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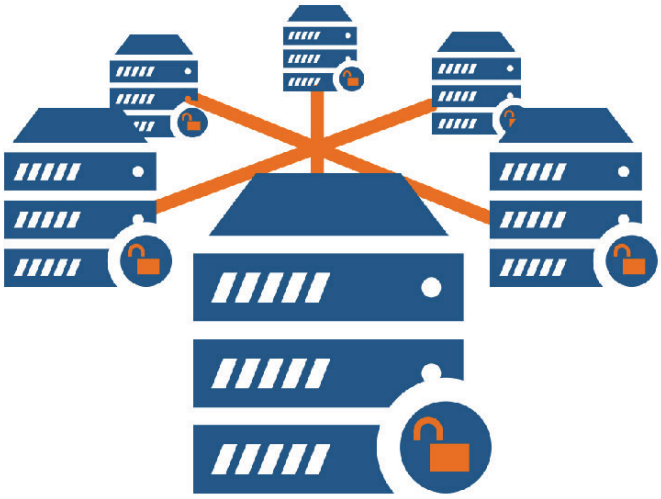

Information Blocking by E-Health Record Firms Threatens CancerLinQ, ASCO Says

By Paul Goldberg

Congress must put an end to the emerging practice of "information blocking" by purveyors of electronic health record systems, American Society of Clinical Oncology urged at a Capitol Hill briefing.

At the briefing Sept. 15, ASCO said that some EHR companies are erecting obstacles that prevent health care providers from sharing data contained in patient health records.

(Continued to page 2)

Baselga: Why I Believe NIH is On Threshold Of the Largest Budget Increase in 12 Years

By José Baselga

As congressional leaders discuss potential ways to avert a government shutdown, which could happen in less than a week if policymakers are unable to agree to a short-term continuing resolution to keep the government running beyond Sept. 30, I remain optimistic that NIH will receive its largest annual budget increase in 12 years.

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In Brief

Vanderbilt, UNC Get "Exceptional" Scores

VANDERBILT-INGRAM CANCER CENTER received an overall "exceptional" score as part of the renewal of the **Cancer Center Support Grant**.

The CCSG provides almost $30 million over five years to support scientific leadership and administration of the cancer center, as well as infrastructure that includes shared resources for cancer investigators.

(Continued to page 6)

ASCO: Information Blocking Jeopardizes CancerLinQ

(Continued from page 1)

ASCO is at the heart of this Big Data controversy because it is developing the CancerLinQ database. If oncology practices are precluded from sharing data—as they increasingly are—CancerLinQ will become unworkable.

"This is tragic, because the success of CancerLinQ and any data-sharing platform, is from being able to draw out information from all individuals that are affected, not just a few of them," Robin Zon, a medical oncologist with Michiana Hematology Oncology, one of the first 15 practices that will participate in CancerLinQ, said at the ASCO briefing.

"The bottom line is, that if data-sharing is not achievable, then vital insights will be lost. I think our patients deserve better."

Clifford Hudis, a breast cancer expert at Memorial Sloan Kettering Cancer Center, a past president of ASCO, and a member of the board of governors of CancerLinQ, said Congress has the power to fix the problem.

"It is common for adjacent facilities using the same health care records to have no ability to transmit them, because their customized installations change the way data fields are recorded, so one has to bring 500 pages of chart in one hospital's record system, take it across the street and scan it back in to the same vendor's product in another facility," Hudis said.

The lack of "interoperability" across EHR systems stems from a fundamental flaw.

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Since the federal government mandated the transition to electronic medical records in the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, a handful of powerful players emerged throughout medicine.

The problem becomes all the more complex because the data being collected by this handful of players throughout medicine are extraordinarily valuable. While interoperability is often discussed, the EHR providers are broken into two groups:

• First and foremost, there is Epic, the largest provider of health record systems.

• The second group is everybody else. Smaller players have formed a consortium called CommonWell Health Alliance that's developing the interfaces that would allow systems to communicate with each other.

While no one owns up to information blocking, oncologists say the practice is on the rise.

"What does information blocking really mean?" Zon said at the ASCO briefing. "As you can imagine, there are EHRs that are competitors in the marketplace. And they don't allow each other's systems to talk with each other.

"So what's happening as a provider—and we're hearing this across all specialties, not just oncology, and across the nation—some of these EHR systems are requiring a transaction fee to import and to export the information.

"There are other EHR systems and vendors that are flat-out refusing or making it prohibitively expensive to make the systems communicate with each other.

"And then, most recently, I heard a report that there was a vendor [that] by contract has disallowed anybody who is using their system from sharing their information with a data system that is not their own."

Asked to name the EHR vendors who contractually block release of information to entities that use the systems supplied by competing vendors, ASCO officials declined to provide specifics.

"ASCO is a membership organization and it is our policy that we not comment on vendors that may have a business relationship with our members," Apoorva Stull, policy communications manager, said in an email.

Anecdotal Evidence

Zon's allegations echo a recent report by the HHS Office of the National Coordinator for Health Information Technology, which catalogued anecdotal reports of information blocking. These practices include:

• Contract terms, policies, or other business or organizational practices that restrict individuals' access

to their electronic health information or restrict the exchange or use of that information for treatment and other permitted purposes.

• Charging prices or fees (such as for data exchange, portability, and interfaces) that make exchanging and using electronic health information cost prohibitive.

• Developing or implementing health IT in non-standard ways that are likely to substantially increase the costs, complexity, or burden of sharing electronic health information, especially when relevant interoperability standards have been adopted by the Secretary.

• Developing or implementing health IT in ways that are likely to "lock in" users or electronic health information; lead to fraud, waste, or abuse; or impede innovations and advancements in health information exchange and health IT-enabled care delivery.

Misunderstanding of privacy laws also presents an obstacle, ONC said in the report.

"Some providers or other persons or entities may mistakenly or even intentionally misinterpret or misrepresent state privacy laws as prohibiting the sharing (disclosure) of electronic PHI—either with individuals directly or with other health care providers that an individual has designated—in circumstances when federal and state law permit such disclosure," the report states.

ASCO isn't alone in facing the challenge of aggregating data. The American Society of Radiation Oncology and the Radiation Oncology Institute recently finished a one-year demonstration project focused on prostate cancer. Altogether, 30 centers were selected to participate, but 11 of them withdrew because of legal and administrative concerns. Another five sites found that they couldn't transfer data. The remaining sites—14 of them—were able to compile data on 430 patients. Some of this required manual data entry.

ROI officials said to The Cancer Letter that they are evaluating these results and preparing to publish them.

Under the Carpet

Maneuvering in this little-understood corner of medicine occurs outside public view, guided by secret plans, shielded by confidentiality agreements between EHR vendors and healthcare providers, and further obscured by the overwhelming complexity of technology and business structures.

An image Winston Churchill used to describe power struggles in the Kremlin can arguably be used to describe the war that now rages at the informatics underlayment of oncology.

It is akin to a battle of bulldogs under a carpet: "An outsider only hears the growling, and when he sees the bones fly out from beneath, it is obvious who won."

Some movements of the carpet can be observed on Capitol Hill.

The sprawling 21st Century Cures legislation passed by the House this summer includes a section on interoperability that affects information blocking, and now the Senate is about to take up the legislation.

Though ASCO is one of the fighting bulldogs, at the congressional briefing Sept. 15, the society strategically pulled back one of the carpet's corners, exposing a fragment of the battlefield.

In a statement, the society said information blocking is on the rise.

"I think that the proposal that payment be linked to this is potentially useful, but part of the concern here is that it's not the clinicians that determine the interoperability, it's the vendors that they're purchasing their electronic records from, and those folks have less stake in the alternative payment models than the clinicians, and what we don't want to do is to add burden to clinicians which in some form or fashion gets passed onto the entire marketplace," Hudis said. "I think there might be an idea in there that might be pursued, but it's not that simple."

In addition to supporting the provisions in the 21st Century Cures Act, ASCO urges Congress to take the following additional steps:

1. Congress should enact legislation as quickly as possible to ensure widespread interoperability is achieved. The legislation should include clear direction and mandates on the elimination of unjustified information blocking.

2. Congress should pass legislation to remove barriers to interoperability, especially information blocking. The legislation should include aggressive deadlines for implementation.

3. Policymakers should ensure that cancer patients, oncologists and other oncology providers do not bear the costs of achieving interoperable electronic health records and of companies refraining from information blocking. Patients and health care providers should not have to subsidize the cost of ensuring that electronic health records are interoperable.

4. Federal officials should work with ASCO and other stakeholders to ensure that healthcare providers have the information necessary to be prudent purchasers and users of health information technology systems. Officials should work with ASCO and other stakeholders to help educate health care providers regarding

contractual provisions, information blocking and other activities that are counterproductive to the national interest of promoting widespread interoperability.

The webcast of ASCO's briefing is posted here.

ASCO is developing CancerLinQ in collaboration with SAP SE (Systems, Applications & Products in Data Processing), a German multinational software corporation that makes enterprise software to manage business operations and customer relations.

ASCO's work on CancerLinQ began in 2010, with an estimated budget of $80 million for the first five years. The funds are raised from philanthropy, ASCO's revenues, its foundation, advocacy organizations, and pharmaceutical companies (The Cancer Letter, Feb. 20, 2015; Jan. 23, 2015; Nov. 22, 2013).

Key players in the field of providing EHRs include Epic Systems, Cerner, Eclipsys Corp., MEDITECH, McKesson Corp., and Flatiron. Players seeking to aggregate oncology data across EMRs include software companies Syapse and IBM Watson, the cancer centers consortium ORIEN, and Intermountain Precision Genomics (The Cancer Letter, July 10, 2015; March 13, 2015; Feb. 27, 2015; March 30, 2014).

New Silos?

While ASCO's analysis of the problem is viewed as on-target, not everyone agrees that congressional involvement is the answer or that EHR vendors would be able to fix the problems.

"I completely agree with ASCO that healthcare data exchange standards need to be legislated," said John McIlwain, chairman of the board and president of Velos, a company that makes research software widely used by cancer centers. "However, EMR vendors are not the only accountable constituency. Providers and payers are also often not incentivized to share data. What's more, all constituencies have to be concerned about HIPAA compliance. Until there are standards and laws that foster robust, safe, inexpensive data exchange, the problem will continue."

Electronic medical records were forced onto the US health care system before data standards could be developed, and ensuring interoperability of EHRs—even when they are supported by the same vendor—is no small task, said Stanley Huff, chief medical informatics officer at Intermountain Healthcare, who also serves as chair of the board of Health Level Seven International, a standards developing organization seeking to provide a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.

"The interoperability parts of the 21st Century Cures are very naive," said Huff, a clinical professor of biomedical informatics at the University of Utah School of Medicine.

The House bill suggests that the flow of data is being impeded and that enforcement has the ability to eliminate these impediments. In reality, data sharing is complex and expensive.

"It makes it sound like if we find the bad guys, the problem will be solved," Huff said to The Cancer Letter. "The real solution is to invest in standards, and development of standards is a voluntary undertaking."

Huff said he has been told about contractual clauses in which EHR providers restrict the flow of information, but has never seen them.

"What I have never seen and don't find credible is that any software vendor would have it in the contract that data cannot be shared," Huff said. "They are prohibiting their own income if they do that. They have no motivation to block information to another system. They have motivation to share."

Transfer of data is expensive and hard to do, and therefore fees for providing this service are appropriate.

"Until we get to better standards, it's hard to create these interfaces," Huff said. Even two hospitals using the EHR systems that are produced by the same vendor have to overcome significant technical problems.

"To exchange with another system they have to change it from local code to standard code, and that takes time and money," Huff said. "If two institutions are regularly exchanging data, the cost of the interface can be spread out over many transfers and therefore is inexpensive. However, if the exchange is one of a few, the cost can be very high."

Huff estimates the construction cost of an interface at roughly $20,000.

In some situations, the incentives line up against sharing data, Huff said. "I can believe that there are health care providers who would be reluctant to share data with direct competitors in the same market," he said. "They would be nervous about another provider stealing their patients."

The situation mentioned by Hudis—where medical records travel from institution to institution in PDF format and are scanned in—is quite common. "That's how it is," said Huff. "They haven't created interface so they have to use the fax or PDF. They can create an interface."

Moving charts is difficult enough, but charts are

just a part of the picture. Lab data are different from drug data and both differ from the diagnosis data.

"The real barriers are need for better standards and the need for monetary incentives to want to exchange data, and standards are created by volunteer organizations, and the pace at which we do this is the pace of volunteering time," Huff said.

If one is to believe the group of EHR vendors, the technical component of the problem of interoperability is being resolved,

"CommonWell Health Alliance is working to improve information exchange across disparate systems by creating real-world interoperability services that are currently being deployed nationwide," Jitin Asnaani, Executive Director of CommonWell Health Alliance said to The Cancer Letter.

"Our services remove the need for multiple interfaces in order to exchange health data–which can be costly and inefficient," Asnaani said. "All members of CommonWell—including EHR market leaders in acute, ambulatory, oncology, imaging, perinatal, population health and post-acute care—support the belief that provider access to health data must be built into health information technologies at a reasonable cost for use by a broad range of health care providers and the populations and people they serve."

That said, Epic is not a member of CommonWell.

A Safety Issue

"While much progress has been made in exchanging structured demographic information, critical information needed by oncologists, such as staging, treatment plans, pathology, and radiology are still exchanged by fax machine," said Jonathan Hirsch, president of Syapse, a company that integrates oncology data from EHRs with genomic data to enable precision medicine. "Extracting structured oncology data from one EHR is difficult enough, but doing so from multiple customized EHR systems and integrated the subsequent patient data requires a herculean effort.

"At its core, this is a patient safety issue. Print-fax-scan and other unstructured medical record transmission mechanisms hinder the ability to coordinate care across the many clinicians who treat a patient during their cancer care journey.

"Health IT vendors, oncologists, and professional societies need to come together and agree on a core set of oncology data elements that can be made accessible by every EHR to any other software system. This will greatly accelerate the sorts of care coordination, clinical decision support, quality improvement, and research programs that ASCO, Syapse, and others are implementing."

The House version of 21st Century Cures required that EHRs meet the following criteria to be considered interoperable:

1. Secure Transfer—The technology allows the secure transfer of all electronically accessible health information to and from any and all health information technology for authorized use under applicable State or Federal law.

2. Complete Access to Health Information—The technology allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law without special effort by the requestor of such health information.

3. No Information Blocking—The technology is not configured, set up, or implemented to information block.

The legislation specifically prohibits vendors, health care providers, and operators of health information exchanges and data registries from engaging in information blocking. Prohibited practices include imposing unreasonable fees and introduction of contractual language to restrict an authorized exchange.

As Shutdown Looms, Long-Term Prospects for NIH Remain Bright

(Continued from page 1)

After 12 years of flat funding, a significant number of members of Congress on both sides of the aisle are enthusiastically backing the NIH, which is the largest supporter of medical research in the world. Many in Congress, Republicans and Democrats alike, appear to be singing from the same song sheet about the importance of prioritizing the NIH budget.

Many are echoing former Speaker of the House, Newt Gingrich (R-Ga.), who pointed out in an op-ed earlier in the year that, "We are in a time of unimaginable scientific and technological progress. By funding basic medical research, Congress can transform our fiscal health, and our personal health, too."

Lawmakers are also competing to one-up each other's suggestions for boosting NIH's budget. For example, in early February, President Barack Obama's fiscal year 2016 budget proposal called for a funding increase of $1 billion for the NIH (a 3.3 percent increase to $31.3 billion).

Then, in June, Rep. Tom Cole (R-Okla.), chairman of the House Labor-HHS-Education Appropriations

Subcommittee proposed a $1.1 billion increase for NIH, and later that same month, Sen. Roy Blunt (R-Mo.), chairman of the equivalent Senate subcommittee, released an appropriations bill that would increase NIH's budget by $2 billion (a 6.6 percent increase to $32.3 billion).

Shortly after proposing this significant funding increase for the NIH, Chairman Blunt told attendees at an event at Washington University in St. Louis that he planned to make NIH funding a priority in his new position as head of the subcommittee. Also, he commented that he clearly understands the message he's received from NIH Director Francis Collins, and others, "that the NIH institutes and centers require steady and sustained growth."

However, it's also clear that for the NIH to receive the increases that have been proposed by the President, House, and Senate, Republicans and Democrats must work together and agree on a broader budget deal to raise the sequester-imposed funding caps for fiscal year 2016.

This point is underscored when considering that the subcommittees in the Senate and House that are proposing these funding increases for NIH are also making significant spending cuts to many other programs in order to adhere to the budget caps outlined in the Budget Control Act of 2013.

Therefore, we are quite pleased to see that Democrats and the White House, as well as many Republicans, are strongly rejecting the sequester-imposed spending levels. Instead, many are pushing for another bipartisan budget agreement in the mold of the 2013 deal negotiated by then-Budget Committee chairs, Rep. Paul Ryan (R-Wis.), and Sen. Patty Murray (D-Wash.), which provided additional overall funding for many priority programs, such as the NIH.

This stance is consistent with the position President Obama took a few months ago when he wrote to the House and Senate Appropriations Committee chairmen to express opposition to the spending level limits and called on them to instead negotiate another bipartisan budget deal to raise the spending caps. In fact, in a bid to prompt such talks, President Obama has said he would not sign any fiscal year 2016 spending measure that adheres to the statutory spending limits.

As the founding organizer and lead sponsor of the 3rd Annual Rally for Medical Research Hill Day, the American Association for Cancer Research is trying to do its part to advocate for the NIH by joining with more than 300 organizations to sustain this current momentum for medical research and further inspire support for the lifesaving research that is funded by the NIH.

During his breakfast remarks to the participants, who were in town for the Rally for Medical Research Hill Day on Sept. 17, Chairman Cole suggested that should such a budget deal be reached, the NIH would likely receive an increase on the order of $1.5 billion in fiscal year 2016.

Of course, this would represent a middle ground between the House and Senate proposals and would be in line with the positive momentum we've seen NIH receive throughout 2015. And if this were to indeed happen, it would be the largest increase in annual appropriations for the NIH since 2003.

Cole's parting message to the Rally Hill Day participants was that they "must keep the pressure on" and tell Congress that they must reach a deal that allows for additional funds for priority areas such as medical research.

Therefore, we have a wonderful opportunity to make a difference for NIH in fiscal year 2016, but as Cole pointed out, the American public must reach out to members of Congress to let them know that they should weigh in on this important matter. Specifically, we must ask them to prioritize NIH funding by providing robust, sustained and predictable budget increases

NIH budget increases will allow us to build on our nation's prior investments in medical research; ensure that our nation is able to respond to emerging health and research needs; boost local economies; and train the future generation of scientists. Medical research has saved the lives of millions of Americans. Robust, sustained, and predictable funding increases will allow us to make quantum leaps forward toward improving the health of all Americans.

The author is president of the American Association for Cancer Research, and physician-in-chief and chief medical officer of Memorial Sloan Kettering Cancer Center.

In Brief

Vanderbilt, UNC Receive "Exceptional" Ratings from NCI

(Continued from page 1)

Despite tight federal budgets, VICC will receive an increase over the previous five-year grant award.

This is the third renewal of VICC as an NCI-designated Comprehensive Cancer Center. It is one of only 45 such centers in the United States and the only Comprehensive Cancer Center in Tennessee providing treatment for both adult and pediatric patients.

VICC is among the few centers in the United States with multiple NCI-designated Specialized Program of Research Excellence (SPORE) grant programs, including breast and gastrointestinal cancer.

VICC has nearly 300 faculty members and generates more than $140 million in annual federal research funding, ranking it among the top 10 centers in the country in competitive grant support. The clinical program sees more than 6,000 new cancer patients each year.

THE UNC LINEBERGER COMPREHENSIVE CANCER CENTER earned an "exceptional" rating from the NCI for a major grant application associated with the center's multidisciplinary research.

The rating was given to UNC Lineberger's application to the NCI for renewal of a five-year grant that supports multidisciplinary research and shared scientific core resources for hundreds of scientists and clinicians in addition to other key center functions.

"This recognition speaks to the excellence of our researchers' work in a wide range of disciplines, from clinical research to cancer genetics to breast cancer and molecular therapeutics," Norman Sharpless, director of UNC Lineberger and the Wellcome Distinguished Professor in Cancer Research, said in a statement. "We are striving to leverage this high-impact research to ultimately reduce cancer incidence and mortality across North Carolina."

The rating followed a rigorous institutional review with a site visit by a panel of 22 peer reviewers. UNC Lineberger researchers made presentations to demonstrate both the depth and breadth of their work spanning the basic sciences, population sciences, clinical sciences and translational research.

UNC Lineberger researchers made presentations to demonstrate both the depth and breadth of their work spanning the basic sciences, population sciences, clinical sciences and translational research.

Researchers presented in each of nine program areas: cancer cell biology, immunology research, molecular therapeutics, virology, cancer genetics, clinical and translational research, breast cancer, cancer prevention and control, and cancer epidemiology.

PETER SCHULTZ was named CEO and **STEVE KAY** was named president of **The Scripps Research Institute**.

Schultz is a member of the TSRI faculty as well as director of the California Institute for Biomedical Research. Kay, a former TSRI faculty member, is dean of the Dornsife College of Letters, Arts and Sciences at the University Of Southern California.

Schultz will take the lead in developing long-term strategy and external alliances, with a focus on building "bench-to-bedside" research capabilities, while Kay will spearhead the academic and operational activities of the Institute, said Dick Gephardt, chair of the TSRI board of trustees and president/CEO of Gephardt Government Affairs.

Schultz assumes his role immediately. His research is at the interface of chemistry and biology. He has pioneered technologies to make and characterize molecules and materials hundreds to millions at a time--work that has dramatically impacted our ability to create new medicines and materials.

He has led the development of new drugs that affect endogenous stem cells for neurodegenerative diseases and diseases of aging, and has directed efforts that have resulted in breakthrough therapies for the treatment of cancer, autoimmune and infectious disease. Most recently his laboratory has successfully created new "synthetic" organisms in which the evolutionary constraints of the 20-amino acid genetic code are lifted.

Kay, an expert on genes and circadian rhythms, will begin as president-elect as he transitions from USC. Kay has founded several biotechnology companies, most recently Reset Therapeutics, a San Francisco-based drug development corporation.

JEFFREY MEDIN was named MACC (Midwest Athletes Against Childhood Cancer) Fund Endowed Professor at the department of pediatrics at the **Medical College of Wisconsin**.

At MCW, Medin will serve as vice chair of research innovation for the department of pediatrics, and research director within the section of pediatric hematology/oncology, where he is expected to expand the Pediatric Hematology/Oncology Transplant Program.

Medin will also serve as director of cell processing laboratories in the MCW Adult and Pediatric Blood and Marrow Transplant Program, with appointments in the MCW Cancer Center and the BloodCenter of Wisconsin's Blood Research Institute.

Medin will also be the Good Manufacturing Practice facility director at MCW, referring to the Good Manufacturing Practice Regulations issued by FDA.

Medin currently serves as a professor in the Department of Medical Biophysics and the Institute of Medical Science, Faculty of Medicine, at the University of Toronto in Ontario, Canada.

He is also a senior scientist with the University

Health Network, and director of the UHN Vector Core Facility at the Krembil Discovery Tower at Toronto Western Hospital.

"Dr. Medin has a distinguished record of accomplishment in the field of pediatric cancers," said Joseph Kerschner, dean of the school of medicine and executive vice president of MCW. "Dr. Medin's appointment represents the importance of fighting cancer as a strategic priority for MCW, and highlights how we work closely with our partners at the MACC Fund and Children's Hospital of Wisconsin to improve outcomes for children and families."

Medin will assume his full duties on Jan. 1, 2016.

EVELYN WHITLOCK named chief science officer of **Patient-Centered Outcomes Research Institute**.

Whitlock is an expert in evidence-based medicine and health policy at Kaiser Permanente Northwest in Portland, Ore., as its new chief science officer.

As CSO, Whitlock will be responsible for leading the ongoing development and management of PCORI's patient-centered comparative clinical effectiveness research portfolio.

Whitlock, a board-certified preventive medicine physician, is the founding director of the Kaiser Permanente Research Affiliates Evidence-based Practice Center, or EPC, one of 13 officially designated EPCs in the nation.

It operates under a multi-year contract to the Agency for Healthcare Research and Quality to produce evidence syntheses based on systematic reviews, lead methodological development for systematic reviews, and support the increased application of systematic reviews and other evidence-based products into policy and practice.

Whitlock sits on the Methods Steering Committee, among other leadership activities for AHRQ's EPC program. Whitlock also serves as the principal investigator for multiple contracts for the U.S. Preventive Services Task Force to provide systematic reviews for USPSTF, which are used to make evidence-based recommendations for clinical preventive services across all ages and health conditions.

She has provided evidence synthesis services to the USPSTF for more than 15 years, as well as to other federal agencies, including the U.S. Centers for Disease Control and Prevention and the National Cancer Institute. In addition, she has helped lead scientific resource centers that provide scientific, methodological, and technical support for large national programs such as AHRQ's Effective Healthcare Program and the USPSTF.

She was a member of the senior faculty of the Oregon Clinical and Translational Research Institute, one of the first 12 NIH-funded centers for clinical and translational sciences, and helped develop and implement its translation of research into policy and practice program.

In addition to her position at Kaiser Permanente, Whitlock serves as a clinical associate professor in the Department of Public Health and Preventive Medicine at Oregon Health Sciences University, where she directed its residency program from 1993-1997. She also is an associate professor in OHSU's Department of Medical Informatics and Clinical Epidemiology.

JOAQUIN ESPINOZA was named associate director of science at the **Linda Crnic Institute for Down Syndrome** at the University of Colorado Denver School of Medicine at the Anschutz Medical Campus (CU Anschutz).

His team will continue investigating diverse cancer genes, while also focusing on the remarkable fact that the population with Down syndrome has a much lower risk of developing solid tumors.

Espinosa's team has moved from the University of Colorado Boulder to the Department of Pharmacology at UCD-SOM in Aurora, where Espinosa will hold a full professorship.

In his new position overseeing science at the Crnic Institute, Espinosa is tasked with expanding beyond the existing Crnic Grand Challenge Grants program that has stimulated 28 labs and nearly 100 scientists to work on Down syndrome research at the University Of Colorado.

He will foster growth in key areas such as Alzheimer's disease, cancer, autoimmune disorders and clinical research in association with the Sie Center for Down Syndrome at Children's Hospital Colorado.

He will also work on establishing public-private-university alliances to stimulate research that benefits people with Down syndrome.

Previously Espinosa held the position of associate professor of molecular, cellular and developmental biology at the University of Colorado Boulder, where he will continue as a visiting associate professor.

He will also continue as the University of Colorado's director of the Functional Genomics Facility and as the co-leader of the Molecular Oncology Program at the University of Colorado Cancer Center.

ROBERT SCHREIBER and **PHILIP GREENBERG** were named editors-in-chief of Cancer Immunology Research, one of eight peer-reviewed journals published by the American Association for Cancer Research.

Cancer Immunology Research publishes original articles reporting advances in cancer immunology and immunotherapies that span the spectrum of science and medicine, from basic investigations in host-tumor interactions to developmental therapeutics in model systems, early translational studies in patients, and late-stage clinical trials.

"In 2013, the AACR launched Cancer Immunology Research with Glenn Dranoff as the founding editor-in-chief to capture the most significant work in the field of cancer immunology and to highlight the relationship of cancer immunology to other areas of cancer research," said Margaret Foti, chief executive officer of the AACR.

"The AACR owes much gratitude to Dr. Dranoff for his editorial vision and for the journal's many early successes. Under the new leadership of Drs. Schreiber and Greenberg, the journal will continue its commitment to publish all aspects of cancer immunology and immunotherapy."

Schreiber is the alumni endowed professor of pathology and immunology and director of the Center for Human Immunology and Immunotherapy Programs at Washington University School of Medicine in St. Louis.

Greenberg is a professor of medicine/oncology and immunology at the University of Washington and head of the Program in Immunology at the Fred Hutchinson Cancer Research Center in Seattle.

CHRISTOPH ZIELINSKI was named editor-in-chief of **ESMO Open**, a new open-access, peer-reviewed online journal published by the European Society of Medical Oncology.

Zielinski, 63, is director of the Clinical Division of Oncology and Chairman of the Department of Medicine I and the Comprehensive Cancer Centre at the Medical University in Vienna.

He has been president of the Central European Cooperative Oncology Group since 1999 and member of the ESMO executive board since 2014.

Zielinski's research focuses on clinical trials in breast, lung cancer, personalized medicine and immuno-oncology. He has published more than 600 papers.

ESMO Open will operate a fast submission and review process with continuous publication online to ensure that timely, up-to-date research is available worldwide and adheres to a rigorous and transparent peer-review process.

The first articles will be published in January 2016.

HUNTSMAN CANCER INSTITUTE became the first **Mediso Preclinical Imaging Center of Excellence** in North America.

Two multi-modality nanoScan in vivo preclinical imaging systems have been installed at HCI: a nanoScan PET/MRI, combining positron emission tomography and magnetic resonance imaging techniques in one integrated system, and a nanoScan SPECT/CT, combining single photon emission tomography and x-ray computed tomography in one combined system.

Both systems integrate four imaging modalities without any compromise in image quality, performance and ease of use.

HCI provides a unique combination with the possibility to perform quantitative preclinical imaging covering four modalities - PET, SPECT, MRI and CT.

The researchers are able to select any combination of the modalities to interrogate a wide range of biological questions by using the common building blocks developed by Mediso, including the Nucline acquisition framework and the MultiCell animal handling and monitoring system.

SCIEX, a company focused on life science analytical technologies, announced a collaboration with the laboratory of Amanda Paulovich, of **Fred Hutchinson Cancer Research Center**, to make targeted proteomics in cancer research more reproducible and specific.

The collaboration provides SCIEX rights to commercialize the immuno-MRM assays that have been made in the Paulovich Laboratory, a member of the National Cancer Institute's Clinical Proteomic Tumor Analysis Consortium.

This effort, aligned with NIH's strategy to make technology more widely accessible through public and private partnerships, will result in commercially available assays that quantitatively

measure phosphorylated and unmodified proteins known to be involved in cancer signaling pathways.

To extend the reach of this technology, and make it more sensitive, and more routine and reproducible, an augmented approach is required over direct-MRM.

Immuno-MRM assays combine the best features of immunoassays and mass spectrometry to provide highly reproducible, specific and sensitive quantification of target proteins, including phosphorylated proteins.

However, a lack of availability of off-the-shelf content for this technique has been holding the field back, and this partnership aims to redress that.

By partnering with the Paulovich Laboratory, SCIEX will offer researchers a complete solution for mass spectrometry-based protein quantification of specific key biological pathways.

At the HUPO 2015 Annual World Congress this week, SCIEX introduced an improved targeted proteomics workflow that includes the new QTRAP 6500+ system and microflow LC, to combine high sensitivity and high throughput, and the Beckman Biomek Laboratory Automated Workstation, with optimized workflows for protein digestion.

The immuno-MRM kits will be commercialized for this workflow, creating a solution that will include sample preparation reagents, antibodies and beads for target enrichment, internal standards for quantification, and related methods for LC-MS and data analysis.

"The research reproducibility crisis has been well-documented in the media recently, especially around antibody quality for Immunoassays." said Aaron Hudson, senior director of academic and clinical research business at SCIEX."

The immuno-MRM kits will be available in 2016.

THE EXPERIMENTAL THERAPEUTICS INSTITUTE at the **Icahn School of Medicine at Mount Sinai** and **Regeneron Pharmaceuticals Inc.** entered into an agreement with the goal of accelerating the discovery of fully-human antibodies directed against therapeutic targets being researched by Mount Sinai investigators.

Regeneron will provide the ETI with access to VelocImmune technology and potential financial support to use the company's proprietary antibody discovery platform to generate antibodies against targets of interest and explore potential therapeutic applications for human disease.

ETI will undertake preclinical research and Regeneron has an exclusive option to negotiate a license to the antibody for future clinical development and commercialization.

Developed by Regeneron scientists, VelocImmune is a genetic engineering platform that enables the fast and efficient creation of superior fully-human monoclonal antibodies for drug development.

THOMAS JEFFERSON UNIVERSITY HOSPITAL and **GenomOncology** are co-developing a multi-assay integrated cancer profiling system.

Jefferson officials said they expects to launch the system for testing acute myeloid leukemia in their molecular pathology laboratory this fall.

Combining karyotype analysis, fluorescence in situ hybridization and the evaluation of mutational status of molecular markers by next generation sequencing, can lead to improved strategies for risk stratification and targeted therapy.

Traditionally, the results of these disparate tests have been reported separately.

To improve this situation, GenomOncology is expanding its GO Clinical Workbench platform to allow both independent and cumulative analysis and reporting of these assays.

GILDA'S CLUB CHICAGO and other organizations across the country launched the **It's About Time** campaign, an initiative to raise awareness of metastatic breast cancer.

"It is our hope that the It's About Time campaign will help inform the public about metastatic breast cancer and metastatic disease in general, while giving those diagnosed, their families and friends a greater voice. " said Laura-Jane Hyde, CEO, Gilda's Club Chicago said in a statement.

It's About Time encourages metastatic breast cancer patients, their families, caretakers and advocacy organizations to engage in a national conversation over the next six weeks about metastatic breast cancer facts, what time means to them, opportunities for increased advocacy and research supporting metastatic breast cancer, and, most importantly, to create a platform for those battling metastatic breast cancer to share their stories.

THE RIDE TO CONQUER CANCER raised $2.1 million for cancer research and accelerates transformational cancer discoveries at **Johns Hopkins Kimmel Cancer Center, Sibley Memorial, Suburban** and **Howard County General Hospitals**.

"The Ride to Conquer Cancer is a testament to strength in numbers and we are very thankful to the

community of riders, donors, sponsors, crew members and volunteers whose commitment has enabled the second annual Ride to be a great success," said William Nelson, director of the Johns Hopkins Kimmel Cancer Center.

Over two years, the two-day 150-mile ride held in the Washington area raised $4.7 million. This year, over 500 riders participated.

Drugs and Targets

FDA Approves Varubi for Chemotherapy-Induced Nausea

FDA approved Varubi (rolapitant) to prevent delayed phase chemotherapy-induced nausea and vomiting.

Varubi is approved in adults in combination with other antiemetic agents that prevent nausea and vomiting associated with initial and repeat courses of emetogenic and highly emetogenic cancer chemotherapy.

Varubi is a substance P/neurokinin-1 (NK-1) receptor antagonist. Activation of NK-1 receptors plays a central role in nausea and vomiting induced by certain cancer chemotherapies, particularly in the delayed phase.

Varubi is provided to patients in tablet form.

The safety and efficacy of Varubi were established in three randomized, double-blind, controlled clinical trials where Varubi in combination with granisetron and dexamethasone was compared with a placebo in 2,800 patients receiving a chemotherapy regimen that included highly emetogenic (such as cisplatin and the combination of anthracycline and cyclophosphamide) and moderately emetogenic chemotherapy drugs.

Patients treated with Varubi had a greater reduction in vomiting and use of rescue medication for nausea and vomiting during the delayed phase compared to those receiving the control therapy.

Varubi inhibits the CYP2D6 enzyme, which is responsible for metabolizing certain drugs.

Varubi is contraindicated with the use of thioridazine, a drug metabolized by the CYP2D6 enzyme, because use of the two drugs together may increase the amount of thioridazine in the blood and cause an abnormal heart rhythm that can be serious.

Varubi is marketed by Tesaro Inc. of Waltham, Mass.

Amgen's supplemental new drug application for Kyprolis (carfilzomib) in relapsed multiple myeloma was granted priority review by FDA.

Amgen said FDA has accepted for priority review the supplemental new drug application (sNDA) of Kyprolis (Carfilzomib) for injection for patients with relapsed multiple myeloma.

The sNDA is designed to expand the current indication to include Kyprolis in combination with dexamethasone for patients who have received at least one prior therapy.

Application based on phase 3 head-to-head trial showing superiority of Kyprolis and dexamethasone over bortezomib plus dexamethasone.

The FDA's acceptance of the sNDA for Kyprolis follows the recent FDA approval for Kyprolis in combination with Revlimid (lenalidomide) and dexamethasone for the treatment of patients with relapsed multiple myeloma who have received one to three prior lines of therapy.

The application is based on data from the phase 3 head-to-head ENDEAVOR study, which showed that patients with relapsed multiple myeloma treated with Kyprolis and low-dose dexamethasone lived twice as long without their disease worsening, demonstrating statistically and clinically significant superiority over bortezomib and low-dose dexamethasone (median progression-free survival [PFS] 18.7 months versus 9.4 months, HR=0.53, 95 percent CI, 0.44 – 0.65; $p<0.0001$).

Treatment discontinuation due to adverse events and on-study deaths was comparable between the two arms. The rates of cardiac failure and renal failure for Kyprolis were comparable to those observed in the Phase 3 ASPIRE study.

In ENDEAVOR, the rates for cardiac and renal failure were higher in the Kyprolis arm versus the bortezomib arm. There was also an increase in the incidence of hypertension and dyspnea in the Kyprolis arm compared to bortezomibin ENDEAVOR.

The Prescription Drug User Fee Act target action date is Jan. 22, 2016.

Roche NimbleGen introduced an enhanced whole exome sequencing solution for medical and translational research.

Roche announced the global launch of the SeqCap EZ MedExome Target Enrichment Kit, a comprehensive whole exome sequencing solution designed to increase the discovery and detection of human genetic variants associated with disease while

reducing sequencing costs.

Pekka Ellonen, head of the sequencing unit for the Institute for Molecular Medicine Finland at the University of Helsinki, said, "We have evaluated a number of target enrichment systems for whole exome sequencing.

The kit is labeled "for research use only. It isn't approved for diagnostic procedures.

CTI BioPharma Corp. said it plans to submit a new drug application to FDA following a productive pre-NDA meeting for pacritinib, an investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R.

The company expects to submit the NDA in the fourth quarter of 2015 and to request faster approval for the treatment of patients with intermediate and high-risk myelofibrosis with low platelet counts of less than 50,000 per microliter.

The NDA will be based primarily on data from the PERSIST-1 phase 3 trial - as well as data from Phase 1 and 2 studies of pacritinib - and additional information requested by FDA, including a separate study report and datasets for the specific patient population with low platelet counts of less than 50,000 per microliter for whom there are no approved drugs.

Submission of an NDA after a single phase 3 trial under accelerated approval, instead of waiting to complete two phase 3 trials, could potentially reduce time to market by up to 14 months.

Amgen Inc. and Xencor Inc. entered into a research and license agreement to develop and commercialize novel therapeutics in the areas of cancer immunotherapy and inflammation.

The research collaboration brings together Amgen's capabilities in target discovery and protein therapeutics with Xencor's XmAb bispecific technology platform.

The collaboration includes molecular engineering by Xencor and the preclinical development of bispecific molecules for five programs proposed by Amgen, leveraging XmAb bispecific Fc domains to make half-life extended T cell engagers and dual targeting bispecific antibodies.

The agreement also includes a preclinical bispecific T cell engager program directed at CD38 and CD3 for multiple myeloma.

Amgen will be fully responsible for preclinical and clinical development and commercialization worldwide. Under the agreement, Xencor will receive a $45 million upfront payment and up to $1.7 billion in clinical, regulatory and sales milestone payments in total for the six programs.

Xencor is eligible to receive mid to high single-digit royalties for candidates directed against Amgen's targets, and high single to low double-digit royalties for Xencor's CD38 bispecific T cell engager.

Bispecific technologies seek to engineer monoclonal antibodies to bind two unique drug targets, as opposed to traditional antibodies designed to bind to a single antigen target.