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Going Generic

Supreme Court Decision Means FTC Scrutiny As Costly Oncology Drugs Go Off-Patent

By Paul Goldberg

The U.S. Supreme Court gave the Federal Trade Commission clear authority to investigate and prosecute "pay-to-delay" agreements, where manufacturers of branded drugs pay the makers of generics to refrain from introducing their products.

The June 17 ruling, which struck down an appeals court ruling by a five-to-three decision, will allow the FTC to aggressively scrutinize corporate deals at a time when many of the current generation of oncology drugs transition from branded to generic forms.

Though it's impossible to tease out the role pay-for-delay has played in oncology, it's common knowledge that companies fight to hang on to their monopoly advantage—or to be the first to get a cut of oligopoly profits.

"The incentives for branded manufacturers of provider-administered oncology drugs to hold on to their patent may be especially strong in comparison to 'conventional' generic drugs, or oral pills and tablets," said Rena Conti, assistant professor of health policy at the University of Chicago. "Prices of these branded therapies have climbed to levels that exceed $100,000 for treating one patient for a year—and many specialty injectables appear to enjoy low levels of generic competition and consequently higher margins."

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Reinventing Cancer Centers

New Jersey Center To Have Two Alliances: One With CINJ—and One With MD Anderson

By Matthew Bin Han Ong

MD Anderson Cancer Center and Cooper University Health Care of Camden, N.J., signed a letter of intent to create a $100 million Cooper-MD Anderson cancer center.

The co-branded 103,000-square-foot cancer institute is slated to open in October.

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In Brief

Salerno Named President, CEO of Komen

JUDITH SALERNO was named president and CEO of **Susan G. Komen for the Cure**.

Salerno replaces Nancy Brinker, the charity's founder, who announced last summer that she would step down as CEO and focus on global mission and development.

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Ruling Means FTC Will Consider Pay-for-Delay Case by Case

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The ruling is likely to affect what happens in the clinic, as research suggests that introduction of a generic drug in oncology affects both the cost of care and doctors' prescribing patterns.

FTC estimates that, across the medical field, pay-for-delay costs American consumers $3.5 billion a year.

According to the agency's analysis, 31 settlements between pharma companies and generic manufacturers contained both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product during the 2010 fiscal year.

Nobody really knows the true prevalence and cost of pay-for-delay, as activities of this sort tend to be shielded from view and often require investigations by regulators. With its ruling, the Supreme Court has ensured that such investigations will continue.

The Supreme Court reversed an appeals court ruling that threw out a regulatory challenge of pay-for-delay. As a result, though not clearly illegal, pay-for-delay now becomes a high-risk strategy for extending exclusivity of a branded drug.

The court stopped short of giving FTC what it wanted—presumption of liability, which would put the burden on defendants to show that efficiencies outweighed anticompetitive effects.

The decision gives even less to the pharma industry, which argued that patent rights should trump antitrust considerations. Had this view held, drug manufacturers would have been able to buy and sell patent rights without regard for the effect their actions have on consumer welfare.

By turning to case-by-case analysis, the court appears to have introduced a lot of uncertainty in the field. This will likely give rise to a massive amount of litigation in the next couple of years as the standards for these cases are further hammered out, lawyers say.

Listening to AndroGel

The case the Supreme Court heard is outside oncology. The agent in question is AndroGel, a testosterone gel sponsored by Solvay Pharmaceuticals Inc.

Two generic manufacturers, Actavis Inc. and Paddock Laboratories Inc., sought to make generic versions of the agent.

After FDA approved the generic, Actavis made "reverse payment" deals with Solvay, and agreed to not bring its generic to market for a number of years and agreed to promote AndroGel. Paddock made a similar agreement with Solvay, as did another generic manufacturer, Par Pharmaceutical Companies.

When FTC challenged the Actavis deal, a district court dismissed the complaint, and an appeals court concluded that as long as the anticompetitive effects of a settlement fall within the scope of the patent's exclusionary potential, that settlement is immune from challenge on the grounds of antitrust laws.

"In our view, however, reverse payment settlements, such as the agreement alleged in the complaint before us, can sometimes violate the antitrust laws," the Supreme Court ruling states. "We consequently hold that the [appeals court] should have allowed the FTC's lawsuit to proceed."

The ruling sends the case back to the lower court with the directive that the courts are to consider future cases under the doctrine of "the rule of reason," which the Supreme Court developed in its interpretation of the Sherman Antitrust Act.

The doctrine holds that specific actions that unreasonably restrain trade are to be subject to actions under the antitrust laws. The doctrine is applied when the circumstances of the actions are to be considered and when possession of monopoly power is not deemed "per se" illegal.

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Generics Affect Clinical Decisions

In oncology, the drugs' transition from branded to generic affects both health care costs and physicians' prescribing patterns. Consider the case of irinotecan:

The price of irinotecan dropped by 85 percent within the first six months of the generic's entry on the market in 2006, according to a paper by Conti and colleagues in the May 2012 issue of the ASCO Journal of Oncology Practice.

But, perversely, the generic entry of irinotecan resulted in a 17 to 19 percent decrease in use among elderly patients with metastatic colorectal cancer, compared with a close therapeutic substitute: oxaliplatin, the researchers found.

This occurred because of "financial incentives implicit in insurance coverage, changes in scientific evidence, and drug promotion," the paper concluded (Rena Conti et al., Infused Chemotherapy Use in the Elderly After Patent Expiration, Journal of Oncology Practice, Vol. 8 Issue 3S).

According to an analysis of databases, including the FDA Orange Book, which maintains a listing of drug patents, 14 drugs used in oncology were due for patent expiration between 2006 and 2011.

These drugs include: anastrozole, bicalutamide, docetaxel, dolasetron, exemestane, gemcitabine, granisetron, irinotecan, letrozole, nilutamide, oxaliplatin, temozolomide, topotecan and toremifene.

Most of these drugs have already undergone patent expiration and generic entry, but at least five appear to be in the midst of patent disputes. The five are: gemcitabine, nilutamide, oxaliplatin, temozolomide and toremifene.

The most interesting case to watch in oncology will be that of the Novartis drug Gleevec (imatinib), expected to go off patent in 2015.

Hagop Kantarjian, chair of the Department of Leukemia at MD Anderson Cancer Center, said the availability of a cheaper version of the drug would revolutionize the management of chronic myeloid leukemia.

"I think the availability of generic imatinib could drastically change the management of CML, depending on the price of the generic, the adjusted price of Novartis's Gleevec, and the maturing data from the ENESTnd and DASISION studies," said Kantarjian, who has emerged as a key advocate of lowering the prices of cancer drugs (The Cancer Letter, May 31).

"For example, if generic imatinib is priced less than $2,000-5,000 per year, the price of Gleevec stays at $90,000-plus, and the updated five-year survival data show a difference in early surrogate events (such as molecular responses, or EFS and PSF) favoring new TKIs, such as nilotinib and dasatinib, but not in survival—then oncologists may choose to treat patients with generic imatinib upfront and salvage them with new TKIs.

"This could save billions of dollars and reduce the cost of CML therapy and care to 10 percent of the estimates if new TKIs are used frontline ($6-8 billion/year).

"This will also certainly change the CML treatment pathways in poorer nations, where most patients and governments struggle with the cost of CML care to the point that less than 30 percent of patients access any form of TKI and many opt for the riskier and more toxic allogeneic stem cell transplant, which is a one-time procedure (curative in 60 percent, but can cause mortality and significant lifetime morbidities) that costs anywhere from $30,000 to $100,000 in some countries."

Winners and Losers

In the court's opinion, the court gives its rationale for granting FTC the opportunity to challenge pay-for-delay. The opinion includes the following:

"The payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product. Suppose, for example, that the exclusive right to sell produces $50 million in supracompetitive profits per year for the patentee. And suppose further that the patent has 10 more years to run. Continued litigation, if it results in patent invalidation or a finding of noninfringement, could cost the patentee $500 million in lost revenues, a sum that then would flow in large part to consumers in the form of lower prices.

"We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit. But settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market—simply keeps prices at patentee-set levels, potentially producing the full patent-related $500 million monopoly return while dividing that return between the challenged patentee and the patent challenger.

"The patentee and the challenger gain; the consumer loses."

FTC officials said they planned to return to prosecuting the AndroGel case.

"We look forward to moving ahead with the

Actavis litigation and showing that the settlements violate antitrust law," the commission's chair Edith Ramirez said in a statement. "We also are studying the court's decision and assessing how best to protect consumers' interests in other pay for delay cases."

One of the authors of the 1984 law that created the modern generic drug industry, Rep. Henry Waxman (D-Calif.) said the court decision was on target.

"The court echoed what I, along with many other members of Congress, have repeatedly said: the overarching goal of [the] Waxman-Hatch [Act] is to foster competition in the pharmaceutical industry," Waxman, the ranking member of the House Committee on Energy and Commerce, said in a statement.

"The type of collusive agreement at issue in this case represents a total perversion of the spirit of this law. This is a significant victory for consumers. But I will continue to vigilantly watch to ensure that Waxman-Hatch patent settlements are pro-competitive and pro-consumer in the future."

The Generic Pharmaceutical Association President and CEO Ralph Neas said that "the ruling continues to provide a lawful pathway for companies to resolve disputes through settlements. This preserves all options for generic manufacturers to bring lower-cost generic medicines to patients as soon as possible."

However, the trade group said that the ruling requires generic companies to take on a greater administrative burden to pursue a patent challenge.

"GPhA's hope is that the implementation of this ruling in the courts will be efficient and will not reduce the number of challenges under the Hatch-Waxman law, which has proven a reliable path to ensure patients access to cost saving generics as soon as possible," the association said in a statement.

The very fact that something as ingenious as "pay-for-delay" has been invented speaks to the sophistication of the players and the lawyers they employ—as well as relatively light punishments that federal regulators are able to impose on those who are found to misbehave.

A former Bristol-Myers Squibb executive, Andrew Bodnar, came closest to doing prison time in connection with an effort to delay the introduction of a generic drug.

Bodnar's case was unusual. It came to light for two reasons. First, in an earlier settlement in a case where BMS was accused of delaying the introduction of generic paclitaxel, the company had to ask state attorneys general to review its deals. And second, a negotiating partner—the CEO of generic maker Apotex—turned in Bodnar to FTC.

Apotex executive Bernard Sherman claimed that Bodnar had proposed a secret deal to delay the introduction of a generic version of Plavix, the BMS blockbuster blood thinner.

Bodnar was charged with providing false certificate to FTC, but avoided prison time after a judge sentenced him to write a 75,000-word book reflecting on his "criminal behavior in this case so that others similarly situated may be guided in avoiding such behavior" (The Cancer Letter, July 3, 2012).

Reinventing Cancer Centers

Camden, N.J., Hospital Affiliates With Two Comprehensive Centers

(Continued from page 1)

The flow of funds between the institutions is still being negotiated, and transactional documents haven't been finalized, said Dan Fontaine, MD Anderson senior vice president for business affairs and chief regulatory officer.

Generally, such arrangements are designed to generate funds for MD Anderson.

"I think it's probably not completely accurate to say, 'Oh, you're just getting paid for a relationship with MD Anderson,'" Fontaine said to The Cancer Letter. "I really believe that it is a robust exchange of value, including expertise about clinical trials, including expertise about research protocol-based treatment—all of those things that go back and forth between the two entities."

Fontaine acknowledged that the final deal between MD Anderson and Cooper remains a work in progress.

This is Cooper's second affiliation with an NCI-designated comprehensive cancer center.

In February 2010, Cooper joined the Cancer Institute of New Jersey Network, a consortium that now has 16 member hospitals across the state, led by Robert Wood Johnson University Hospital. CINJ, New Jersey's only NCI-designated comprehensive cancer center, will become part of Rutgers University July 1.

Through CINJ, Cooper has access to clinical trials available at NCI-designated cancer centers, their networks and the national cooperative cancer research groups. Cooper also receives professional education, community education and outreach, and other services from CINJ.

Until the details of the MD Anderson deal are better understood, it will be impossible to determine how the two concurrent collaborations will function, said insiders in New Jersey and Philadelphia.

The Cooper-MD Anderson cancer institute,

announced June 10, appears to be similar to the Banner MD Anderson Cancer Center collaboration, which was created as part of the Houston cancer center's four-year partnership with Banner Health, a Phoenix healthcare organization.

MD Anderson previously opened affiliated facilities in Orlando in 1989 and Madrid in 1999.

"Banner made the capital investment for both the location and facility for Banner MD Anderson Cancer Center," MD Anderson officials said in response to questions from The Cancer Letter.

"Additionally, MD Anderson is compensated by both a fixed and variable fee for its contribution to the center's operation, including but not limited to, its intellectual capital, training, expertise, supervision and quality management," officials said.

Sources said that in past agreements involving MD Anderson and co-branded institutions, the partner typically pays the cost of consulting plus 3 to 5 percent per year.

"I have no doubt that [the Camden institute] will include the Cooper name and the MD Anderson name and be operated much as our relationship with the Banner system," Fontaine said.

Sources said MD Anderson hired McKinsey & Company, a consulting firm, to identify markets for the expansion of the center's brand. MD Anderson is not alone in creating affiliated facilities—Mayo Clinic, the Cleveland Clinic, and Geisinger Health System in Danville, Penn., are pursuing a similar strategy.

"We were approached by Cooper sometime in spring 2012, because they wanted to access our education and consultative services, because they wanted to do something to take their cancer care up to a higher level," Fontaine said to The Cancer Letter. "Oftentimes, we'll be contacted not to create any type of permanent relationship, but to go in and share our knowledge and provide education on what we do at MD Anderson that is unique to our practices and delivery systems."

Cooper and MD Anderson moved rapidly from a consultant-client relationship to a partnership, Fontaine said.

"The facility is underway, and we are targeting to making that operational in the fall of this year with us being a part of that from day one as it moves forward," he said.

"Although we haven't decided finally on what the name will be, because there's always some branding discussions and how to make them work together, it will be a co-branded institute."

Staffing and Funding the Institute

Physicians from Cooper will be trained at MD Anderson, and programs will focus on integration of staff from both institutions, Fontaine said.

Fontaine didn't comment on the compensation model for the required training in Houston.

"There are direct reporting relationships between leaders of the medical staff at the partner member and our medical leadership here in Houston as well as ongoing collaborative efforts in terms of multidisciplinary conferences," Fontaine said.

"We have leadership meetings where we get together that we talk about on a quarterly basis—what the big plans are for the next quarter, and then sub-teams are working together on a constant basis.

"When you look at the management of the medical quality of the cancer program, it will be a joint effort, but ultimately, looking at that program and taking the responsibility for MD Anderson to continue to help Cooper to move it to a higher and higher level will fall on the shoulders of MD Anderson," Fontaine said.

"It's one of those things we obligate ourselves to do."

Though the two institutions will likely engage in recruitment and training, Fontaine said it remains to be determined whether any physicians will relocate from MD Anderson to Cooper.

Cooper employs over 500 physicians and has more than 100 outpatient offices throughout southern New Jersey and Pennsylvania.

"I don't want to presume that people will or will not move," Fontaine said. "If you look at the physicians that are involved in leadership roles in the Banner program, we have folks that moved from Houston to Phoenix to be part of that program."

However, sources in Houston indicate that most of the established clinical faculty members are not anticipating a move to Camden, whereas several faculty members were clearly interested in considering a move to Arizona.

"We were successful in recruiting people that had worked at MD Anderson at one time, gone to another place to practice their medicine and then look favorably upon an opportunity to come back into an MD Anderson-connected organization," Fontaine said.

"While I think it isn't a guarantee that there will be anyone from Houston that ends up there, I think it is also a guarantee that the people that are there will have both some mixture of past MD Anderson training or be involved in current MD Anderson training," Fontaine said.

A Competitive Market

Cooper Board Chairman George Norcross said cancer patients in southern New Jersey would no longer have to travel far for comprehensive cancer treatment.

"For those of us who live in the seven southern counties, cancer treatment is largely something that is done across the bridge," Norcross said at the June 10 press conference announcing the project. "There are no comprehensive centers.

"The MD Anderson-Cooper facility will be the first to allow citizens in the southern part of the state to enjoy world-class services that exist in Philadelphia and New York, and other regions."

New Jersey Governor Chris Christie and MD Anderson President Ronald DePinho also spoke at the event.

Cancer care in the Philadelphia area is available at several excellent venues, including the University of Pennsylvania, Fox Chase Cancer Center and Thomas Jefferson University. UPenn and Fox Chase are NCI-designated comprehensive cancer centers, and Thomas Jefferson, located a mile away from Cooper, is an NCI-designated clinical cancer center.

"I don't view the competitive circumstances of any of our potential locations or our existing locations to be any markedly more or less than others," Fontaine said. "I think there's lots of competition out there.

"Our view is that the more good choices the cancer patients and their families have across all areas of the cancer care continuum, from prevention to diagnosis to treatment to survivorship, the more it's going to serve the segment of the community that is facing the burden of a loved one or themselves being diagnosed with cancer."

Earlier this year, Cooper was embroiled in a controversy involving allegations that the hospital paid physicians serving on the institution's advisory board to refer patients to Cooper's Heart Institute for treatment.

A joint federal-state investigation ensued, alleging that Cooper sought and received reimbursement through Medicare and Medicaid for treating inappropriately referred patients—a violation of state and federal law.

Cooper resolved the allegations January 24 with a $12.6 million settlement, and agreed to reform certain practices to enhance accountability.

Sequestration

Senate Committee Approves $1.058 Trillion To Reverse Cuts

By Matthew Bin Han Ong

The Senate Committee on Appropriations approved a spending allocation of $1.058 trillion June 20 for the fiscal year 2014, a move that would reverse sequestration and restore funding for cancer research.

The Senate markup, led by Democrats, would increase spending on infrastructure, transportation and technology, and reverse sequestration for the next nine years. The measure would restore funds for scientific research.

"Congress must pass a budget resolution by April 15, in order to establish a limit on spending for the coming fiscal year," Appropriations Chair Sen. Barbara Mikulski (D-Md.) said in a statement June 20. "The Senate passed its budget resolution on March 23, but it has been three months without an agreement between the House and Senate.

"In the absence of a budget resolution, it is essential that the committee adopt a spending allocation so that we can begin marking up our fiscal year 2014 bills," Mikulski said.

The House of Representatives is expected to reject the markup. The House austerity budget, proposed by Rep. Paul Ryan (R-Wis.), calls for a $5 trillion cut in federal spending—and includes the repeal of the Affordable Care Act and an overhaul of Medicare. The plan supports some funding for basic science research, but removes loan guarantees and other dollars for sectors such as alternative energy.

The House hasn't approved its version of the HHS appropriations bill.

"An allocation of $1.058 trillion is needed to… invest in medical breakthroughs," Mikulski said. "I am not willing to accept that the sequester is 'the new normal.'

"The $967 billion ceiling in this alternative spending allocation and the Ryan budget is the sequester level for fiscal year 2014—it does not meet the needs of a growing nation."

Senate Republicans say the $1.058 trillion allocation, about $91 billion above the discretionary spending limit required by the Budget Control Act, puts the federal government on the path to another sequester. The $967 billion cap is $17 billion below current levels.

"The majority's top-line number ignores the law and puts us on the path to another sequester," said Appropriations Vice Chair Sen. Richard Shelby

(R-Ala.) in a separate June 20 statement. "If enacted, a discretionary spending level of $1.058 trillion would trigger an automatic cut that is 65 percent larger than the 2013 sequester.

"As members of the Appropriations Committee, it is our job to set the priorities for government funding and not have them dictated to us by an indiscriminate formula," Shelby said. "This is one reason why I opposed the Budget Control Act. It is, however, the law.

"Although Republican members will not vote to support the $1.058 trillion level, it is still my hope that we can work together to write the bills that adhere to the spending limit allowed by the law."

Democrats said House efforts to increase Pentagon spending also ignore the budget cap, and would trigger another sequester.

"While the House plan tries to avoid cuts to defense at the expense of infrastructure and education, they won't be able to protect the Pentagon without an agreement," said appropriations committee member Sen. Patty Murray (D-Wash.) June 20. "$552 billion in defense spending would be sequestered back down to $498 billion unless we can get a bipartisan deal."

Cancer research advocates applaud the proposal by Senate appropriators.

"Reinvesting in cancer research, prevention and health programs that promote access to care comes at a critical moment when the country has a great opportunity to capitalize on past progress," said Christopher Hansen, president of the American Cancer Society Cancer Action Network.

"By proposing to turn off [the sequestration] cuts in the FY 2014 Labor, Health and Human Services Appropriations bill, senators are laying the groundwork to fund urgent national priorities such as the fight to defeat cancer, which kills more than 580,000 people in America each year.

"Today's proposal is also crucial for proven programs at the Centers for Disease Control and Prevention that enable hundreds of thousands of people to access affordable breast, cervical and colon cancer screenings, as well as proven methods for quitting tobacco use," Hansen said. "It would also offer important support for implementation of critical patient protections that are improving access to quality, affordable health care nationwide."

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In Brief

Judith Salerno Named President And CEO of Komen for the Cure

(Continued from page 1)

Brinker's new title is founder and chair of global strategy. Salerno will be based at the Komen headquarters in Dallas.

Salerno is the executive director and chief operating officer of the Institute of Medicine of the National Academy of Sciences, where she oversees the National Cancer Policy Forum.

Salerno has served in executive, operational, research and public policy roles at the Institute of Medicine, NIH, the National Institute on Aging, the U.S. Department of Veterans Affairs and with community health and research organizations.

Salerno is board-certified in internal medicine and earned her M.D. from Harvard Medical School in 1985 and a Master of Science degree in Health Policy from the Harvard School of Public Health in 1976. She continues to see patients as a volunteer physician.

JERRY SULS was appointed senior scientist of the Behavioral Research Program in the **NCI Division of Cancer Control and Population Sciences**.

The Behavioral Research Program was recently reorganized into six scientific branches: the Basic Biobehavioral and Psychological Sciences Branch; the Health Behaviors Research Branch; the Health Communication and Informatics Research Branch; the Process of Care Research Branch; the Science of Research and Technology Branch; and the Tobacco Control Research Branch.

Suls is a former Editor of Personality and Social Psychology Bulletin and Social and Personality Psychology Compass. He has served on the editorial boards of Annals of Behavioral Medicine, Journal of Behavioral Medicine, Health Psychology, Journal of Personality and Social Psychology, and Health Psychology Review.

He was a member of the National Science Foundation Social Psychology Advisory Panel and the NIH Behavioral Medicine Interventions and Outcomes Study Section. He is past member-at-large and president of Division 38 (Health Psychology) of the American Psychological Association.

ALON WEIZER was named medical director of the **University of Michigan Comprehensive Cancer Center**.

Weizer is associate professor of urology at the University of Michigan Medical School. His clinical and research interest focuses on prevention and early detection of bladder cancer, treatments for early bladder cancer, and the use of minimally invasive approaches to treat bladder, prostate, kidney, testicular and other genitourinary malignancies.

YOUNG CHAN CHAE received of the **Wistar Institute Ching Jer Chern Memorial Award**. The annual award is given to the Wistar postdoctoral fellow who has published the best scientific paper during the year.

Chae's research focuses on how heat shock protein 90 interacts with tumor mitochondria. Chae's work demonstrated how tumor cells exploit HSP90 behavior, using the protein to produce energy while disabling its self-destruct capability.

"Under harsh environmental conditions, HSP90 chaperones tumor energy transformation by enabling cancer mitochondria to maintain energy production in cancer cells," Chae said.

Chae delivered his Chin Jer Chern Memorial Award Lecture titled " Mitochondrial HSP90 in Tumor Bioenergetics" at the award ceremony lecture on June 11.

His paper, "Control of Tumor Bioenergetics and Survival Stress Signaling by Mitochondrial HSP90s" appeared in the September 2012 issue of Cancer Cell. Collaborating with Chae were Dario Altieri, Meenhard Herlyn and Jessie Villanueva of The Wistar Institute.

THE LEUKEMIA & LYMPHOMA SOCIETY joined the **Dana-Farber Cancer Institute** to establish a network of sites for clinical trial testing of innovative blood cancer therapies in community oncology settings.

The Blood Cancer Research Partnership will bring clinical trials closer to where patients live and help to address one of the primary bottlenecks in the development of new cancer therapies: the need for more patients to take part in trials.

Eleven potential sites have been identified for the trials—in New York, Georgia, Colorado, Illinois, California, Florida, Texas, Kansas, Tennessee, New Jersey, and Washington.

The society is investing $1,050,000 in the three-year project, and will have two seats on the trials steering committee. The agreement requires that certain milestones be met, including the number of trials initiated and number of patients accrued for each trial. The trials will be either phase I or II, with patient accrual taking place over an 18-month period. Dana-Farber is the lead institute for the partnership and each of the community sites will follow the clinical trial protocols established by one centralized agreement.

A number of different clinical trial proposals are currently under consideration, including several for chronic lymphocytic leukemia, myeloma and stem cell transplant.

PRINCESS MARGARET CANCER CENTRE and the **King Hussein Cancer Center** of Amman, Jordan, signed a memorandum of understanding to

begin discussions about an international partnership.

At a ceremony in Toronto, the two centers established the principal areas of focus for the partnership, including: working together to enhance academic and research opportunities at both organizations, sharing best practices in cancer care diagnostics and therapeutics, exploring joint ventures in clinical practice, and promoting e-health and new distance education initiatives.

Signing the memorandum on behalf of the Princess Margaret Cancer Centre were Robert Bell, president and CEO of University Health Networks, and Mary Gospodarowicz, medical director of the center's cancer program. Her Royal Highness Princess Dina Mired of Jordan signed on behalf of the King Hussein Cancer Center and Foundation.

Regulatory News

FDA Approves New Implant For Breast Reconstruction

FDA approved the MemoryShape Breast Implant to rebuild breast tissue in women of any age and to increase breast size for use in women at least 22 years old.

The approval was based on six years of data from 955 women demonstrating that there is a reasonable assurance of safety and effectiveness for this implant. The implant showed similar rates of complications and outcomes as previously approved breast implants.

FDA requires that Mentor Worldwide, the implant's manufacturer, conduct a series of post-approval studies to assess long-term safety and effectiveness outcomes and the risks of rare disease and continue to follow women who received the implant as part of a pre-market study.

The Japanese Ministry of Health, Labour and Welfare approved Avastin (bevacizumab) for the treatment of malignant glioma, including newly diagnosed glioblastoma, in combination with radiotherapy and temozolomide chemotherapy, and as monotherapy for treatment of recurrent GBM and certain other types of high grade glioma following prior therapy.

The approval was based on data from three clinical studies in GBM: the phase II BRAIN study, a Japanese phase II study (JO22506), and the phase III AVAglio study, which demonstrated an increase in progression-free survival but no significant increase in overall survival. Avastin is sponsored by Roche.

Obituaries

Keith Amos, UNC Cancer Surgeon

Keith Amos, assistant professor of surgery at the University of North Carolina School of Medicine, died June 17 while on a Dr. Claude Organ, Jr., Travel Award from the American College of Surgeons in Edinburgh, Scotland. He was 42.

Amos was a member of the Department of Surgery in the Division of Surgical Oncology at the UNC Lineberger Comprehensive Cancer Center. The cause of his death was not provided.

"He was truly an amazing person and physician to everyone here at UNC," said UNC Deputy Director of Communications Dianne Shaw. "A lot of us are just in shock and devastated—his colleagues, his patients, his family, his friends—it's a really big loss for us and for everybody."

Amos was recruited to UNC in 2007. He earned his medical degree from Harvard University, and completed surgery residency at Washington University in Saint Louis and fellowship at MD Anderson Cancer Center.

His interest in cancer education made Amos was an ambassador for the University of North Carolina, travelling across the state to talk to numerous communities about the importance of cancer screening and cancer disparities, Shaw said.

Memorial gifts may be made payable to UNC Lineberger Comprehensive Cancer Center, CB 7295, Chapel Hill, NC 27599. UNC Lineberger is working with the family on designating memorial gifts to a program meaningful to Amos. A memorial service will be held on the UNC campus Saturday, June 29.

Amos is survived by his wife, Ahaji, and their three young daughters.

Trudy Small, Pediatric Hematologist At Memorial Sloan-Kettering

Trudy Small, pediatric hematologist at Memorial Sloan-Kettering Cancer Center, died June 14 at her home. The cause of death was not announced.

Small specialized in the diagnosis and care of children undergoing hematopoietic stem cell transplantation for congenital immune deficiencies and those with hematologic malignancies.

Small received her MD degree from SUNY Upstate Medical University and completed residencies at Duke University Medical Center and the University of Minnesota. After completing a fellowship at

Memorial Sloan-Kettering, she joined the faculty in 1987.

Her research focused on the cellular interactions that promote or limit immune reconstitution after transplantation and provided the first evidence linking age-related changes in the human thymus with impaired recovery of cell-mediated immunity in older marrow transplant recipients.

Small also conducted pioneering studies examining how best to vaccinate patients following hematopoietic stem cell transplantation and other cancer therapies so as to most effectively stimulate their newly transplanted immune systems and protect patients from infections.

Her work provided the underpinnings for the National Center for Disease Control Guidelines for vaccination of adult and pediatric transplant recipients. She was also an authority on lethal genetic immune deficiencies and the application of HLA-matched sibling and half-matched parent-derived marrow transplants to correct them.

"Dr. Small's passing is a profound loss to her colleagues—to whom she was a beloved friend, a generous collaborator, and a mentor—and to her patients and their families, on whose behalf she never stopped working," said MSKCC Physician-in-Chief José Baselga.

Plans for a memorial service will be announced at a later date.

Small is survived by her husband, Robert Knowles, and her children, Molly and Sam.

Kie Kian Ang, MD Anderson Radiation Oncologist

Kie Kian Ang, a professor in the Department of Radiation Oncology in the Division of Radiation Oncology at MD Anderson Cancer Center, died June 19 from cancer. He was 63.

Ang has been a member of MD Anderson's radiation oncology faculty since 1984. He held the endowed Gilbert H. Fletcher Distinguished Memorial Chair and recently assumed an additional role as Vice President of MD Anderson's Global Academic Program.

In this capacity, he orchestrated academic and educational collaborations between MD Anderson and 26 leading cancer centers throughout the world.

"This responsibility fit Ang's passion for making a difference on global health and is reflective of his own international heritage," said MD Anderson Provost Tom Buchholz.

His clinical contributions included refining head-and-neck cancer therapy by developing regimens in preclinical models for testing in multi-institutional trials.

Ang's research interests focused on enhancing radiation response of various tumors by chemotherapy and/or modulation of growth factor signaling pathways and discovery of prognostic and predictive biomarkers.

Born in China and raised in Indonesia, Ang earned both his medical degree and doctor of philosophy degree from the Catholic University and University Hospital in Leuven, Belgium, where he also completed his radiation oncology training.

Ang spent the first four years of his independent faculty career in Belgium before joining MD Anderson. He spent the rest of his career at MD Anderson, where he served as the Deputy Chairman for Radiation Oncology and Deputy Division Head for Radiation Oncology for more than two decades.

Ang's leadership extended far beyond MD Anderson, Buchholz said.

Ang led many committees in national organizations dedicated to radiation oncology, including serving as president and subsequently chairman of the Board of ASTRO, the leading international society of radiation oncology. He also served on the board of directors of the American Board of Radiology and as president of the Gilbert Fletcher Society.

Ang was chair of the head-and-neck committee of the Radiation Therapy Oncology Group, a cooperative group dedicated to advancing radiation treatments through clinical trials research. He was awarded fellowships from both the American College of Radiology and from ASTRO, and in 2011 he was selected as the ASTRO Gold Medal Recipient, the highest honor bestowed by the society. His research was published in more than 350 peer-reviewed articles, including manuscripts in medicine's top journals, such as the New England Journal of Medicine.

"Dr. Ang combined all of these skills with a warm, genuine and humble nature," Buchholz said. "He was universally respected and was a role model, mentor, and educator to many of the future leaders of cancer medicine.

"He was known for his passion for life, his love for his family, his friendship to so many, and his athleticism."

Ang is survived by his wife, his daughter and her husband, and his son and his wife.