THE CANCER LETTER

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Politics and Peer Review

House Appropriator Claims NCI, NLM Grants Funded Political Activity, Seeks OIG Probe

By Paul Goldberg

Congressional Republicans asked the HHS Office of Inspector General to investigate the appropriateness of funding a prominent scientist whose publications found a link between tobacco companies and the Tea Party conservative movement.

A letter signed by Rep. Jack Kingston (R-Ga.), chairman of the House Appropriations Subcommittee on Labor, HHS and Education, asked HHS Inspector General Daniel Levinson to review three NCI grants to Stanton Glantz, a professor in the Department of Medicine at the University of California San Francisco, as well as a member of the Helen Diller Family Comprehensive Cancer Center and director of the Center for Tobacco Control Research and Education.

The letter also challenges a grant the National Library of Medicine gave to Catherine Gallagher, a Cochrane Collaboration leader and a criminology professor at George Mason University, who studies health problems of young prison inmates as well as gun violence.

"I would appreciate your review of these grants to determine if the lobbying prohibition was in fact violated," Kingston wrote to Levinson.

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Capitol Hill

Continuing Resolution Averts Shutdown; Locks in Sequestration Cuts for NIH, NCI

By Matthew Bin Han Ong

Congress passed a continuing resolution March 21 to keep the federal government open through the end of September—effectively locking in the 5.1 percent across-the-board sequestration cuts.

The Senate version of the resolution was passed by the House of Representatives with a 318-109 vote. The bill now goes to President Barack

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In Brief

NCCN Admits Two New Member Institutions

THE NATIONAL COMPREHENSIVE CANCER NETWORK named two NCI-designated comprehensive cancer centers as its newest member institutions. They are **UC San Diego Moores Cancer Center** and the **University of Colorado Cancer Center**.

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Rep. Kingston Seeks OIG Probe Of NCI, NLM Peer-Reviewed Grants

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"Please ensure your review also examines if and when NIH updated its procedures and guidelines to ensure NIH-supported activity does not violate any lobbying restrictions," wrote Kingston.

The letter to Levinson was not officially released, but a copy was obtained by The Cancer Letter.

Kingston's request for an investigation appears to be a part of a broader strategy by Republicans to push NIH and other HHS agencies away from public health research and public health programs that may influence policy.

Several science advocates say that this latest episode in America's ideological war threatens to undermine the foundations of peer-reviewed research:

• "There are people interested in finding truth and saving lives; there are people interesting in hiding truth and making money—and the latter cohort often attacks the former, and is often funded by big tobacco," said Otis Brawley, chief medical and scientific officer of the American Cancer Society.

"While a federal grant should not be used to lobby, and I have no information that this grant money was—the study of how big tobacco manipulates public health intervention is fair game. Anyone truly interested in public health research must support Glantz at this time." ACS has funded Glantz's work in the past.

• "The need to protect the NIH peer review process and integrity is critical even when very controversial topics are handled," said David Abrams, executive director of the Schroeder Institute for Tobacco Research and Policy Studies; and a professor in the Department of Health, Behavior and Society at the Johns Hopkins Bloomberg School of Public Health.

"The issue of the politics, of course, is also a sensitive one that can be used to undermine the freedom of scientists to conduct their work once approved by NIH peer review, which is process that is the admiration of the entire world." The Schroeder Institute is a part of Legacy, the foundation that established Glantz's endowed chair and has funded his work.

• "To lobby is to try to influence a public official to take a certain action on behalf of a constituency; to publish in a peer reviewed journal is to advance a claim for knowledge based on a methodology that meets the standards of a discipline," said Sheldon Krimsky, the Lenore Stern Professor of Humanities & Social Sciences at Tufts University.

"To conflate the two can only be viewed as a step toward the censorship of science." Krimsky is the author of an upcoming book, "Biotechnology in Our Lives: What Modern Genetics Can Tell You About Assisted Reproduction, Human Behavior, Personalized Medicine, and Much More."

NIH Director Collins Grilled at Congressional Hearing

While the controversy over the boundaries between research and politics isn't new, the challenge from Republican legislators has intensified in recent weeks.

At an appropriations hearing last week, self-described Tea Party member Rep. Andy Harris (R-Md.) confronted NIH Director Francis Collins with the findings in Glantz's recent paper that appeared in Tobacco Control, a peer-reviewed journal published by British Medical Journal Group.

Collins didn't defend the Glantz paper, saying instead that he was "troubled" by it (The Cancer Letter, March 8).

Kingston is asking the Office of the Inspector General to expand what appears to be the agency's ongoing investigation of HHS grantees using federal funds for lobbying.

OIG is involved in a related investigation of the Communities Putting Prevention to Work Program, funded by the Centers for Disease Control and Prevention. The program is funded through the American Recovery and Reinvestment Act and the Patient Protection and Affordable Care Act. The

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investigation was prompted by House Republicans and is included in the OIG work plan for 2013.

Though Kingston's letter asking OIG to focus on Glantz and another researcher was dated Feb. 25, it's not clear whether Collins would have known about it at the time he was confronted at the appropriations hearing.

"I can confirm to you that we did receive that letter," said Donald White, a spokesman for OIG. "We are giving the letter from the Chairman very careful review. The next step, after review, it will be assigned, as appropriate, to a component within the Office of Inspector General if there is going to be further action taken."

White said he could neither confirm nor deny the existence of a broader investigation of lobbying by HHS grantees noted in Kingston's letter. However, other sources said that the investigation is ongoing.

Peer Review Called the Study "Flawless"

Glantz first learned about the Kingston letter from The Cancer Letter.

"We welcome a careful review of our work," Glantz said. "We wrote a well-documented academic paper in a peer-reviewed journal."

Gallagher, director of the Cochrane Collaboration College for Policy and an associate professor of Criminology, Law and Society at George Mason University, was also singled out by Kingston. Her grant, which pays $50,000 a year for up to three years, focuses on health problems of young prison inmates.

"The preponderance of evidence portrays adults and adolescents under the control of the criminal and juvenile justice systems as disproportionately shouldering the burden of nearly every type of negative health condition, from premature death to representing the single largest infectious disease carrying population," a summary of the grant states.

"As such, the tens of millions of people currently involved in the criminal and juvenile justice systems are critical to the public health of their larger communities, while also representing an overwhelming loss of human potential. Despite these facts, there remains a dearth of coherent policy specifically designed to address the health of, and the health service delivery for, this population.

"The lack or rational policy and evidence-based guidelines may be viewed as the failure of the scientific community to rigorously organize the knowledge base on health prevalence, interventions and outcomes, and to disseminate findings in a manner conducive to guideline development that will resonate with care providers."

Like Glantz, Gallagher was unaware of Kingston's letter.

"This piece of research almost got a perfect score in the NIH peer review," said Gallagher. "You want a 10. I got a 13. It was called 'flawless.' All of the independent scientists said it's written flawlessly; it's compelling, it's organized. You don't get a 13— it's a once-in-a-lifetime score. If NIH has people having a problem with a grant that got 13, where are we?"

Gallagher said she is unaware of any specific incident that could have singled her out to House Republicans. However, she has conducted Congressional briefings on juvenile justice and gun violence. Gallagher said she has no position on gun control. "I have no position how to fix it," Gallagher said. "What I have a position on is what it does to kids and what it dies to their futures and their lives, but that's all from research. It's not me saying people shouldn't have a gun. I am looking at prevalence and correlates.

"You are taking someone who works with Cochrane, the most independent research organization around the globe, and saying that somehow they are going to be lobbying," Gallagher said. "The goal is to ensure that we are bias-free, and that we report bias, and we reduce bias."

The letter from Kingston focuses on a phrase from the NIH abstract, which states that her project "is intended to engage the medical, public health, criminal justice, policy, legal, and advocacy communities by uniting diverse disciplines around a common issue."

Gallagher said she had to deal with advocacy communities, because the cohort she is studying is in prison. "They are locked up," Gallagher said. "It may have been better to say 'to involve patient populations and patient representatives.' That may have been the politically correct language to use. I don't know. It just seems very silly."

Letter Seeks to Broaden Ongoing Investigation

The text of Kingston's letter follows:

Dear Mr. Levinson,

On May 11, 2012, my colleagues and I requested you to begin an investigation on the possible use of federal dollars by Department of Health and Human Services' (HHS) grantees for lobbying activities in violation of federal law. I write today to submit additional information on other alleged activities that may also have violated this provision.

Specifically, recent media reports assert federal funds associated with National Institutes of Health (NIH) grant numbers R01 CA087472-13, R01 CA061021-19 and to the University of California San Francisco Fellowship Program via R25 CA113710-O7 may have been used to fund the development of a political document related to alleged funding ties to certain political movements.

In addition, NIH grant number [1G13LM010936-01] appears, on the surface, to sponsor an advocacy group to develop lobbying type material. The NIH grant abstract reads in part it "is intended to engage the medical, public health, criminal justice, policy, legal and advocacy communities by uniting diverse disciplines around a common issue."

I would appreciate your review of these grants to determine if the lobbying prohibition was in fact violated. Please ensure your review also examines if and when NIH updated its procedures and guidelines to ensure NIH-supported activity does not violate any lobbying restrictions.

If any grants are indeed found to be in violation, in addition to official Anti-Deficiency Act notification, I request your office provide specific recommendations on how NIH can strengthen its review, approval, and monitoring procedures to prevent further violations from occurring.

Thank you in advance for your attention to this request. I look forward to periodic updates on this and the more comprehensive review requested in the May 11, 2012, letter.

NIH Ethics Rules, Grants Restrict Lobbying

HHS grantees and contractors are precluded from using federal money for political purposes, but it's far from clear whether these rules would apply to researchers whose findings may have political relevance.

The ethics rules for NIH grantees and contractors state:

• The HHS appropriations act also provides that no appropriated funds may be used to pay the "salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature."

• The Department of Justice has interpreted such provisions as prohibiting the use of federal funds for any type of lobbying by federal grantees and contractors, not merely "grass roots" lobbying that the Department itself is prohibited from performing.

• Grantees and contractors are not prohibited from lobbying with non-federal funds. Care should be exercised that, in communicating with contractors and grantees about this particular restriction, Department officials do not imply any general restriction on lobbying that could lead to an allegation of First Amendment infringement.

• The Department of Justice has stated that any lobbying activities undertaken by grantees and contractors must be conducted at their own expense, and that federal funds must be segregated from other sources to demonstrate compliance with that requirement.

• Uniform cost principles for no-profit organizations issued by the Office of Management and Budget (OMB in OMB Circular A-122 and Federal Acquisition Regulations (FAR), 48 C.F.R. §§ 31.205-22; 31.701 *et seq*., also prohibit reimbursement from federal funds for lobbying or political activities conducted by grantees and contractors. These restrictions generally apply to attempts to influence any federal or state legislation through direct or "grass roots" lobbying campaigns, or political campaign contributions or expenditures, but exempt any activity authorized by Congress, or when providing technical and/or factual information related to the performance of a grant or contract when in response to a documented request.

The terms and conditions for accepting an NIH grant include:

Recipients of Federal grants, cooperative agreements, contracts, and loans are prohibited by 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," from using appropriated Federal funds to pay any person for influencing or attempting to influence any officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress with respect to the award, continuation, renewal, amendment, or modification of any of these instruments.

These requirements are implemented for HHS in 45 CFR part 93, which also describes types of activities,

such as legislative liaison activities and professional and technical services, which are not subject to this prohibition.

Applicants for NIH awards with total costs expected to exceed $100,000 are required to certify that they

• have not made, and will not make, such a prohibited payment;

• will be responsible for reporting the use of non-appropriated funds for such purposes; and

• will include these requirements in consortium agreements and contracts under grants that will exceed $100,000 and obtain necessary certifications from those consortium participants and contractors.

DISCLOSURE: Goldberg and Brawley are co-authors of How We Do Harm: A Doctor Breaks Ranks About Being Sick in America (St. Martin's Press, 2012).

Capitol Hill

Senate Amendment Creates Reserve Fund for NIH Budget

(Continued from page 1)

Obama, who is expected to sign it when he returns from the Middle East this weekend.

Having secured federal operations for the next six months, lawmakers now return to wrangling over taxes and spending for the next several years.

Also on March 21, the House approved—and the Senate rejected—the 2014 budget proposed by Rep. Paul Ryan (R-Wis.). Ryan's austerity plan calls for a $5 trillion cut in federal spending—including the repeal of Obama's Affordable Care Act and an overhaul of Medicare.

Members of the Senate, on the other hand, are advancing a bipartisan amendment to create a deficit-neutral reserve fund for NIH, said Jon Retzlaff, managing director of science policy and government affairs at the American Association for Cancer Research.

The amendment was introduced by Sens. Dick Durbin (D-Ill.), Jerry Moran (R-Kan.), Barbara Mikulski (D-Md.) and Ben Cardin (D-Md.), and will likely be voted on shortly.

"It will provide a framework of growth for the NIH budget over the next decade and allow the budget committee chair to adjust the budget resolution's overall spending limits and spending allocation for the appropriations committee," said Retzlaff.

"We are hoping that would mean the beginning of an era of growth for NIH."

Sequestration Kicks In after Close Shave

Congress came perilously close to missing deadlines on the final continuing resolution: the measure was passed a day before a two-week recess, and six days before the current spending bill expires.

Parts of the government deemed nonessential—including Labor HHS agencies—would have been forced to shut down had a continuing resolution failed to pass. Nevertheless, layoffs are expected in a number of federal agencies, and as many as 800,000 civilian workers await furlough notices from the Defense Department due to sequestration. It's not publically known how NIH and FDA expect to manage the automatic budget cuts.

The six-month continuing resolution was designed to mitigate the impact of sequestration by increasing spending in priority programs and agencies through amendments—just before the cuts kick in at the end of March.

NIH will receive $67 million above fiscal 2012 levels through an amendment by Sens. Mikulski and Richard Shelby (R-Al.).

Another amendment, by Sen. Tom Harkin (D-Iowa), to increase NIH funding by $211 million fell six votes short of the 60 required for passage.

"The current CR includes a 0.612 percent increase over FY2012 that was removed from the full-year CR due to the change in the discretionary caps enacted in January," NIH officials said to The Cancer Letter.

The continuing resolution is estimated to reduce the NIH sequestration cuts for fiscal 2013 to $1.486 billion, down from $1.553 billion.

"While any increase in this environment shows bipartisan prioritization of biomedical research, it still needs to be considered in the light of the reduction the agency received due to the sequester," said Carrie Wolinetz, president of United for Medical Research. "It is our hope that as we move into FY14 and beyond we can work with Congress and the administration to restore NIH to a path of sustainable funding increases."

Neither NIH nor NCI has the final budget numbers, but NCI would likely receive a $10 million increase, according to a statement from the American Society of Clinical Oncology.

"We are pleased that Congress has taken a small step to recognize the importance of biomedical research in this difficult economic climate," said ASCO President

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Sandra Swain. "But sequestration is still a serious threat on top of previous years of stagnant funding in the face of biomedical research inflation."

"Specifics have not been announced, but [NCI Director Harold] Varmus has said that he hopes to fund just as many grants in FY 2013 than it did in FY 2012," said Retzlaff. "They can now start putting their plans into place and communicating them to us because they have a final budget for FY 2013."

The sequestration isn't being prorated, according to NIH officials. The 5.1 percent cut is based on the full fiscal year and has to be implemented over the remaining half of the year.

"We were happy to see that Congress came to a bipartisan agreement in advance of the continuing resolution deadline, with an increase to NIH," said Barbara Duffy Stewart, executive director of the Association of American Cancer Institutes.

"However, this does not change the unprecedented budget cuts that our nation's cancer centers face due to sequestration," said Stewart. "It is our hope that Congress will work together to avoid future cuts to NIH and ultimately, NCI."

"AACI cancer centers and young scientists cannot afford to see promising research slowed or halted."

Sequestration and the Cost of Biomedical Inflation

"We are gratified that on a bipartisan basis, Congress provided extra dollars for NIH, NSF and FDA in the continuing resolution, but those modest gains were obliterated by sequestration," said Mary Woolley, president and CEO of Research!America. "Unless and until policymakers repeal these annual across-the-board cuts, biomedical and health research will be in decline.

"We cannot let these arbitrary, counterproductive cuts stand."

The loss to NIH's purchasing power may total 23 percent over a decade, according to a recent fact sheet published by the Federation of American Societies for Experimental Biology.

After a stretch of flat funding and inflation, sequestration would reduce the NIH funding capacity to $20.7 billion—nearly a one-quarter loss.

California and Massachusetts may lose as much as $180 million and $127 million in NIH funding due to sequestration, respectively, according to FASEB estimates.

"I think the suddenness of [sequestration] and the depth of it would be a disaster for research, which is not an activity that you can turn on and off from year to year," said Elias Zerhouni, former NIH director and president of global research and development at Sanofi. "The most impacted are the young, new investigator scientists, who are coming into science, and will now abandon the field of science."

"We are going to maim our innovation capabilities if you do these abrupt deep cuts at NIH," Zerhouni said. "It will impact science for generations to come."

Sequestration cuts amount to more than the fiscal 2012 funding of $1.491 billion for three major research programs at the NCI that study the mechanisms, diagnosis and prevention of cancer. That amount is also more than the $1.48 billion budget for the National Institute of Mental Health, according to a March 13 report by Research!America.

"It's extremely frustrating, because we are going in completely the wrong direction, as this budget for NIH in FY 2013 accelerates the decline in medical research funding that we have been facing for the past decade, especially when taking into account how NIH's budget has not been keeping up with the annual rate of inflation," Retzlaff said. "This crisis situation is why we as a community are joining together on April 8 to Rally for Medical Research.

"Thousands will be participating in person at the rally while millions will be participating nationwide to ask our policy makers to make NIH and medical research a national priority," Retzlaff said.

Drug Shortages

Institutions Report Halting Enrollment In Clinical Trials

A national survey of health professionals showed that drug shortages are taking a heavy toll on cancer patients, forcing treatment changes and delays that for some patients meant worse outcomes, more therapy-related complications and higher costs.

The survey focused on oncology pharmacists and others involved in managing cancer drug shortages for academic medical centers, community hospitals and other cancer treatment facilities nationwide.

Of the 243 individuals who completed the survey, 98 percent reported having dealt with a shortage of at least one chemotherapy agent or other essential cancer-related drug in the previous 12 months and 93 percent reported that shortages forced delays in chemotherapy administration or other changes in cancer drug therapy.

Researchers found the shortages also disrupted cancer research and added to the cost and risks associated

with cancer treatment. One institution linked a patient's death to a shortage-related medication mistake.

Overall, 16 percent of respondents tied shortages to adverse patient outcomes, including disease progression or more treatment-related complications.

The survey was conducted by the Hematology/Oncology Pharmacy Association and focused on a 12-month period ending in October 2011. The results appear in the April 1 edition of the American Journal of Health-System Pharmacy.

According to the survey, drug shortages have forced 44 percent of institutions to either halt or delay enrollment in clinical trials.

About one-third of institutions in the survey reported pharmacy staff spent at least 20 hours each week working on issues related to the drug shortage, including time spent trying to find scarce medications to purchase or identify alternatives. Eighty-five percent of respondents reported shortages led to higher medical costs.

"This survey documents the risk that drug shortages pose to cancer patients of all ages," said senior author James Hoffman, an associate member of the St. Jude Children's Research Hospital Department of Pharmaceutical Sciences and the hospital's medication outcomes and safety officer.

"There are few, if any, therapeutically equivalent alternatives available for many oncology drugs in short supply. Drug supplies remain unpredictable and serious problems persist."

Fluorouracil, leucovorin, liposomal doxorubicin and paclitaxel were the drugs most frequently reported as being in short supply.

The survey follows an earlier St. Jude-led study that linked a shortage of the chemotherapy drug mechlorethamine to a greater risk of relapse for some young Hodgkin lymphoma patients.

In February, the University of Utah Drug Information Service was tracking national and regional shortages of more than 320 drugs, which is the highest number since 2010.

The service tracks drug shortages and provides advice about managing shortages through the American Society of Health-System Pharmacists.

Earlier studies have shown that most shortages occur in the supply chain of generic injectable drugs, particularly medications to combat cancer and infections. In 2012, new federal legislation gave the FDA additional tools to prevent and ease drug shortages, including requiring manufacturers to report anticipated supply problems of key medications.

"While the FDA and others have worked diligently to address the problem, additional action is needed to address continuing shortages," Hoffman said.

Ali McBride, of The Ohio State University, is the first and corresponding author. Other authors are Lisa Holle of the University of Connecticut; Colleen Westendorf, formerly of University of Kentucky and now of St. Jude; Margaret Sidebottom and Niesha Griffith of Ohio State; and Raymond Muller of Memorial Sloan-Kettering Cancer Center.

Medicare

IOM Commitee Considers Cost Variations by Region

An Institute of Medicine committee found that providing higher Medicare payment rates in regions characterized by good health outcomes and relatively lower spending—while decreasing rates in regions with overall lesser quality and higher spending—would not incentivize providers to provide care more efficiently.

The amount Medicare spends per person varies greatly across the country. The program pays out as much as 44 percent more in some regions than it does in others, even after adjusting for regional price differences in wages, rents, and other factors.

Studies indicate that—in the regions where Medicare spends more—better health outcomes or greater patient satisfaction is not consistently achieved.

A geographic value index has been proposed as a way to encourage greater efficiency in health care—by raising payment rates in low-cost regions, where the quality of care and health benefits are high, and by decreasing payments in high-cost areas, where the quality and benefits are low relative to their spending.

Using a geographically based value index to set Medicare reimbursements would reward underperforming providers in some regions and penalize those achieving good outcomes at lower cost in other areas, according to the committee.

The committee released an interim report of the ongoing study measuring regional variations in health care spending, use, and quality—and the merits of adopting a geographic value index.

A final report, due this summer, will contain the committee's conclusions and recommendations as well

as additional analyses of other data, such as private insurance payments.

The feasibility of a geographic value index depends on whether individual practitioners or health care organizations behave similarly within defined regions, so that all would be equally deserving of any geographically based increase or decrease in their payment levels.

It also depends on whether altering payment rates based on regional measures of cost and quality is likely to spur more efficient care, the report notes.

Through its review of the evidence so far, the committee observed that differences in use of services and spending occur at every geographic level as well as between hospitals within regions and between providers within a single hospital or group practice. In addition, health care decisions are made by providers rather than at a regional level.

To be effective, payment reforms need to encourage behavioral changes at the point of health care decision making, which occurs at the level of individual providers and health care organizations, the committee noted.

Several initiatives—such as value-based purchasing, accountable care organizations, and bundled payments—target decision makers rather than regions, although these reforms are relatively new and there is little evidence yet about their effects.

In Brief

UCSD, Univ. of Colorado Become NCCN Members

(Continued from page 1)

"These two institutions add substantial strength and expertise to the excellence of cancer care, research, and education characteristic of the other 21 world-class Member Institutions," said NCCN CEO Robert Carlson. Originally founded in 1995, NCCN membership now stands at 23 institutions.

The NCCN Clinical Practice Guidelines in Oncology are used as the standard for clinical policy in oncology by clinicians and payers. The guidelines are developed through a review of the evidence integrated with expert medical judgment and recommendations by multidisciplinary panels from NCCN member institutions.

The addition of new members was announced at the NCCN annual conference last week. Vanderbilt-Ingram Cancer Center was the last addition to the NCCN roster, six years ago.

In another development, NCCN issued its first NCCN Guidelines for survivorship.

The NCCN member institutions are: City of Hope Comprehensive Cancer Center; Dana-Farber/Brigham and Women's Cancer Center Massachusetts General Hospital Cancer Center; Duke Cancer Institute; Fox Chase Cancer Center; Huntsman Cancer Institute at the University of Utah; Fred Hutchinson Cancer Research Center/Seattle Cancer Care Alliance; The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins; Robert H. Lurie Comprehensive Cancer Center of Northwestern University; Memorial Sloan-Kettering Cancer Center; Moffitt Cancer Center; The Ohio State University Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute; Roswell Park Cancer Institute; Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine; St. Jude Children's Research Hospital/The University of Tennessee Health Science Center; Stanford Cancer Institute; University of Alabama at Birmingham Comprehensive Cancer Center; UC San Diego Moores Cancer Center; UCSF Helen Diller Family Comprehensive Cancer Center; University of Colorado Cancer Center; University of Michigan Comprehensive Cancer Center; UNMC Eppley Cancer Center at The Nebraska Medical Center; the University of Texas MD Anderson Cancer Center; and Vanderbilt-Ingram Cancer Center.

THE FDA Center for Drug Evaluation and Research Office of Medical Policy will conduct a webinar on draft guidance for industry on **Enrichment Strategies for Clinical Trials to Support Approval of Human Drugs and Biological Products**.

The webinar will be hosted by Robert Temple, CDER deputy director for clinical science, and held March 25 at 2 p.m.

ARNO MUNDT was appointed president of the **American College of Radiation Oncology**.

Mundt, professor and chair of the UC San Diego School of Medicine Department of Radiation Medicine and Applied Sciences, was inaugurated as the president of ACRO at the organization's 2013 annual meeting in February.

Mundt will oversee the board of chancellors, whose members are elected from the membership, and will serve as the chief executive officer of the organization for the next two years.

He led a team of eight radiation oncologists,

one gynecologist and three physicists, as well as therapists and volunteers, to Senegal as part of a project sponsored by the charity Radiating Hope.

Senegal has only one radiation oncology center, which serves 13 million people, including patients from multiple neighboring countries. The team installed the country's first modern high-dose-rate brachytherapy machine, which will allow doctors to better treat cervical cancer and many other malignancies.

GARRETT BRODEUR will receive the Pediatric Oncology Award from the **American Society of Clinical Oncology**.

He will deliver the Pediatric Oncology Lecture May 31 during the ASCO annual meeting in Chicago.

Brodeur, a pediatric oncologist at The Children's Hospital of Philadelphia, is an expert in neuroblastoma, the most common childhood solid tumor.

Over his career, Brodeur has focused on identifying the genes, proteins and biological pathways that give rise to neuroblastoma and drive its clinical behavior. He also has built on this knowledge to develop more effective and less toxic treatments for children by targeting specific pathways.

First demonstrated in the 1980s, his research showed that when neuroblastoma cells developed multiple copies of the MYCN gene, a high-risk subtype of neuroblastoma occurs, necessitating more aggressive treatment. This discovery helped usher in the current era of genomic analysis of tumors, both in adult and pediatric oncology.

Brodeur and his colleagues also identified deletions of important genes on chromosome 1 and on chromosome 11 as markers of high-risk neuroblastoma. He has collaborated with other Children's Hospital researchers who identified the ALK gene as the gene responsible for most cases of hereditary neuroblastoma.

Another major focus of his research has concerned receptor tyrosine kinases, a family of signaling proteins that control the clinical behavior of neuroblastomas. His preclinical work led to a clinical trial with a novel drug that selectively blocks TRK signaling. He is now working on second-generation TRK inhibitors, as well as on nanoparticle delivery systems to treat patients more effectively, and with less toxicity.

Brodeur has been a member of the hospital's medical staff since 1993, and holds the Audrey E. Evans Endowed Chair in Pediatric Oncology. He also is a professor of pediatrics in the Perelman School of Medicine at the University of Pennsylvania, where he is an associate director of the Abramson Cancer Center.

MARK VELLECA, chief policy and advocacy officer of the **Leukemia & Lymphoma Society**, will expand his role to include oversight of the newly integrated patient advocacy, policy and programs department.

He will now supervise patient and professional education and patient advocacy, while continuing to lead the society's legislative and regulatory policy initiatives.

Velleca was the founder and senior vice president of CGI Pharmaceuticals. He served as a senior advisor at Gilead Sciences following its acquisition of CGI in 2010 before joining LLS in 2012.

THE OHIO STATE UNIVERSITY Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Institute launched a statewide initiative to screen newly diagnosed colorectal cancer patients and their biological relatives for Lynch Syndrome, the most common form of inherited colorectal, ovarian and uterine cancer.

The Ohio Colorectal Cancer Prevention Initiative is led by **Heather Hampel**, associate director of the Division of Human Genetics at the OSUCCC –James. The effort, made possible through money raised by Pelotonia, will identify family members who may be at risk of developing these cancers so they can take precautionary measures.

About 3 percent of colorectal cancer cases result from Lynch Syndrome, which is characterized by inherited mutations in one of four genes for DNA-repair proteins. Each colorectal cancer patient with Lynch Syndrome has, on average, three relatives with the syndrome, heightening their risk for colorectal cancer.

The initiative includes 42 hospitals throughout Ohio that will implement the Lynch Syndrome screening program at their own institutions. They will advise patients and their physicians of the results, offer genetic counseling and make high-risk cancer surveillance recommendations to patients and family members found to have Lynch Syndrome.

Ohio Gov. John Kasich has declared March 22 as Lynch Syndrome Hereditary Cancer Public Awareness Day to encourage patients to learn their family histories of cancer.

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CELGENE Corp. has begun two research collaborations—one with **Bluebird Bio**, and one with the **Baylor College of Medicine Center for Cell and Gene Therapy**—to develop genetically modified chimeric antigen receptor T-cells designed to target and destroy cancer cells.

The multi-year collaboration could lead to the development and commercialization of CAR T-cell products. Celgene has an option to license any products resulting from the collaboration after the completion of a phase I clinical study for each product. Bluebird will be responsible for research and development through phase I studies.

The gene therapy products currently in clinical development at Bluebird for the treatment of childhood cerebral adrenoleukodystrophy, beta-thalassemia and sickle cell disease are independent of this collaboration.

FDA Approvals

Dotarem Contrast Agent Approved For CNS Imaging

FDA approved Dotarem (gadoterate meglumine) for use in magnetic resonance imaging of the brain, spine and associated tissues of patients aged two years and older.

Dotarem is a gadolinium-based contrast agent that helps radiologists see abnormalities on images of the central nervous system and surrounding tissues.

Dotarem's safety and effectiveness were established in a clinical trial of 245 adult and 38 pediatric patients over two years old with suspected CNS abnormalities. Each patient received a baseline MRI without Dotarem, and then the MRI was repeated following Dotarem administration.

Results showed that, in comparison to the baseline images, Dotarem MRI helped radiologists better see CNS lesions. Dotarem also helped the radiologists identify lesion borders and other lesion features. Similar results were obtained in a clinical trial conducted among patients who were known to have CNS abnormalities.

All GBCAs, including Dotarem, carry a boxed warning about the risk of nephrogenic systemic fibrosis, a rare but serious condition associated with the use of GBCAs in certain patients with kidney disease. NSF is characterized by pain and thickening of the skin, and can cause fibrosis of internal organs. There is no known treatment for NSF, and all approved, professional GBCA labeling describes ways to minimize the NSF risk.

Dotarem is the seventh GBCA approved by the FDA for use in patients undergoing CNS MRI. Other FDA-approved GBCAs with a CNS MRI indication include Magnevist, Prohance, Omniscan, Optimark, Multihance and Gadavist.

Dotarem is marketed by Guerbet LLC.