THE CANCER LETTER

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Feds Set Guidelines For Helping Patients While Steering Clear Of Anti-Kickback Law

By Paul Goldberg

Federal regulators are offering drug companies two options for giving therapies to patients who can't afford them:

Provide drugs directly to patients and their doctors or give money to an independent foundation that would help patients make the co-payments they can't afford.

But there is a catch: any drug company that steers patients to its therapies, causing Medicare to pick up the rest of the tab, runs the risk of criminal prosecution under the federal anti-kickback statute, regulators warn.

As the May 15 deadline for enrollment in the new Medicare Part D approaches, pharmaceutical companies are redesigning their assistance programs.

At the same time, foundations are gearing up for the business of

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In the Cooperative Groups & Cancer Centers:

Hortobagyi To Lead SWOG Breast Committee, Pienta Named Head Of Translational Medicine

SOUTHWEST ONCOLOGY GROUP Chairman **Laurence Baker** announced two leadership changes in the group's committees. **Gabriel Hortobagyi** will become chairman of the Breast Cancer Committee in June 2007, when he completes his term as president of the American Society of Clinical Oncology. **Kenneth Pienta** was named chairman of the Translational Medicine Committee. Hortobagyi is chairman of the Department of Breast Medical Oncology, directs the Breast Cancer Research Program and holds the Nellie B. Connally Chair in Breast Cancer at the University of Texas M.D. Anderson Cancer Center. Pienta is a professor of internal medicine and urology and is director of the Urologic Oncology Program of the Comprehensive Cancer Center at the University of Michigan. The appointments were announced April 22 at the group's semiannual meeting. . . . **GENENTECH** donated $2.5 million in honor of the company's 30th anniversary to Cold Spring Harbor Laboratory. The funds will establish the Genentech Center for the History of Molecular Biology and Biotechnology in the CSHL Carnegie Building. The expanded facility will house the archival collections of leaders in biotechnology including Nobel laureates **James Watson, Sydney Brenner, Barbara McClintock**, and **Hermann Muller**. "Thirty years ago, biochemist **Herb Boyer** and venture capitalist **Bob Swanson** founded Genentech, the first biotechnology company, and

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Advocates Consider Ethics Of Offering Co-Pay Assistance

(Continued from page 1)

establishing patients' qualifications to receive assistance, and providing that assistance.

Preparing for change, many companies are encouraging patients who used to receive free drugs to enroll in Medicare Part D, instead.

"The pharmaceutical industry would rather have Medicare and patients become paying customers," said Maria Hardin, vice president for patient services at National Organization for Rare Disorders. "We are getting calls from many patients who were getting free drugs, who now have been told by the companies that they are no longer eligible after May 15 for free drugs."

Under Part D, pharmaceutical companies will be able to collect from Medicare some portion of the cost of drugs that would otherwise be given away, but they have to refrain from using co-payment subsidies to steer patients toward specific products. In a "special advisory bulletin" last November, the HHS Office of the Inspector General warned companies against such schemes:

"We conclude that pharmaceutical manufacturer [patient assistance programs] that subsidize Part D cost-sharing amounts present heightened risks under the anti-kickback statute," the bulletin warned. "However, … cost-sharing subsidies provided by bona fide, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions." Violation of the law can lead to a five-year imprisonment and a $25,000 fine.

For cancer patients, the cost of drugs can easily reach six figures annually. For society, the cost of cancer care will likely continue to rise, in part because many of the new, expensive treatments now used in advanced disease are expanding to new indications and edging closer to the front-line and adjuvant settings, where they would be used by a larger number of patients.

"Black Holes"

In recent months, several advocacy groups have been asked informally by drug company contacts whether they would be interested in setting up co-pay foundations.

Advocates realize that foundations can generate millions of dollars in revenues for helping patients pay for treatment. However, opening a co-pay foundation would mean becoming a link in the system of drug distribution.

"CancerCare is focused on the individual patient; it's not our mission to focus on the pricing and distribution of drugs," said Diane Blum, executive director of the New York-based nonprofit organization. "If we were to take co-pays, we then become part of that system. It's my thought, with support from my senior staff as well as the board, that we don't want to get ourselves organizationally involved about what oxaliplatin costs, or what Avastin costs, or what Gleevec costs."

Over its 62-year history, CancerCare has developed the expertise needed to run a co-pay foundation. "We have a whole system here of assessing and disbursing; we have a structure to do it," Blum said. Yet, financial assistance is just one part of the overall counseling CancerCare provides.

"I am looking at [patient assistance programs] as a resource, because we get 900 new calls for help every week, and half of them have a financial need," Blum said. "We should be well-informed in a systematic way, not an anecdotal way, about what those programs are, and whether they can help our patients."

Musa Mayer, a breast cancer patient advocate and editor of the Web site Advanced Breast Cancer (www.advancedbc.org), said co-pay foundations function as "an arm of industry."

"It's a way of making it appear as if what's happening—escalation in price—is not really happening, or if it is, that it won't really hurt," she said. "Having advocates participate in that feels to me like an

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endorsement of that process.

"The system is broken here, and advocates need to help address that."

NORD's Hardin sees no moral dilemma in administering patient assistance programs. "Drug companies are never going to bring those prices down," she said. "If anything, when Part D went into effect, they raised their prices."

NORD first became involved in patient assistance in 1987, when Sandoz Pharmaceutical Corp. asked the group to help distribute Sandimmune (cyclosporine), an immunosuppressant used to prevent rejection of transplanted organs.

"Sandoz Pharmaceuticals came to us and said, 'We don't want to play God here. We are going to donate the drug, we want you to screen the patients, we want you to set up the process to make sure they get uninterrupted delivery of drugs,'" Hardin said.

Later, the group administered the expanded access program for the AstraZeneca drug Iressa, and developed programs for distribution of drugs to the needy and co-pay assistance.

"It used to be for totally uninsured patients, and then we started getting underinsured patients, and then we started getting patients on Medicare Part D with these humongous doughnut holes—black holes, I call them," Hardin said.

Under the Part D program, patients are responsible for up to $3,600 in drug costs every year. "This is humongous to somebody who is making $700 a month on Social Security," Hardin said.

According to tax documents for 2004, NORD's administration of indigent care programs generated $1.7 million in fees paid by drug companies. NORD's total revenues were $7.6 million in 2004.

The health care industry plays a role in creating co-pay foundations, with or without cooperation from established patient groups.

In 2004, Covance, a health care consulting company, created the HealthWell Foundation, which provides co-pay assistance. Similarly, the Lash Group, a subsidiary of AmerisourceBergen, created the Patient Access Network Foundation, another co-pay charity. The parentage of these groups was reported by The Wall Street Journal April 8.

OIG Defines A Charity

The OIG first determined the rules for co-pay foundations under the Medicare Part B program in an "advisory opinion" issued to the Patient Advocate Foundation in October 2004.

A later advisory document suggests that a similar administrative structure can be used under the new Medicare Part D benefit. According to an announcement on its web site, Patient Advocate Foundation is offering assistance with co-payment under the new prescription drug benefit.

The foundation's executive director Nancy Davenport-Ennis didn't return calls from The Cancer Letter.

The OIG advisory opinion allows pharmaceutical companies to turn to non-profit groups to distribute assistance to patients. The document states that "[PAF's] interposition as an independent charitable organization between donors and patients and the design and administration of the proposed program provide sufficient insulation so that [PAF's] subsidy of Medicare Part B cost-sharing obligations should not be attributed to any of its donors."

Contributors to the foundation would be prevented from steering patients to particular therapies, the OIG opinion states:

"Donors will not be assured that the amount of financial assistance their patients, clients, or customers receive will bear any relationship to the amount of their donations. Indeed, donors will not be guaranteed that any of their patients, clients, or customers will receive any financial assistance whatsoever from [PAF].

"In these circumstances, we do not believe that the contributions made by donors to [PAF] can reasonably be construed as payments to eligible beneficiaries of the Medicare program."

The document (advisory opinion No. 04-15) is posted at http://oig.hhs.gov/fraud/advisoryopinions/opinions.html#1.

Foundations formed following the issuance of the advisory opinion have broken down financial contributions into separate funds that allow donors—primarily drug companies—to subsidize co-payments for specific diseases.

According to tax documents filed by Patient Access Network Foundation for 2004, these include anemia, cutaneous T-cell lymphoma, cytoprotection, and rheumatoid arthritis. Documents show that the foundation was started on Oct. 1, 2004, and had raised $12.5 million in "direct public support" over the following three months.

The foundation's Web site contains a list of covered medications and the following disclosure:

"The Patient Access Network Foundation receives financial support from the manufacturers of some of the drugs listed above, though not from all of them. Support

from manufacturers does not determine whether drugs appear on this list, nor is it considered when PANF reviews applications and provides grants to assist patients with their out-of-pocket costs."

NORD's Hardin said charities set up by healthcare companies can't be entirely independent from drug companies. Advocacy groups like hers can be, she said. "It's not a business for us," Hardin said. "It's a service that we are trying to provide."

NORD doesn't solicit business, Hardin said. "We don't go to them; they come to us," she said. "They come to us, because they have to have a legal mechanism to keep their customer base. But we tell them the OIG says that we have to do it this way: you donate to a fund.

"We can't tell you how much to donate. You have your demographics. You know how many patients you have that either have insurance or Medicare. And you can give us the donation, or you can spread it out if you want.

"You know that OIG is watching you. And we have to abide by the guidelines. We can't tell you how many of the people in a program are your customers. You can give them aggregate figures at the end of the year.

"You can say, 'We took care of 2,800 patients,' and they have no idea how many of them are taking one drug vs. another."

PANF isn't physically separated from the for-profit corporation that started it. The phone number cited on the tax forms is answered by a recording: "Thank you for calling Lash Group Health Care Consultants."

PANF attorney Scott Haenni, who is also an attorney at Lash Group, didn't return calls from The Cancer Letter.

A Part D Advisory Bulletin

Last year, before Part D coverage became available, pharmaceutical companies asked OIG for guidance on patient assistance under the Part D program.

The resulting guidance bulletin identified "potentially abusive PAP structures." According to the document, a PAP should have the following characteristics:

—"Neither the pharmaceutical manufacturer nor any affiliate of the manufacturer (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) exerts any direct or indirect influence or control over the charity or the subsidy program;

—"The charity awards assistance in a truly independent manner that severs any link between the pharmaceutical manufacturer's funding and the beneficiary (i.e., the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer);

—"The charity awards assistance without regard to the pharmaceutical manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan;

—"The charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and

—"The pharmaceutical manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products."

The document is posted at www.oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdvisoryBlletinFinal-Final.pdf

Companies Can Give Away Products

Earlier this year, a group of seven pharmaceutical companies attempted to offer discounts of at least half of their drug costs for Medicare beneficiaries who reach the "doughnut hole."

The program, called Bridge Rx, was designed for people whose income falls between $14,000 and $18,620.

OIG responded informally that the proposed program wouldn't offer uniform discounts on all drugs and could induce patients to switch from generic drugs to branded medication.

Further addressing the issue, OIG issued an advisory opinion suggesting that one company, Schering-Plough, could continue to give away its products directly to patients and their doctors. This can be done without involving an independently-run foundation, as long as Medicare Part D isn't asked to pick up any portion of the cost.

The April 18 opinion stated that the Schering-Plough programs were acceptable because they didn't involve company subsidies toward the patient's "true out-of-pocket spending" under Part D, and, in fact, bypassed Medicare reimbursement by sending drugs directly to patients or their doctors.

The opinion lists potential legal pitfalls of PAPs operated directly by manufacturers:

"Manufacturer PAPs that subsidize the cost-sharing amounts for the manufacturer's drugs payable in whole or in part by the Part D program present all of the usual risks of fraud and abuse associated with

kickbacks, including steering enrollees to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing enrollees' incentives to locate and use less expensive, equally effective drugs."

However, the Schering-Plough PAP avoids these pitfalls, the document states:

"In this case, the requestor operates the PAPs entirely outside of the Part D benefit. Operating outside of the Part D benefit means the enrollees obtain their drugs without using their Part D insurance benefit.

"No claims for payment for the drugs provided outside the Part D benefit are filed with a Part D plan or the beneficiary, and the assistance does not count toward the enrollee's [true out-of-pocket, TrOOP] or total Part D spending for any purpose.

"Having reviewed the arrangement, we conclude that the arrangement contains safeguards sufficient to ensure that the PAPs operate entirely outside the Part D benefit, and, therefore, there is minimal risk of fraud and abuse under the Part D program.

"First, the PAPs notify enrollees' Part D plans that the free drugs are being provided outside the Part D benefit. The PAPs will accomplish this via data sharing agreements with CMS. In conjunction with the PAPs' patient notification procedure, this data arrangement helps ensure that no payment is made for the free drugs by Medicare or by any Part D plan, and no part of the cost of the free drug is counted toward any Part D enrollee's TrOOP. Effective coordination with the enrollee's Part D plan may also enhance patient safety and quality of care.

"Second, eligibility for PAP assistance for Part D enrollees is determined based solely on patients' financial need, using a methodology (i.e., percent of Federal poverty level combined with percent of household revenues spent on drugs) that is entirely divorced from considerations related to a Part D enrollee's choice of Part D plan, the benefit design of the enrollee's Part D plan, or where a Part D enrollee is on his or her Part D plan's benefit spectrum.

"For Part D enrollees, financial need is determined in a reasonable, uniform, and consistent manner, without regard to the providers, practitioners, or suppliers used by the patient or the Part D plan in which the patient is enrolled.

"Moreover, the PAPs provide assistance for the whole Part D coverage year (or for the portion of the coverage year remaining after the patient begins receiving PAP assistance), and the PAPs continue to provide assistance even if the patient's use of the free drug is periodic during the coverage year. In addition, the PAPs operate, and will continue to operate, in compliance with all then-existing guidance from CMS. Finally, the PAPs maintain accurate and contemporaneous records of the free drugs provided to the Part D enrollees.

"This facilitates appropriate transparency and accountability.

"Taken as a whole, these safeguards substantially mitigate the risk (1) that the free drugs are or will be used to tie Medicare beneficiaries to particular outpatient prescription drugs payable by the Medicare Part D program; or (2) that the free drugs are or will be used to increase costs to the Medicare Part D program (for example, by increasing the number of beneficiaries who reach the catastrophic benefit, by hastening the point during the coverage year at which a beneficiary reaches the catastrophic benefit, or by inducing beneficiaries to use higher cost drugs during the catastrophic benefit instead of equally effective, lower cost alternatives).

"We note that the use of physicians to distribute free drugs from pharmaceutical manufacturer PAPs could potentially create additional risk under the anti-kickback statute if the free drugs were to inure to the economic benefit of the physicians.

"However, in this instance, the risk is mitigated by several safeguards, including the designation of the drugs for use only by particular patients, limitations on the quantities shipped, the physicians' agreement to dispense the drugs only to designated patients and to refrain from billing for the drugs, and the notification processes for both the Part D plans and enrollees."

The document (advisory opinion No. 06-03) is posted at http://oig.hhs.gov/fraud/advisoryopinions/opinions.html#1.

In the Cancer Centers:

Genentech Gives $2.5 Million To Cold Spring Harbor

(Continued from page 1)

in the process launched a whole new industry," said **Richard Scheller**, executive vice president of research at Genentech. "Today, biotechnology drives medical innovation and provides therapies for millions of patients worldwide with serious and life-threatening illnesses. We are excited to collaborate with Cold Spring Harbor Laboratory, the birthplace of the genetics research that laid the groundwork for biotechnology, to honor and preserve the history of this groundbreaking science and industry." . . . **CITY OF HOPE** Cancer Center received

a $2.5 million gift to establish the Pauline and Martin Collins Family Chair in Urology for clinical and basic research in urologic cancer. **Timothy Wilson**, director of the Department of Urology and Urologic Oncology and director of the Prostate Cancer Program, is the first to hold the endowed chair. . . . **FRED HUTCHINSON** Cancer Research Center received $500,000 from the Susan G. Komen Breast Cancer Foundation to support the Breast Health Global Initiative, a program for breast cancer needs in developing nations. The funds will enable BHGI to further its international initiatives in breast-cancer early detection, treatment and public-health-care policy, said **Benjamin Anderson**, BHGI chairman and director. . . . **ANTHONY ALBERG** of the Bloomberg School for Public Health at Johns Hopkins University, was appointed the Blatt Ness Distinguished Endowed Chair in Oncology at the Medical University of South Carolina Hollings Cancer Center. He will also serve as associate director of prevention and control, said **Andrew Kraft**, cancer center director. Alberg was co-director of the George W. Comstock Center for Public Health Research and Prevention, director of the Cancer Epidemiology Program and an associate professor at The Sidney Kimmel Cancer Center at Johns Hopkins University. . . . **M. D. ANDERSON** Cancer Center received the Small Business Administration's Dwight D. Eisenhower Award for Excellence in Research and Development, which recognizes large contractors that have excelled in their use of small businesses as suppliers and subcontractors. It is the first time a comprehensive cancer center has won the award. . . . **CLARA BLOOMFIELD** was elected president of the Association for Patient Oriented Research, which advocates support for clinical research at academic medical centers. Bloomfield is the William G. Pace III Professor of Cancer Research, professor of internal medicine, and a senior advisor at Ohio State University Comprehensive Cancer Center. . . . **AZIZA SHAD** was named the Amey Distinguished Professor at Lombardi Comprehensive Cancer Center. The new chair is a gift from Scott and Debbie Amey, whose daughter was successfully treated by Shad for a brain tumor. Shad is director of pediatric hematology and oncology at Lombardi. . . . **WEILL Medical College of Cornell University** received a $6 million pledge from the Lehman Brothers Foundation to establish the Lehman Brothers Lung Cancer Research Center, a component of the newly established Lung Cancer Research Institute. The center, led by **Nasser Altorki**, the David B. Skinner, M.D., Professor of Thoracic Surgery, will bring together basic and clinical scientists for translational work in lung cancer. . . . **SCOTT WEIR** joined the University of Kansas Cancer Center as the first director of its Office of Therapeutics, Discovery and Development, which reports to center director **Roy Jensen**. Weir was senior director of preclinical technologies for Aptuit LLC. From 1999 to 2005, he was with Quintiles Inc. At KU Lawrence, Weir holds an appointment in the Department of Pharmaceutical Chemistry. He is a professor at the KU Medical Center Department of Pharmacology, Toxicology and Therapeutics and the Frank B. Tyler Professor in Cancer Research. Weir's appointment is the first of four planned this year as the university prepares to seek NCI designation for the KU Cancer Center. The center anticipates hiring a deputy director, as well as an assistant director for basic science at the Lawrence campus. The center also plans to add an associate director for basic science this year. . . . **AMERICAN RUSSIAN CANCER ALLIANCE**, a consortium of American and Russian cancer research institutes including Fox Chase Cancer Center, the University of Maryland Greenebaum Cancer Center, N.N. Blokhin Cancer Center, and the Russian Research Centre-Kurchatov Institute, held a conference last month in Moscow on the prevention and treatment of tobacco-related cancers. NCI and the International Union Against Cancer also sponsored the conference.

Appointments:

NCI's Stefanek Named VP, ACS Behavioral Research

MICHAEL STEFANEK, chief of the Basic and Biobehavioral Research Branch in the NCI Division of Cancer Control and Population Sciences, was named vice president of the American Cancer Society Behavioral Research Center. Stefanek, a researcher in psychosocial and behavioral oncology, has published extensively on issues relating to women at high risk of developing breast cancer, cancer treatment decision-making, and cancer treatment side-effects. . . . **ROGER GLASS,** known for developing and introducing rotavirus vaccines in the developing world, was named director of the Fogarty International Center and associate director of NIH for international programs. Glass, who is chief of the Viral Gastroenteritis Section at the Centers for Disease Control and Prevention, will join NIH in May. He joined CDC in 1977 as a medical officer assigned to the Environmental Hazards Branch. In 1983, he joined the NIH Laboratory of Infectious Diseases, where he worked on the molecular biology of rotavirus. Glass returned to CDC in 1986 as chief of

the Viral Gastroenteritis Unit at the National Center for Infectious Diseases.

Societies & Advocacy:

NCCS Celebrates 20th Year

NATIONAL COALITION FOR CANCER SURVIVORSHIP held its annual Rays of Hope awards gala on April 26 in celebration of its 20th anniversary. NCCS recognized individuals who have made extraordinary contributions to NCCS and to cancer survivorship: **Gen. Norman Schwarzkopf, Katie Couric, Lilly Tartikoff, Sam Donaldson, Cokie Roberts, Harold Freeman, Connie Mack, John D. Rockefeller IV, Deborah Pryce, Lois Capps, Scott Hamilton, Queen Noor of Jordan, Fitzhugh Mullan, Antonia Novello, Pearl Moore, John Durant, Julia Rowland, Jessica Turri, the Cancer Survival Toolbox Team**, and the **Institute of Medicine**. **Dan Abrams**, host of MSNBC's Abrams Report and NBC news chief legal correspondent, hosted the event in Washington, D.C. . . . **INTERCULTURAL CANCER COUNCIL** has produced a new report, "Cancer Survivorship and the Medically Underserved: Reducing the Disparities in Cancer Care," examining the prospects for ethnic minorities and the poor to achieve a long-term cancer survival. The assessment finds that because of disparities in care at all points along the cancer continuum -- from screenings and diagnosis through access to cancer therapies and follow-up care -- the medically underserved are the most likely to experience a shortened period of survival with a lesser quality of life. The report is available at www.iccnetwork.org. . . . **AMERICAN SOCIETY for Therapeutic Radiology and Oncology** moved its headquarters from Reston, Va. The new address is 8280 Willow Oaks Corporate Dr., Suite 500, Fairfax, Va. . . . **G&P FOUNDATION for Cancer Research** will make seven Medical Research Awards of $1.6 million to junior investigators for leukemia, lymphoma, and related cancers research. The recipients will be awarded $75,000 a year for three years. The funding is part of the $3.3 million raised by the foundation in 2005 for cancer research. The non-profit foundation, begun by songwriter **Denise Rich**, funds basic and clinical medical research in both conventional and integrative disciplines for prevention, treatments and quality of life issues of leukemia, lymphoma, and related cancers. . . . **US ONCOLOGY** opened a government affairs office in Washington, D.C. Led by **Dan Cohen**, a healthcare policy specialist, the office will be involved in national cancer policy advocacy efforts. Cohen was head of global corporate operations, public affairs and government relations for Inamed Corp. US Oncology also recognized three nurses during its annual meeting last month. **Pearl Moore**, CEO of the Oncology Nursing Society, was honored as the 2005 US Oncology Honoree for her 30-plus year career in oncology nursing. The Pearl Moore Excellence in Nursing Leadership Award was presented to **Bridget Babu**, an oncology nurse at Texas Oncology P.A. **Jan Draper**, lead staff nurse at Arizona Oncology Associates, received the Overall Excellence Award for the Betsy York Memorial OCN of the Year Award. . . . **NEVADA GOV. Kenny Guinn** and the state Cancer Council issued a 46-page Nevada Comprehensive Cancer Plan making recommendations for reducing cancer rates by coordinating and implementing strategies in prevention, early detection and diagnosis, treatment, clinical trials, quality of life, and palliative care. The council consists of 56 member organizations. Based on rates of incidence in the state, as well as effective and measurable intervention strategies for prevention, detection and treatment, four cancers were identified for priority efforts: lung and bronchus cancer, breast cancer, colorectal cancer, and prostate cancer. . . . **ASIAN AMERICAN NETWORK** for Cancer Awareness, Research and Training and the American Cancer Society have begun an online database of Asian-language cancer materials, supported by NCI. The site, www.cancer.org/apicem, provides access to information in the following languages: Khmer, Chamorro, Chinese, Hawaiian, Hmong, Ilokano, Korean, Samoan, Tagalog, Tongan, and Vietnamese.

Obituary:

ROBERT MILLER, physician, epidemiologist and NCI scientist who worked in childhood cancers, died Feb 23 of colon cancer at his home in Bethesda. He was 84.

While studying the survivors of the Hiroshima blast for the Atomic Bomb Casualty Commission, Miller found that children who were in their mother's wombs at the time of the attack had a far greater frequency of birth defects due to radiation exposure than expected. He linked forms of childhood cancer, including kidney tumors and eye cancer, to genetic and environmental causes. He came to Washington in 1955 to work at the National Academy of Sciences. He joined NCI in 1961 and was chief of the epidemiology branch until 1974. He served as chief of the clinical epidemiology branch from 1975 to1994. He had been a scientist emeritus at the institute for the past 12 years.

CORRECTION: A story in the March 31 issue of The Cancer Letter incorrectly described the NCI Early Detection Research Network as a contract program. EDRN is a series of grants of $22 million to $23 million a year.

CLARIFICATION: An item in the "In Brief" section in the March 31 issue of The Cancer Letter incompletely described the American Society of Clinical Oncology's plans to spend a $290,000 grant from the John A. Hartford Foundation. The funds will support Annual Young Investigator Awards in geriatric oncology as well as a new award and lecture called the B.J. Kennedy Annual Award and Lecture for Scientific Excellence in Geriatric Oncology. Also, the funds will be used to host Geriatric Oncology Retreats at the ASCO

Funding Opportunities:

RFP Available

RFP N02-CN-65002-46: Cancer Prevention Clinical Trials Monitoring and Informatics Support. Proposal Receipt due date: June 1. NCI Division of Cancer Prevention seeks a contractor to provide services for chemoprevention studies and cancer prevention trials; to provide training regarding the conduct of cancer prevention trials to staff at clinical sites; and to provide on-going development, support and maintenance of the DCP central database, the DCP cancer prevention clinical trials database, and the mechanisms used to collect, analyze and report clinical trial data. Full text: http://rcb.nci.nih.gov.

Program Announcements

PA-06-359: Exfoliated Cells, Bioactive Food Components, and Cancer. R21. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-359.html. Inquiries: Cindy Davis, 301-594-9692; davisci@mail.nih.gov.

PA-06-360: Exfoliated Cells, Bioactive Food Components, and Cancer. R03. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-360.html. Inquiries: Cindy Davis, 301-594-9692; davisci@mail.nih.gov.

PA-06-351: Exploratory Grants for Behavioral Research in Cancer Control. R21. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-351.html. Inquiries: Sabra Woolley, 301-435-4589; sw215x@nih.gov.

PA-06-349: Memory T Lymphocytes in Cancer Immunology. R21. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-349.html. Inquiries: Susan McCarthy, 301-496-7815;mccarths@mail.nih.gov.

PA-06-350: Memory T Lymphocytes in Cancer Immunology. R01. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-350.html. Inquiries: Susan McCarthy, 301-496-7815;mccarths@mail.nih.gov.

PA-06-348: The Effect Of Racial And Ethnic Discrimination/Bias On Health Care Delivery. R03. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-348.html. Inquiries: Vickie Shavers, 301-594-1725; shaversv@mail.nih.gov.

PA-06-343: Methodology And Measurement In The Behavioral And Social Sciences. R21. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-343.html. Inquiries: Bryce Reeve, 301-594-6574; reeveb@mail.nih.gov.

PA-06-344: Methodology And Measurement In The Behavioral And Social Sciences R03. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-344.html. Inquiries: Bryce Reeve, 301-594-6574; reeveb@mail.nih.gov.

PAR-06-313: Cancer Prevention Research Small Grant Program. R03. Full text: http://grants.nih.gov/grants/guide/pa-files/PAR-06-313.html. Inquiries: Padma Maruvada, 301-496-3893; maruvadp@mail.nih.gov.

PA-06-338: Research on Malignancies in AIDS and Acquired Immune Suppression. R21. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-338.html. Inquiries: Elizabeth Read-Connole, 301-496-6085; bconnole@mail.nih.gov.

PA-06-337: Decision Making in Health: Behavior Maintenance. R21. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-337.html. Inquiries: Wendy Nelson, 301-435-4590; nelsonw@mail.nih.gov.

PA-06-321: Cross-Disciplinary Translational Research At NIH. R21. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-321.html. Inquiries: Allison Chausmer, 301-402-5088; achausme@nida.nih.gov.

PA-06-322: Cross-Disciplinary Translational Research At NIH. R03. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-322.html. Inquiries: Allison Chausmer, 301-402-5088; achausme@nida.nih.gov.

PA-06-315: Basic and Preclinical Research on Complementary and Alternative Medicine R21. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-315.html. Inquiries: Wendy Smith 301-435-7980; smithwe@mail.nih.gov.

PA-06-314: Pilot Studies in Pancreatic Cancer. R03. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-314.html. Inquiries: Mukesh Verma, 301-594-7344; E-mail: vermam@mail.nih.gov.

PAR-06-294: Small Grants Program for Cancer Epidemiology. R03. Full text: http://grants.nih.gov/grants/guide/pa-files/PAR-06-294.html. Inquiries: Mukesh Verma, 301-594-7344; vermam@mail.nih.gov.

PAR-06-293: Quick-Trials for Imaging and Image-Guided Interventions: Exploratory Grants. R21. Full text: http://grants.nih.gov/grants/guide/pa-files/PAR-06-293.html. Inquiries: Lalitha Shankar, 301-496-9531; shankarl@mail.nih.gov.

PA-06-361: Testing Tobacco Products Promoted to Reduce Harm. R21. Full text: http://grants.nih.gov/grants/guide/pa-files/PA-06-361.html. Inquiries: Mirjana Djordjevic, 301-496-8584; djordjev@mail.nih.gov.

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Business & Regulatory Report

Clinical Trials:

Millennium, J&J, Begin Phase III Trial Of Velcade + Rituximab For Lymphoma

Millennium Pharmaceuticals Inc. (NASDAQ: MLNM) of Cambridge, Mass., and co-development partner **Johnson & Johnson Pharmaceutical Research & Development L.L.C.** announced the initiation of a phase III clinical trial of Velcade in combination with rituximab in patients with relapsed or refractory follicular lymphoma, a subtype of non-Hodgkin's lymphoma.

The study builds on clinical data observed in previous trials of Velcade that showed high objective response rates and a favorable safety profile across a variety of lymphomas.

"We accelerated the timeline for initiating this high-priority trial," said Robert Tepper, president, research & development, at Millennium. "Based

(Continued to page 2)

Deals & Collaborations:

Myeloma Consortium Picks MDS Pharma As Preferred CRO, Begins Genome Initiative

Multiple Myeloma Research Consortium of New Canaan, Conn., said it has selected **MDS Pharma Services**, to serve as its preferred Contract Research Organization.

MDS Pharma Services will manage and execute the MMRC pre-clinical and clinical research efforts, including data management related to the tissue accrual into the MMRC Tissue Bank, the consortium said. MMRC also said it will recommend MDS Pharma Services to industry partners as additional protocols are brought through the consortium.

"MDS Pharma Services offers a full spectrum of advanced scientific and technological expertise to accelerate the drug discovery and development pathways," said Nancy Sumberaz, president the MMRC.

In another development, MMRC said it has begun the Multiple Myeloma Genomic Initiative in collaboration with the **Translational Genomics Research Institute** and the **Eli and Edythe L. Broad Institute** of MIT and Harvard for cancer genomics research.

The research and discovery programs of the initiative hinge on the ability to study, analyze, and characterize a large number of untreated myeloma patient tissue samples in great detail, the consortium said. The MMRC Tissue Bank houses high-quality bone marrow aspirates and matching peripheral blood samples accrued under Good Laboratory Practice standards with hundreds of tissue samples. Accrual is ongoing at sites nationwide, allowing s access to the mass of tissue necessary to start the genomic initiative.

"We expect that findings from the Multiple Myeloma Genomic Initiative

(Continued to page 4)

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Millennium, J&J, Begin Trial Of Velcade For Lymphoma

(Continued from page 1)

on previous study results that demonstrated substantial single-agent and combination activity in this patient population, we are excited about the potential of Velcade to benefit patients with this form of NHL, a disease that is not curable with standard therapy."

The phase III study is expected to enroll approximately 670 patients with relapsed or refractory, rituximab naïve or sensitive follicular NHL. Patients will be randomized to either the combination regimen of once-weekly Velcade plus rituximab or rituximab alone.

The primary endpoint is progression-free survival. Secondary endpoints of the study include the overall response rate and duration of response as assessed by the International Workshop to Standardize Response Criteria for NHL. The weekly dose of Velcade in this study is 1.6 mg/m^2 and rituximab will be administered at 375 mg/m^2.

Velcade is indicated for the treatment of multiple myeloma patients who have received at least one prior therapy. Risks associated with Velcade therapy include new or worsening peripheral neuropathy, hypotension observed throughout therapy, cardiac and pulmonary disorders, gastrointestinal adverse events, thrombocytopenia, neutropenia and tumor lysis syndrome.

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The agent is being co-developed by Millennium Pharmaceuticals, Inc. and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. Millennium is responsible for commercialization of Velcade in the U.S.; Janssen-Cilag is responsible for commercialization in Europe and the rest of the world. Janssen Pharmaceutical K.K. is responsible for commercialization in Japan.

* * *

Allos Therapeutics Inc. (NASDAQ: ALTH) of Westminster, Colo., said an independent data and safety monitoring committee has completed a planned interim analysis from its phase III ENRICH trial with Efaproxyn (efaproxiral) and has recommended the trial continue per the protocol.

The review was triggered by 94 deaths, the company said. In order to protect the integrity of the trial, the results of the efficacy analysis will not be made available to the company until the study is completed. No major patient safety concerns were identified by the committee, the company said.

ENRICH is a randomized, open-label, multi-center trial comparing the effect of whole brain radiation therapy with supplemental oxygen with or without Efaproxyn in women with brain metastases originating from breast cancer, the company said. The trial would enroll 360 patients at up to 125 sites worldwide. The primary endpoint is survival.

* * *

Bioniche Life Sciences Inc. (TSX: BNC) of Belleville, Ontario, said FDA has given approval to proceed with the second of two phase III trials with its proprietary Mycobacterial Cell Wall-DNA Complex for bladder cancer, trademarked Urocidin.

The protocol for the first trial had been approved, the company said.

The second phase III 630-patient trial will be a randomized, double-blind multi-center study comparing Urocidin to Bacillus Calmette-Guerin as first-line therapy in non-muscle invasive bladder cancer at high risk of recurrence or progression, the company said.

BCG is a live, attenuated strain of Mycobacterium bovis that is the standard therapy for bladder cancer, but is associated with treatment-limiting side effects, the company said. The study will be conducted in Europe.

The first phase III trial of 105, will be carried out at the same time as the second. It will be an open-label study showing the efficacy of Urocidin as therapy in non-muscle invasive bladder cancer that is refractory to BCG, the company said. The study will be conducted in North America.

"The safety profile of MCC is much better than BCG and, certainly, MCC is easier to handle, from the pharmacist's, nurse's and physician's points of view due to the risk of acquiring a serious infection from improper handling of BCG which is a live bacteria as opposed to MCC that contains only bacterial cell wall fragments and DNA," said Alvaro Morales, professor of urology and oncology at Queen's University and international principal investigator for the Bioniche phase III program. "Biohazard precautions are required for BCG but not for MCC, which is also a significant plus for the latter."

Approximately 142,000 patients in North America and Europe are newly- diagnosed with non-muscle invasive bladder cancer each year, of which 96,000 are high-risk cases, of which 30 percent+/- are refractory to standard therapy, the company said.

Mycobacterial Cell Wall-DNA Complex is formulated from Mycobacterium phlei, a non-pathogenic strain of mycobacteria and has been shown to have immune stimulatory and apoptosis activity against cancer cells, the company said.

* * *

Cytokinetics Inc. (NASDAQ: CYTK) of South San Francisco announced the initiation of a phase I/II clinical trial of its second Kinesin Spindle Protein inhibitor, SB-743921, in non-Hodgkin's lymphoma.

SB-743921 is the second drug candidate in clinical development arising from a collaboration between Cytokinetics and **GlaxoSmithKline** to discover, develop and commercialize novel small molecule therapeutics targeting human mitotic kinesins for applications in the treatment of cancer and other diseases.

GSK is conducting a broad phase II trials program for the lead drug candidate from this program, the KSP inhibitor ispinesib (SB-715992), and is evaluating SB-743921 in a phase I trial in advanced solid tumors.

The phase I/II trial is an open-label, non-randomized study to investigate the safety, tolerability, pharmacokinetic, and pharmacodynamic profile of SB-743921, administered as a one-hour infusion on days 1 and 15 of a 28 day schedule, in patients with non-Hodgkin's lymphoma.

The objective of the phase I portion of the clinical trial is to identify the maximum tolerated dose of SB-743921 on this schedule, in patients with either Hodgkin's or non-Hodgkin's lymphoma, first without prophylactic administration of granulocyte colony stimulating factor.

If the dose-limiting toxicity determining this first MTD is neutropenia, a second MTD will be determined with SB-743921 given with prophylactic administration of GCSF. Following review of the Phase I data from this clinical trial, the optimal dose and regimen of SB-743921 (i.e., without or with prophylactic administration of GCSF) will be determined for phase II.

In phase II, 70 NHL patients, with either aggressive or indolent disease, are planned to be treated with the objective of evaluating frequency and duration of disease response in these patients.

* * *

GlaxoSmithKline (NYSE: GSK) of Philadelphia said it has halted enrollment in its phase III trial evaluating the combination of Tykerb (lapatinib ditosylate) and capecitabine (Xeloda) versus capecitabine alone for advanced breast cancer following analysis by the IDMC of 321 patients.

The trial evaluated women with refractory advanced or metastatic breast cancer who have documented ErbB2 overexpression and whose disease progressed following treatment with trastuzumab (Herceptin) as well as other cancer therapies, the companies said.

The trial, EGF100151, is an international, multi-center, randomized, open-label study to evaluate and compare TTP with documented ErbB2 (HER2) overexpressing refractory advanced or metastatic breast cancer treated with Tykerb in combination with capecitabine versus capecitabine alone, the company said. The primary endpoint was to detect a 50 percent increase in TTP in the combination arm compared with the capecitabine alone arm. 392 patients have been enrolled in the study of which 321 were included in the analysis (160 in the combination arm and 161 in the monotherapy arm). The most common drug-related adverse events in the combination arm of the study were diarrhea and nausea.

Those enrolled will continue to be followed and those who are receiving capecitabine alone will be offered the option of switching to the combination therapy of capecitabine and Tykerb in consultation with their physician, the company said.

Tykerb, a small molecule that is administered orally, inhibits the tyrosine kinase components of ErbB1 and ErbB2 receptors, the company said.

* * *

Medarex Inc. (NASDAQ: MEDX) of Princeton said it has begun a registrational trial of ipilimumab (MDX-010) as a monotherapy for previously-treated metastatic melanoma.

The study is an open label, single-arm, monotherapy registrational 150-patient trial for unresectable stage III or stage IV metastatic melanoma where progress has

occurred after at least one prior regimen of another melanoma treatment other than ipilimumab, the company said.

A group will receive a dose of 10 mg/kg of ipilimumab once every three weeks for up to four doses. Subsequently, those eligible who have not experienced disease progression at week 24 will continue in a maintenance phase where a single dose of ipilimumab will be administered once every 12 weeks until disease progression. The study would assess best objective response rate as the primary endpoint. Secondary endpoints include disease control rate, disease progression and survival data, as well as duration of best objective responses, the company said.

Ipilimumab is a fully human antibody against human CTLA-4, a molecule on T cells that suppresses the immune response, the company said.

Deals & Collaborations:

Arius, Takeda To Collaborate On Discovery, Development

(Continued from page 1)

will lead to the discovery of new druggable targets for myeloma and, ultimately, to the development of better, more effective therapies that are active against these targets," said Jeffrey Trent, president and scientific director of TGen.

Findings from the MMGI will be made accessible to the academic and commercial world via pre-publications and important findings will be directly communicated to the scientific community, the consortium said.

* * *

Arius Research Inc. (TSX-V: ARI) of Toronto and **Takeda Pharmaceutical Company Ltd.** of Japan said they have entered into a three-year, multi-product collaboration agreement using the Arius FunctionFIRST Platform for cancer and other disease discovery.

Under the agreement, Arius said it would receive an upfront technology access fee of $2 million, consisting of $1 million each in cash and equity investment respectively, and research funding for the three years. Takeda would assume the responsibility and costs of development and commercialization while Arius would have an option to co-develop any product, the company said.

The Arius business model, which uses the FunctionFIRST platform for discovery and development collaborations, generated over 350 antibodies for the Arius library, the company said.

* * *

Array BioPharma Inc. (NASDAQ: ARRY) of Boulder said it would received a $1 million milestone payment from **AstraZeneca AB** for a third compound from their small molecule MEK anti-cancer program.

The second compound was selected in 2006, which also paid a $1 million milestone to Array, the company said. In 2003, Array said it partnered the oncology portion of its MEK program, including its lead compound, ARRY-142886 (AZD6244), for co-development and commercialization with AstraZeneca. At that time, the companies established a collaboration for research and development of additional clinical candidates.

MEK is an enzyme at the intersection of several biological pathways, which regulates cell proliferation and survival as part of the Ras/Raf/MEK/ERK pathway, the company said. Constitutive activation of the Ras/Raf/MEK/ERK pathway has been implicated in cancers, including lung, pancreatic, colon, melanoma and thyroid caused by cancer-associated, mutational activation of bRAF and Ras proteins.

* * *

Celera Genomics (NYSE: CRA) of Rockville, Md., said **Pharmacyclics** (NASDAQ: PCYC) of Sunnyvale, Calif., has acquired multiple small molecule drug candidates for cancer treatment and other diseases from Celera Genomics.

Under agreement, Pharmacyclics has acquired Celera technology and intellectual property for drugs that target histone deacetylase enzymes, selective HDAC enzymes, angiogenesis molecules and B cell tyrosine kinases involved in immune function, the company said.

The financial terms include an upfront cash payment of $2 million and an equity payment of between five hundred thousand and one million shares of Pharmacyclics common stock, the company said.

Pharmacyclics has acquired the following from Celera: HDAC inhibitor drug candidates in phase I trials for refractory solid tumors; a first-in-class HDAC-8 selective inhibitor in preclinical development for cancer; a first-in-class Factor VIIa inhibitor targeting a tumor signaling pathway involved in angiogenesis, tumor cell growth and metastases, and B-cell-associated tyrosine kinase inhibitors for lymphoma and autoimmune diseases, the company said.

* * *

ChemDiv Inc. of San Diego and **Carna Biosciences Inc.** of Kobe, Japan said they have signed a collaboration agreement to develop and market annotated kinase libraries targeting kinases for pathways and disease.

The ChemDiv proprietary chemistry permits small molecule drug development for such kinases while the Carna expertise in kinase assay development and profiling provides rapid screening results for an added annotated component to the ChemDiv kinase libraries, the company said.

* * *

Cytogen Corp. (NASDAQ: CYTO) of Princeton, NJ, announced the sale of its 50% ownership interest in **PSMA Development Company LLC**, the company's joint venture with **Progenics Pharmaceuticals Inc.** (NASDAQ: PGNX) for the development of in vivo cancer immunotherapies based on prostate-specific membrane antigen (PSMA).

Under the agreement, Cytogen sold its 50% interest in PDC to Progenics for an upfront cash payment of $13.2 million, potential future milestone payments totaling up to $52 million payable upon regulatory approval and commercialization of PDC products, and an undisclosed royalty on future PDC product sales. Cytogen will no longer be responsible for funding PDC. In 2005, Cytogen's share of the loss associated with PDC was $3.18 million.

"PSMA is an important and broadly studied target, and the terms of our agreement with Progenics reflect both companies' recognition of the potential value of PSMA products," said Michael Becker, president and chief executive officer of Cytogen. "Through this transaction, Cytogen realizes an attractive valuation for its 50% ownership in PDC and retains a financial interest in PDC's future success. In addition, we retain the right to develop our CYT-500 radiolabeled antibody program. The agreement also reduces Cytogen's investment in early-stage projects and provides additional capital to support our core commercial business strategy."

PSMA is a protein expressed on the surface of prostate cancer cells, with an increased expression in high-grade cancers, metastatic disease and hormone-refractory prostate cancer.

In April 2006, Cytogen announced the submission of an Investigational New Drug application to FDA for CYT- 500, the company's lead therapeutic candidate targeting PSMA. CYT-500 incorporates the same monoclonal antibody utilized in Cytogen's Prostascint (capromab pendetide) molecular imaging agent, but is linked to a therapeutic payload.

* * *

Discovery Partners International Inc. (NASDAQ: DPII) of San Diego and **Infinity Pharmaceuticals Inc**. of Cambridge, Mass., said they have entered into a definitive merger agreement to create a public entity on cancer drug discovery and development, with Infinity Pharmaceuticals Inc. remaining as the biopharmaceutical company.

Under the agreement, DPI would issue, and Infinity stockholders would receive, in a tax-free transaction, shares of DPI common stock such that Infinity stockholders would own approximately 69 percent of the combined company on a pro forma basis and DPI stockholders would own 31 percent, the companies said.

The percentages are subject to downward and upward adjustment under the terms of the merger agreement based on the DPI net cash at closing. The new company common stock is expected to trade under the ticker symbol (NASDAQ: INFI) under the name Infinity Pharmaceuticals Inc. The DPI ticker symbol, DPII, will become inactive, the companies said.

The Infinity management team, including Steven Holtzman, chairman and CEO, Julian Adams, president and CSO, and Adelene Perkins, EVP and CBO, will assume management of the new public entity.

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Fleming & Co. Pharmaceuticals of Fenton, Mo., said HHS has purchased an additional 3.1 million bottles of its Thyroshield Potassium Iodide Oral Solution, a thyroid blocking medicine to be used in a radiation emergency only. The federal government purchased 1.7 million bottles last year.

Thyroshield is supplied to the 31 states with commercial nuclear power plants through the Nuclear Regulatory Commission's program to supply KI within the 10-mile Emergency Planning Zone. HHS is moving forward to expand KI availability out to the 20 mile EPZ as mandated by the Bioterrorism Act of 2002.

Thyroshield is the only FDA approved liquid potassium iodide product indicated for thyroid protection in a radiation emergency.

* * *

MedMira Inc. (NASDAQ: MMIRF) of Halifax said it has entered into an agreement to acquire an emerging cancer marker technology, to commercialize through its Maple Biosciences division.

The technology, developed by Shou- Ching Tang, an oncologist working on the prognostic significance of BAG-1 for cancer, and member of the MedMira Board of Directors, focuses on BAG-1, a protein found in cancer cells including breast, lung and prostate cancers, the company said. Shou- Ching Tang also is senior associate consultant at the Mayo Clinic, the company said.

The BAG-1 technology would be integrated with the Maple Biosciences platform to bring faster, more

advanced tests for breast, lung and prostate cancers to the clinical laboratory market, the company said. The test uses a tissue sample for diagnostic, prognostic results, as well as information used in formulating a treatment and therapy plan. The technology will be most powerful when combined with other cancer markers to diagnose a specific type of cancer, the company said.

Under the acquisition agreement, MedMira said it would acquire the BAG-1 technology for a purchase price of $600,000, which would be paid through the issuance of common shares. The maximum number of shares to be issued is 1,260,504 common shares. The shares issued will be subject to a 4 month hold period, the company said.

* * *

Spectrum Pharmaceuticals Inc. (NASDAQ: SPPI) of Irvine, Calif., announced the closing of the transaction to acquire the oncology drug assets of **Targent Inc.**

The key product acquired is levofolinic acid, the pure active isomer of calcium leucovorin, a component of 5-fluorouracil (5-FU) containing regimens for the treatment of colorectal cancer and other malignancies.

Spectrum acquired the rights for sales and marketing of LFA in the U.S., Canada and Mexico, along with several other oncology drugs in various stages of development. LFA is currently marketed by Wyeth, Sanofi-Aventis and others in certain parts of the world, including Europe and Japan. It is estimated that the current market for LFA outside of North America is $200 million.

Under the agreement, Spectrum issued to Targent an aggregate amount of 600,000 shares of the company's common stock. Only 1/3rd (200,000) of these shares will be registered for resale. The remaining 2/3rd (400,000) shares will not be registered and therefore will be subject to restrictions on resale under rule 144 of the Securities Act of 1933. Spectrum shall pay Targent additional shares of common stock and cash upon achievement of certain regulatory and sales milestones.

Product Approvals & Applications:

Genentech Submits sBLA For Avastin For NSCLC

Genentech Inc. (NYSE: DNA) of South San Francisco said it has a submitted to FDA a supplemental Biologics License Application for Avastin (bevacizumab) in combination with platinum-based chemotherapy for first-line advanced, non- squamous, non-small cell lung cancer.

Genentech said it has requested Priority Review for this sBLA and would submit another sBLA for the drug in metastatic breast cancer. Avastin is approved for the first-line metastatic colorectal cancer in combination with intravenous 5-FU-based chemotherapy.

The results of a randomized, controlled, multicenter phase III, or E4599, trial of 878 patients with locally advanced, metastatic or recurrent non-small cell lung cancer with histology other than predominant squamous cell, showed that with Avastin plus paclitaxel and carboplatin chemotherapies, there was a 25 percent improvement in overall survival, which was the primary endpoint, compared to with chemotherapy alone. This was based on a hazard ratio of 0.80, which is equivalent to a 20 percent reduction in the risk of death. In addition, the median survival with Avastin plus chemotherapy was 12.3 months, compared to 10.3 months for treatment with chemotherapy alone, the company said.

"This is the first time that patient survival was extended beyond one year in a clinical study of advanced non-small cell lung cancer, a disease that typically has a one-year survival rate of 30 to 35 percent," said Alan Sandler, director of thoracic oncology at Vanderbilt-Ingram Cancer Center. "If approved for the indication, Avastin may be part of an entirely new approach to treating this type of lung cancer."

The E4599 trial was sponsored by NCI, under a Cooperative Research and Development Agreement between NCI and Genentech Inc., and conducted by researchers led by the Eastern Cooperative Oncology Group, the company said.

Avastin is a therapeutic antibody that inhibits Vascular Endothelial Growth Factor.

In another development, **Genentech Inc.** and **Biogen Idec Inc.** (NASDAQ: BIIB) of Cambridge, Mass., said they have submitted a supplemental Biologics License Application to FDA for Rituxan (Rituximab) for low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with CVP (cyclophosphamide, vincristine and prednisone) or CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) chemotherapy or following CVP chemotherapy for those with a response of stable disease or better.

The sBLA submission is based on efficacy and safety data from two randomized, controlled studies of Rituxan in 644 previously-untreated patients, the company said. The first study, a phase III trial in 322 patients with follicular, CD20-positive, B-cell NHL met its primary endpoint of an improvement in progression-free survival when Rituxan was used in

combination with CVP chemotherapy as compared to CVP chemotherapy alone, the company said.

Data from a phase III trial was also the basis for the sBLA, where Rituxan was given in a series of infusions over a two year period of time to evaluate efficacy and safety in 322 patients who had achieved a response or demonstrated stable disease to first-line CVP chemotherapy and who were then randomized either to receive Rituxan or observation, the company said. This study, E1496, an NCI-sponsored intergroup trial led by the Eastern Cooperative Oncology Group, met its primary endpoint of an improvement in progression-free survival.

* * *

Bayer Pharmaceuticals Corp. (NYSE: BAY) of West Haven, Conn., and **Onyx Pharmaceuticals Inc.** (NASDAQ: ONXX) of Emeryville, Calif., said the Swiss Agency for Therapeutic Products, Swissmedic, has approved Nexavar (sorafenib) tablets for advanced renal cell carcinoma, or kidney cancer, after nepherectomy and prior palliative or adjuvant therapy with cytokines (IL-2, IFN).

Bayer will market the drug in Switzerland.

Nexavar, an oral multi-kinase inhibitor, targets both the tumor cell and tumor vasculature. The agent has been studied in 20 tumor types and in 8,000 clinical trial patients and is in phase III trials for advanced hepatocellular carcinoma, or liver cancer, and metastatic melanoma, or skin cancer, the company said. A phase III trial in non-small cell lung cancer is ongoing.

Nexavar is being co-developed by Bayer and Onyx Pharmaceuticals.

In a related development, **Bayer** and **Onyx Pharmaceuticals** said Nexavar has been granted orphan medicinal product status for the treatment of hepatocellular carcinoma by the European Commission.

This designation is based on a recommendation from the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency.

A phase III trial of Nexavar administered as a single agent is ongoing. The study is designed to measure differences in overall survival, time-to-symptom progression and time-to-tumor progression of Nexavar versus placebo in liver cancer patients. A randomized Phase II trial for liver cancer patients to evaluate the efficacy of Nexavar in combination with the chemotherapeutic agent doxorubicin is also ongoing.

Nexavar received approval from FDA in December 2005 to treat patients with advanced renal cell carcinoma . The European Commission has also granted Nexavar an orphan medicinal product designation for kidney cancer and a Marketing Authorization Application had been submitted to EMEA in September 2005 for approval to market Nexavar within the European Union for kidney cancer.

Nexavar is in phase III clinical trials for the treatment of liver cancer, metastatic melanoma, or skin cancer, and non-small cell lung cancer , and has been studied in more than 20 tumor types and in more than 8,000 clinical trial patients. In addition to company-sponsored trials, there are a variety of Nexavar studies being sponsored by government agencies, cooperative groups and individual investigators.

* * *

Celgene Corp. (NASDAQ: CELG) of Summit, N.J., said the European Medicines Agency has accepted for review its Marketing Authorization Application for Lenalidomide-Celgene Europe (lenalidomide).

Two phase III special protocol assessment trials, North American Trial MM-009 and International Trial MM-010, evaluating lenalidomide plus dexamethasone in multiple myeloma with at least one prior therapy, achieved the primary endpoint of time-to-disease progression with combination therapy of lenalidomide and dexamethasone over that of placebo and dexamethasone, the company said.

Revlimid has been designated as an Orphan Medicinal Product in the EU for multiple myeloma and myelodysplastic syndromes, the company said.

Lenalidomide is an analogue of Thalidomide, the company said.

* * *

Cephalon Inc. (NASDAQ: CEPH) of Frazer, Penn., said the FDA Office of Orphan Products Development granted orphan drug designation for lestaurtinib (CEP-701) for acute myeloid leukemia.

The designation will provide a seven-year period of marketing exclusivity for the indication from the date of final FDA marketing approval of the compound, the company said.

Lestaurtinib, the orally active, investigational compound is in a phase II/III trial, inhibits tyrosine kinases including FLT-3 and TrkA, the company said.

* * *

Cytogen Corp. (NASDAQ: CYTO) of Princeton, N.J., said the approval of its submission of an IND application to FDA for prostate-specific membrane antigen would lead to a phase I trial of CYT-500, for hormone- refractory prostate cancer.

CYT-500 incorporates the same monoclonal antibody utilized in the Cytogen Prostascint (capromab

pendetide) molecular imaging agent, but is linked to a therapeutic as opposed to an imaging payload, the company said. The product candidate delivers a cytotoxic agent to PSMA-expressing cells.

Cytogen said it retains full and exclusive development rights to CYT-500.

* * *

Novartis of East Hanover, N.J., said it has submitted applications in the U.S. and Europe for Gleevec (imatinib mesylate) tablets for four cancers.

Gleevec has been shown to inhibit the function of the tyrosine kinase Bcr-Abl in Philadelphia-chromosome positive (Ph+) chronic myeloid leukemia, and the receptor tyrosine kinase Kit in Kit CD117-positive gastrointestinal stromal tumors, the company said. The treatment also inhibits other receptor tyrosine kinases, including platelet-derived growth factor.

The submissions are based on a Novartis-sponsored clinical study and clinical data from trials done by independent medical researchers and cooperative trial groups demonstrating efficacy and safety of Gleevec in different rare diseases, the company said.

* * *

Pharmion Corp. (NASDAQ: PHRM) of Boulder, Colo., said it has submitted a new drug application supplement to FDA to add IV administration to instructions in the prescribing information for its demethylating agent Vidaza.

Under the submission, the dosing for Vidaza would remain the same at 75 mg/m2 daily, for seven days, every four weeks, the company said.

Vidaza exerts its antineoplastic effects by causing hypomethylation of DNA and direct cytotoxicity on abnormal hematopoietic cells in the bone marrow, the company said.

Oncology Management:

M.D. Anderson To Use Alaris, Cardinal's Infusion System

Cardinal Health Inc. (NYSE: CAH) of Dublin, Ohio, said it has signed an agreement with **M. D. Anderson Cancer Center** for the Alaris System.

The Alaris System with Guardrails Suite MX software is safety system available for all types of infusions and has the ability to enable pre-configured limits around both total dose and duration of intermittent drug infusions including chemotherapy, the company said.

The system has demonstrated measurable improvements in safety and clinical performance in managing IV medications at the point of care and offers a modular platform that includes infusion therapy and patient monitoring, the company said.

"One module we are implementing, the Alaris Auto-ID module, will allow us to scan the patient's wristband, clinician's ID and IV bag prior to administration, which will help improve data capture and safety," said Jane Kwan, finance manager, department of pharmacy, M. D. Anderson Cancer Center.

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USBiogistics of Atlanta said M. D. Anderson will implement Concourse, USBiogistics' integrated real-time enterprise workflow applications, including asset management and equipment charge capture solutions.

Using an enterprise applications approach together with RFID data capture at the patient room level will allow M. D. Anderson to more accurately track and manage its moveable medical equipment. Initial efforts will target almost 6,000 pieces of infusion equipment for administration of cancer therapy, the company said.

Knowing exactly where the equipment is, and to which patient it is assigned, will result in improved accuracy of patient accounting and billing, more time for clinical care, and less labor expended on asset management and charge capture.

Under the agreement, USBiogistics RFID infrastructure and workflow applications will be interfacing directly with Cardinal Health's Alaris System infusion devices, including IV, syringe, and PCA pumps. This will allow more timely information to be in the hands of caregivers, pharmacists, and other staff, without having to be in physical proximity of the infusion equipment.

M. D. Anderson Cancer Center has been using USBiogistics' enterprise software applications for over five years to successfully manage equipment distribution and charge capture across both inpatient and outpatient settings, the company said.

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Onmark of South San Francisco said it has signed an agreement with **Cardinal Health**, a specialty pharmaceutical distribution business.

Under the agreement, Cardinal Health customers can purchase oncology products through the Onmark contracts and have access to member offerings, including contract management services, practice optimization tools and educational programs, the company said.

Onmark, an OTN company, is one of the largest group purchasing organizations for community oncology, representing $4 billion in annual drug purchases, the company said.