THE CANCER LETTER

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Pharma Industry Critics Seek Grassroots Support

By Paul Goldberg

Many people are studying the rising prices of cancer drugs. A growing group of oncologists want to do something different: they want to give them a downward push.

Last week, a group of 118 oncologists signed an editorial published in the Mayo Clinic Proceedings in which they laid out seven specific actions that they argue would moderate drug prices.

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Conversation with The Cancer Letter

The War on Cancer (Drug Prices): Political Education of Hagop Kantarjian

Here is what Hagop Kantarjian has learned over the past two years of his campaign to lower the prices of cancer drugs:

People would rather avoid disputing you head-on.

Instead, they seek to draw you into a *process*. And as this process drags on, things remain as they are.

Kantarjian, chair of the Department of Leukemia at MD Anderson Cancer Center, is too savvy and too impatient to get sucked into chasing elusive solutions.

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Baylor Earns Comprehensive Designation; Tisch Institute Becomes NCI Cancer Center

B*y Matthew Bin Han Ong*

The Dan L. Duncan Cancer Center at Baylor College of Medicine and the Tisch Cancer Institute at the Icahn School of Medicine at Mount Sinai received NCI designations this week.

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Pharma Industry Critics Seek Grassroots Support

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The editorial cites a petition on Change.org, a social media platform routinely used to get hundreds of thousands signatures for campaigns, including ones to convince drug companies to provide developmental drugs to individual patients on compassionate basis, or to bring attention to medical practices including the use of power morcellation.

"A cancer patient-based grassroots movement that advocates against the high price of cancer drugs can accomplish a great deal," the Mayo Clinic Proceedings editorial states. "Should this petition or any other similar grassroots efforts generate in aggregate an immense number of unique supporters (e.g., >1 million petition signees or a comparable mass action quantified in other terms), this quantified support can then be used by advocates, lobbyists, and others to advocate against the aforementioned harms generated by the high price of cancer drugs."

The seven actions listed in the paper are:

(1) Creating a post-FDA drug approval review mechanism to propose a fair price for new treatments, based on the value to patients and heath care.

(2) Allowing Medicare to negotiate drug prices.

(3) Allowing the Patient-Centered Outcomes Research Institute, created through the Affordable Care Act initiatives to evaluate the benefits of new treatments, and similar organizations to include drug prices in their assessments of the treatment value.

(4) Allowing importation of cancer drugs across borders for personal use (e.g., prices in Canada are about half of prices in the U.S.).

(5) Passing legislation to prevent drug companies from delaying access to generic drugs (pay-for-delay).

(6) Reforming the patent system to make it more difficult to prolong product exclusivity unnecessarily (patent "evergreening").

(7) Encouraging organizations that represent cancer specialists and patients (e.g., American Society of Clinical Oncology, American Society of Hematology, American Association for Cancer Research, American Cancer Society, National Comprehensive Cancer Network) to consider the overall value of drugs and treatments in formulating treatment guidelines.

Focusing on Prices

"When you consider that cancer will affect one in three individuals over their lifetime, and [with] recent trends in insurance coverage [that] put a heavy financial burden on patients with out-of-pocket expenses, you quickly see that the situation is not sustainable," said Ayalew Tefferi, a hematologist at Mayo Clinic and lead author of the paper. "It's time for patients and their physicians to call for change."

An interview with Tefferi and the Mayo Clinic is available here.

The editorial and the petition are direct, more focused outgrowth of a campaign launched by Hagop Kantarjian, chair of the Department of Leukemia at MD Anderson Cancer Center.

Kantarjian's conversation with The Cancer Letter appears on page 1.

The Change.org petition has received over 20,000 supporters so far.

Many key players in oncology are focused on the price of cancer drugs. ASCO published the conceptual framework for assessment of value of cancer therapies (The Cancer Letter, June 26). Similarly, Peter Bach, a researcher at Memorial Sloan-Kettering Cancer Center, released his DrugAbacus tool for assessing the value of cancer drugs (The Cancer Letter, June 19).

These petitions have been known to succeed on occasion, prompting companies to make drugs available to individual patients, but drug pricing is infinitely more complex than turning over an unstudied agent to one person who wants it.

So far, the only case where a drug company has rolled back its price occurred three years ago, when top doctors at Memorial Sloan-Kettering Cancer Center said publicly that they would exclude a Sanofi drug from the center's formulary because it was priced twice as high

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as an analogous drug (The Cancer Letter, Nov. 16, 2012; Nov. 8, 2012; Nov. 2, 2012).

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• Marc Stewart, Seattle Cancer Care Alliance

• Michael Thompson, Aurora Research Institute, Aurora Health Care

• Julie Vose, University of Nebraska Medical Center

• Peter Wiernik, Cancer Research Foundation

Conversation with The Cancer Letter

The War on Cancer (Drug Prices)

(Continued from page 1)

His next course of action is to change the game entirely, by building a political constituency for lowering drug prices.

Kantarjian described the lessons learned and his current game-changing strategy in conversation with Paul Goldberg, editor and publisher of The Cancer Letter.

Paul Goldberg: *You've been on this quest for almost two years—politically, what have you learned? How does the system function?*

Hagop Kantarjian: I have realized that even when people were willing to engage in discussion, often there was no forward movement.

Each of the interested parties kept repeating their previous arguments. Since there was no movement, we had to do something different.

What we are doing is proposing solutions that will make the market forces work better; and second, we are engaging cancer patients in the same way that AIDS patients successfully engaged in advocating for their medical care. Patients with cancer are hurting and they are being harmed by high cancer drug prices, which make treatments unaffordable and thus unavailable.

We must have a strategy that will reduce the cancer drug prices.

And there are some straightforward solutions, such as allowing the importation of drugs for personal use from Canada; encouraging ASCO and other organizations to develop pathways that incorporate drug prices, what they refer to now as treatment values;

and encouraging the development of an FDA approval mechanism that sets a fair price for cancer drugs.

I have proposed these solutions in several editorials, and then began to consider the immense potential if we were to help build a new patient engagement movement. After just a few months, this grassroots concept has begun to blossom. This group of determined patients, with a small bit of assistance, was instrumental in launching a petition on Change.org, just a few months ago in early March.

Together we are gathering online support signatures. The overall goal is to collect enough signatures, so that we can go to our legislators and tell them: Here are our signatures. Our petition represents real cancer patients—we are not just another special interest group. We want to put an end to high cancer drug prices. Most recently, as oncologists, we helped publicize the Change.org petition.

Last week, 118 leading cancer experts wrote an editorial in support of the petition which was published in the Mayo Clinic Proceedings. Our goal was to purposely advance the cause, and help highlight the harm of high cancer drug prices and the critical need to control them. The public heard about us via an overwhelming response by the mainstream media who covered our editorial. But this is just the start of a battle yet to be won on behalf of our patients.

PG: *It's interesting how conflicts are not really resolved; everybody just repeats their points. Disputants don't meet each other at a halfway point. So you're at the next point, where you're actually doing something to move people off dead center. Is that correct?*

HK: Correct. So far our original move to highlight the cancer drug prices and to get the drug companies to pay attention to that has not made the companies change their pricing.

In fact, what we saw from 2012 to now is continued increases in high cancer drug prices. In 2012, the cancer drug prices came at close to $100,000 a year. In 2014, all of them came to close to $120,000 a year, and there continues to be an average 10-percent increase in the prices of the old cancer drugs.

To give an example, Gleevec, which was priced at $92,000 a year in 2012, became $132,000 a year in 2014.

So not only are the drug companies not paying attention, but they are continuing along the same path of increasing drug prices in an exorbitant and greedy fashion, and they are harming the patients more and more.

PG: *How much support have you received from oncology organizations in this? Do you feel that they are doing what they can?*

HK: I think they are doing what they can, in the sense that they continue to be quite dependent on the pharmaceutical companies.

It was very encouraging to see that ASCO, and perhaps ASH, have moved into discussions of pathways that highlight treatment value. But they have shied away from supporting the petition, because they felt that it was not in line with the initiative of ASCO, which is developing pathways that incorporate treatment value—which considers not only the price of the drug, but the respective benefits.

And I think it's a good movement.

But I think cancer societies are wary of the influence of pharmaceutical companies, and they try to be more modest and moderate in their advocacy.

PG: *And obviously you've moved in a different direction. What's next? You have a petition. How would you be seeking to force the companies to change?*

HK: I think next—the ball is in the court of the patients.

They have to realize and they have to be hurt enough to create a louder voice in the discussion.

Patients who read this article have a link to the Change.org petition. When we reach our goal in signatures—a target in excess of 100,000, or even one million signatures—then we will deliver our petition to the White House and to Congress. We will ask Washington to join us in supporting cancer patients by implementing the proposals as outlined in our petition.

And when we accomplish the implementation of legislation as discussed in the petition, this will create strong market forces to lower drug prices.

PG: *Do you think this is viable as a political strategy?*

HK: I think it is. We are in a democracy.

If we have so many hundreds of thousands or millions of Americans with cancer who are hurting, and if these Americans present a strong voice to their legislators through the petition, then our elected representatives have to represent Americans rather than the drug companies—unless our system has turned from a democracy to a 'pharmaceutocracy.'

PG: *This is the first time I heard this term. Have you just coined it?*

HK: I coined it in a previous editorial, but I think it will catch on.

PG: *In the drug pricing arena, there are players who want to moderate the prices for their own capitalistic reasons—and that's the payers. Not the government, but private payers. Have they been helpful to you in any way?*

HK: I've been approached by some payers and we have discussed some potential strategies of mutual benefit, but they have not joined us, because I believe that they are concerned that their engagement will result in a direct war between insurance companies and drug companies.

PG: *Do you need an organization of some sort to help you? Do you need to create an organization? How do you do this?*

HK: Patient support groups have to step into the arena and take this on the same way that patients with AIDS did.

The problem with patients with cancer, in contrast with patients with AIDS, is that the patients with AIDS were younger, they lived longer, they were savvy about their advocacy, and they were desperate.

Their advocacy had an immediate impact. Within a few years you saw a complete change in the approach to AIDS research and discovery. And over 10 years, we now have over 30 drugs that work with AIDS, and patients live their normal lives.

When you look at the price pattern yearly, patients with AIDS pay anywhere between $10,000 and $18,000 a year per year lived. So why is it that patients with cancer have to pay $120,000-plus per year lived? I think that's the analogy that we have to be looking at.

Patients with cancer need to start organizing and becoming more vocal, and the petition is one way for them to become more engaged with the discussion.

PG: *If I could make an observation, I've been covering patient advocacy for 30 years or so, and patient groups have always been very dependent on support from pharma companies. Most patient groups.*

HK: I realize this—when the petition came online, there were some patient advocacy groups that contacted me, and they were encouraging the process, but they were very concerned that if they became more visible about it, that the drug companies would cut their support.

What I have realized, is that many of the cancer patient groups are so dependent on the drug companies that they have become an arm; they have become de facto spokespersons for the drug companies.

When we launched the petition, I noticed that there were particular patient advocacy groups that took positions against the petition, and I think that's because they were enticed by the drug companies that support them to do so.

PG: *It's an uphill battle?*

HK: It is. But I know that the patients are strong. They will adopt and support this cause and take this on, realizing that many of them are hurting and dying from the complications from cancer because they simply cannot afford these expensive treatments. But still, there will be some of the current patient advocacy groups who are simple extensions of the drug companies, because they are so dependent on the drug companies' support.

PG: *So basically what has to happen is that the grassroots have to be redefined. It's not the patient groups that exist. It's the patient groups that need to be formed.*

HK: Yes, there must emerge a true grassroots patient group—an independent leadership group who will speak on behalf of the patients, that does not just repeat what the drug companies try to tell them to say.

Baylor Granted Comprehensive Designation; Tisch Designated As NCI Cancer Center

(Continued from page 1)

The Duncan Cancer Center—which was named an NCI-designated cancer center in 2007—was awarded the Comprehensive Cancer Center designation, which includes a $14.56 million, five-year grant. The designation moves the cancer center into an elite class of 45 centers in the U.S. whose programs demonstrate significant depth and breadth in basic, clinical and translational research.

TCI has been named an NCI-designated cancer center, making it the 69th cancer center to earn designation, and it received a five-year, $8.5 million grant to complement the $79 million in cancer research grants awarded to TCI.

The applications for both institutions were rated as outstanding, said Henry Ciolino, acting director of the NCI Office of Cancer Centers.

"Mount Sinai showed a particular expertise in immunology and liver carcinogenesis signaling pathways," Ciolino said to The Cancer Letter. "They described a very unique catchment area in the Upper East Side of New York, including central and east Harlem—40 percent of their accruals to therapeutic clinical trials were from those two areas.

"Baylor was judged to have the depth and breadth necessary to be promoted to the level of a Comprehensive Cancer Center. In particular, we were impressed with their work on the Texas Children's Hospital in pediatric oncology."

The Huntsman Cancer Institute at the University of Utah and the University of New Mexico Cancer Center also received comprehensive designations this month

(The Cancer Letter, July 10).

There will not be any additional designations this year, Ciolino said.

"This was the entire fiscal year 2015 cohort of centers that were reviewed. We don't make funding decisions until after all centers are reviewed," Ciolino said. "We won't have any new information about new centers or comprehensive centers until May or June of next year."

The Duncan Cancer Center has been focused on achieving comprehensive status since its inception in 2006, said Kent Osborne, director of the Duncan Cancer Center.

"This means you meet the highest standards set forth by the National Cancer Institute," Osborne said in a statement. "Each cancer center undergoes a rigorous review process to achieve the highly-coveted comprehensive designation."

NCI commended TCI for excellence in basic science, clinical research, and community-based outreach.

"The NCI designation recognizes our deep commitment to advance the field of cancer research, treatment, and prevention, and to bring these innovations to cancer patients and their families," said Steven Burakoff, Lillian and Henry M. Stratton Professor of Cancer Medicine and director of TCI. "The designation reflects Mount Sinai's significant investment in cancer research, world-class faculty, and cutting-edge facilities."

Dramatic Growth

Over the last five years, the Duncan Cancer Center's research portfolio has increased dramatically, Osborne said.

"Research funding since the initial NCI-designation in 2007 has grown from approximately $99 million to $152 million annually," Osborne said. "This is an impressive statistic given that many cancer centers have seen significant cutbacks in research funding."

In 2011, the cancer center recruited Melissa Bondy, an epidemiologist. Bondy, a McNair Scholar, together with Hashem El-Serag, professor of medicine-gastroenterology at Baylor, lead the Cancer Prevention and Population Sciences Program.

Osborne said the program has made significant contributions to molecular and genetic epidemiology and behavioral research in addiction and tobacco cessation, obesity, brain, breast, liver and esophageal cancers—the latter two being the most rapidly increasing cancers in Texas.

"Our affiliated hospitals are critical and key to our research and clinical care programs," said Osborne. "They each involve a different patient population, allowing us to cover all segments of our community, which is a huge advantage for us."

Seventy percent of the patients seen in the Duncan Cancer Center affiliates come from Harris County.

The Texas Children's Cancer Center, one of the largest children's cancer centers in the country, serves 50 percent of all pediatric cancer patients in Texas and 90 percent from the Houston region. Its research program received the highest possible "exceptional" rating on the recent NCI evaluation.

"The NCI designation of comprehensive status confirms the excellence of the research—both in the lab and the clinic—being conducted in our center and importantly highlights the relevance of our research to the types of cancer most prevalent in our community", said David Poplack, director of the Texas Children's Cancer Center and deputy director of the Duncan Cancer Center.

Duncan Cancer Center physicians also provide care through Baylor St. Luke's Medical Center, a joint venture of Baylor and Catholic Health Initiatives St. Luke's Health, as well as through the College's outpatient practices.

"There are many new exciting adventures ahead as we plan for our new hospital and facilities at Baylor St. Luke's, as well as design and build our new outpatient cancer center clinical space on the McNair campus to provide our patients with new state-of-the-art facilities for their care," Osborne said.

At TCI, recent growth has included the recruitment of a number of prominent physicians and researchers—55 overall in the last seven years—including William Oh, associate director for clinical and translational research and chief of hematology and medical oncology; Randall Holcombe, deputy director and chief medical officer for cancer; Marshall Posner, associate director for clinical trials infrastructure and medical director of head and neck cancer; and Paolo Boffetta, associate director for population science and director of translational epidemiology.

In its assessment, NCI praised Burakoff's leadership in recruiting strong leaders at TCI.

"Through Dr. Burakoff's leadership, Mount Sinai has become a national leader in basic, clinical, and population cancer research and treatment," Kenneth Davis, president and CEO of the Mount Sinai Health System, said in a statement. "The strengths in research that were central to our NCI designation include harnessing the immune system to attack cancer cells,

studying the impact of environmental toxins on cancer, understanding liver cancer biology, and based on our unique New York ethnic communities, studying the genetic differences and care disparities that drive greater cancer risk in some patients."

The following TCI research programs were highlighted in the NCI application and commended for their strong foundation and national acclaim:

• **Cancer Immunology**, led by Nina Bhardwaj and Miriam Merad, which addresses anti-tumor immunity and fosters the development of cancer vaccines;

• **Cancer Mechanisms**, led by Ramon Parsons and Ross Cagan, which seeks to understand the biology of cancer cell development;

• **Liver Cancer**, led by Scott Friedman and Josep Llovet, whose focus is to discover novel approaches to diagnose and treat liver cancer; and

• **Cancer Prevention and Control**, led by Boffetta and William Redd, which addresses the important aspects of primary and secondary cancer prevention.

"The Tisch Cancer Institute at Mount Sinai reflects a vital trend seen in recent years: real world, complex medical problems being solved by teams that successfully integrate many disciplines," said Dennis Charney, Anne and Joel Ehrenkranz Dean of the Icahn School of Medicine at Mount Sinai and president for academic affairs for the Mount Sinai Health System. "The NCI designation is based on our exceptional leadership, extensive research facilities, and an institution-wide commitment to research, including a focus on the role of genetics, obesity, and diabetes in cancer.

"The NCI designation will facilitate expansion of novel treatment options and clinical trials for patients throughout the Mount Sinai Health System."

Guest Editorial

Kids v Cancer: Laws Need to Catch up to the Science

By Nancy Goodman

Emma Whitehead was a six-year-old girl battling relapsed leukemia for the third time when her parents were told she had run out of treatments. Her doctors offered one last hope—enrollment in a clinical trial at Children's Hospital of Philadelphia in a completely new immunotherapy. It was a phase I toxicity trial for both children and adult patients, and few patients on phase I trials are ever cured. But Emma's family was given the miracle they had prayed for. Five years later, Emma is now a happy, healthy, 11-year-old girl who likes to play piano and soccer. Emma is cured.

It's a beautiful story and one that you'd love to hear over and over again. However, you won't. In the United States, drug companies have no obligations to study their promising, possibly curative cancer drugs on kids with cancer.

Kids with cancer are the last, not to first, to get on trials of promising new drugs. And, when drug companies abandon their unapproved cancer drugs, as they do 95 percent of the time for all sorts of reasons, the chance to study those drugs for kids with cancer goes away forever.

There is a law in the United States, the Pediatric Research Equity Act, which was designed to address this problem. PREA requires companies developing drugs for adult indications to also develop them for children who suffer from the same indication. However, PREA doesn't protect kids with cancer because kids don't get breast cancer or prostate cancer. The problem is that PREA was written before cancer drugs were developed as targeted therapies with mechanisms of action that might be common between adult cancers, such as breast cancer, and pediatric cancers, such as neuroblastoma. PREA is out of date.

Kids v Cancer has been advocating for the Kids Innovative Drugs Initiative to update and modernize PREA and Best Pharmaceuticals for Children so that the law catches up to the science, and kids with cancer are covered.

Some want to wait at least two years and try to revise PREA and BPCA in the 2017 reauthorization of Prescription Drug User Fee Act, but that is always a highly uncertain process and there is both urgency and opportunity to act now. A large coalition with more than 100 patient advocacy groups and major hospitals is urging Congress to ensure that the 21st Century

Cures Act provides cures not just for adults, but for kids with cancer, too.

Last week, kids with cancer achieved a major victory when the European Union's European Medicines Agency revoked existing waivers on drug companies' obligations to study certain drugs in kids, including cancer drugs, when there was a common mechanism of action or a pharmaceutical receptor commonality between the adult and pediatric disease. This decision was a much needed correction to update European law to take into account the shift in cancer research.

It's a great victory that the EMA will now require companies to study cancer drugs in kids, but now, more than ever, we need the United States Congress to pass the KIDS Initiative.

The EMA decision will bring more drugs into clinical trials for kids with cancer, but those trials will largely be in Europe, not in the United States. Without the passage of the KIDS Initiative, American kids with cancer still will not have access to trials for promising, potentially live saving unapproved cancer drugs.

Moreover, to comply with these new European regulatory requirements, companies will turn away from the U.S., and U.S. pediatric researchers are concerned that they will have an even more difficult time accessing unapproved drugs for their research or receiving industry funding. It's great that the 21st Century Cures bill recently passed by the House of Representatives provides significant additional funding to NIH, but for pediatric researchers, if they can't get access to unapproved drugs, then they still cannot do their research.

Finally, the EMA program on pediatric development has some problems as well, problems that the U.S. could help fix if the KIDS Initiative were passed into law here in the United States. If the KIDS Initiative were enacted in the U.S., then FDA would have the authority to review and require pediatric cancer studies at the same time as the EMA. The FDA could work with the EMA to ensure that the prioritization of drugs studied for kids with cancer is based on which drugs are most promising for children, not which companies are the quickest in developing drugs for adults.

So, congratulations to the Europeans. They have done right by kids with cancer and other diseases for which targeted therapies are developed. Now, let's pass the KIDS Initiative to bring those benefits home quickly to kids in the United States.

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

In Brief

Schulam to Serve as Interim Director of Yale Cancer Center As Lynch Plans to Step Down

THOMAS LYNCH JR., director of **Yale Cancer Center** and physician-in-chief of Smilow Cancer Hospital at Yale-New Haven, will leave Yale in August to become chairman and chief executive officer of the Massachusetts General Physicians Organization.

Peter Schulam, professor of urology and chief of Yale's Department of Urology, will serve as the interim director of Yale Cancer Center and physician-in-chief at Smilow.

Lynch joined Yale Cancer Center as director in 2009 and assumed the role of inaugural physician-in-chief at Smilow, which opened that year. During his tenure, more than 130 scientists and clinicians joined the institutions, new-patient volume grew from 3,500 to 9,000 through key affiliations, and participation in therapeutic clinical trials grew by 325 percent.

The center also renewed its NCI Comprehensive Cancer Center Grant, and joined the NCI's National Clinical Trials Network and the National Comprehensive Cancer Network.

Schulam joined in 2012 as inaugural chief of the Department of Urology at Yale-New Haven Hospital and chair of the department at Yale School of Medicine, where he has established a multidisciplinary team in urologic oncology. He has implemented a program for MRI-fusion guided biopsy of prostate cancer and leads a research program focused on prostate cancer imaging. In addition, he co-founded the Yale Center for Biomedical and Interventional Technology.

KAREN RECKAMP was named medical director for clinical research operations at **City of Hope**.

In this newly created position, Reckamp will expand her current role as chair of the Cancer Protocol Review and Monitoring Committee. She will also serve as medical director of the Clinical Trials Unit and as coordinating liaison for pharmaceutical contracts, as well as share responsibility for the review and selection of clinical trials within City of Hope.

Reckamp is also co-chair of the institution's Lung Cancer and Thoracic Oncology Program. She is currently principal investigator for an arm of the NCI-MATCH trial.

Reckamp joined City of Hope in 2007, as assistant professor of medicine in the Department of Medical Oncology & Therapeutics. In 2012, she became

associate professor in the Department of Medical Oncology & Therapeutics Research and co-director of the Lung Cancer and Thoracic Oncology Program.

She received her medical doctorate from the University of Chicago Pritzker School of Medicine, and her Master of Science degree from the University of California, Los Angeles, where she also received specialized training in advanced research and clinical research. She completed a fellowship in hematology/oncology at UCLA, and an internship and residency at Barnes-Jewish Hospital in St. Louis.

TIMOTHY LASH was named leader of the Cancer Prevention and Control Research Program at **Winship Cancer Institute of Emory University**.

Andrew Miller will continue to serve as co-leader of the program. Lash succeeds Roberd "Robin" Bostick, who served as leader of the program since 2008.

Lash is a professor of epidemiology in the Emory University Rollins School of Public Health; he joined the university in 2013. His research focuses on molecular biomarkers that predict cancer recurrence. He also is interested in age-related disparities in the quality of cancer care.

Earlier this year, Lash was among a select group that received the Emory 1% Award recognizing faculty whose competitive research grant application is ranked in the first percentile. Lash also serves as the editor-in-chief of Epidemiology. He previously held faculty appointments at Wake Forest University School of Medicine, the University of Aarhus in Denmark, and Boston University's Schools of Public Health and Medicine.

THE CENTRE FOR DRUG RESEARCH AND DEVELOPMENT and the **Ontario Institute for Cancer Research** announced a call for pre-proposals from Canadian academic investigators focused on early-stage technologies.

The two organizations are looking to collaborate on projects that will advance the preclinical development of targeted therapeutics or approaches including small molecules, biologics and cell-based therapies.

Unlike traditional grants, CDRD and OICR will work in partnership with academic investigators to develop collaborative project plans addressing the steps required to advance cancer therapies from the lab to the clinic. Projects will be milestone-driven with clear go/no-go decision points with budgets depending on the scope of the project.

More information on the program can be found on the CDRD website.

Drugs and Targets

Lenvima Receives Breakthrough Therapy Designation from FDA

FDA granted a Breakthrough Therapy Designation to Lenvima (lenvatinib) in patients with advanced or metastatic renal cell carcinoma who were previously treated with a vascular endothelial growth factor-targeted therapy.

Lenvima is indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer. Lenvima is not indicated for patients with metastatic renal cell carcinoma.

Lenvima received the designation based on results of a phase II open-label, multicenter study involving 153 patients who were previously treated with a VEGF-targeted therapy and randomized 1:1:1 to receive Lenvima and everolimus (18+5 mg once a day), Lenvima (24 mg once a day) or everolimus (10 mg once a day).

Nearly all patients (99 percent) had received one prior VEGF-targeted therapy, 1 percent had received two prior VEGF-targeted therapies, and 18 percent had received prior immunotherapy treatment. The results of this study were presented in an oral presentation at the 2015 annual meeting of the American Society of Clinical Oncology.

Lenvima, sponsored by Eisai, inhibits the kinase activities of vascular endothelial growth factor receptors VEGFR1-3. Lenvima also inhibits other RTKs that have been implicated in pathogenic angiogenesis, tumor growth, and cancer progression in addition to their normal cellular functions, including fibroblast growth factor receptors FGFR1-4; the platelet derived growth factor receptor alpha, KIT, and RET.

Lenvima was approved under the Priority Review designation for locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer by the FDA in February 2015.