018 Bypass Budget, especially since it's a tool for us to use when talking to policymakers about the extraordinary opportunities that exist today in cancer research," said Jon Retzlaff, managing director for science policy and government affairs at AACR. "This annual budget document from NCI also specifies the investments that are needed to support the innovative and cutting-edge science that will ultimately make a major difference for cancer patients and their loved ones, as well as highlights the evidence-based ideas and approaches for preventing cancer from ever occurring in the first place.

"As we all know, if Vice President Biden's Cancer Moonshot Initiative is going to meet its overall objective of achieving a decade's worth of advances in five years, it's going to require robust, sustained, and predictable funding increases for NCI. Therefore, in addition to fighting hard during the upcoming lame duck session of Congress to ensure that significant resources are allocated to the NCI in FY 2017 to carry out many of the National Cancer Moonshot programs and initiatives that have been proposed, we also need to begin establishing a foundation to ensure that this momentum for increased resources continues into FY 2018 and beyond.

"Of course, we will be provided with such an opportunity once the NCI releases its FY 2018 Bypass Budget. We are optimistic about NCI's budget being supplemented in FY 2017 with some significant research dollars that are increasingly likely to be included in the respective 21st Century Cures Bills in the House and Senate when Congress reconvenes after the elections for a lame duck session. The Cures bills are important vehicles for ensuring that the NCI receives the funding that's necessary for the agency to implement the initiatives and programs that have been proposed as part of the Vice President's Cancer Moonshot program."

• **American Cancer Society Cancer Action Network**: "The Bypass Budget is essential for the National Cancer Program. It enables the NCI director to clearly communicate what resources are necessary to meet cancer researchers' scientific needs as well as advance the most promising research opportunities, including those recommended by the Blue Ribbon Panel," said Chris Hansen, president of ACS CAN. "The cancer community relies heavily on the bypass budget for its planning of various types of related work and initiatives."

The White House and NIH officials deflected The Cancer Letter's questions to NCI, and NCI



officials didn't respond by deadline.

The Bypass Budget mentions NCI's primary role in the cancer program.

"As coordinator of the National Cancer Program, NCI seeks and supports new ideas to understand and intervene in the cancer process, from the earliest stages to the most advanced," Lowy writes in the introduction. "Improvements in prevention, screening, diagnosis, and treatment have resulted in lower death rates for most cancers."

Lowy mentions the moonshot, too:

"I am privileged to put forward this Annual Plan & Budget Proposal for Fiscal Year 2018 at a unique and exciting moment in time, when two major initiatives—the President's Precision Medicine Initiative (PMI) in oncology and the Cancer Moonshot, led by Vice President Biden— have the potential to transform cancer research," he writes. "The Cancer Moonshot aims to accelerate progress against cancer, accomplishing a decade's worth of advances in just 5 years. As part of this effort, a Blue Ribbon Panel of experts and cancer advocates."

In another highlight, Lowy mentions the NCI Blue Ribbon Panel and its recommendations.

"As part of this effort, a Blue Ribbon Panel of experts and cancer advocates from around the country identified specific opportunities poised to accelerate research progress and formalized a set of 10 bold, yet feasible, recommendations to the National Cancer Advisory Board," he writes. "I was gratified to see not only the recommendations themselves but also the spirit of collaboration that was so evident among these leading cancer experts from academia, industry, and the public and private sectors."

Matthew Bin Han Ong contributed to this story..

Guest Editorial

Goodman: Too Many PD-1 Trials for Adults, Too Few for Children

(Continued from page 1)

Alas, as of Friday, Oct. 7, clinicaltrials.gov shows only two open trials for a PD-1 or PD-L1 trial for patients 0 to 17 years of age, and both are monotherapies. There are no listed combination trials that are open and accept kids. There are no PD-L2 trials listed that accept kids.

The 160,000 slots for adults to enter PD-1 trials exist because we all know how exciting these drugs are. But, if so, why are there so few trials for which children and young teens would qualify? Shouldn't kids and teens also get a shot at exciting investigational drugs?

When my son, Jacob, was treated for medulloblastoma, there were so many adult brain cancer trials open. None of them would accept a 10-year-old boy. Even on a compassionate use basis. Perhaps none of these drugs would have conferred a benefit to Jacob. However, I am still sorry that he wasn't given a chance to at least try.

Sponsors provide no scientific or ethical rationales on the clinicaltrials.gov summaries to explain the eligibility requirements and the prohibition of enrolling children and young teens in trials.

So let's consider the major impediments to including children on the 803 PD-1 trials:

Would a dead child on a trial slow down PD-1 clinical development?

There is the issue of dead kids on trials. As a mother of a child who died of a pediatric cancer, I can say this. There is the uncomfortable and unspoken concern that a child on a trial could have a new toxicity or die, thereby slowing down the adult drug development. Could a child die in a PD-1 trial, thereby slowing down the other 803 PD-1 trials?

There is no evidence that the FDA has ever penalized a sponsor for a dead kid, absent gross negligence. I cannot find cases of a dead child on a trial resulting in a terminated adult trial—and I've spoken to many pharmaceutical companies to find cases.

I would ask those for whom this is a concern to put forward examples so that we can all examine these instances together. The urban myth that a dead kid on a trial will cause the FDA to delay adult development has not be substantiated, and is not a good reason to block terminally ill children from potentially beneficial treatments.

Others argue that it is unethical to put a child on a PD-1 trial early—perhaps because there is new or unknown toxicity that could bring death earlier to a child. With respect to PD-1 drugs, how could it be unethical to include a child on a PD-1 trial, when there are other approved PD-1 drugs that kids are already taking off-label?

For children who are terminally ill, I would argue that the most ethical position is to give the child, the child's family and the child's physician the opportunity to weigh the known and unknown risks to assess what the best trial is for that child.

Can we identify new toxicities or different pharmacokinetics for PD-1 drugs for kids that would exclude kids of certain ages from PD-1 trials?

If there are toxicity concerns that would exclude 17 year olds, or 15 year olds, or even 9 year olds from PD-1 trials, then let's discuss them. In fact, the two pediatric trials for PD-1 drugs that are open presumably addresses this question satisfactorily.

For other classes of drugs, usually, developmental toxicities can be predicted. In addition, pharmacokinetic differences between children and adults can be usually identified by pediatric pharmacologists early in a drug's clinical development process.

Do we need to prioritize clinical research of PD-1 drugs in kids, given how few kids have cancer?

Some argue that before we put kids on more than the two open PD-1 trials, the 803 open adult trials should be prioritized so that all the trials are completed, science progresses and children are not "used" by being put on trials that will not be completed.

The problem of prioritization for children is a theoretical problem that we should be so lucky as to have. For children with cancer, the problem is not that there are too many unprioritized trials, it is that kids cannot get onto trials.

If children were admitted to trials when there wasn't a scientific reason to exclude them, then children with cancer would achieve a major win: earlier access to PD-1 drugs. There might even be new efficacy or toxicity data to be found and collected. The two open pediatric trials might have a more difficult time accruing, but these two trials are both monotherapies in an environment of hundreds of combination PD-1 trials.

In other areas of clinical research—such as written requests leading to pediatric exclusivity and post-market studies—prioritization is not required. Let's not block early access to drugs for kids by raising the flag of prioritization here with PD-1 drugs.

Eventually, if we are very lucky, and if the problem of early access to drugs for children with cancer has been solved, then we will have to come together as a community to start to talk about prioritization. We are years and years away from such a wonderful problem.

I propose two steps to ensure that children are not denied access to potentially life-extending drugs such as PD-1 drugs merely because of convention:

1) Pass the RACE for Children Act (S 3239, HR 5858).

Pursuant to the Pediatric Research Equity Act (PREA), sponsors developing drugs for indications for which there are pediatric populations have certain obligations to undertake pediatric trials. However, PREA does not apply to cancer because cancer indications are defined by organ of tumor origin. In other words, children do not get prostate cancer or breast cancer.

The RACE for Children Act would update PREA: as cancer drugs are now developed by molecular target, RACE would authorize FDA to require sponsors to undertake certain PREA pediatric studies if the molecular target of investigational drugs is relevant to pediatric cancers.

For example, if sponsors studying PD-1 trials are only studying the drugs for adult cancers—breast cancer, lung cancer, ovarian cancer, pancreatic cancer—does it make sense for sponsors not be required to undertake PREA pediatric studies because children do not have these cancers? The RACE for Children Act would require sponsors to undertake PD-1 trials in pediatric cancers for which PD-1 therapies are scientifically relevant.

The RACE for Children Act has solid science. It has been endorsed in a Nature editorial and by over 100 patient groups and hospitals.

Congress should pass the RACE for Children Act as soon as possible.

2) Lower the minimum age of eligibility and put kids and young teens on cancer trials unless there is a scientific or ethical reason not to.

Sponsors should be asked to explain their decision to cut off eligibility for trials at 18 years of age or any other age.

FDA has the authority to make these inquiries about eligibility by age and has begun to do so. Given the promise of these drugs for terminal kids awaiting their approval, and given the practice of use of these drugs on an off-label basis by these kids, FDA is authorized to continue to press companies to explain and justify their eligibility requirements as standard practice.

Moreover, NIH-funded trials should include children and young teens unless there is a scientific or ethical reason not to. Though we, as a society, permit private companies to exclude children and young teens from trials for non-scientific reasons, we should ask government agencies such as NIH and the Department of Defense to refrain from also excluding children from clinical research when there is no scientific rationale.

The author is executive director and founder of Kids v Cancer.

In Brief

Adrian Lee named director of the Institute for Precision Medicine

ADRIAN LEE was named director of the **Institute for Precision Medicine**, a joint effort by UPMC and the University of Pittsburgh.

A breast cancer expert, Lee is a professor in the Department of Pharmacology and Chemical Biology at Pitt, and director of the Women's Cancer Research Center, University of Pittsburgh Cancer Institute.

In addition to studying the hormonal regulation of breast cancer, Lee is part of the team working to implement the technology infrastructure needed for precision medicine. He succeeds Associate Vice Chancellor Jeremy Berg, who will remain as a senior adviser to the IPM, founded in 2013 and formerly known as the Institute for Personalized Medicine.

Under Lee, the IPM will build on precision medicine efforts underway at Pitt and UPMC, including implementation of new clinical trials and procurement of significant National Institutes of Health and state funding.

In July, the NIH announced an award to Pitt that could top $46 million over five years to build the infrastructure and partnerships needed to launch the Cohort Program of President Obama's Precision Medicine Initiative—a landmark effort to engage more than 1 million U.S. participants in providing clinical, genomic and other data that could lead to new ways of preventing and treating disease.

Potential IPM initiatives over the next five years include:

• Building upon current Pitt and UPMC efforts to share clinical, tissue and genomic data, enabling researchers to perform precision medicine research. The IPM also will seek out new ventures with companies and other academic centers to expand data sharing nationally.

• Positioning Pitt and UPMC for future federal and commercial precision medicine efforts. The IPM will work with the Pittsburgh Health Data Alliance—backed by UPMC, Pitt and Carnegie Mellon University—and UPMC Enterprises, the commercialization arm of UPMC, to coordinate and help fund precision medicine research.

• Leveraging clinical data and tissue collections at Pitt and UPMC. For instance, large-scale machine learning will be used on more than 288,000 unique cases in the UPMC Cancer Registry to identify predictors of disease prognosis and outcomes.

• Developing education programs and policy in precision medicine, including expansion of the role of genetic counselors.

• Facilitating the testing of precision medicine in clinical trials. This work will be integrated with studies of patient-reported outcomes and health costs to help develop new models of care.

KWOK-KIN WONG was named chief of hematology and medical oncology at the **Perlmutter Cancer Center at NYU Langone Medical Center**.

Wong will join the Perlmutter faculty in January,.

He is a professor of medicine at **Harvard Medical School** and a clinical oncologist at **Dana-Farber Cancer Institute**. His research focuses on understanding the pathogenesis and genetic alterations involved in lung cancer and on testing novel lung cancer therapeutics *in vivo*. His laboratory integrates genomic studies of human lung cancer, new mouse models of lung cancers, and studies of novel drug treatment in these models.

To understand the genetic role of mutated oncogenes such as *KRAS, BRAF, HER2* and *EGFR* in lung cancer, his laboratory has generated various inducible bitransgenic mice harboring these mutations. The lab's work has demonstrated that activation of *EGFR* and *BRAF* are oncogenic *in vivo*, because mice expressing these activated alleles develop lung tumors *de novo*. These mouse models have enabled characterization of novel mechanisms of lung carcinogenesis and serve as unique platforms for testing therapeutics that specifically target these pathways.

YANIS BOUMBER joined the Department of Thoracic Medical Oncology and the Molecular Therapeutics Program at **Fox Chase Cancer Center**.

Boumber first joined Fox Chase's Department of Medical Oncology in 2013 and now returns to Fox Chase from the University of New Mexico Comprehensive Cancer Center. He specializes in treating patients with thoracic cancers, including lung cancer, thymoma, and mesothelioma, and his clinical and research focus at Fox Chase will be on thoracic malignancies.

In his time away from Fox Chase, Boumber has continued to collaborate with numerous Fox Chase scientists and clinicians.

Boumber and Erica Golemis, deputy chief

science officer and co-leader of molecular therapeutics at Fox Chase, led a study that found the Musashi-2 protein, a regulator of mRNA translation, may serve as a predictive biomarker of non-small cell lung cancer aggressiveness. Their findings were published in the Proceedings of the National Academy of Sciences in June 2016.

In further work with Golemis and another colleague, James Duncan, Boumber helped identify a role for the TGF-beta/BMP superfamily member anti-Mullerian hormone in drug resistance in non-small cell lung cancer, and also evaluated STA-8666, a targeted therapy for lung cancer.

STANLEY MARKS, a **University of Pittsburgh Medical Center** oncologist, was honored by UPMC and his medical partners at **Oncology Hematology Association** through the establishment of the Stanley M. Marks--OHA Endowed Chair in Hematology/ Oncology Leadership.

Every one of his 48 partners at OHA, a UPMC-owned practice, financially committed to create this chair, which also was supported by UPMC, for a total of $2.2 million.

The permanent endowment will support the recruitment and retention of outstanding leaders in the University of Pittsburgh Division of Hematology/ Oncology. It also will help to train professionals devoted to research and improved treatments for patients.

"This endowment will enable us to recruit a medical and scientific star, ultimately leading to better care for our patients," Marks said.

Marks has directed and overseen the continued growth and success of the UPMC CancerCenter, a partner with the University of Pittsburgh Cancer Institute and now one of the largest cancer care networks in the nation.

Marks serves as chairman of UPMC CancerCenter, chief of the Division of Hematology and Oncology at UPMC Shadyside, and as a clinical professor of medicine at the University of Pittsburgh School Of Medicine. He also has been named consistently as one of the "Top Physicians in Pittsburgh" and "Best Doctors of America" in hematology and medical oncology by Best Doctors.

ROBERT FIGLIN was appointed deputy director of the Integrated Oncology Service Line at the **Cedars-Sinai Samuel Oschin Comprehensive Cancer Institute.** Previously, he was director of the Hematology Oncology Division at the institute.

In his new role, Figlin will work with clinicians and investigators to unify the health system's approach to treating cancer.The integration of cancer care means that patients will get the same level of quality services whether they're treated at Cedars-Sinai's main campus or at one of its highly regarded affiliates, including Tower Hematology Oncology and The Angeles Clinic.

"Dr. Figlin was tailor-made to do this," said **Steven Piantadosi**, director of the Samuel Oschin Comprehensive Cancer Institute and professor of medicine at Cedars-Sinai. "He's an experienced leader who knows cancer care in the Cedars-Sinai system, throughout Los Angeles and beyond."

A kidney cancer specialist, Figlin will continue working to develop clinical trials, translate research findings from the laboratory to the clinical setting and lead initiatives such as Cedars-Sinai's effort to contain the high cost of cancer drugs.

Figlin, who joined Cedars-Sinai six years ago, is the Steven Spielberg Family Chair in Hematology Oncology. Since his arrival, he has established the Experimental Therapeutics Program and successfully recruited clinical and research faculty in critical specialty areas such as breast cancer, bone marrow transplant, gastrointestinal oncology, genitourinary oncology, survivorship, and cancer biology, among many other achievements.

SURESH RAMALINGAM, deputy director of **Winship Cancer Institute of Emory University** and assistant dean for cancer research in the Emory School of Medicine, was selected to hold the Roberto C. Goizueta Distinguished Chair for Cancer Research. The endowment was established to support a key leader in Winship's lung cancer program. The position was previously held by Fadlo Khuri.

"Ramalingam has provided extraordinary leadership to Winship's research efforts against lung cancer, and in his new role as Winship's deputy director, he is leading Winship's broad cancer research portfolio across the entire university," Winship's executive director Walter Curran, Jr. said.

Ramalingam, a professor in the Department of Hematology and Medical Oncology, is an internationally recognized lung cancer physician-investigator. He serves as Winship's director of medical oncology and its Lung Cancer Working Group, and he currently co-leads Winship's Discovery and Developmental Therapeutics Research Program.

Ramalingam chairs the Thoracic Malignancies

Committee and serves as deputy chair for the Therapeutics Program within ECOG-ACRIN, a NCI-supported national clinical trials network group. His research focuses on development of novel anti-cancer agents and ways to individualize therapies for patients with small cell and non-small cell lung cancer.

Ramalingam, who is board certified in medical oncology and internal medicine, has authored over 200 scientific publications and is the section editor for "Chest Diseases" for the journal Cancer. He is on the editorial boards of the *Journal of Clinical Oncology, Annals of Oncology,* and *Clinical Lung Cancer.*

Ramalingam is a graduate of Kilpauk Medical College at the University of Madras. He completed his residency in internal medicine at Wayne State University, and his fellowship in hematology and medical oncology at the University of Pittsburgh Cancer Institute.

He joined Winship in 2007 and is the recipient of several awards including the James Eckman Award for Excellence in Teaching at Emory, ECOG-ACRIN Young Investigator Award, and the NCI Cancer Clinical Investigator Team Leadership Award. He was named a Georgia Cancer Coalition Distinguished Cancer Scholar in 2008.

JACQUELINE CORRIGAN-CURAY was selected as the permanent director of the **FDA Office of Medical Policy at the Center for Drug Evaluation and Research**.

Corrigan-Curay most recently served as a supervisory medical officer with the Immediate Office of the Director at NIH's **National Heart, Lung, and Blood Institute**, where she worked on establishing a new trans-NHLBI initiative to further optimize NHLBI's clinical trials, with a goal of maximizing scientific impact and improving public health. Corrigan-Curay developed new policies and procedures to help the institute better identify those trials that answer critical public health questions, are likely to succeed, and have been designed to the highest scientific and ethical standards. She also worked to develop standard operating procedures for management of clinical trials, and served as the NHLBI liaison to the CDER Drug Safety Board—identifying new opportunities for NIH-FDA collaboration on drug safety research.

Corrigan-Curay served in director and acting director roles with the Office of Biotechnology Activities, Office of Science Policy at NIH, where she was executive secretary of the NIH Recombinant DNA Advisory Committee. She developed recommendations to improve the scientific and ethical conduct of novel clinical and basic recombinant research. As director of the Recombinant DNA Program, Corrigan-Curay supported NIH oversight of recombinant DNA research, including gene therapy, stem cell therapies and basic recombinant and synthetic DNA research.

Before joining NIH, Corrigan-Curay held positions as an attending physician with the Veterans Affairs Medical Center, a policy analyst with the Congressional Office of Technology Assessment, and a practicing attorney in Washington.

ANN RICHMOND, **Vanderbilt University** cancer researcher, has won the **2016 William S. Middleton Award**, the highest honor for scientific achievement bestowed by the Biomedical Laboratory Research and Development Service of the U.S. Department of Veterans Affairs.

Richmond is Ingram Professor of Cancer Research and professor of Cancer Biology and Medicine at Vanderbilt University School of Medicine, and Senior Associate Career Scientist with the VA Tennessee Valley Healthcare System, Nashville campus.

She was honored for significant contributions to understanding "chemokines," inflammatory proteins that can regulate tumor growth. Her research has helped lay the foundation for understanding how to improve the effectiveness of immunotherapies against melanoma, a potentially lethal skin cancer that occurs disproportionately among Gulf War veterans.

Richmond was nominated for the award by **Donald Rubin**, associate chief of staff for research at the VA Tennessee Valley Healthcare System's Nashville campus, and professor of Medicine and of Pathology, Microbiology and Immunology at Vanderbilt.

Richmond is the third woman and second Vanderbilt faculty member to receive the annual award, which was created in 1960.

The award, which recognizes outstanding achievement in biomedical or behavioral research, is named for the late William S. Middleton, who served as the VA's Chief Medical Director from 1955 to 1963. It will be presented to Richmond later this year during a ceremony at VA headquarters in Washington, D.C.

Richmond has been a member of the Vanderbilt faculty since 1989. Her research to identify and characterize one of the first chemotactic cytokines (chemokines), now known as CXCL1, has been continuously funded by a VA MERIT grant, and she has

held a VA Research Career Scientist Award since 1988.

Richmond explained that Gulf War veterans are at higher risk of developing melanoma, and dying from the disease, compared to the general population because of their intense and prolonged exposure to the damaging rays of the sun during their tours of duty.

MARC BENIOFF and wife **Lynne** gave $20 million toward construction of the **Lawrence J. Ellison Institute for Transformative Medicine of University of Southern California**, a center in Los Angeles that will combine interdisciplinary research with the holistic prevention and treatment of cancer.

In recognition of their gift, the lobby of the Ellison Institute will be named in honor of Marc Benioff's late father, Russell Benioff.

A pioneer of cloud computing and chairman and CEO of Salesforce, Marc Benioff has served as a member of the USC Board of Trustees since 2010. He is noted for integrating philanthropy into the core of his business with the creation of the 1-1-1 model of philanthropy, donating 1 percent of Salesforce's equity, employee time and product to nonprofits and educational institutions to improve communities around the world. More than 1,000 companies around the world have adopted this model through Pledge 1%.

The Ellison Institute in west Los Angeles will house interdisciplinary cancer research laboratories that will harness proteomics, molecular biology, genetics and nanotechnology to seek new ways of ending cancer. The institute's collaborative environment will include patient care clinics, a think tank, education and outreach, and a wellness program.

David Agus, professor at the Keck School of Medicine of USC and USC Viterbi School of Engineering, will lead the institute, which will draw collaborators from many disciplines to study cancer and potential ways to prevent, detect and treat the disease. The institute will complement and integrate cancer research being conducted by faculty physicians and scientists across the university.

BORIS LUSHNIAK was named dean of the **University of Maryland School of Public Health.** Lushniak will officially assume his new role on Jan. 9, 2017.

Lushniak is a professor and chair of the Department of Preventive Medicine and Biostatistics, and professor of dermatology, at the F. Edward Hébert School of Medicine at **Uniformed Services University of the Health Sciences**.

Prior to joining USUHS, Lushniak served as the U.S. Deputy Surgeon General. He also oversaw the operations of the **U.S. Public Health Service Commissioned Corps**.

From 2013 to 2014, Lushniak served as acting surgeon general and was responsible for the release of the 50th Anniversary Surgeon General's Report on Smoking and Health and the first ever Surgeon General's Call to Action to Prevent Skin Cancer. He also served as commander of the USPHS Monrovia Medical Unit in Liberia, the only U.S. government hospital providing care to Ebola patients. He retired from the USPHS as a Rear Admiral in 2015.

Lushniak began his USPHS career in the **Epidemic Intelligence Service** and initially served with the **CDC's National Institute for Occupational Safety and Health**, where he conducted epidemiological investigations of workplace hazards.

SOUTHERN RESEARCH INSTITUTE was awarded a five-year IDIQ contract with a potential value of $19 million from NCI to study the preclinical toxicology of new drugs that are under development for treatment of cancer.

The toxicology contract is one of three ongoing contracts between Southern Research and the NCI, and is the latest in a series of contracts with the NCI that have been in place continuously since 1979.

The two additional ongoing contracts between Southern Research and the NCI are for research on the pharmacology of potential new cancer drugs, and for evaluation of drugs intended for the prevention of cancer.

"Our ultimate goal with this contract is to help the NCI develop an understanding of how different drug candidates interact with and affect living systems," said **Charles Hebert**, senior program leader and principal investigator on the project for Southern Research. "The collection of this information is necessary so the FDA can determine whether a particular drug candidate is safe for clinical trial testing in humans."

DR. SUSAN LOVE RESEARCH FOUNDATION received a $3 million NCI grant to further test a **computer assisted diagnosis triage software product** that can triage palpable breast lumps and identify those that are suspicious.

The technology is being developed for use in low- and middle-income countries.

The three-year UH3 Phase II exploratory cooperative agreement will support further development

of a technology, which, when used in conjunction with handheld ultrasound units by local health aides, may determine which lumps are benign and those which might be malignant and should be biopsied. The $3 million phase II award comes after a successful $1 million phase I for an award total of $4 million.

The CAD development and clinical validation are being performed in collaboration between Dr. Susan Love Research Foundation and ClearView Diagnostics. The team is led by Susan Love, chief visionary officer of the foundation and principal investigator on the grant, Christine Podilchuk, CEO of Clearview Diagnostics, and Richard Mammone, founder of Clearview Diagnostics. Also collaborating on the grant is breast imaging radiologist and clinical trial expert Wendie Berg, of the University of Pittsburgh School of Medicine, Magee-Womens Hospital of UPMC.

"While screening has been the focus in western countries, in developing countries breast cancer most commonly presents as a palpable lump in women younger than 50 years old," said Dr. Love. "The most common types of palpable breast lumps in young women are distinguishable on ultrasound and fewer than 25% are cancer." During the first phase of the NIH-funded study, the CAD system demonstrated that it could have potentially reduced the number of benign lesions that were biopsied by around 50%. A pilot study in Mexico demonstrated that health care workers without imaging training could acquire images equivalent to those obtained by a trained radiologist and that the CAD was able to distinguish between cancers and benign lesions.

The UH3 grant will be used to apply what was learned during Phase I to the LMIC environment in Mexico.

NIH, as part of its national **Precision Medicine Initiative Cohort Program,** has expanded a five-year funding award to **The Scripps Research Institute** from $120 million to $207 million.

The award marks a significant increase in scope from the initial award announced in July and provides additional details about the network of partners in the TSRI-led consortium.

"The size of this award underscores the critical nature of this research in improving our ability to prevent and treat disease," TSRI President Peter Schultz said. "We are thrilled to be part of such a major undertaking and look forward to supporting Dr. Eric Topol in leading this unprecedented project."

Topol, who is director of the Scripps Translational Science Institute, professor of genomics at TSRI, and chief academic officer at Scripps Health, will direct the award as part of the PMI Cohort Program.

The new award expands the group's role in overseeing the enrollment of 350,000 "direct volunteers," individuals interested in joining the PMI research study directly rather than through a healthcare provider organization. In addition, the award funds the creation of a Participant Technologies Center to develop, test, maintain and upgrade the mobile applications and technology platform used to enroll, consent, collect data from, communicate with and retain participants. The PTC will also develop parallel platforms to deliver these same functions to those without smartphones.

MOUNT SINAI received a $10 million grant from NCI to explore the cellular and molecular mechanisms of acute graft-versus-host disease, a common side effect that occurs after allogeneic bone marrow transplantation, and to develop novel therapeutic strategies for BMT patients with cancer that begin in the cells of blood-forming tissue or hematologic malignancies.

James Ferrara, Ward-Coleman Professor of Cancer Medicine and director of the Center for Translational Research in Hematological Malignancies at **The Tisch Cancer Institute** at the Icahn School of Medicine at Mount Sinai, will lead the collaborative project which includes research teams at **University of Michigan-Ann Arbor**, and **Baylor College of Medicine**, as well as a consortium of 20 transplant centers that will conduct trials in GVHD.

Recent studies have demonstrated that alterations in intestinal microbiota composition are linked to GVHD, and this grant will fund research projects to investigate this intestinal environment and the role that it plays in GVHD. The studies seek to understand the ability of microbial metabolites to influence the resistance of intestinal epithelial cells to donor T-cell-mediated damage and the role of the antimicrobial peptide regenerative 3 alpha in protecting intestinal stem cells.

Researchers will also design a clinical trial of biomarker-guided therapy to prevent the development of steroid-refractory gastrointestinal GVHD.

The study will also look at how the microbiome affects immune responses, and the proposed studies will likely have implications not only in gastrointestinal GVHD but in cancer immunotherapy in general. The projects all interact, and the study is highly integrated

around a strong central theme of exploring the cellular and molecular mechanisms of GVHD to improve the care for the BMT patients.

THE UNIVERSITY OF MICHIGAN COMPREHENSIVE CANCER CENTER and **Tempus**, a health-tech company focused on personalizing cancer care, and have partnered to bring MI-ONCOSEQ to patients and healthcare providers across the country who are seeking the high quality data and analyses necessary to personalize treatment for their patients.

The MI-ONCOSEQ panel was developed at the University of Michigan under the leadership of Arul Chinnaiyan. It uses high-throughput gene sequencing techniques in a clinical setting to help find new options for cancer patients for whom either there is no standard of care for their disease, or the standard of care has proven ineffective.

With each cancer having a different molecular and genetic profile that can involve hundreds or thousands of genes, unprecedented amounts of data are needed to identify patterns that will improve the outlook for patients. Tempus has recruited a world-class team of accomplished geneticists, computational biologists, data scientists and software engineers who have developed software and analytic tools that scales the integration of molecular sequencing and analysis in the clinical setting, providing decision support for physicians whose patients are not responding to conventional therapies.

With the MI-ONCOSEQ platform, sequencing of germline and tumor DNA as well as the RNA of the tumor are used to help guide clinicians' recommendations of clinical trials or targeted therapies based on the molecular profile of each patient's tumor.

The panel has been used at University of Michigan to help guide the care of hundreds of metastatic cancer patients. In addition, researchers have made new discoveries in both common tumors - for example, a mutation in the estrogen receptor that makes breast cancer resistant to aromatase inhibitors - and rare tumors, such as a gene fusion in solitary fibrous tumor.

Chinnaiyan serves as a scientific adviser to Tempus.

MERCK KGaA announced the recipients of the **2016 Grant for Oncology Innovation**, who will share a EUR1 million grant to progress their respective research initiatives. The winners were formally awarded Oct. 9 evening at an award presentation coinciding with the 2016 annual **European Society for Medical Oncology Congress** in Copenhagen.

The three winning proposals, which focus on breast cancer, colorectal cancer, and lung cancer, were selected from a total of 405 applications representing 49 countries, following a comprehensive review by an expert scientific steering committee made up of internationally renowned oncologists. These awards mark the third year for GOI.

The 2016 GOI winners are:

• **Alberto Bardelli,** University of Torino, Italy, for his proposal: "Heterogeneity and clonal evolution as a therapeutic opportunity for colorectal cancers"

• **Enriqueta Felip**, Vall d'Hebron Institute of Oncology, Spain, for her proposal: "New technologies for new treatments: liquid biopsy meets immunotherapy"

• **Dongxu Liu**, Auckland University of Technology, New Zealand for his proposal: "How does SHON expression in tumors determine the efficacy of endocrine therapy in breast cancer?"

RESEARCH!AMERICA's 21st annual Advocacy Awards will honor advocates for research whose contributions to health and medicine have saved lives and improved quality of life for patients worldwide. The event will take place March 15, 2017, at the Andrew W. Mellon Auditorium in Washington, DC.

The 2017 Advocacy Award winners announced Oct. 6, with additional awardees to be named in the coming weeks, are:

• **Anthony Fauci**, who will receive the Legacy Award, is the director of the National Institute of Allergy and Infectious Diseases at NIH. Since his appointment as NIAID director in 1984, Fauci has overseen an extensive research portfolio devoted to preventing, diagnosing, and treating infectious and immune-mediated diseases. Fauci also is chief of the NIAID Laboratory of Immunoregulation, where he has made numerous important discoveries related to HIV/AIDS and is one of the most-cited scientists in the field. Fauci serves as one of the key advisors to the White House and Department of Health and Human Services on global AIDS issues, and on initiatives to bolster medical and public health preparedness against emerging infectious disease threats such as Ebola and pandemic influenza.

• **Phillip Sharp**, institute professor at the Massachusetts Institute of Technology, has been selected to receive the Raymond and Beverly Sackler

Award for Sustained National Leadership for his powerful advocacy efforts for cancer research, serving as chairman of Stand up to Cancer's Scientific Advisory Committee since the organization's inception in 2008. His research interests have centered on the molecular biology of gene expression relevant to cancer and the mechanisms of RNA splicing. His landmark achievement was the discovery of RNA splicing in 1977. This work provided one of the first indications of the startling phenomenon of "discontinuous genes" in mammalian cells. The discovery that genes contain nonsense segments that are edited out by cells in the course of utilizing genetic information is important in understanding the genetic causes of cancer and other diseases. This discovery, which fundamentally changed scientists' understanding of the structure of genes, earned Sharp the 1993 Nobel Prize in Physiology or Medicine.

• **Leland Hartwell**, Nobel laureate and director of the Center for Sustainable Health at Arizona State University's Biodesign Institute and Virginia G. Piper Chair of Personalized Medicine, is selected to receive the Geoffrey Beene Builders of Science Award, for his leadership and determination in building an outstanding scientific research organization as president and director of the Fred Hutchinson Cancer Research Center from 1997 to 2010. His leadership further elevated FHCRC into a premier research center working to prevent, diagnose and treat cancer, HIV/AIDS and other diseases. In 2010, Leland Hartwell joined the Arizona State University where he has appointments in the Schools of Education, Biomedical Engineering, and Sustainability. He leads a team that teaches Sustainability Science for all pre-service K-8 Teachers, and aspires to provide continuing education, internationally, for in-service teachers. In addition, Hartwell leads the HoneyBee program at ASU overseeing a series of small clinical trials using wearable devices to monitor physiological parameters in clinical patients for a variety of diseases.

• **The Lupus Foundation of America** has been selected to receive the Paul G. Rogers Distinguished Organization Advocacy Award. LFA was founded in 1977 when a group of more than two dozen independent local lupus organizations came together to provide national leadership for lupus research, patient and professional education, and public awareness. Since then, LFA has grown to become the nation's leading nonprofit voluntary health agency dedicated solely to lupus by providing national, state, and local programs through a nationwide network of more than chapters and support groups. LFA provides grants to researchers working on promising studies that could save and improve lives. Investigators who have received funding from LFA have made contributions towards achieving many of the most important advances in research on lupus including the development of one of the first diagnostic test specifically for lupus and discoveries in specific risk factors and biomarkers.

The annual Research!America Advocacy Awards program was established by the Board of Directors in 1996 to honor outstanding advocates for medical, health and scientific research.

Drugs and Targets

Genentech receives second Breakthrough Therapy Designation from FDA for Alecensa

GENENTECH, a member of the Roche Group, received a second **Breakthrough Therapy Designation** from FDA for its anaplastic lymphoma kinase inhibitor, Alecensa (alectinib). The latest BTD was granted for the treatment of adult patients with advanced ALK-positive non-small cell lung cancer who have not received prior treatment with an ALK inhibitor.

"The J-ALEX study that supports the second Breakthrough Designation for Alecensa showed superior efficacy versus the standard of care, crizotinib, in Japanese people with advanced ALK-positive disease," said Sandra Horning, M.D., chief medical officer and head of Global Product Development. "The decision by the FDA to grant a second Breakthrough Therapy Designation is recognition of the clinically meaningful improvement in efficacy and safety that Alecensa brings to the care of people with advanced ALK-positive lung cancer who have not received prior treatment with an ALK inhibitor."

Alecensa received its first FDA BTD in June 2013 for people with ALK-positive NSCLC whose disease progressed on treatment with crizotinib.

Alecensa was granted accelerated approval in December 2015 for the treatment of ALK-positive NSCLC who have progressed on or are intolerant to crizotinib. ALEX, a global, randomized Phase III study, is ongoing, comparing Alecensa to crizotinib as an initial (first-line) treatment for people with advanced NSCLC whose tumors were characterized

as ALK-positive by a companion VENTANA ALK (D5F3) CDx Assay immunohistochemistry (IHC) test developed by Roche Tissue Diagnostics. This study is part of the company's commitment to convert the current accelerated approval in people with ALK-positive, metastatic NSCLC who have progressed on or are intolerant to crizotinib to a full approval as an initial treatment.

The J-ALEX study conducted by Chugai is an open-label, randomized Phase III study that compared the efficacy and safety of Alecensa to crizotinib in Japanese people. The J-ALEX study enrolled 207 people with ALK-positive, advanced or recurrent NSCLC who had not been previously treated with an ALK inhibitor. People were randomized to the Alecensa group or the crizotinib group in a one-to-one ratio. Results include:

• Alecensa reduced the risk of disease worsening or death (progression free survival, PFS) by 66 percent compared to crizotinib (HR=0.34, 99 percent CI: 0.17-0.70, p<0.0001).

• Median PFS was not reached in the Alecensa arm (95 percent CI: 20.3 months-not estimated) versus 10.2 months in the crizotinib arm (95 percent CI: 8.2-12.0).

• Grade 3-4 adverse events (AEs) occurred with greater frequency in the crizotinib arm compared to the Alecensa arm (27 percent vs. 51 percent)

• The most common AE occurring with > 30 percent frequency with Alecensa was constipation (36 percent). The most common AEs for crizotinib were nausea (74 percent), diarrhea (73 percent), vomiting (59 percent), visual disturbance (55 percent), alteration in taste (dysgeusia; 52 percent), constipation (46 percent), and an elevation in liver enzymes called alanine transaminase (ALT, 32 percent) and aspartate transaminase (AST, 31 percent).

GAMIDA CELL said FDA has granted **Breakthrough Therapy Designation** to the company's lead product candidate, NiCord, in development as a novel graft modality for bone marrow transplantation in patients with high risk hematological malignancies.

The international, multi-center phase III registration study of NiCord is planned to begin before the end of the year, the company said.

Data from the Pilot, and phase I/II studies of NiCord to date, have demonstrated clinically meaningful improvement in time to neutrophil engraftment over cord blood transplantation, the company said. Additionally, NiCord study data have shown fewer infections, reduced length of hospitalization, quicker platelet engraftment and improved non-relapse mortality when compared to unmanipulated cord blood transplantation.

FOUNDATION MEDICINE, INC. announced the addition of new clinical markers to its **FoundationOne** and **FoundationOne Heme** products, which are designed to enhance oncologists' insight into potential response to immunotherapies.

This ability to determine TMB and MSI from its assays is additional to the existing comprehensive profiling of genes provided by FoundationOne and FoundationOne Heme. Taken together, the molecular information provided by Foundation Medicine enhances physicians' ability to predict response to immunotherapies, identify targeted therapeutic options, and improve access to clinical trials all from a single assay.

"Cancer immunotherapies are at the forefront of cancer treatment, and new, quantitative approaches are needed to predict clinical responses to this important, but also expensive, class of therapies," said **Vincent Miller**, chief medical officer of Foundation Medicine. "Prior to our ability to measure TMB and MSI with FoundationOne, these biomarkers could only be detected separately, either through tests such as immunohistochemistry, polymerase chain reaction or whole exome sequencing. Importantly, high-quality, predictive TMB scoring can only be accurately performed with sophisticated algorithms developed to work with broad, hybrid capture-based platforms that can analyze all relevant alterations simultaneously. Integrating this capability to measure TMB and MSI with one tissue sample, and reported in one test, represents an important advance in clinical care."

A growing body of evidence, most recently presented at the **American Society of Clinical Oncology** annual meeting this year, validates the ability of a new independent marker, TMB, to predict the likelihood of response to cancer immunotherapies. TMB is reported as the total number of DNA mutations per megabase in a tumor sequence. This phenomenon has been validated across a wide range of tumor types, including advanced bladder cancer, lung cancer, breast cancer, colorectal cancer, advanced head and neck cancer and melanoma. Some tumors develop high TMB as a result of defective mismatch repair of DNA, a condition in which the length of certain DNA areas becomes more widely varied than normal. This condition, which is referred to as MSI-high and MSI-

high tumors, almost always has a high TMB.

ABBVIE said **Health Canada** has issued a Notice of Compliance with Conditions for **Venclexta** (venetoclax). The therapy has been approved for previously treated chronic lymphocytic leukemia patients, who have either a genetic mutation, known as 17p deletion, or no other available treatment options. Under NOC/c policy, AbbVie will provide Health Canada with data from additional studies to confirm the clinical benefit of Venclexta.

Venclexta is a first-in-class, oral, once-daily medicine that works by inhibiting the BCL-2 protein, which is responsible for helping cancer cells survive in the blood. The BCL-2 protein blocks apoptosis (programmed cell death) of cells, including some cancer cells that can be overexpressed in CLL. In phase 2 clinical trials, patients taking Venclexta had an overall response rate of 79 percent.

Venclexta is being developed by AbbVie and **Genentech**, a member of the Roche Group. It is jointly commercialized by the companies in the U.S. and by AbbVie outside of the U.S.

THE US ONCOLOGY NETWORK selected **Myriad Genetics** as its preferred provider laboratory for hereditary cancer testing.

As part of the collaboration, Myriad and The US Oncology Network will work together to perform hereditary cancer research through the Genetic Risk Evaluation and Testing program within The Network affiliated practices.

Under this program, the two organizations will collaborate to create a database that links patient outcomes with genetic test results. Principal among the research aims of this program is to better understand the genotype-phenotype correlation, gene prevalence, and research related to improving patient counseling and access to testing.

Funding Opportunities

Pershing Square Sohn Cancer Research Alliance Accepts Applications for Prize for Young Investigators in Cancer Research

THE PERSHING SQUARE SOHN CANCER RESEARCH ALLIANCE is accepting applications for its **Prize for Young Investigators in Cancer Research.**

The prize of $200,000 per year for up to three years is awarded annually to at least five New York City-based scientists, enabling them to continue to pursue explorative and high-risk/high-reward research at a stage when traditional funding is lacking.

Now entering its fourth year, the prize aims to help bridge the gap between academia and the business community while supporting young scientists at a formative stage in their careers. To facilitate these collaborations, each prize winner is given a mentor in the pharmaceutical industry and the opportunity to present his or her work to scientific and business audiences.

In May 2016, PSSCRA awarded the prize to seven new winners: Omar Abdel-Wahab, Memorial Sloan Kettering Cancer Center; Uttiya Basu, Columbia University Medical Center; Christopher Mason, Weill Cornell Medicine; Agnel Sfeir,, NYU School of Medicine; Samuel Sidi, Icahn School of Medicine at Mount Sinai; Christopher Vakoc, Cold Spring Harbor Laboratory; Andrea Ventura, Memorial Sloan Kettering Cancer Center.

To apply for the prize, applicants must have between two to eight years of experience running their own laboratories and must have a PhD, MD or MD-PhD (or equivalent). The deadline to submit the Letter of Intent is Nov. 7. For details on the application process, visit: www.psscra.org.