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NCI Proposal Would Give Drug Sponsors Commercial Rights To Biomarker Inventions

By Paul Goldberg

NCI officials are revamping the standard technology transfer agreements to enhance intellectual property protection given to pharmaceutical companies.

Though the institute's policy is not finalized, a recently circulated proposal changed the standard language of the Cooperative Research and Development Agreements to expand the benefits pharma companies get in exchange for providing drugs and other contributions for NCI-sponsored studies.

Under the proposal, sponsors would automatically receive worldwide commercial rights to patented discoveries stemming from correlative research

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In the Cancer Centers:

Seattle Institutions Win $16 Million In Grants For Comparative Effectiveness Research

FRED HUTCHINSON CANCER RESEARCH CENTER, Group Health Research Institute, and the University of Washington schools of Public Health and Pharmacy have been selected to lead four projects backed by about $16 million in federal stimulus funding for comparative-effectiveness research in cancer.

The American Recovery and Reinvestment Act dedicated $1.1 billion to fund such research via the NIH Grand Opportunities grants program. The Seattle-based projects include:

—A $4 million project based at the Hutchinson Center and led by **Scott Ramsey**, a member of the center's Public Health Sciences Division and a professor of medicine at UW School of Medicine, will fund the development of an infrastructure to support the Center for Comparative Effectiveness Research in Cancer Genomics, or CANCERGEN. This public-private consortium will design and conduct prospective, controlled clinical trials of promising cancer genetic tests working in close collaboration with the University of Michigan-based Southwest Oncology Group.

Researchers in the SWOG Statistical Center, co-located at the Hutchinson Center and the Seattle nonprofit Cancer Research And Biostatistics, will design the statistical structure of the study and lead data management and analysis. CANCERGEN will develop the tools that help SWOG researchers determine which proposed trials will have the greatest clinical benefit for

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Sponsors May Abandon NCI CRADAs—As May Scientists

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that follows clinical trials. For example, if researchers working with tumor blocks find a biomarker associated with response (or resistance) to a drug, the drug's sponsor would automatically receive non-exclusive commercial rights to the invention.

Currently, drug-makers are entitled to use inventions in research, but have to obtain commercial rights from clinical trials cooperative groups and institutions that conduct research that correlates the characteristics of tumors obtained through clinical trials with the outcomes of treatment.

The stakes in the game being played by NCI, cooperative groups, and cancer centers are high:

• Under CRADAs, drug-makers provide agents that can be worth tens of millions of dollars. They have a lot to lose if findings come up negative or result in limiting the use of these agents. If companies withdraw from the game, the NCI research system could be rendered idle.

• However, it's also plausible that if scientists and their institutions are deprived of the potential to benefit financially from their discoveries, correlative science would grind to a halt.

"In our CRADA negotiations, this is an issue that has to be resolved between the investigators and the companies we work with, and we are trying to seek a compromise," said Jeffrey Abrams, associate director of the NCI Cancer Therapy Evaluation Program.

"The scientists can honestly say, 'It's our invention. We put a lot of time and resources into making this invention, and we should be allowed to commercialize it,'" Abrams said in an interview.

"On the other hand, the company feels, 'Well, we put millions of dollars into this agent. We were the ones who gave NCI the agent so you could do the trial and then get the clinical data off which you did this correlative science work. So we feel we should have exclusivity to any inventions.'

"Both sides have their arguments, and the question is how to effect the compromise."

Sources involved in the controversy said top oncology officials at Genentech Inc. were the first to ask NCI to change its standard CRADA language. Now it appears that many of the individuals who got NCI involved in the controversy left the company after it was taken over by Roche.

However, NCI officials have indicated during numerous discussions with cooperative groups that the interest spearheaded by Genentech is now shared by other makers of therapeutic agents. The Cancer Letter was unable to verify the extent of this support.

Genentech officials confirmed that they brought the issue to NCI's attention. "We value our relationship with NCI, and as part of our ongoing collaboration, it's important that we work with them to address changing technology, new researchers focuses, involving regulatory requirements, etc.," said Charlotte Arnold, a Genentech spokesman. "Our discussions with them are very specific to Genentech's CRADAs. While these discussions may have prompted them to look at theior contracts with other parties, our discussions have been very specific to our CRADAs."

Insiders say that correlative research involving a Genentech's drug Avastin (bevacizumab) has been described as illustrative of the problem. This research resulted in a paper by Bryan Schneider et al., published in the Oct. 1, 2008, issue of the Journal of Clinical Oncology.

Researchers used tumor blocks obtained from patients enrolled in the E2100 trial of Avastin in metastatic breast cancer to find an association between the presence of vascular endothelial growth factor genotype and overall survival and grade 3 and 4 hypertension.

While the trial led to approval of Avastin for metastatic breast cancer, the results of the correlative study—if confirmed—have the potential to limit the agent's use. Confirmation is by no means assured, since

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the E2100 was not designed as a registration trial and the correlative study was a retrospective subset analysis.

Genentech's Arnold said no single study prompted the company to initiate discussions with NCI. "It was not specific to E2100," she said. "It was part of our ongoing collaboration with them."

NCI officials describe their approach to changing the CRADA language as a work in progress. The language will eventually be published in Federal Register, and there will be a public discussion at the Nov. 4 meeting of the NCI Clinical Trials Advisory Committee.

However, in its first iteration, the proposed language on intellectual property caused consternation among heads of the cooperative groups. The proposal, unveiled by NCI in late July, would give companies "a royalty-free, worldwide, non-exclusive license for commercial purposes."

Under existing CRADA language, such rights are granted to drug-makers for research purposes. The purchase of commercial rights is handled in separate negotiations.

At a recent meeting of cooperative group chairs, Robert Comis, chairman of Eastern Cooperative Oncology Group, said the provision would cripple correlative research, which is typically conducted at cancer centers, using specimens obtained in cooperative group trials.

"This can't be viewed as a cooperative group issue," Comis said at the meeting of group chairs Oct. 9. "This is an NCI-wide, NIH-wide issue, and you are going to have to get agreement from others, not just us. If we don't get the buy-in of the academic programs that are the lifeblood of our work, I think they will walk.

"You are worried about the industry walking, and I am worried about our scientific base walking," Comis said. "I think these two things need to be considered, and I think it needs to be a broad-based look at this."

Critics of the initial NCI proposal argue that the institute is underestimating the value of publicly funded trials it provides to drug-makers. Also, they warn that enhanced intellectual property rights could allow companies to suppress research that may limit the market for their agents.

"Companies come to the cooperative groups to perform trials not out of any sense of generosity, but because the NCI and NCI-associated investigators will perform work for them on the public's tab," said George Sledge, professor of oncology, pathology and laboratory medicine at the Indiana University and one of the authors of the E2100 paper linked to the controversy.

"In the phase III setting, the company gets the benefits of an existing infrastructure, a proven track record of clinical trial conduct, and expense savings, since the cooperative groups are maintained on a starvation diet," Sledge said in an email to The Cancer Letter.

"The bottom line is that the relationship is not an act of charity, but rather a win-win for the public and for the companies.

"I am concerned about the inclusion of language that would in essence give the companies veto power over translational science and the development of new diagnostic assays," Sledge said. "Would a company be enthusiastic about the next RAS mutation story, with its potential to turn a mass market agent into a niche agent? Should a drug company have the right to direct (as opposed to negotiate with) researchers acting in the public interest? I have personal experience of companies that have actively opposed the study of therapeutic individualization for their particular drug. And if a diagnostic test is developed, at great expense, by a diagnostic company (one thinks of Mammaprint or OncotypeDx) based on a publicly-funded trial (one thinks of NSABP B-20 for OncotypeDx), should the therapeutic company garner the benefits of work performed by others? Especially in trials where, one suspects, the patients (as representatives of the public) are altruistic enough to offer their tissues for scientific exploration in the hope that future patients will benefit?"

NCI's Abrams acknowledges potential problems. "Those are legitimate points that have been brought up by the cooperative groups and cancer center investigators, and we would try to find insurances in the language to protect against hiding inventions that aren't beneficial to the company's plans for licensing or using the drug," Abrams said in an interview.

One solution could be to notify drug-makers about inventions and offer them the option to negotiate commercial licensing agreement within a specified time frame, suggested Richard Schilsky, chairman of Cancer and Leukemia Group B.

"The big problem with the original proposal is the notion that the company would immediately be granted the license, even though it would be non-exclusive," Schilsky said at the group chairs' meeting.

"But we do understand that these inventions impact company development plans, and I don't think it's unreasonable that a company should be informed, should have a period of exclusivity in terms of evaluating the invention, and then having to declare within a limited

period of time whether or not they intend to negotiate for a license, which could be exclusive, non-exclusive, royalty-free, or royalty-bearing," Schilsky said.

"But the negotiation would have to be completed within another agreed-upon period of time, so it could not be a continuous negotiation that would go on for years that would prevent the inventor from going elsewhere."

This would solve the problem, Schilsky said. "My interpretation of what the companies are concerned about is that they will be blindsided by an invention that may limit the use of their drug without them knowing anything about it," he said at the meeting.

The correlative study stemming from the E2100 trial doesn't appear to be a good example of a sponsor being blindsided by a discovery.

For one thing, Genentech provided $69,000 for evaluation of tumors, said Schneider, assistant professor at the department of hematology/oncology at the University of Indiana Melvin and Bren Simon Cancer Center.

The finding has resulted in a patent filing (WO 2009073540). However, Genentech has the option to have to patent assigned to it without compensation to the inventors or their institution, Schneider said.

Though he doesn't stand a chance to make any money from his work, Schneider said he is not despondent. "I do oncology because I feel passionate about trying to make things better," he said. "That's why I am in academic oncology right now. We have the potential to make the drugs we are using better for our patients.

"At the end of the day, that's really what this is all about."

The text of the NCI's draft of new CRADA language follows:

Intellectual Property Option (Cover Letter)

Background: The Intellectual Property Option to Collaborator (IP Option) has been one of the most successful innovations that DCTD has instituted over the past decade.

The IP Option in its current form was first implemented in 1999 and has enabled hundreds of investigational combination and rare population cancer studies that would not have been possible in its absence.

While the IP Option has been incredibly successful over the past ten years, the relationship between industry, government and academia has evolved with the entrance into clinical trials of molecularly targeted agents that depend more on defining targets and developing, biomarkers to use to eventually select patients or to serve as intermediate endpoints.

The NCI is receiving requests from all parties to modify the IP Option to address issues, such as the following, stemming from this current approach to clinical research:

1. The current IP Option and most of our collaborative agreements and funding agreements are silent as to the disposition of agent-treated human tumor samples. The IP framework surrounding agent-treated samples and the associated clinical data have become increasingly important.

2. One common request DCTD receives from extramural investigators, especially those engaged in early phase clinical development, is for greater and earlier access to cutting edge therapeutics for both pre-clinical and clinical evaluation.

3. Institution technology transfer offices have requested alteration or removal of assignment language from the MTAs.

4. As DCTD and the research community have moved toward earlier stage research, the likelihood of new inventions has increased. Collaborators have requested freedom to operate provisions for blocking IP generated under the scope of CRADAs and CTAs which provide their proprietary agents to DCTD-funded investigators or which make use of agent" treated samples and data.

DCTD Priorities: In balancing the needs of Collaborators with those of the extramural Investigators, the [Division of Cancer Treatment and Diagnosis] considers the following priorities to be paramount:

1. The ability to provide cutting edge cancer therapeutics to NCI-funded investigators for clinical and pre-clinical research of benefit to cancer patients in accordance with the NCI mission to improve the lives of cancer patients.

2. The ability to provide agent treated and untreated tumor samples to the broadest community of researchers possible and to ensure that these valuable research resources are utilized in the most efficient way to benefit cancer patients.

3. The ability to ensure that materials are available for vital research in the areas of biomarker and diagnostic cancer testing.

4. The creation of an IP Option that is fair, encourages participation from all parties, and promotes the development of therapeutics and diagnostics of benefit to the cancer community.

Statistics: DCTD currently has approximately

100 active INDs and 80 collaborative agreements with pharmaceutical companies for the clinical development of anticancer agents. There are an additional 20 CRADAs in various stages of negotiation for agents approved for development by DCTD.

DCTD activates over 100 clinical trials every year and has about 500 active studies at any given time, from phase I to randomized phase III trials that could support registration. This is supported by a network of over 11,000 investigators from over 1000 institutions, including the Pacific Rim, Canada, Australia, Israel and South America.

Conclusion: The attached draft revision to the IP Option is an attempt to address concerns from all parties in order to expedite negotiations and increase DCTD's ability to initiate high priority clinical trials in a timely manner.

We have removed the assignment language that funded institutions have found objectionable.

In addition, we have expanded the scope of the non-exclusive license option to be congruent with what is now standard in most institution-industrial collaborative agreements.

Finally we have added a framework to enunciate more clearly the rights Collaborators have in tumor samples treated with their proprietary agent under a DCTD-funded study.

We look forward to presenting these revisions to the research community for comment and input.

Review of Proposals and Manuscripts for human samples treated with a Collaborator's agent and/or Clinical Data:

1. Requests for samples treated with a Collaborator's agent and/or clinical data after the clinical trial has closed must undergo scientific review per NIH/NCI/CTEP policies and terms of awards for grantees and contractors conducting CTEP-sponsored studies. CTEP will forward approved requests to the Collaborator who will have an opportunity to comment on the proposal. Review of these proposals will be handled in the same manner as clinical protocols; the Collaborator will have approximately two weeks to provide comments back to CTEP for consideration by CTEP and/or the scientific committee overseeing review of the request and the organization/principal investigator responsible for the request/study.

2. Manuscripts resulting from the studies listed above will also be handled in accordance with the policies for manuscripts and abstracts for clinical trials. Collaborators will have a minimum of 30 days to review and provide comments on manuscripts and 3 days for abstracts or other presentations. These should be submitted to CTEP electronically at: ncicteppubs@mail.nih.gov.

Intellectual Property Option

The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute's Division of Cancer Treatment and Diagnosis (DCTD) obtains agents from biotechnology and pharmaceutical companies (hereinafter "Collaborators") for use in NCI-funded research via collaborative research agreements.

As part of its arrangement with these Collaborators, DCTD must ask the extramural community receiving the agents to agree to certain conditions. Among those conditions is the assurance that no unauthorized modifications to the agent will be created and that no unauthorized research with the agent will be conducted. If a receiving party conducts any unauthorized activities with the agent, DCTD is obligated to report it to the provider of the investigational agent once DCTD becomes aware of it.

References to "Institution" shall mean the entity conducting the research described herein.

A. The IP Option described in this Section A will apply to studies involving a Collaborator's investigational agent and/or clinical data:

For inventions made by Institution's investigator(s) or any other employees or agents of the Institution, which are or may be patentable or otherwise protectable, which are conceived or first actually reduced to practice in the performance of Section A studies ("Section A Inventions"), Institution agrees to grant to Collaborator(s): (i) a royalty-free, worldwide, non-exclusive license for commercial purposes; and (ii) a time-limited first option to negotiate an exclusive, or co-exclusive, if applicable, world-wide, royalty-bearing license for commercial purposes, including the right to grant sub-licenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and Institution.

If Collaborator accepts the nonexclusive commercial license, the Collaborator agrees to pay patent prosecution and maintenance costs which will be pro-rated and divided equally among all licensees.

If Collaborator obtains an exclusive commercial license, in addition to any other agreed upon licensing arrangements such as royalties and due diligence requirements, the Collaborator agrees to pay all patent prosecution and maintenance costs.

For all Section A Inventions, regardless of Collaborator's decision to seek a commercial license,

Collaborator will be granted a paid-up, nonexclusive, royalty-free, world-wide license for research purposes only. Institution shall retain a non-exclusive, paid-up license to use any Section A Invention for all non-profit research, including for educational purposes.

B. The IP Option in this Section B will apply to studies utilizing specimens from patients treated with a Collaborator's investigational agent (including specimens obtained from NCI funded tissue banks) but not utilizing clinical data:

For inventions made by Institution's investigator(s) or any other employees or agents of Institution, which are or may be patentable or otherwise protectable, and are conceived or first actually reduced to practice in the performance of Section B studies ("Section B Inventions") Institution agrees to grant to Collaborator a paidup, nonexclusive, royalty-free, world-wide license for research purposes only. Institution shall retain a non-exclusive, paid-up license, to use any Section B Invention for all non-profit research, including for educational purposes.

C. Institution Notification

Institution agrees to promptly notify CTEP, NCI (NCICTEPpubs@mail.nih.gov) and Collaborator(s) in writing of any Section A Inventions or Section B Inventions upon the earlier of: (i) any submission of any invention disclosure to Institution relating to a Section A Invention or a Section B Invention, or (ii) the filing of any patent applications related to a Section A Invention or a Section B Invention. Institution will provide a copy of either the employee invention report or the patent application to the Collaborator and to CTEP, NCI which will treat it confidentially. These requirements do not replace any reporting requirements under Bayh-Dole to the extent federal funding agreements are involved in this research. If Collaborator elects to negotiate an exclusive commercial license to a Section A Invention, then Institution agrees to file and prosecute patent application(s) diligently and in a timely manner and will give Collaborator an opportunity to comment on the preparation and filing of any such patent application(s).

D. Exercise of License Option for Commercial Licenses

Collaborator(s) shall notify Institution, in writing, if it is interested in obtaining a commercial license to any Section A Invention within three (3) months of Collaborator's receipt of notice of such Section A Invention.

In the event that Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator's option shall expire with respect to that Section A Invention, and Institution will be free to dispose of its interests in accordance with its policies.

If Institution and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Institution may agree) on the terms for an exclusive license for a particular Section A Invention, then for a period of three (3) months thereafter Institution shall not offer to license the Section A Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator shall have a period of thirty (30) days in which to accept o reject the offer.

Protection of Proprietary Data

Clinical data and results and raw data will be provided exclusively to the NCI, CTEP the Collaborator(s), and the FDA, as appropriate and unless additional disclosure is required by law or court order.

Additionally, all clinical data and results and raw data will be collected, used and disclosed consistent with all applicable federal statutes and regulations for the protection of human subjects, including, if applicable, the Standards for Privacy of Individually Identifiable Health Information set forth in 45 C.F.R. Part 46.

This provision shall not affect the investigator's right to use data for non-commercial research purposes, publish or present.

In the Cancer Centers:

Four Large CER Projects Based At Seattle Institutions

(Continued from page 1)

patients. Researchers at the UW School of Pharmacy and the Center for Medical Technology Policy in Baltimore will co-lead the effort.

—A $4 million project based at the UW School of Public Health and led by **Larry Kessler**, professor and chair of the UW Department of Health Services, will fund research to evaluate the effectiveness of cancer diagnostics to determine the extent of disease and plan treatment. The project, called "Advancing Innovative Comparative Effectiveness Research in Cancer Diagnostics," or ADVICE, will be co-led by investigators from the UW schools of Pharmacy and Medicine, Group Health, Veterans Affairs and the Hutchinson Center, which will serve as the study's data center.

—A $4 million project led by Group Health will support comparative-effectiveness research of

conventional and cutting-edge breast cancer imaging techniques to help determine which modalities are most effective for women according to individual patient demographics and risk factors. It will use data from the NCI's Breast Cancer Surveillance Consortium. With modeling experts from NCI's Cancer Intervention and Surveillance Modeling Network, the project will compare the effectiveness of various breast cancer screening strategies such as film-screen mammography, digital mammography and breast MRI. The grant will be co-led by investigators at Group Health, the University of North Carolina at Chapel Hill, the University of California at San Francisco, the University of Vermont and Georgetown University.

—A $4 million project based at Group Health aims to lay the groundwork for studies to improve the effectiveness of colorectal and cervical cancer screening and increase participation in such screening. The project, called SEARCH: Screening Effectiveness and Research in Community Based Healthcare, will be co-led by **Chyke Doubeni**, assistant professor in family medicine and community health at the University of Massachusetts Medical School. The project will be conducted with seven other health-maintenance organizations in the NCI's Cancer Research Network.

Also, Group Health is collaborating on a $4 million GO grant based at Dana Farber Harvard Cancer Center that will address the costs and effectiveness of treating advanced cancer and the lack of population-based research on patterns and outcomes of cancer care in populations not covered by Medicare, such as those under 65 and the poor. The data from the study will be provided, in part, by the Cancer Research Network, a research consortium of health-maintenance organizations that is based at Group Health. **Paul Fishman**, of Group Health, is co-investigator on the project.

These GO grants represent just a fraction of federal stimulus funding for biomedical research awarded to these Seattle institutions. In total, as of Oct. 1, the UW schools of Medicine, Public Health and Pharmacy had received $79.6 million for 186 projects, the Hutchinson Center had received nearly $40.4 million for 60 projects, and Group Health had received more than $17 million for 15 projects.

Among Hutchinson Center faculty, **Amanda Paulovich**, an associate member of the Clinical Research Division, was awarded the single largest stimulus grant at $4.8 million. Her project is a pilot study to assess the feasibility and scalability of a human proteome detection and measurement project. **Ulrike Peters**, an associate member of the Public Health Sciences Division, received a $4.6 million grant to identify genetic variants associated with colorectal cancer, the second leading cause of cancer death in the U.S. **Colleen Delaney**, an assistant member in the Clinical Research Division, won a $1.74 million grant to study a method to reduce the risk of infection and early death in patients who receive cord blood transplants to treat tumors of the blood, such as leukemia and lymphoma.

PAUL OKUNIEFF has been named director of the University of Florida Shands Cancer Center and chairman of the UF College of Medicine department of radiation oncology, effective Dec. 1. Okunieff is the Philip Rubin professor in radiation oncology and chair of the department of radiation oncology at the University of Rochester School of Medicine and Dentistry. He also is director of the university's Robert A. Flavin Radiosurgery Center. Prior to his appointment at Rochester in 1998, Okunieff served as branch chief of radiation oncology at the NCI. He will bring with him tens of millions of dollars in active federal and other extramural grant funding. Many members of his research team will join him in Gainesville. Okunieff succeeds **Joseph Simone**, who headed the cancer center and helped to advance an alliance with UF, Shands HealthCare and the Moffitt Cancer Center that was forged in 2008, and **Robert Amdur**, a professor and interim chair of the department of radiation oncology since 2006. . . . **GEORGETOWN LOMBARDI CANCER CENTER** established the Otto J. Ruesch Center for the Cure of Gastrointestinal Cancers with a $6.75 million gift from Georgetown University board member **Jeanne Ruesch**. The center will be directed by **John Marshall**, chief of the Division of Hematology-Oncology for Georgetown University Hospital and associate director for clinical research at cancer center. The Ruesch Center, Marshall's vision, will focus on personalized cancer treatments, drug discovery and patient advocacy including an innovative nurse navigator program. . . . **ROSWELL PARK CANCER INSTITUTE** received a $2.5 million NCI grant to study the relationship between dietary changes and the advancement of prostate cancer. **James Mohler**, chair of urologic oncology and a co-leader of the Prostate Program, and **James Marshall**, senior vice president for cancer prevention and population sciences, are co-investigators of the five-year Men's Eating and Living study. The study plans to enroll 460 men, half of whom will be actively coached, while the other half will serve as control subjects. The study aims to show that if men change their diet from a high-fat, meat-intensive diet to one with increased vegetable intake, particularly

cruciferous vegetables, it might be possible to alter the course of their disease. Other participating centers in the CALGB study include University of California at San Diego, Southeast Medical Oncology Consortium, Ohio State University, Memorial Sloan-Kettering, Yale University, University of California at San Francisco, Washington University, Johns Hopkins University, the Arthur Smith Institute of Long Island Jewish Hospital, and University of Pittsburgh. **RPCI** also received a $2.1 million NIH grant to assess smokers' interest in smokeless tobacco products. **Richard O'Connor**, of the Health Behavior Department at RPCI, is the principal investigator. . . . **INDIANA UNIVERSITY MELVIN AND BREN SIMON CANCER CENTER** named **Harikrishna Nakshatri** associate director for education. Nakshatri is the Marian J. Morrison Professor in Breast Cancer Research at the IU School of Medicine, and a researcher with the IU Simon Cancer Center. He also becomes a senior leader at the cancer center. . . . **NEWYORK-PRESBYTERIAN HOSPITAL**/Weill Cornell Medical Center established a Prostate Cancer Institute. **Ashutosh Tewari**, a urologic surgeon, was named as its director. Tewari will continue to serve as director of the LeFrak Center for Robotic Surgery and as director of robotic prostatectomy and prostate cancer–urologic oncology outcomes. . . . **UNIVERSITY OF COLORADO CANCER CENTER** scientists received an NIH Challenge Grant to find biomarkers for head and neck cancer stem cells. **Xiao-Jing Wang**, **Antonio Jimeno**, **John Song**, and **Stephen Malkoski** are the co-investigators on the grant, which will be funded at $870,000 over two years. Wang and Jimeno have two different models of head and neck cancer. Jimeno studies human tumors transplanted into the animal models, which then mimic human cancer development. Wang studies tumors that grow because of genetic mutations in the animal. By using both models in this study, the researchers will be able to compare any markers they find to accurately identify them as head and neck cancer markers. . . . . **UNIVERSITY OF CALIFORNIA** institutions are collaborating on a study to design and test new approaches to breast cancer research, technology, and health care delivery. Called the ATHENA Breast Health Network, the project will initially involve 150,000 California women, who will be screened for breast cancer and followed for decades through the five UC cancer centers. The ATHENA project is supported by a $5.3-million University of California grant, and by a $4.8-million grant from the Safeway Foundation. The centers involved in the demonstration project include UCLA's Jonsson Cancer Center, UC San Francisco, UC Davis, UC San Diego and UC Irvine. Also participating in the collaboration are the UC Berkeley School of Public Health, the Northern California Cancer Center, Quantum Leap Healthcare Collaborative, NCI's BIG Health Consortium, and the Center for Medical Technology Policy. . . . **MEMORIAL SLOAN-KETTERING CANCER CENTER** opened its 16-story Breast and Imaging Center housing the MSKCC Imaging Center and the Evelyn H. Lauder Breast Center, established with a gift of $50 million from the Leonard and Evelyn Lauder Foundation. MSKCC treats more breast cancer patients than any other cancer center in the U.S., and the new Breast Center is the world's largest freestanding comprehensive breast center. . . . **UCLA JONSSON CANCER CENTER** member **Edward De Robertis** was appointed by **Pope Benedict XVI** to a lifetime term on the Pontifical Academy of Sciences, a organization of 80 scientists that reports to the Pope. De Robertis is a professor of biological chemistry and the Norman Sprague Professor of Molecular Oncology. . . . **RICHARD PAZDUR**, director of the FDA Office of Oncology Drug Products, was selected as the Loyola University Stritch School of Medicine Alum of the Year for 2009 in recognition of his accomplishments in oncology research. He was presented with the honor Sept. 26. . . . **BERNARD FISHER**, distinguished service professor of surgery at the University of Pittsburgh, is the recipient of the 15th Jacobson Innovation Award of the American College of Surgeons in recognition of his overturning the Halsted anatomic and mechanistic paradigm that had led to radical mastectomy as the standard treatment for breast cancer. . . . **LAMAR MCGINNIS JR**. was installed as the incoming president of the American College of Surgeons on Oct. 11. He is clinical professor of surgery at the Emory University School of Medicine and former medical director of the Eberhart Cancer Center of the DeKalb Medical Center. . . . **GABRIEL HORTOBAGYI**, professor and chairman of the Department of Breast Medical Oncology at University of Texas M. D. Anderson Cancer Center, received an Honorary Doctorate from the Universidad Autonoma de Monterrey, Mexico. . . . **SOUTHWEST ONCOLOGY GROUP** Young Investigator Training Course was attended by five young researchers: **Neeraj Agarwal**, Huntsman Cancer Institute; **Eduardo Gharzouzi**, Guatemalan Cancer Institute; **Reshma Jagsi**, University of Michigan; **Dipen Parekh**, University of Texas Health Science Center San Antonio; and **Brian Till**, University of Washington and Fred Hutchinson Cancer Research Center.

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