THE CANCER LETTER

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Two Reports Offer Definitions, Plans For Comparative Effectiveness Research

By Paul Goldberg

The Institute of Medicine and a government-wide coordinating group on earlier this week issued reports intended to guide the $1.1 billion federal effort to jump-start research in comparative effectiveness.

The IOM report, which is more specific of the two documents, included 100 projects for comparative effectiveness studies. Of these projects, 12 seem to be directly relevant to cancer, and at least a couple more could be construed as partially relevant.

The reports also include largely similar definitions of comparative effectiveness research.

Some projects appear to be relatively straightforward evaluations of

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In the Cancer Centers:

Fred Hutchinson Director Lee Hartwell To Retire Next Year; Board Begins Search

FRED HUTCHINSON Cancer Research Center board of trustees said its president and director, **Lee Hartwell**, plans to retire in June 2010. Hartwell, a recipient of the 2001 Nobel Prize in physiology or medicine, has been president and director of the Hutchinson Center since 1997.

"It's time," Hartwell said. "I have been president and director of the Center for 12 years. It's time for new leadership."

Hartwell, who will turn 70 in October, says he informed the board's executive committee more than a year ago of his desire to retire and to begin the transition to new leadership. The exact timing of his departure was worked out over the last few months.

Doug Walker, chairman of the board, said the search for Hartwell's successor will begin immediately. "Lee's leadership over these last 12 years has been extraordinary," Walker said. "It's hard for us to picture Fred Hutchinson Cancer Research Center without Lee at the helm. We're fortunate that Lee will be around to ensure that the transition to new leadership will be an extremely smooth one."

Board member **Steve Davis**, a senior adviser at McKinsey & Co., will head the search committee, which will also include members of the board and scientific faculty.

"The first thing we need to do is make a thorough assessment of the position and discuss the qualifications for the next center leader with

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Reports Offer First Glance At $1.1 Billion CER Program

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technologies. One of the most daunting—at least in oncology—is a project comparing treatments for early-stage prostate cancer:

"Compare the effectiveness of management strategies for localized prostate cancer (e.g., active surveillance, radical prostatectomy [conventional, robotic, and laparoscopic], and radiotherapy [conformal, brachytherapy, proton-beam, and intensity-modulated radiotherapy]) on survival, recurrence, side effects, quality of life, and costs."

How would one approach this cluster of research questions?

"Remember that not all CER has to be prospective studies, and a study of this topic would almost certainly not be a prospective randomized trial, even though that would be optimal," said Richard Schilsky, professor of medicine at the University of Chicago, chairman of the Cancer and Leukemia Group B and one of the experts who reviewed the IOM report.

"Prospective comparisons of prostatectomy vs. radiation therapy have already been attempted and failed due to lack of equipoise, and any prospective study would likely be of a non-inferiority design and would therefore be large, lengthy and expensive, even if it could be completed," Schilsky said.

Altogether, HHS will spend $1.1 billion on comparative effectiveness research over the next 20 months. Of this amount, $400 million will be spent by NIH, another $400 million by the Office of the HHS Secretary, and $300 million by the Agency for Healthcare Research and Quality. For such research to continue beyond 2010, the government would have to build a new infrastructure for funding research and review of findings.

The two reports released this week demonstrate how the elements of CER are starting to come together and suggest strategies for researchers vying to conduct these studies:

—The stimulus law directed IOM to come up with a list of potential comparative effectiveness research projects that would receive $1.1 billion in stimulus funds. The IOM report makes a series of recommendations for CER. The document is posted at http://www.nap.edu/catalog.php?record_id=12648#toc.

—An excerpted list of cancer related topics identified by IOM appears on page 5. The projects aren't ready for bidding. The complete list of 100 projects is posted by IOM at http://www.iom.edu/CMS/3809/63608/71025/71032.aspx.

—Similarly, the stimulus bill formed the Federal Coordinating Council for Comparative Effectiveness Research, and advisory group created by the law, published its recommendations for the $400 million in funds that will be allocated directly by the Office of the HHS Secretary. The council's most important recommendation is to devote the largest amount of OS resources to creating a data infrastructure. The group's report is posted at http://mail.google.com/mail/?ui=2&view=bsp&ver=1qygpcgurkovy.

Next, on July 30, HHS will be required to submit a specific plan for the $1.1 billion in comparative effectiveness research.

Defining Comparative Effectiveness

IOM put together a definition of comparative research, as did a panel of government research officials called the Federal Coordinating Council for Comparative effectiveness.

The IOM Definition:

Comparative effectiveness research (CER) is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.

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The council's definition:

Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

—To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations and subgroups.

—Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.

—This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.

IOM's 10 Recommendations

Recommendation 1: Prioritization of CER topics should be a sustained and continuous process, recognizing the dynamic state of disease, interventions, and public concern.

The committee acknowledges the critical role that the general public and other stakeholders played in this current report and their potential to enhance CER in the future. CER generates results that bear directly on decisions in which individual patients play an active role. Active involvement of consumers, patients, and caregivers is essential to identifying CER topics of real concern to them as well as for suggesting criteria for the prioritization process that reflect public goals and values.

Recommendation 2: Public (including consumers, patients, and caregivers) participation in the priority-setting process is imperative to provide transparency in the process and input to delineating research questions.

The committee noted that more complete background information about the suggested research topics would have substantially enhanced its prioritization process. A national CER enterprise should, on an ongoing basis, collate national data concerning the significance of diseases and conditions as well as information about current research gaps and redundancies related to the specific research topics under consideration. The committee found that the descriptions of research topics were often difficult to understand; an opportunity for a priority-setting body to interrogate CER topic nominators would help to clarify the nominator's intent.

Recommendation 3: Consideration of CER topics requires the development of robust, consistent topic briefs providing background information, current practice, and research status of the condition and its interventions.

The committee concluded that a high level of transparency is essential for setting priorities for expending public funds on research from which the public expects so much. Given the magnitude of public investment in CER, a rolling evaluation of the selection and prioritization processes, as well as the return on investment of prior CER research by application throughout the health system should be incorporated in the prioritization process to ensure quality improvement.

Recommendation 4: Regular reporting of the activities and recommendations of the prioritizing body is necessary to evaluate the portfolio's distribution, its impact for discovery, and its translation into clinical care in order to provide a process for continuous quality improvement.

The committee's work, including stakeholder input, revealed the scope of research infrastructure needed to support CER in its goal of improving health care decisions and their implementation. The committee does not attempt to fill in all the details, but it concludes that the country must have a federal organizational infrastructure with appropriate responsibility and authority to coordinate the prioritization process, support the development of necessary databases and registries, fund the training of needed researchers, conduct the research, and support a vigorous translational effort to help bring research findings into everyday clinical practice. Without federal support for an infrastructure to coordinate the national CER effort, all the CER that the committee identified as high priority is unlikely to occur (see Chapter 6 for a discussion of infrastructure issues).

Objectivity will be central to the public's trust and confidence in the integrity of the CER Program. CER is as vulnerable to bias and conflict of interest as any other area of medical research. A recent IOM report, Conflict of Interest in Medical Research, Education, and Practice, recommends principles to inform the design of policies

to identify, limit, and manage conflicts of interest in health care research. The committee urges that the CER Program be constituted and managed in accordance with the recommendations of this report.

Recommendation 5: The HHS Secretary should establish a mechanism—such as a coordinating advisory body—with the mandate to strategize, organize, monitor, evaluate and report on the implementation and impact of the CER Program.

A central focus on the patient is fundamental to high-quality health care. To meet the requirement of patient-centeredness, respect for individual patients' unique needs, beliefs, and values must drive the development of the field of CER and the application of its findings to patient care. Consumers, patients, and caregivers have a key role to play in informing and framing CER. They typically have different perspectives from researchers, and there is strong evidence that many consumers—but not all—want to be involved in decision making about their care. Involving them in CER will help to keep the research relevant and applicable to real-world settings. Also, if consumers, patients, and caregivers are engaged and informed about CER activities, they are more likely to trust the research findings and insist that their own care take account of the results.

Recommendation 6: The CER Program should fully involve consumers, patients, and caregivers in key aspects of CER, including strategic planning, priority setting, research proposal development, peer review, and dissemination.

The CER Program should develop strategies to reach out to, engage, support, educate, and, as necessary, prepare consumers, patients, and caregivers for leadership roles in these activities. The CER Program should also encourage broad participation in CER in order to create a representative evidence base that could help identify health disparities and inform decisions by patients in special population groups.

CER comprises a broad spectrum of established and emerging research methods including clinical trials, observational studies, and systematic reviews of existing evidence. There is a significant need for better research methods. Current study designs—experimental and nonexperimental—must be refined to ensure scientific rigor. Clinical trials will always be essential to CER, but more efficient, larger, simpler, and pragmatic designs are needed. In systematic reviews, for example, research is needed on how to identify and use evidence from observational studies on intervention effectiveness, and also on how to assess a heterogeneous body of evidence.

New analytic techniques are needed to evaluate the effects of bias due to confounding when assessing comparative effectiveness using large observational datasets.

Recommendation 7: The CER Program should devote sufficient resources to research and innovation in the methods of CER, including the development of methodological guidance for CER study design such as the appropriate use of observational data and more informative, practical, and efficient clinical trials.

CER should also draw from analyses of existing data, such as that held by payers, health care delivery systems, and electronic health records. However, if the CER enterprise is to harness the rich potential of these data, it must protect the privacy and maintain the security of patient data, develop efficient means for linking data from multiple databases, and engage holders of large datasets such as health insurers, health care delivery systems, and health care providers.

Recommendation 8: The CER Program should help to develop large-scale, clinical and administrative data networks to facilitate better use of data and more efficient ways to collect new data to inform CER. The CER Program should ensure that CER researchers and institutions consistently adhere to best practices to protect privacy and maintain security. The CER Program should support the development of methodologies for linking patient-level data from multiple sources. The CER Program should encourage data holders to participate in CER and provide incentives for cooperation and maintaining data quality.

ARRA's infusion of federal funds into CER will stress the limited capacity of the current CER workforce. AHRQ's CER appropriation alone increased tenfold. Whether the current research workforce can meet the human resource demands of the $1.1 billion ARRA appropriation for CER is uncertain. A significant increase in CER activity will certainly create a substantial need for experts in biostatistics, epidemiology, systematic reviews (including meta-analysis), clinical trials (including head-to-head effectiveness trials), statistical modeling, observational analytic methods, use of analysis of large datasets, cost-effectiveness analysis, clinical outcomes research, and communication of research findings. The methods of CER must advance, which will require training and career support for methodologists.

Recommendation 9: The CER Program should develop and support the workforce for CER to ensure the nation's capacity to carry out the CER mission.

Important next steps include: Development of a strategic plan for research workforce development and long-term, sufficient funding for early career development including expanding grants for graduate and postgraduate training opportunities in comparative effectiveness methods as well as career development grants and mid-career merit awards.

The substantial geographic variability in health care delivery suggests that physicians differ in what they consider to be "best practice." By discovering what works best, for whom, and under what circumstances, CER has the potential to narrow the spectrum of what health professionals consider to be best practice. Health care professionals and patients should be able to use CER results to make informed decisions based on the best available evidence, the patients' preferences, and the patient's unique characteristics. However, an ambitious research enterprise alone will not improve health care in the United States without significant attention to high fidelity translation of knowledge into practice. At present, the translation of research findings into practice is slow and incomplete. Barriers include perverse reimbursement incentives, physician perceptions about patients' expectations, and patients' concerns about denials of care or their reluctance to question clinicians.

The CER Program should require researchers to publish all federally funded CER studies and make the research available to the public. Moreover, research into knowledge translation must be a high priority.

Recommendation 10: The CER Program should promote rapid adoption of CER findings and conduct research to identify the most effective strategies for disseminating new and existing CER findings to health care professionals, consumers, patients, and caregivers and for helping them to implement these results in daily clinical practice.

Coordinating Council's Recommendations

The Federal Coordinating Council prioritized the investments into three categories:

Primary investment. This area of investment should represent a large portion of the OS funds. It best fulfills the full range of prioritization criteria and requires scaled investment in order to be successful. The Council recommends that CER Data Infrastructure be the primary investment.

Secondary investments. These areas should also receive significant investment. They are as critical to success in CER as the primary focus, but individually may require a smaller amount of funding to be successful. The Council recommends that Dissemination and Translation of CER, Priority Populations, and Priority Types of Intervention be secondary investments.

Supporting investments. These areas should not be the major focus of OS funding as they do not fulfill the prioritization criteria as well as primary and secondary investments, but some funding may be necessary to support and enable investments in higher priority areas and fill identified gaps. The Council recommends that Human and Scientific Capital, Research, and Conditions receive supporting investments. It is important to note that these recommendations pertain only to OS funds; AHRQ, NIH, and VA have a history of significant investments in Research, Human and Scientific Capital, and Conditions.

IOM Report Includes List Of Cancer Research Priorities

The IOM committee recommended the research priority areas after consulting health professionals, consumer advocates, policy analysts, and others who submitted nominations through an online form and through presentations at public meetings.

The committee received 1,268 unique topic suggestions, which it narrowed to 100 based on a set of criteria that included its charge to develop a balanced portfolio.

"This report lays the foundation for an ongoing enterprise to provide the evidence that health care providers need to make better decisions and achieve better results," co-chair Sheldon Greenfield, Donald Bren Professor of Medicine and executive director, Health Policy Research Institute, University of California, Irvine, said in a statement. "To make the most of this enterprise, HHS will need to ensure that the results are translated into practice and that the public is involved in priority setting to ensure that the research is relevant to everyday health care."

The report is dedicated to the memory of Maria Carolina Hinestrosa, executive vice president of the National Breast Cancer Coalition, who worked on the report until its completion. Hinestrosa died on June 21.

The following list includes cancer-related projects listed and prioritized by the IOM panel.

First Tier

Compare the effectiveness of upper endoscopy utilization and frequency for patients with gastroesophageal reflux disease on morbidity, quality of life, and diagnosis of esophageal adenocarcinoma.

Compare the effectiveness of comprehensive care coordination programs, such as the medical home, and usual care in managing children and adults with severe chronic disease, especially in populations with known health disparities.

Compare the effectiveness of management strategies for localized prostate cancer (e.g., active surveillance, radical prostatectomy [conventional, robotic, and laparoscopic], and radiotherapy [conformal, brachytherapy, proton-beam, and intensity-modulated radiotherapy]) on survival, recurrence, side effects, quality of life, and costs.

Compare the effectiveness of management strategies for ductal carcinoma in situ (DCIS).

Compare the effectiveness of imaging technologies in diagnosing, staging, and monitoring patients with cancer including positron emission tomography (PET), magnetic resonance imaging (MRI), and computed tomography (CT).

Compare the effectiveness of genetic and biomarker testing and usual care in preventing and treating breast, colorectal, prostate, lung, and ovarian cancer, and possibly other clinical conditions for which promising biomarkers exist.

Compare the effectiveness of interventions (e.g., community-based multi-level interventions, simple health education, usual care) to reduce health disparities in cardiovascular disease, diabetes, cancer, musculoskeletal diseases, and birth outcomes.

Second Tier

Compare the effectiveness of robotic assistance surgery and conventional surgery for common operations, such as prostatectomies.

Compare the effectiveness of film-screen or digital mammography alone and mammography plus magnetic resonance imaging (MRI) in community practice-based screening for breast cancer in high-risk women of different ages, risk factors, and race or ethnicity.

Compare the effectiveness of new screening technologies (such as fecal immunochemical tests and computed tomography [CT] colonography) and usual care (fecal occult blood tests and colonoscopy) in preventing colorectal cancer.

Fourth Tier

Compare the effectiveness of smoking cessation strategies (e.g., medication, individual or quitline counseling, combinations of these) in smokers from understudied populations such as minorities, individuals with mental illness, and adolescents.

Compare the effectiveness of traditional behavioral interventions versus economic incentives in motivating behavior changes (e.g., weight loss, smoking cessation, avoiding alcohol and substance abuse) in children and adults.

Compare the effectiveness of diagnostic imaging performed by non-radiologists and radiologists.

Compare the effectiveness of different techniques (e.g., audio, visual, written) for informing patients about proposed treatments during the process of informed consent.

In the Cancer Centers:

Hartwell To Continue Work In Early Cancer Detection

(Continued from page 1)

the center's scientific faculty as well as community leadership," Walker said. "We'll use this information to determine the qualities and qualifications of the person we hope to recruit." Walker said there is no specific time frame attached to the search. "It will conclude when we have the best candidate for the position," he said.

After Hartwell retires in 2010, he plans to continue to be involved with the center as director emeritus and also will continue his work in early cancer detection and science education. He will also continue his role as chairman of the executive committee of the Partnership for Personalized Medicine, an Arizona-based global effort to improve patient outcomes and reduce health care costs.

* * *

THE CENTER FOR STEM CELL & REGENERATIVE MEDICINE, comprised of Case Western Reserve University, Cleveland Clinic, University Hospitals, and Athersys Inc., has received $5 million from Ohio's Third Frontier Commission under the Research Commercialization Program. The funding will help support new stem cell technologies including two commercial, four emerging, and three pilot projects. This funding will be matched by each of the projects to create a $10 million grant benefiting stem cell and regenerative medicine in Ohio. "This funding provides CSCRM the support it needs to continue to aggressively move new technologies from academic labs towards commercial development," said **Stan Gerson**, director of the center. . . . **VIRGINIA COMMONWEALTH UNIVERSITY** Massey Cancer Center researcher **Steven Grant**, a professor of medicine and Massey's associate director for translational research, and his research team have received an NCI renewal grant of $1.25 million to develop a more selective approach to the treatment of multiple myeloma. The renewal award builds upon

recent work from Grant's laboratory demonstrating that exposure of human multiple myeloma and leukemia cells to agents known as Chk1 inhibitors disrupts the ability of these cells to arrest progression through the cell cycle and to repair DNA damage. The ultimate goal of this project is to develop a selective approach to multiple myeloma therapy combining clinically relevant Chk1 inhibitors with antagonists of the Ras/MEK/ERK pathway. The research is the basis for a phase II, multi-institutional clinical trial that is expected to open later this year, with Grant as the principal investigator. . . . **JENNIFER PIETENPOL**, director of the Vanderbilt-Ingram Cancer Center, has been named one of 15 new members of the Johns Hopkins University Society of Scholars. Pietenpol, who was a fellow in the Oncology Center at Johns Hopkins from 1991 to 1994, was recognized for major contributions to the understanding of the p53 signaling network. . . . **UCLA'S JONSSON COMPREHENSIVE CANCER CENTER** opened a new center offering such services as art therapy and QiGong, one-on-one and group counseling and advice on nutritional, spiritual and complementary approaches to healing. Formerly the Ted Mann Family Resource Center, the Simms/Mann-UCLA Center for Integrative Oncology is designed to help patients and family members optimize wellness and assist them in dealing with challenges during and after their cancer treatment. **Anne Coscarelli**, a psychologist, is the center's founding director. . . . **NORTHWESTERN UNIVERSITY** researcher **Chad Mirkin**, one of the world's leaders in nanotechnology research and its application, has been awarded the prestigious 2009 $500,000 Lemelson-MIT Prize. Mirkin, the George B. Rathmann Professor of Chemistry in the Weinberg College of Arts and Sciences, director of the International Institute for Nanotechnology at Northwestern, and member of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University, is being honored for his discoveries and contributions to science and invention. Mirkin is best known for the invention, development and commercialization of two technologies: the nanoparticle-based medical diagnostic assays underlying the FDA-approved Verigene IDTM system, and Dip-Pen Nanolithography, an ultra-high-resolution molecule-based printing technique. Both inventions were born, in part, out of Northwestern's Nanoscale Science and Engineering Center, funded by the National Science Foundation. . . . **UNIVERSITY OF ROCHESTER** Medical Center's James P. Wilmot Cancer Center recruited lung cancer expert **Manoj Agarwal**, from the Sutter Cancer Center in Sacramento, Calif. He is director of the multidisciplinary thoracic oncology program at the Wilmot Cancer Center. He is an active member of the Southwest Oncology Group and has led a number of clinical studies in lung, prostate and renal cancers.

NCI News:

NCI And Chile In Alliance For Cancer Research

NCI and the Ministry of Health of the Republic of Chile have signed a letter of intent to collaborate on a broad range of mutual interests, including basic and clinical cancer research, bioinformatics, data systems and informatics, and transfer of technology.

Also, the nations seek to develop competencies and training of researchers by sharing technology and expertise. The alliance also will work to enhance existing cancer registries and execution of early phase clinical studies with cultural sensitivity.

In 2006, cancer was estimated to be the second leading cause of death in Chile. Each year, 36,500 new cases are diagnosed. Cancer mortality rates for Chilean males are highest in stomach, lung and prostate cancers, while for Chilean females the highest mortality rates are in gallbladder, breast, and stomach cancers.

On June 16, Chilean Undersecretary of Public Health Jeanette Vega, representing the Ministry of Health of Chile, and NCI Director John Niederhuber, representing the U.S. Department of Health and Human Services, signed a letter of intent outlining the collaboration.

"We're eager to work with the United States on this very important effort," said Vega. "Chile and the U.S. have much to share in the area of cancer. We can share our longstanding experience in the area of gallbladder cancer and the U.S. can share their knowledge in the area of breast cancer. The key to be able to advance globally in these areas is to collaborate, collaborate and collaborate."

"Cancer knows no borders and we must conquer this disease globally," Niederhuber said. "This new partnership holds great promise to facilitate science that elucidates why cancer so often affects patients of different ethnicities and nationalities in unique ways, such as the high prevalence of stomach and gallbladder cancer in Chile. We're eager to work with Chile on this very important effort."

This cooperative effort may include promoting the exchange of technical information and research materials, development of collaborative research

projects, reciprocal access to laboratories, databases and research repositories, visits of professional specialists or experts, training activities and collaborative forums such as seminars, workshops, symposiums and conferences.

Chile joined four other Latin American countries and the U.S. in the United States-Latin America Cancer Research Network which will support high-quality cancer research and care in Latin America. This network is responsible for developing a comprehensive understanding of the burden of cancer and the current status of the research and care infrastructures in Latin America. In addition to Chile, the network includes Argentina, Brazil, Mexico, Uruguay, and the U.S.

The first collaborative pilot project of the United States-Latin America Cancer Research Network will focus on breast cancer because it is among the deadliest cancers in each of the five participating Latin American countries. The alliance will conduct research on those cancers that have the greatest impact on Latin America.

NCI-TACF Clinical Investigator Award

The ASCO Cancer Foundation is partnering with NCI to provide funding and recognition of clinical investigators who lead cancer research programs at academic cancer centers.

The Clinical Investigator Team Leadership Award will provide two years of salary support (10-15%) for up to 10 clinical investigators who play leadership roles in clinical trials at NCI-designated cancer centers.

This award will recognize outstanding clinical investigators whose work fosters collaborative team science and promotes retention of clinical investigators in the academic setting. NCI and The ASCO Cancer Foundation will provide up to 10 two-year awards of up to $50,000 per year, including salary, fringe benefits, and associated facilities and administrative costs.

The intent of the Cancer Clinical Investigator Team Leadership Award is to support academic clinical investigators who are not Principal Investigators on an NIH grant, but who are participating extensively in NCI-funded collaborative clinical trials. These are the people who play a leadership role that allows an institution to run a successful NCI-funded cancer research program.

NCI-designated cancer centers have been invited to submit one application on behalf of a clinical investigator. The funds will be provided to the cancer center as a supplement to its P30 Cancer Center Support Grant.

Further information: http://cancercenters.cancer.gov/grants_funding/program_announ.html#ASCO_08.

FDA Seeks Public Input on Tobacco Regulation

FDA is seeking public input on the implementation of its historic new authority overseeing tobacco products in the U.S. In a Federal Register notice, the agency invites the public to provide information and share views on a wide range of topics, from product content to advertising and marketing. All public comments will be posted online.

"We're interested in receiving input from across the country as the FDA begins to implement this important new authority intended to reduce the enormous toll of suffering and death caused by tobacco products in the United States," said FDA Commissioner Margaret Hamburg. "We look forward to the public's response."

The Federal Register notice can be viewed at: http://www.federalregister.gov/OFRUpload/OFRData/2009-15549_PI.pdf.

Funding Opportunities:

Modification to RFA-CA-09-012 to Increase Applicants Flexibility in Selecting the Research Focus for the Proposed Nanotechnology Centers http://grants.nih.gov/grants/guide/notice-files/NOT-CA-09-029.html

The Early Detection Research Network: Biomarker Developmental Laboratories (U01) (RFA-CA-09-017) Application Receipt Date: Oct. 29. http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-09-017.html

Cancer Intervention and Surveillance Modeling Network (CISNET) (U01) (RFA-CA-09-025) Application Receipt Date: Nov. 3. http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-09-025.html

NIH Extramural Loan Repayment Programs (LRP) (NOT-OD-09-107) http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-107.html

Extramural Loan Repayment Program for Clinical Researchers (LRP-CR): http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-108.html

Extramural Pediatric Research Loan Repayment Program (LRP-PR): http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-109.html

Extramural Loan Repayment Program for Health Disparities Research (LRP-HDR): Program Specific Information (NOT-OD-09-110) http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-110.html

Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (NOT-OD-09-112) http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-112.html

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THE CANCER LETTER

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Business & Regulatory Report

Deals &Collaborations:

Debiopharm, Moffitt Cancer Center Sign License Agreement For Small Molecule

Debiopharm Group of Lauzanne, Switzerland, and **Moffitt Cancer Center** signed an exclusive license agreement for the development and commercialization of Debio 0928, a small molecule in early preclinical development that inhibits the protein-protein interaction between Raf-1 (key signalling kinase in the MAP kinase pathway) and Rb (retinoblastoma protein).

Rb acts as a barrier to cell division and proliferation. However, when Raf-1 physically interacts with Rb, it triggers a cascade of signals that eventually overcomes this barrier, thus inducing cellular proliferation. By preventing the interaction between Raf-1 and Rb and blocking the cell cycle,

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Oncology Management:

US Oncology Launches iKnowMed Electronic Health Record System

US Oncology Inc. of Houston announces the launch of **iKnowMed** to the open market. iKnowMed is an oncology-specific electronic health record system designed for oncologists.

US Oncology acquired iKnowMed in 2004. The comprehensive collaboration between the oncology physicians since the acquisition has led to a technology excellence that is completely focused on the needs of community oncologists and their patients.

iKnowMed goes beyond delivering standard EHR features by leveraging technology that helps physicians focus on clinical excellence and cost effectiveness in community cancer care. iKnowMed facilitates access to powerful new solutions such as US Oncology's Innovent Oncology program, which provides Level I evidence-based medicine pathways to help oncologists realize the benefits of pay-for-performance. For practices participating in the US Oncology Research network, iKnowMed can match patients to appropriate clinical trials, increasing access to the latest treatment opportunities across the nation.

Other features of iKnowMed include oncology-specific terminology, decision support, outcomes reporting, imaging reports, comprehensive patient history, comprehensive cancer regimen library, dictation and transcription, lab results, detailed cancer diagnosis and staging content, and

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Moffitt, Debiopharm Agree To Develop Small Molecule

(Continued from page 1)

Debio 0928 creates a new strategy in the fight against cancer and is thus a potentially promising novel anti-tumour drug.

Under the agreement, Debiopharm will pay Moffitt an up-front fee, as well as predefined advanced milestone payments during the development of Debio 0928.

"This discovery, made by the collaboration between Drs. Srikumar Chellappan, Said Sebti, and Nicholas Lawrence at Moffitt, is a novel approach to the treatment of cancer," said Rolland-Yves Mauvernay, president and founder of Debiopharm Group. "Being able to de-activate a key signaling kinase like Raf-1, known to be involved in many types of cancer, could open the door to more effective oncology treatments in the future."

Biomodels LLC of Watertown, Mass., a preclinical research organization specializing in cancer support care, said its customized research program allowed **ActoGeniX NV**, a development stage biopharmaceutical company, to rapidly attain FDA approval for phase 1b clinical trials of AGO13 in cancer patients with oral mucositis.

The FDA approval permits ActoGeniX to initiate a phase 1b trial in six major oncology centers in the U.S. AGO13 could become the first approved therapy for oral mucositis in patients undergoing treatment of solid tumors or head/neck cancers, according to ActoGeniX.

Exosome Diagnostics Inc. and **DxS Ltd.** announced that they will collaborate on the development of blood-based companion diagnostics for key cancer gene mutations, such as KRAS, BRAF and EGFR.

The collaboration will use DxS' Scorpions real-time PCR Mutation Test Kits in conjunction with ExosomeDX's xOS technology which harvests high-quality nucleic acids from blood exosomes.

The collaboration will initially focus on developing blood-based measurement of KRAS, BRAF, EGFR and other key mutations for predicting patient response to targeted therapies, the companies said.

Palkion Inc. of San Diego said it has initiated preclinical development studies for its orally available anemia therapeutic candidate that modulates the Hypoxia-Inducible Factor Prolyl Hydroxylase (HIF-PH) enzyme system.

In February 2008, Palkion was founded when a novel drug discovery and development firm, **CrystalGenomics** (KOSDAQ: CRYSTAL [A083790]) and the US-based venture capital firm, **ProQuest Investments**, formed a new joint venture entity.

Under the strategic alliance, CrystalGenomics is receiving upfront and research funding for two years from Palkion, in addition to development and sales milestone payments of potentially more than $200 million. CrystalGenomics' role is to use its unique structure-based drug discovery platform to identify novel drug candidates while Palkion oversees the clinical development.

All currently available Erythropoietins are injectables.

Morphotek Inc. of Exton, Penn., announced a research collaboration agreement with **Synageva BioPharma Corp.** to express and develop therapeutic monoclonal antibodies for the potential treatment of various forms of cancer and infectious disease.

Morphotek is a subsidiary of Eisai Corporation of North America.

Under the agreement, Synageva will use its proprietary Synageva Expression Platform technology and its expertise to produce and develop a therapeutic monoclonal antibody. SEP is an integrated platform of proprietary systems for protein production, processing

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and purification.

Through the use Morphodoma technology, Morphotek develops optimized antibodies, including antibodies optimized for affinity and/or titer, for therapeutic applications and high-titer manufacturing cell lines. The company has assembled a portfolio of lead human and humanized antibodies to antigens associated with cancer, neovascular, inflammatory and infectious disease. The antibodies within the company's pipeline are targeted against antigens licensed from its collaborative partners.

Regulatory Approvals & Applications:

CHMP Supports Approval Of Javlor For Urothelial Cancer

Laboratoires Pierre Fabre of Castres, France, said the Committee for Medicinal Products for Human Use, has issued a positive opinion supporting approval and is recommending to grant marketing authorisation for Javlor as monotherapy in metastatic treatment of advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen.

CHMP is the scientific advisory committee of the European Medicines Agency.

CHMP has issued a positive opinion based on two phase II study results and on the only phase III randomized study ever conducted in the indication of metastatic treatment of bladder cancer after failure of a prior platinum-containing regimen.

After the EMEA will grant the marketing authorization, Javlor will become the first monotherapy approved in Europe for the treatment of adult patients with advanced or metastatic transitional cell carcinoma of the urothelial tract after failure of a prior platinum-containing regimen, where the expectation is important for both oncologists and patients, the company said.

Discovered by scientists at the Pierre Fabre Research Center, vinflunine is a new bi-fluorinated MTI (Microtubule inhibitor) obtained by chemistry exploiting the reactivity of Vinca scaffold in superacidic media. Such strategy, finalized in collaboration with experts at the University of Poitiers (France), enabled the selective introduction of two fluorine atoms in a part of that structure previously inaccessible by classic chemistry, thereby leading to the first bi-fluorinated vinca alkaloid**.**

Apthera Inc. of Scottsdale, Ariz., said it has reached an agreement with FDA under a Special Protocol Assessment for its planned phase III clinical trial of the company's lead drug, NeuVax.

The SPA is a written agreement between the trial's sponsor and the FDA regarding the design, endpoints, and planned statistical analysis of the Phase III trial to be used in support of a Biologics License Application.

The multicenter, double-blind, randomized pivotal trial is expected to enroll 700 women diagnosed with HER2/neu-expressing tumors and who have completed standard of care consisting of surgery, chemotherapy and radiotherapy. Women must have a common HLA haplotype (HLA-A2 or -A3) and must agree to be followed for 5-10 years. The primary endpoint of the study is disease-free survival (DFS) as determined by disease recurrence or death from any cause, and the first analysis of the data will occur after 70 recurrence events or approximately 3 years from the start of the study.

Cell Therapeutics Inc. of Seattle (NASDAQ and MTA: CTIC) said it has completed the submission of the New Drug Application to FDA for pixantrone to treat relapsed or refractory, aggressive non-Hodgkin's lymphoma.

CTI requested priority review, which if granted could lead to an approval decision from the FDA in the fourth quarter of 2009. Pixantrone is currently available in Europe on a named-patient basis.

"This is a major milestone for CTI and is the cornerstone of a turnaround strategy for us in meeting our goals of becoming a profitable operating business," said James A. Bianco, CEO of CTI.

CTI's EXTEND clinical trial was a phase III single-agent trial of pixantrone for patients with relapsed or refractory, aggressive NHL who received two or more prior therapies and who were sensitive to treatment with anthracyclines. The trial enrolled 140 patients and patients were randomized to receive either pixantrone or another single-agent drug currently used for the treatment of this patient population as selected by the physician.

CTI previously announced that its pivotal PIX 301 EXTEND trial had achieved its primary endpoint with patients randomized to treatment with pixantrone achieving a significantly higher rate of confirmed (CR) and unconfirmed complete remissions (CRu) compared to patients treated with standard chemotherapy (14 out of 70 patients (20.0%) for the pixantrone arm compared to four out of 70 patients (5.7%) for the standard chemotherapy arm, p=0.02). No patient (0%) in the standard chemotherapy arm achieved a confirmed complete remission compared to eight out of 70 (11%)

of pixantrone recipients. Pixantrone treatment also significantly increased the overall response rate (ORR) (26 out of 70 (37.1%) for the pixantrone arm compared to ten out of 70 (14.3%) for the control arm, p=0.003). Additionally, pixantrone experienced a statistically significant improvement in median progression-free survival (PFS), compared with other single-agent chemotherapeutic agents (4.7 months vs. 2.6 months, p=0.007, respectively). PFS, CR/CRu and ORR were determined by an independent assessment panel that was blinded to the treatment assignments.

The most common grade 3/4 adverse event observed on the pixantrone arm was neutropenia in 41.2% of patients versus 19.4% on the comparator arm. However, the incidence of grade 3/4 febrile neutropenia was only 7.4% versus 3.0% in the comparator arm. Grade 3/4 infections had a similar incidence in both study arms (18% vs. 13%). Although the grade 3/4 cardiac disorder was similar among the two treatment groups (1.5% vs. 1.5%), there was a slightly higher incidence of serious cardiac disorders in patients treated with pixantrone than among patients who received comparator agents (8.8% vs. 4.5%). Events considered cardiac disorders included cardiac arrest, congestive heart failure, myocardial infarction, cyanosis, pericardial effusion, and tachycardia.

Pixantrone (BBR 2778), is a major groove binder with an aza-anthracenedione molecular structure that differentiates it from the anthracyclines and other related chemotherapy agents. Anthracyclines are the cornerstone therapeutic for the treatment of lymphoma, leukemia, and breast cancer. Although they are sufficiently effective to be used as first-line (initial) treatment, they cause cumulative heart damage that may result in congestive heart failure many years later. As a result, there is a lifetime limit of anthracycline doses and most patients who previously have been treated with an anthracycline are not able to receive further anthracycline treatment if their disease returns. It also can be administered through a peripheral vein rather than a central implanted catheter as required for other drugs in this class.

OncoGenex Pharmaceuticals Inc. (NASDAQ: OGXI) of Bothell, Wash., said it has reached an agreement with FDA via the special protocol assessment process on an amendment to the design of a phase III registration trial of OGX-011 for castrate resistant prostate cancer.

FDA has agreed on modifications to the study population of a previously reviewed phase III trial featuring survival as the primary endpoint. The study population has been modified to evaluate patients receiving first-line chemotherapy, rather than those receiving second-line chemotherapy. FDA agreed that the amended protocol adequately addresses the objectives necessary to support a regulatory submission.

"We are now ready to proceed with two phase III trial designs from the FDA via the SPA process, one in first-line and one in second-line treatment of advanced prostate cancer," said Scott Cormack, president and CEO. "The trial for first-line treatment evaluates overall survival benefit for OGX-011 while the trial for second-line treatment evaluates for a durable pain palliation benefit. Based on the robustness of the OGX-011 survival benefit observed in the randomized phase II trial for first-line docetaxel treatment, we felt evaluating both of these patient populations, as well as both endpoints, in our phase III trials better positions the availability of OGX-011 treatment to a larger number of men with prostate cancer."

The revised trial will be a randomized, controlled, international study in 800 men with metastatic CRPC who are in need of first-line chemotherapy. Patients will be randomized to receive treatment with either OGX-011 and docetaxel/prednisone or docetaxel/prednisone alone. The primary endpoint of the study will be overall survival. It is expected that approximately 80 sites, primarily from the U.S. and Canada, will participate in this study.

OGX-011 is designed to inhibit the production of clusterin, a protein that is associated with cancer treatment resistance, and has completed phase 2 clinical trials in prostate, lung and breast cancer.

OGX-011 has received Fast Track designation from the FDA for the treatment of progressive metastatic prostate cancer in combination with docetaxel.

Clinical Trials:

Oncothyreon, Merck Begin Phase III Trial Of Stimuvax

Oncothyreon Inc. (NASDAQ: ONTY) (TSX: ONY) of Seattle said **Merck KGaA** of Darmstadt, Germany, has initiated a global phase III trial of Stimuvax (BLP25 liposome vaccine, L-BLP25) in patients with hormone receptor-positive, locally advanced, recurrent or metastatic breast cancer. Stimuvax is an investigational therapeutic cancer vaccine being developed by Merck KGaA under a license agreement with Oncothyreon.

The phase III trial, named STRIDE (STimulating immune Response In aDvanced brEast cancer),

is anticipated to enroll more than 900 patients at approximately 180 sites in over 30 countries including North America, Europe, Asia and Australia.

Patients with estrogen receptor-positive and/or progesterone receptor-positive, non-resectable locally advanced, recurrent or metastatic breast cancer receiving hormonal therapy will be randomized to receive either Stimuvax or a placebo in a 2:1 ratio. The primary endpoint of STRIDE is progression-free survival. Overall survival, quality of life, tumor response and safety will also be assessed in this study.

Stimuvax is an investigational therapeutic cancer vaccine designed to induce an immune response to cancer cells that express MUC1, a glycoprotein antigen widely expressed on common cancers. MUC1 is over-expressed on many cancers such as lung cancer, breast cancer, prostate cancer and colorectal cancer. Stimuvax is thought to work by stimulating the body's immune system to identify and destroy cancer cells expressing MUC1.

In addition to STRIDE, Merck KGaA currently is conducting a global phase III trial of Stimuvax known as START (Stimulating Targeted Antigenic Responses To NSCLC). START is a randomized, double-blind, placebo-controlled study that will evaluate patients with documented unresectable stage III NSCLC who have had a response or stable disease after at least two cycles of platinum-based chemo-radiotherapy. START is expected to enroll more than 1,300 patients in over 30 countries. For more information on the START trial log on to www.nsclcstudy.com or www.clinicaltrials.gov.

Lixte Biotechnology Holdings (OTC Bulletin Board: LIXT) announced that investigators of the National Institute of Neurological Disorders and Stroke and the National Cancer Institute and Lixte reported that its novel compound, LB-1.2, enhances the effectiveness of two standard chemotherapy drugs in mouse models of human cancers.

This research is being conducted under a Cooperative Research and Development Agreement between NINDS and Lixte. The report was published online in the early edition (June 29) of the Proceedings of the National Academy of Science. The print version will appear July 14.

John Kovach, president and CEO of Lixte, said "LB-1.2 exerts anti-cancer activity directly on the cancer cell and, more dramatically, by preventing cancer cells from recovering from DNA-damage produced by standard anti-cancer drugs. In mouse models, LB-1.2 plus Temozolomide caused complete regression without recurrence in 50 % of animals bearing tumors of human glioblastoma multiforme (GBM), the most common and aggressive brain tumor of adults, and also, marked regression of neuroblastoma, the most common cancer of children. Temozolomide, the standard drug for the treatment of patients with GBM, by itself caused regression but with recurrence of all tumors."

Kovach added "that, since LB-1.2 has a biochemical action similar to an older drug used for anticancer treatment for many years in China, we are cautiously optimistic that LB-1.2 will be well tolerated by cancer patients and hopefully, will potentially be as effective as it is in animal models of human cancer. We believe that adding LB-1.2 may be a general method for improving the effectiveness of several standard anticancer drugs not only against tumors of the brain and neural tissue but also against other cancers sensitive to drugs that work by damaging DNA. Safety, of course, must be demonstrated first in animal studies and subsequently in Phase I clinical trials before evaluation of therapeutic effectiveness can be assessed against different cancer types in patients."

Yaupon Therapeutics, a privately held specialty pharmaceutical company based in Radnor, Penn., said it has completed enrollment for a phase II trial of Clearazide in early-stage cutaneous T-cell lymphoma.

The study, which is being conducted under a Special Protocol Assessment with the FDA, has enrolled 260 patients in 13 cancer centers in the US. The study is focused on stages 1-2a. The randomized, double-blind, controlled clinical study is the largest ever undertaken involving patients with cutaneous T-cell lymphoma, the company said.

Clearazide is a topical form of nitrogen mustard.

Oncology Management:

US Oncology Launches iKnowMed Electronic Record

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practice efficiencies.

"As America's healthcare system moves toward a pay-for-performance environment, in which higher-performing doctors receive preferred compensation, it is essential that oncology practices accurately document and report outcomes while achieving greater efficiency," says Cindy Chavez, vice president of iKnowMed. "iKnowMed provides solutions that will help drive this clinical excellence."

iKnowMed provides physicians with online access

to patient records 24 hours a day, 7 days a week. This allows treatment decisions to be made from anywhere at any time, without the need of a hardcopy patient record. Patient safety is enhanced by eliminating handwritten notes and orders, minimizing misinterpretations, and the system detects possible medication conflicts, generating a safety alert to the attending oncologist and staff. The system also helps practices stay current on billing as charge codes, billable units, primary diagnosis codes and billable drug waste for each visit are calculated, allowing staff to spend more time focusing on patient care.

Community oncologists across the nation are invited to attend a special webinar focusing on the Medicare Health Information Technology Stimulus at 2 pm EDT, July 10. Sponsored by iKnowMed, this webinar will feature a status report of standards for qualified EHRs and meaningful use requirements. To register for the webinar, visit www.opspharmacist.com/HITStimulus.

American Society of Clinical Oncology has commissioned a study, funded by Susan G. Komen for the Cure, to find out how non-physician practitioners, such as nurse practitioners and physician assistants, can provide vital services to cancer patients as part of continued efforts to address projected future oncology workforce shortages.

The study, to be conducted for ASCO by Oncology Metrics, will be a comprehensive analysis of how oncology practices provide patient care, through collaborative care teams made up of oncologists, nurse practitioners, and physician's assistants, ASCO said.

The study of up to 40 private and hospital-based oncology practices will specifically examine the satisfaction, efficiency and productivity of each collaborative care team in order to establish "best practices."

"ASCO and the Workforce Advisory Group continue to explore a variety of solutions to the anticipated oncology workforce shortage," said ASCO President Douglas Blayney. "We believe collaborative practice models will help cancer care professionals cope with the realities of having too many patients and not enough doctors."

The number of Americans aged 65 and older will double by 2030 as baby boomers age. At the same time, people are living longer with cancer, requiring ongoing care. Cancer specialists will struggle to handle the patient load: a 2007 ASCO workforce study said demands for visits will leap by 48 percent by 2020, but the number of oncologists will fall 4,000 short.

ASCO's Workforce Advisory Group identified the increased use of non-physician practitioners in an oncology practice as a possible way to narrow the gap between supply and demand for oncology services. According to ASCO's 2007 Workforce Study, 56 percent of oncologists work with nurse practitioners or physician's assistants, and providers who use nurse practitioners/ physician's assistants have higher visit rates than those who do not.

The practices being included in the survey will vary in size, patient population, and location. "This study will enable us to address the unique problems oncology practices are facing across the country and potentially offer some solutions. Obviously, a small rural practice will have different needs than a large practice in an inner city," said Dean Bajorin, co-chair of ASCO's Workforce Advisory Group.

Some of the services that nurse practitioners and physician's assistants provide in a practice setting include ordering and administering routine chemotherapy, as well as patient education and counseling.

The study results are expected to be released in early 2011, ASCO said. This study is part of a collaboration between the ASCO Cancer Foundation, ASCO and Komen for the Cure, in which Komen is providing $10 million in support of projects and programs designed to improve the quality of cancer care in the U.S.

Varian Medical Systems Inc. of Palo Alto, Calif., (NYSE: VAR) said it has acquired the assets of Houston-based **IKOEmed** and **IKOEtech**, privately-owned suppliers of software used in the planning of radiotherapy and radiosurgery treatments.

The acquisition enables Varian to offer hospitals and clinics an additional software tool to automate and accelerate the most time-consuming portion of the treatment planning process. Varian is paying approximately $2.2 million plus an additional amount based on achievement of specified milestones to acquire the IKOE assets.

The software is designed to achieve greater than 50 percent reduction in the contouring portion of the radiotherapy treatment planning process, which typically takes anywhere from 30 minutes to 4 hours. It automates the contouring process by matching patient images with pre-contoured images from an expert database created by renowned radiation oncologists. This eliminates the need for clinicians to manually outline between 10 and 20 organs in each of anywhere from 100 to 200 images of a patient's disease site.