THE CANCER LETTER INTERACTIVE

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NIH Orders Duke Medical Center To Stop Enrollment In Human Research Studies

The NIH Office of Protection from Research Risks earlier this week ordered Duke University Medical Center to suspend enrollment in all of its 2,000 research studies that involve human subjects.

OPRR officials said the agency took this drastic action May 10 because Duke was slow to improve its human subjects protection procedures, despite being directed to do so five months ago. The issue of Duke's compliance with federal regulations arose following a random site visit last December, officials said.

Problems listed by OPRR included failure of the medical center's Institutional Review Board to oversee studies after they began, failure to

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In Brief:

GM Awards Recognize Levine, Levy, Roeder, Tjian; U.S. Science, Tech Medals Awarded

FOUR SCIENTISTS have been recognized by the General Motors Cancer Research Foundation for their seminal contributions to cancer research. The award recipients are **Arnold Levine**, president of The Rockefeller University; **Ronald Levy**, professor of medicine and oncology and chief of the Division of Oncology at Stanford University; **Robert Roeder**, professor and head of the Laboratory of Biochemistry and Molecular Biology at Rockefeller University; and **Robert Tjian**, professor of molecular and cell biology at University of California, Berkeley. Levine was awarded the Charles S. Mott Prize for the isolation, cloning, and characterization of the biological properties of the p53 tumor suppressor gene. Levy received the Charles F. Kettering Prize for demonstrating that the administration of monoclonal antibodies can produce objective clinical responses in patients with B cell lymphomas. Roeder and Tjian will share the Alfred P. Sloan Prize for their discoveries on the mechanism and regulation of gene transcription in eukaryotic cells. The awards will be presented during a ceremony at the State Department in Washington on June 9. **Samuel Wells Jr.** is president of the GM Cancer Research Foundation and **Phillip Sharp** serves as chairman of the Awards Assembly. . . . **PRESIDENT CLINTON** presented the National Medals of Science and the National Medals of Technology at the White House recently. Recipients of the science medal were: **Bruce Ames**, professor of biochemistry and molecular biology, University of California, Berkeley; **Don Anderson**, professor of geophysics, California Institute of

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Duke Barred From Enrolling Patients On Clinical Trials

(Continued from page 1)

document that special protections for children were in place, and failure to develop a plan for continuing education of IRB members. OPRR also listed numerous record-keeping deficiencies at IRB meetings, and ordered the medical center to start a second IRB since the existing board was apparently unable to cope with the workload.

Duke officials said no patients were harmed, and characterized the problems as "administrative."

Ralph Snyderman, Duke chancellor for health affairs, said the medical center expected to submit its response to OPRR for review by May 14. "We regret the need for OPRR's decision, but we agree with the importance of the administrative changes the agency has identified," Snyderman said in a statement dated May 11. "We are firmly committed to providing participants in clinical studies with the utmost protection against research risks and intend to work closely with OPRR to ensure absolute compliance with federal requirements."

Duke officials were scheduled to meet with OPRR on May 13. Research involving previously enrolled subjects "may continue only where it is in the best interests of individual subjects," an OPRR official wrote in the May 10 letter to Duke.

At the Duke Comprehensive Cancer Center this week, physicians were turning away patients who had been scheduled to receive investigational therapies, but who had not yet signed informed consent forms, said Henry Friedman, professor of pediatrics at Duke University.

"We have patients with desperate needs, and we don't have non-clinical trial interventions to offer them," Friedman said to **The Cancer Letter**. "I understand the justification for OPRR to push the institution to meet the standards they are empowered by Congress to set, but I'm also getting calls from patients concerned that their needs are not going to be met. I am hoping that at least for the therapeutic clinical trials we will be able to go back on-line again soon."

Clinical investigators around the country said they were surprised by the OPRR directive. "This comes as a total shock," said a cancer center director who asked not to be quoted by name. "Duke does fine clinical research, very high-quality work."

The action could indicate an apparent failure on the part of Duke officials to act on specific directives contained in a December 1998, letter from OPRR, sources said. "I would not thumb my nose at OPRR," said an NCI official involved in cancer clinical trials. "You don't want them on your doorstep one morning telling you to stop your trials. These regulations are in place for a reason."

Some cancer researchers said they feared the negative publicity about human subjects research could affect the Study of Tamoxifen and Raloxifene, for the prevention of breast cancer. The trial, conducted by the National Surgical Adjuvant Breast and Bowel Project, is scheduled to begin officially on May 25, sources said. Four cancer centers in the southeast—Duke, University of North Carolina-Lineberger Comprehensive Cancer Center, and Wake Forest Comprehensive Cancer Center, all in North Carolina, and Emory University Cancer Center in Atlanta—were planning a joint press conference to announce the trial, sources said.

The OPRR action may signify a more aggressive stance by the agency, sources said. Only four times in the past decade has the agency directed institutions to halt enrollment to studies, and two of those were within the past 12 months. In March, the agency suspended enrollment in studies at the Los Angeles Veterans Administration Hospital, and took similar action last year against Rush-Presbyterian-St. Luke's Medical Center.

"We do random visits rarely," J. Thomas Puglisi,

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Founded Dec. 21, 1973 by Jerry D. Boyd

director of the Division of Human Subject Protections, said to **The Cancer Letter**. "Most site visits are for cause."

In a report issued last June, the HHS Inspector General said the nation's system for protection of human research subjects was in danger of collapse. The report is available at http://www.nih.gov/grants/oprr/hsp_report/hsp_final_rpt.pdf.

Investigators who conduct clinical research at Duke said the medical center's IRB, headed by pediatric oncologist John Falletta, is generally considered very professional and thorough. One investigator described the IRB as "nitpicky." Even OPRR noted the "high priority which DUMC places on the protection of human subjects" in its December 1998 letter to Duke officials.

IRB issues can be difficult and time-consuming, researchers say. Faculty are not paid for their service on IRBs. As the number of research studies has increased in the past decade, many academic medical centers have formed multiple IRBs to keep up with the workload.

OPRR had recommended in December that DUMC form a second IRB, but the medical center failed to do so, the agency said in its letter to the medical center earlier this week.

"These compliance issues are very important, but the academic research centers are under enormous burdens today," Ellen Sigal, a board member of the Duke medical center and the cancer center, said to **The Cancer Letter**. "The demands are extraordinary and resources are limited.

"We have to find ways to help universities deal with these enormous infrastructure issues," said Sigal, who also serves on the NCI Board of Scientific Advisors and chairman of the Friends of Cancer Research.

Duke Received Repeated Warnings

The OPRR action against Duke may be instructive for officials of other academic medical centers. "I would guess that many centers are looking at their procedures at this very moment," one administrator said to **The Cancer Letter**.

Letters from OPRR to DUMC, obtained from NIH under the Freedom of Information Act, provide the following chronology:

December 1998: OPRR conducted a random site visit at DUMC Dec. 15 and 16. Five agency staff members and four consultants met with Duke officials, IRB members and staff, and 15 federally-funded researchers, according to a Dec. 18 letter written by Michael Carome, acting chief of the OPRR Compliance Oversight Branch. More than 50 protocols and the minutes of eight IRB meetings were reviewed.

In the letter, which listed 22 deficiencies or concerns, Carome wrote that OPRR was acting to restrict the medical center's license for human subjects research pending the completion of several "corrective actions." Among the actions requested:

—The medical center must audit IRB records of all HHS-supported human subject research;

—Submit a plan for review of all future grant applications for HHS-supported research prior to submission to a funding agency;

—Submit a plan for continuing education of IRB members about the regulatory requirements;

—Submit quarterly progress reports to OPRR.

OPRR required DUMC to suspend enrollment of new subjects "for any research where (i) the IRB file does not contain the grant application, or (ii) the grant application and the DUMC IRB research protocol are discrepant in any way."

The agency said it was concerned that the IRB may be "overburdened by the large volume of research for which it has oversight responsibility." The IRB should have a full-time administrator and additional staff, OPRR said. Also, the agency said it was concerned that the IRB membership lacked diversity.

Duke University, which is covered under a separate license for human subjects research, had similar deficiencies, the agency said. OPRR would be "willing to entertain" a proposal from Duke officials for a single license with multiple IRBs, Carome wrote in the Dec. 18 letter.

Also, OPRR was concerned that the director and assistant director of Duke's Office of Grants and Contracts served as alternate voting members of the IRB. Grant and contract officials should not serve as voting members of IRBs, because of the apparent conflict of interest, OPRR said.

February 1999: DUMC submitted a report to OPRR on Feb. 1 responding to the December letter, according to an OPRR letter dated Feb. 4 to Duke chancellor Snyderman. The center had suspended enrollment of new subjects in 11 projects. Five of those projects were still suspended. None of the five studies involved cancer research.

OPRR said it found the medical center's proposed corrective action plan incomplete for the

following reasons:

—The plan did not propose to review the complete copies of grant applications, but only the application research plans.

—The proposed education plan "should include provisions for IRB members and staff to attend on a regular basis local, regional, and national meetings related to human subject protections," and include an expanded training program for investigators.

—The IRB should receive more than "a simple signed statement from the PI" ensuring human subject protections. Issues of subject recruitment, selection, privacy, and welfare "should be specifically addressed in detail in the IRB protocol submission."

—Duke had not yet addressed the problem of the IRB workload by establishing a second IRB, increasing the frequency of IRB meetings, or appointing a co-chairman for the IRB.

Duke sent reports to OPRR as requested on March 1 and April 1, according to the OPRR letter of May 10. NIH cannot release copies of the Duke responses to OPRR because the letters are part of an investigatory file, an NIH spokesman said to **The Cancer Letter**.

Duke officials also declined to release the letters.

May 10, 1999: OPRR responded to Snyderman's reports of March 1 and April 1, acting to suspend the medical center's license to conduct human subject research and finding the following problems:

—OPRR said the education plan proposed in Snyderman's letters was "unsatisfactory" and "appears to provide only minimal improvements" over procedures that were in place previously.

—Although Snyderman wrote in his Feb. 1 report that the director and assistant director for grants and contracts were removed as voting members of the IRB as the agency requested in December, OPRR found that the two officials had served as voting members at IRB meetings Jan. 21, 25, and Feb. 1.

—Because the grant and contract officials ought not to have participated at the meetings, there was not a quorum, and any actions taken at those meetings are invalid, OPRR said.

—IRB meeting minutes "still uniformly fail to meet" OPRR requirements, and there were discrepancies between the listed attendance at the meetings and total number of members voting on specific protocols.

—OPRR was still "unable to determine" from Snyderman's April 1 report whether the IRB conducts "substantive and meaningful continuing review" of research.

—IRB minutes provided no evidence that the IRB makes required findings when reviewing protocols involving children.

—OPRR found inadequate review of informed consent documents that indicated that the IRB required additional training. Some informed consent documents contained exculpatory language, which is prohibited by HHS. Specifically, OPRR said, the statement, "you are giving up ownership of your DNA," and "all rights to the DNA will remain with the investigator," can be considered exculpatory. "It would be acceptable for consent forms to state that DUMC investigators do not intend to share with the subject any commercial profits that may result from research using the subject's DNA sample," Carome wrote.

—Duke had "defined" two IRBs, but did not expect to have new IRB members recruited and trained until July or August. "OPRR is concerned about the slow pace at which this corrective action is being implemented," Carome wrote.

—Duke had not hired a full-time IRB administrator or additional staff, and had not addressed the issue of the diversity of IRB membership.

—OPRR noted other deficiencies regarding protocol amendments and review of HHS grant applications.

"In summary, OPRR finds the scope and pace of DUMC's implementation of corrective actions required by OPRR in its letter of December 18, 1999 to be inadequate," Carome wrote. "Indeed, the significant lack of progress demonstrated by DUMC over the more than three-month period since OPRR presented its findings to you at its site visit exit interview suggests a failure of leadership in DUMC's human subject protection system."

Among OPRR's requirements to have its license reinstated, Duke must address all of the agency's concerns; restructure and enhance its institutional commitment to human subject protections; form additional IRBs; better educate IRB members, staff, and investigators; re-review research proposals approved at the three IRB meetings in January and February; and provide the agency by June 1 with lists of the federally-funded research projects that were suspended.

NCI requires that clinical and comprehensive

cancer centers that hold Cancer Center Support Grants use a two-tiered system of review. First, research proposals are submitted to protocol review committees, which make a judgment on the proposals' scientific rationale and importance.

Subsequently, the proposals are sent to the IRB, which focuses solely on the issues of protection of research subjects. Most of the clinical and comprehensive cancer centers have had the two-tier review system in place for the past five or six years, sources said.

Cancer Advocacy:

Jay Hedlund Resigns As Head Of Prostate Cancer Coalition

Jay Hedlund last week resigned from his position as president and CEO of the National Prostate Cancer Coalition.

Hedlund, who will leave May 14, said he is considering "other professional options, particularly in the health and cancer field."

During his two-years at NPCC, Hedlund united the coalition's disparate groups behind a single agenda that includes increasing federal funding for prostate cancer research and building a grassroots organization. The coalition said it has begun a search for Hedlund's successor.

Meanwhile, day-to-day operations will be managed by NPCC vice chairman Richard Atkins, president of the CaP CURE Government Research Initiatives Group.

NCI Programs:

Geographic Information System Contract Awarded As Part Of Long Island Cancer Study

NCI has awarded a contract to AverStar Inc., of Vienna, VA, to develop and implement a prototype geographic information system for breast cancer studies as part of the Long Island Breast Cancer Study Project.

The contract award is for $4,872,309. In the first phase of the contract, to last two years, the firm is to develop and deliver the computer system. The second phase of the contract, with a three-year option, is for system maintenance and data expansion to respond to research needs.

"The Long Island geographic information system provides the opportunity to apply a powerful emerging technology to the study of environmental causes of breast cancer," said G. Iris Obrams, associate director of the NCI Epidemiology and Genetics Research Program in the Division of Cancer Control and Population Sciences. "This prototype GIS will be the first such system developed to study relationships between environmental exposures and breast cancer, and will provide researchers a new tool with which to conduct their investigations."

The Long Island study is investigating whether environmental factors are responsible for breast cancer in Suffolk, Nassau, and Schoharie Counties, NY, and in Tolland County, CT. The investigation began in 1993 and is funded and coordinated by NCI, in collaboration with the National Institute of Environmental Health Sciences.

The GIS is to include geographic data for general mapping purposes and demographic data. Data on health care facilities, health care surveys, breast cancer, and the environment will also be included.

The environmental data will include information on contaminated drinking water; sources of indoor and ambient air pollution, including emissions from aircraft; electromagnetic fields; pesticides and other toxic chemicals; hazardous and municipal waste; and radiation. The system will rely chiefly on existing databases obtained from federal, state, and local governments, and private sources, with emphasis placed on high-quality data. The Long Island community will also be asked to provide descriptive information about the environment and history of the area, NCI said.

"The geographic information system for Long Island will be modular, flexible, and expandable so that it can be adapted to research needs," said Ellen Heineman, NCI project officer for the contract. "As additional exposure data become available, they can be added to allow researchers to explore important exposure-disease relationships."

Although some of the data to be included in the GIS are publicly available, other data are confidential or proprietary, such as medical records. As a result, various levels of access to the GIS will be established to safeguard data while maximizing the system's usefulness as a research tool, NCI said.

NCI said a web site will be created that will contain information on the progress of the GIS development. The Institute plans to form an oversight committee to govern access to the system.

Funding Opportunities:

Resources For Development Of Prevention Agents Offered

Rapid Access To Preventive Intervention Development

Deadline: Nov. 1

NCI announces a new initiative: Rapid Access to Preventive Intervention Development. RAPID will make available to academic investigators the preclinical and early clinical drug development contract resources of NCI's Division of Cancer Prevention. The goal of RAPID is the rapid movement of novel molecules and concepts from the laboratory to the clinic for clinical trials of efficacy. RAPID will assist investigators who submit successful requests by providing any (or all) of the pre-clinical and phase 1 clinical developmental requirements for phase 2 clinical efficacy trials.

These include, for example, preclinical pharmacology, toxicology, and efficacy studies; bulk supply, GMP manufacturing, and formulation; and regulatory and IND support and phase 1 clinical studies. Suitable types of agents for RAPID may range from single chemical or biological entities to defined complex mixtures with the potential to prevent, reverse, or delay carcinogenesis. For further information, visit the web site, http://dcp.nci.nih.gov/CB/

Requests for RAPID resources are to be submitted as described in the web site. Written requests will be evaluated by a specially constituted RAPID panel, consisting of selected NCI staff and outside experts from academia and industry. Requests must be received on or before Nov. 1. Inquiries: James A. Crowell, Ph.D., Division of Cancer Prevention, NCI, 6130 Executive Blvd Suite 200B, Bethesda, MD 20892, Rockville, MD 20852 (for express/courier service), phone 301- 594-0459, fax 301-402-0553, 301-594-2943, email: jc94h@nih.gov

NCI Request For Applications

RFA CA-99-012: Cooperative Prostate Cancer Tissue Resource

Letter of Intent Receipt Date: July 29

Application Receipt Date: Aug. 27

The Resources Development Branch of the Cancer Diagnosis Program, NCI Division of Cancer Treatment and Diagnosis, invites applications for cooperative agreements from organizations (individual institutions or consortia) capable and interested in working together to create a virtual resource to be known as the NCI Cooperative Prostate Cancer Tissue Resource. A virtual resource is comprised of the specimen archives, which remain at the institution where they were collected, and data associated with the specimens that is maintained in a central database. The Resource will make tissue specimens, with associated demographic, clinical and outcome data, available to support prostate cancer research. Participants will identify critical data elements, design the Resource database, and enter data related to the selected cases. The quality of the specimens and data will be ascertained, a website designed, and a marketing plan developed. Prospective collection of frozen tissue specimens will begin in the second year, both to meet current needs and to create a bank to meet future needs. Demographic, clinical and pathology data related to banked frozen specimens will be collected and entered into the database. Follow-up and outcome data will be added to the database as it becomes available.

NCI intends to commit approximately $1.5 million in FY 2000 to fund 3 to 5 new awards. Since the collection and distribution of fresh/frozen specimens will not be initiated until year two, the anticipated budget will increase to $2.4 million per year for years 2-5. An applicant may request a project period of up to 5 years.

Inquiries: Jules J. Berman, Ph.D., M.D., Resources Development Branch, Cancer Diagnosis Program, NCI, 6130 Executive Blvd Room 700 MSC-7420, Bethesda MD 20892-7240, Rockville, MD 20850 (for express/courier service) phone 301-496-7147, fax 301-402-7819, email: bermanj@mail.nih.gov

NCI Program Announcements

PAR-99-094: NCI Transition Career Development Award (K22)

Application Receipt Date: June 1, Oct. 1, 1999; Feb. 1, 2000

The purpose of the NCI Transition Career Development Award (K22) is to provide "protected time" for newly independent investigators to develop and receive support for their initial cancer research programs. This award is intended to facilitate the transition of investigators from the mentored to the independent stage of their careers in cancer research. It applies to clinicians who are pursuing basic science careers; clinicians who are pursuing careers in patient-oriented research; and to individuals pursuing careers in the prevention, control and population sciences. To apply, a candidate must have completed two years or more of postdoctoral, mentored research or have been in an independent position for less than one year at the time of the application. The unique feature of this award is that individuals may apply without a sponsoring institution while they are still in a "mentored" position. Successful postdoctoral applicants will be given up to 12 months to identify an independent, preferably tenure-track, position at a sponsoring institution before an award can be activated. Awardees must apply for an R01 research grant or equivalent prior to the end of the second year of the award.

Eligible candidates are doctorally degreed individuals who have been educated as clinicians (e.g. M.D.s, Oncology Nurses) or as prevention, control and

population scientists (e.g., PhDs, DPHs, M.D.s) and are ready to pursue independent careers in cancer research. The Transition Career Development Award (K22) is not for basic scientists following a traditional basic science research career track (e.g., Ph.D.s in molecular biology). Individuals pursuing basic science cancer research careers should apply for the Howard Temin Award (K01). Candidates should refer to the following URL address for information on the Howard Temin Award: http://www.nih.gov/grants/guide/pa-files/PAR-99-063.html.

Inquiries: Dr. Lester S. Gorelic, Centers, Training and Resources Program, NCI, 6130 Executive Blvd Room 520 MSC 7390, Bethesda, MD 20892-7390, phone 301-496-8580, fax 301-402-4472, email: lg2h@nih.gov

Dr. Andrew Vargosko, Centers, Training and Resources Program, NCI, 6130 Executive Blvd Room 520 MSC 7390, Bethesda, MD 20892-7390, phone 301-496-8580, fax 301-402-4472, email: av8b@nih.gov

PAR-99-095: Cancer Education And Career Development Program

Application Receipt Date: June 1, Oct. 1, 1999; Feb. 1, 2000

The purpose of this specialized Cancer Education Program (R25) is to support the development and implementation of curriculum-dependent programs to train predoctoral and postdoctoral candidates in cancer research settings that are highly inter-disciplinary and collaborative. This program is particularly applicable to cancer prevention and control, epidemiology, nutrition, and the behavioral and population sciences; but should also be considered by other highly interdisciplinary areas of research such as imaging and molecular diagnosis that will require sustained leadership, dedicated faculty time, specialized curriculum, interdisciplinary research environments, and more than one mentor per program participant to achieve their education and research career development objectives.

Inquiries: Dr. Lisa Begg, Office of Centers, Training and Resources, NCI, 6130 Executive Blvd Room 520 MSC 7383, Bethesda, MD 20892-7383, fax 301-402-4472, email: beggl@mail.nih.gov

CDC Offers Funds To States For 5-A-Day Evaluation

The Centers for Disease Control and Prevention and NCI announce the availability of fiscal year 1999 funds for a grant program to support the evaluation of 5-A-Day Nutrition Programs.

Eligible applicants are state public health agencies. Approximately $535,000 is available in FY 1999 to fund 7 awards. It is expected that the average award will be $75,000, ranging from $55,000 to $90,000.

Inquiries: Lucy Picciolo, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 99088, CDC, 2920 Brandywine Rd Room 3000, Atlanta, GA 30341-4146, phone 770-488-2757, email: lip6@cdc.gov

CDC Program Announcement

CDC PA 99117: Prevention Research Using Genetic Information To Prevent Disease and Improve Health

The Centers for Disease Control and Prevention, Office of Genetics and Disease Prevention, in cooperation with the Office of Prevention Research, Office of the Director, announces the availability of fiscal year 1999 funds for a cooperative agreement program for Prevention Research Using Genetic Information to Prevent Disease and Improve Health. The program will provide funding for conducting population-based research to:

1. Assess how risk for disease and disability in well-defined populations is influenced by the interaction of human genetic variation with modifiable risk factors.

2. Ensure that genetic tests and services are incorporated in population-based interventions that promote health and prevent disease and disability.

Approximately $700,000 is available in FY 1999 to fund two awards. It is expected that the average award will be $350,000 to begin on or about Sept. 30 for a 12-month budget period within a project period of up to 3 years.

Inquiries: call 1-888-GRANTS4 (1-888-472-6874). For questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Mattie Jackson, Grant Management Specialist, Procurement and Grants Office, CDC, 2920 Brandywine Rd Room 3000, Atlanta, GA 30341-4146, phone 770-488-2718, email: mij3@cdc.gov

NCI Contract Awards

Title: Prostate, Lung, Colorectal And Ovarian Cancer Screening Trial

Contractors: NCI intends to negotiate with the following Screening Centers of the PLCO Trial for implementation of the following protocol Modifications (1) Add CA125 and PSA tests in years T4 and T5; (2) Add biorepository collections in T4 and T5; and (3) Follow-up extended for three years, through 2011. The contracts are as follows: University of Alabama, Georgetown University, Henry Ford Hospital, Marshfield Medical Research and Education Foundation, Straub Pacific Health Foundation, University of Colorado, University of Minnesota, University of Pittsburgh, University of Utah, Washington University. Inherent duplication of cost to the government and privacy rights of PLCO participants make competition unfeasible.

Title: Clinical Trials and Information Management Support

Contractor: EMMES Corp., Rockville, MD; $6,958,812.

In Brief:

Biogen, Bristol-Myers, Win National Technology Medals

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Technology Seismological Laboratory, Pasadena; **John Bahcall**, professor of natural sciences, Princeton University; **John Cahn**, a fellow at the National Institute of Standards and Technology in Gaithersburg, MD; **Cathleen Morawetz**, professor emerita, Courant Institute of Mathematical Sciences of New York University; **Janet Rowley**, a cancer researcher at the University of Chicago; **Eli Ruckenstein**, professor of chemical engineering, State University of New York, Buffalo; **George Whitesides**, professor of chemistry, Harvard University; and **William Julius Wilson** of the John F. Kennedy School of Government at Harvard University. Recipients of the technology medal were: **Denton Cooley**, founder, president and surgeon-in-chief, Texas Heart Institute, Houston; **Kenneth Thompson** and **Dennis Ritchie**, of Bell Laboratories and Lucent Technologies, Murray Hill, NJ; **Robert Fraley**, **Robert Horsch**, **Ernest Jaworski** and **Stephen Rogers** of Monsanto, St. Louis; **Biogen Inc**. of Cambridge, MA; and **Bristol-Myers Squibb Co**. of Princeton, NJ. . . . **STEVEN ROSEN**, director of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University, was awarded a five year, $1 million grant from The Coleman Foundation Inc. for development of the center's Health Care Policy and Outcomes Research Program. **Charles Bennett** and **David Cella** will head the program development effort, which has identified three high priority areas for public policy in the cancer field: quality of care and patient decision-making for breast and ovarian cancer populations; impact of low literacy in cancer screening and treatment; and long-term survival issues for pediatric cancer patients. The funding will support undergraduate and post-doctoral training and provide support investigators conducting research projects in these areas. . . . **BARTON KAMEN**, of University of Texas Southwestern Medical Center, Dallas, was named director of pediatric oncology at the Cancer Institute of New Jersey and chief of the Division of Pediatric Hematology-Oncology at UMDNJ-Robert Wood Johnson Medical School. . . . **DOUGLAS YEE** was named to the Tickle Family Chair in Breast Cancer Research at the University of Minnesota Cancer Center. Yee, a medical oncologist who served as a medical staff fellow at NCI, has been a faculty member of the University of Texas Health Science Center in San Antonio since 1989, and was program leader of the Growth Factor Program at San Antonio Cancer Institute. . . . **KATHLEEN O'DONNELL**, former director of strategic alliances and patient support, Bristol-Myers Squibb Co., has formed a partnership with **LOUISE HOMER**, a licensed clinical social worker, healthcare administrator, and organizational development consultant, to provide strategic communications and public policy services to health care organizations, companies, and individuals. The company, O'Donnell & Homer, is based in Massachusetts. The principals may be reached by email at kathyod@banet.net or louhomer@ma.ultranet.com. . . . **GEOFFREY ROBB**, a faculty member at University of Texas M.D. Anderson Cancer Center for the past eight years, was appointed chairman of the Department of Plastic Surgery. He has served as interim chair since May 1997. . . . **JOHN DIGIOVANNI**, an M.D. Anderson faculty member for 16 years, was named director of the cancer center's Science Park-Research Division in Smithville, TX, and chairman of the Department of Carcinogenesis. He leads 33 faculty and 165 staff members at the carcinogenesis research facility near Austin. . . . **HOWARD HUGHES** Medical Institute has extended its support of the Cold Spring Harbor Laboratory's scientific courses with a grant for $1.32 million. The funds will help support advanced courses in neuroscience, molecular biology, and structural biology, as well as a new program in advanced imaging techniques, CSHL said. . . . **STEVEN SAVONA** was appointed medical director of the University of Pittsburgh Cancer Institute at UPMC St. Margaret. He also is an associate clinical professor of medicine at University of Pittsburgh School of Medicine. . . . **PUBLIC SERVICE** Awards were presented May 10 by the Federation of American Societies for Experimental Biology to **Sen. Arlen Spector** (R-PA) and **Sen. Tom Harkin** (D-IA) for their support of biomedical research. . . . **"CANCER CRUSADERS"** awards, sponsored by La Salsa Holding Co., a Los Angeles based restaurant company, were presented by **Rep. J.C. Watts** (R-OK) to **Sherry Lansing**, of Paramount Pictures; **Ellen Sigal**, founder of Friends of Cancer Research; and **Anna Barker**, president and CEO, OXIS International Inc. The three were honored for their work on The March: Coming Together to Conquer Cancer.

THE CANCER LETTER

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Business & Regulatory Report

Formerly "Cancer Economics"

BMS Files NDA For Taxol As Adjuvant Therapy For Node Positive Breast Cancer

Bristol-Myers Squibb Co. (NYSE: BMY) of Princeton, NJ, said it has submitted a supplemental New Drug Application to FDA for Taxol (paclitaxel) administered sequentially to standard combination therapy for the adjuvant treatment of node-positive breast cancer.

The application is based on the results of a trial headed by the Cancer and Leukemia Group B.

"This represents one of the most significant advances in the treatment of early-stage breast cancer since the introduction of doxorubicin," said CALGB Chairman Richard Schilsky, director of the University of Chicago

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Oncology Management:

Accrediting Organization Accepts Facilities Approved By Commission On Cancer

The Joint Commission on Accreditation of Healthcare Organizations and the **American College of Surgeons Commission on Cancer** have initiated a cooperative agreement aimed at reducing duplicative onsite evaluations of cancer treatment facilities.

The Joint Commission said it will henceforth accept Commission on Cancer accreditation decisions for cancer treatment facilities or cancer hospitals affiliated with health plans and health systems applying for accreditation under the Joint Commission's Network Program.

The two organizations said they expect that Joint Commission recognition of Commission on Cancer accredited cancer treatment programs will be expanded to include all Joint Commission-accreditation programs during the next year.

The Commission on Cancer accredits approximately 1,500 cancer programs located in hospitals, outpatient centers, and freestanding cancer treatment facilities in the U.S.

The Joint Commission launched an initiative to reduce redundancy in the quality oversight process for health care organizations in 1994. This is the eighth formal cooperative accreditation agreement to be signed since then.

The Joint Commission has been accrediting integrated delivery networks, PPOs, and health plans since 1994. The Joint Commission is the only managed care accreditor whose standards-based evaluation includes both the network's or health plan's central office and the sites

(Continued to page 6)

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BMS Seeks Taxol Approval For Adjuvant Treatment Of Node Positive Breast Cancer

(Continued from page 1)

Cancer Research Center. "This new combination therapy has the potential to save tens of thousands of lives worldwide each year. We anticipate that this regimen will become the standard against which new therapies will be compared."

The phase III study (CALGB 9344) was the largest adjuvant breast cancer trial ever conducted and the largest study ever completed with Taxol. The trial enrolled over 3,000 women and included the participation of 1,000 investigators affiliated with CALGB, Eastern Cooperative Oncology Group, the Southwest Oncology Group and the North Central Cancer Treatment Group.

The trial compared standard chemotherapy—doxorubicin plus cyclophosphamide—with the same two drugs plus Taxol. Patients in the study had lymph node involvement under the arm.

According to the preliminary analysis, the study demonstrated that administering Taxol in addition to a standard reduced mortality rate by 26 percent and reduced the risk of recurrence by 22 percent, compared to standard treatment. These results have been updated to include the 30-month survival results in the FDA filing.

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Of the more than 180,000 women diagnosed with breast cancer each year in the U.S., about 75,500 are candidates for adjuvant therapy.

"These data clearly demonstrate that we are substantially improving a woman's chances for remaining alive and free of her breast cancer by adding Taxol sequentially to the standard regimen of doxorubicin and cyclophosphamide," said Larry Norton, head of the Division of Solid Tumor Oncology at Memorial Sloan-Kettering Cancer Center and chairman of the Breast Committee of CALGB.

Taxol is approved as first-line (in combination with cisplatin) and subsequent therapy, for advanced carcinoma of the ovary, and for the treatment of breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracyline, unless clinically contraindicated.

Taxol is also indicated for use in combination with cisplatin, for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy, and for the second-line treatment of AIDS-Related Kaposi's Sarcoma.

Clinical Trials:

Aronex Begins Three Trials Of New Anticancer Agents

Aronex Pharmaceuticals Inc. (Nasdaq: ARNX) of The Woodlands, TX, has begun three clinical trials:

—A phase II trial of the chemotherapeutic agent Platar in patients with metastatic renal cell carcinoma. The trial is being conducted by researchers at The University of Texas M.D. Anderson Cancer Center under an Institutional Investigational New Drug application. Platar is a liposomal formulation of a platinum product designed to overcome the toxicity and drug resistance that currently limit the usefulness of platinum. Platar is also being evaluated at MDACC under an Institutional IND in a phase II clinical trial for the treatment of mesothelioma.

—A phase I/II clinical trial of Atragen in patients with bladder cancer. Atragen is an injectable formulation of all-trans-retinoic acid being developed for the treatment of hematologic malignancies and solid tumors. The agent is being evaluated in early-stage clinical trials in progressive non-Hodgkin's

lymphoma, prostate cancer and renal cell carcinoma.

—A phase I/II trial of Annamycin for refractory or relapsed acute myelogenous leukemia, acute lymphocytic leukemia or blast crisis of chronic myelogenous leukemia.

Annamycin is a liposomal anthracycline designed to treat a broad range of cancers, including those that exhibit multiple drug resistance, the company said. The agent was designed to overcome two major limitations seen in anthracyclines that are currently on the market: cardiotoxicity and multiple drug resistance. In addition, activity against tumors that are refractory to other agents is a potential advantage of Annamycin.

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Avax Technologies Inc. (Nasdaq: AVXT) of Kansas City, MO, said its investigational proprietary Autologous Cell vaccine for the treatment of stage 3 melanoma, known as M-Vax, received Orphan Drug designation from the FDA. The designation gives Avax seven years of exclusivity in the US as well as other benefits.

To date, over 300 patients have been treated with the M-Vax vaccine under an investigational new drug application, the company said. Patient enrollment is underway at about 30 sites in the US.

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BioLabs Inc. (OTC Bulletin Board: BILB) of New York said Biotherapies Inc. has received approval from FDA to begin phase I and II trials using mammastatin to treat breast cancer.

The trials will be conducted at M.D. Anderson Cancer Center, the company said. The scope of the trials will include safety testing and dose optimization studies of human mammary epithelial cell derived mammastatin for use as a replacement therapy in refractory stage IV breast cancer patients.

In addition to BioLabs' equity interest in Biotherapies, BioLabs holds a 50 percent interest in a joint venture to manufacture and distribute the Mammastatin Serum Assay blood test. It is anticipated that the MSA test will potentially screen for breast cancer risk by measuring the mammastatin levels in women's blood. The joint venture agreement includes exclusive worldwide rights to manufacture, market and distribute the MSA test. Trials under a 510K application are anticipated to commence in June, the company said.

• • •

Cell Genesys Inc., (Nasdaq: CEGE) of Foster City, CA, said it has begun a second phase I/II trial of GVAX cancer vaccine for prostate cancer in about 40 patients whose disease progressed after treatment with hormone therapy. The vaccine is comprised of irradiated prostate cancer cells that have been genetically modified to produce GM-CSF.

The trial follows a multicenter phase I/II trial which began last December and will enroll about 40 earlier stage patients who have not received hormone therapy, the company said.

Both of these expanded trials were prompted by encouraging results in the initial study of GVAX prostate cancer vaccine conducted last year which demonstrated that the treatment was safe and well-tolerated and resulted in antitumor activity as measured by prostate specific antigen, the company said.

The two multicenter trials are being conducted at the Johns Hopkins Medical Institutions in Baltimore, the University of California, San Francisco and PRN Research Inc. in Dallas.

Cell Genesys' initial clinical trial of GVAX was conducted in 21 patients at the Johns Hopkins Medical Institutions. The patients had rising PSA levels following prostatectomy and had not received other treatment for prostate cancer.

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Genta Inc. (Nasdaq: GNTA)of Lexington, MA, said it has initiated a phase I/IIa study of its lead development compound G3139 at the Lombardi Cancer Center at Georgetown University Medical Center.

The study will investigate G3139 administered with Taxotere(docetaxel. The principal investigator is Daniel Hayes, clinical director of the Breast Cancer Program at the Lombardi Cancer Center. Co-investigators are Marc Lippman, John Marshall and Helen Chen.

G3139 is designed to reduce the Bcl-2 protein level in cancer through an antisense mechanism that specifically targets the bcl-2 gene product, the company said.In several human cancers, the protein produced by the bcl-2 gene is believed to be a major factor in resistance to treatment with many anticancer drugs, including docetaxel.

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Sugen Inc. (Nasdaq:SUGN) of South San Francisco said it intends to collaborate with NCI on multiple phase II and I/II studies of SU5416, Sugen's lead angiogenesis inhibitor, to be conducted at approximately 20 cancer centers in the US.

Under the Clinical Trials Agreement, NCI has

selected more than 20 studies out of 51 proposals from investigators at cancer centers and clinical research hospitals to test SU5416 as either a single agent or in combination with other drugs in a variety of cancer indications. Between 500 and 700 patients are expected to be enrolled in the trials, which are anticipated to begin later this year, the company said.

SU5416 will be used as single agent therapy in phase II studies, which will include renal, head and neck, sarcoma, and prostate cancers. SU5416 will also be tested in phase I/II studies in combination with standard and investigational chemotherapy in patients with advanced malignancies, including colorectal, renal, ovarian, and breast cancers, and certain leukemias.

"Currently, we are focusing our own resources on registrational studies of SU5416 in lung and colorectal cancers, and Kaposi's sarcoma, and could not have afforded the substantial investment that this broad phase II program represents," said Stephen Evans-Freke, Sugen chairman and CEO.

"However, SU5416 may potentially be the first angiogenesis inhibitor to reach the market, and these NCI-sponsored trials will provide the clinical community with important data about the optimal usage of the drug once it does become available," Evans-Freke said in a statement.

Sugen said that id addition to SU416 it is developing two other anti-cancer drugs: SU101 (a PDGF receptor inhibitor) is in phase III trials in refractory brain cancer, will be entering phase III in refractory prostate cancer this year, and is in phase II in ovarian and non-small cell lung cancers; and SU6668 (a multi-mechanism inhibitor of angiogenesis and tumor growth) is in phase I for the treatment of solid tumors.

The company has research and development collaborations with Zeneca, ASTA Medica, Allergan and Taiho.

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SuperGen Inc. (Nasdaq: SUPG, SUPGW) of San Ramon, CA, said it has expanded clinical trials of RFS 2000 for the treatment of a a variety of solid tumors.

The studies are being initiated in the United Kingdom, Italy, France, Germany, Holland and Denmark. Studies in the U.S. aim at a broad range of tumor types, including the phase III program under way in pancreatic cancer, which is increasing to about 200 centers.

Data from a phase II study of RFS 2000 conducted by SuperGen's licensor, the Stehlin Foundation for Cancer Research in Houston, was recently published in the May issue of the International Journal of Oncology. It was reported that RFS 2000 either shrank the pancreatic tumor or stabilized the disease in 63 percent of 60 patients with advanced disease who were evaluable in responses, the company said.

A clinical study at the M.D. Anderson Cancer Center using RFS 2000 has shown efficacy in fifty percent of patients suffering from myelodysplastic syndrome/chronic myelomonocytic leukemia, the company said.

RFS 2000 is given orally on an outpatient basis. Side effects include manageable hematological toxicities, cystitis, and some gastrointestinal disorder, the company said.

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Techniclone Corp. (Nasdaq: TCLN) said it has enrolled and is treating its first patient with newly diagnosed glioblastoma multiforme in a phase II trial of Cotara, a Tumor Necrosis Therapy.

Cotara is a chimeric monoclonal antibody labeled with an Iodine-131 radioisotope. The patient is being treated at the Medical University of South Carolina under the direction of Sunil Patel, principal investigator on the study.

Cotara binds to necrotic cells in the core of solid tumors. In addition to the phase II trials in the U.S. for malignant glioma, a phase I/II clinical trial will commence soon in Mexico City for the treatment of pancreatic, prostate and liver cancer, the company said.

Approvals & Applications:

FDA Approves DepoCyt For Lymphomatous Meningitis

FDA has given accelerated approval for DepoCyt for the treatment of patients with lymphomatous meningitis, said **SkyePharma plc** (Nasdaq: SKYEY; LSE:SKP). The drug is sponsored by **DepoTech Corp.,** a subsidiary of SkyePharma.

DepoCyt is a sustained-release formulation of cytarabine. Using SkyePharma's lipid-based drug delivery technology, DepoCyt releases the cytarabine into the cerebral spinal fluid and extends the dosing interval to once every two weeks, as compared to the standard intrathecal chemotherapy dosing of two times per week.

The drug will be marketed in the U.S. by **Chiron**

Corp. (Nasdaq:CHIR).

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Abgenix Inc. (Nasdaq: ABGX) of Fremont, CA, said it has signed a research collaboration, option and license agreement with **Amgen Inc.** (Nasdaq: AMGN) of Thousand Oaks, CA.

Abgenix will use its XenoMouse technology to generate for Amgen fully human monoclonal antibodies to an undisclosed antigen. In return, Abgenix will receive an upfront research payment and could receive additional fees and milestone payments plus royalties on future product sales by Amgen, the company said. Amgen will be responsible for product development, manufacturing, and marketing of any products developed through the collaboration.

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ALZA Corp. (NYSE: AZA) of Palo Alto, CA, said FDA has accepted for priority review a supplemental New Drug Application for Doxil (doxorubicin HCl liposome injection) for refractory ovarian cancer. Doxil has been granted orphan drug status for ovarian cancer.

The sNDA seeks marketing approval for the use of Doxil in the treatment of metastatic carcinoma of the ovary in patients refractory to both paclitaxel- and platinum-based chemotherapy, and who may be refractory to topotecan therapy.

Refractory is defined as a patient having progressive disease while on treatment, or within six months of completing treatment. The December 1998 submission was supported by two phase II trials, the company said.

FDA has agreed that there is an unmet medical need for patients addressed by this sNDA, and as such, the agency would evaluate the supplemental application under accelerated approval regulations. Applications targeted for accelerated approval typically receive a priority review. The FDA goal for review and action on priority review applications is six months from the date of submission.

Doxil is indicated for treatment of Kaposi's sarcoma in patients with disease that has progressed following first-line chemotherapy, or in patients who are intolerant to such therapy.

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Enzon Inc. (Nasdaq: ENZN) of Piscataway, NJ, said it has filed an IND with FDA for PEG-Camptothecin (prothecan).

Prothecan is a Pro Drug form of the topoisomerase 1 inhibitor camptothecin, a compound known to be a very efficacious oncolytic agent with significant delivery problems. Using its PEG technology, Enzon has been able to overcome the solubility problems that have plagued previous versions of camptothecin, the company said. Enzon will evaluate several cancer indications in the phase I clinical trials of this compound. The clinical trials are expected to begin in the second half of 1999, the company said.

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Gensia Sicor Inc. (Nasdaq: GNSA) of Irvine, CA, said its subsidiary, **Gensia Sicor Pharmaceuticals Inc.**, has received a supplemental ANDA for Daunorubicin Hydrochloride.

Daunorubicin is used in the remission induction in acute myelogenous leukemia in adults and acute lymphocytic leukemia in children and adults.

According to IMS, a market research firm, U.S. sales of daunorubicin were approximately $7 million in 1998. The branded version of daunorubicin, Cerubidine, is marketed by Bedford Laboratories.

Deals & Collaborations:

Firms Expand Collaboration To Include Gene Therapy

Cell Genesys Inc. (Nasdaq: CEGE) of Foster City, CA, and **Mitotix Inc.** of Cambridge, MA, announced the expansion of a worldwide license and research collaboration to include cancer gene therapy.

Under this collaboration, Cell Genesys exclusively licensed from Mitotix a series of cell cycle inhibitor genes essential to the growth and regulation of human cells, including p16, p27 and additional p27/p16 fusion molecules for the development of products for cardiovascular gene therapy. Based on its recently reported positive findings in preclinical studies of cancer gene therapy, Cell Genesys will now have exclusive rights to these genes for cancer applications.

The p16 and p27 cell cycle inhibitor genes, also referred to as cyclin dependent kinase inhibitors (CDKi), play a key role in the natural regulation of cellular division. The p16 gene, a known tumor suppressor gene, has been shown to be missing or mutated in many important cancers.

The genes through the control of cell replication could potentially be used to treat cancer by blocking tumor cell growth or inducing tumor cell death, the companies said. In addition, these genes can be used

in the treatment of restenosis, which results from the abnormal growth of blood vessel smooth muscle cells following angioplasty for coronary artery disease and peripheral vascular disease. Cell Genesys said it intends to seek a pharmaceutical partner to commercialize potential products based on p27/p16 gene therapy with revenue being shared with Mitotix.

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CellPath Inc. of Seattle said it has entered into a research collaboration with **Genzyme Molecular Oncology** (Nasdaq: GZMO) to identify new anti-cancer drug candidates using CellPath's proprietary cell-based cancer assays.

Under the agreement, Genzyme Molecular Oncology will provide CellPath with access to more than 1.5 million compounds from Genzyme's small molecule compound library.

CellPath will screen the library of compounds against their cell-based cancer assays to find novel drug candidates.

After the screening is complete, the parties will negotiate a research collaboration agreement covering the development and commercialization of any active compounds discovered as a result of the screening.

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Eli Lilly and Co. (NYSE: LLY) of Indianapolis and **Sanofi** said they are forming a U.S.- based joint venture in the oncology market. The companies said they would jointly submit, register, develop and market oxaliplatin, a platinum-based cancer treatment developed by Sanofi.

An FDA submission for oxaliplatin is planned by the end of the third quarter of 1999, as a first-line treatment in combination with 5-fluorouracil for all forms of advanced metastatic colorectal cancer, the companies said.

Oxaliplatin is a platinum agent which represents a different approach for treating this type of cancer, the companies said. Sanofi markets oxaliplatin in France and 14 other countries for the first and second-line treatment of advanced colorectal cancer in association with 5-FU.

Under the agreement with Lilly, Sanofi will receive an up-front payment and milestone payments, the companies said.

Also, Lilly will contribute to the capitalization of the joint venture. In exchange, Lilly will receive a percentage of the joint venture profits derived from sales of oxaliplatin in the U.S. The companies would share in the cost of commercialization and development.

The companies said they are examining the possibility of cosponsoring the clinical development of oxaliplatin with Gemzar, among other compounds, as a combination therapy for multiple types of tumors.

Sanofi acquired the license for oxaliplatin in 1994 from the Swiss pharmaceutical company Deblopharm.

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Sugen Inc. (Nasdaq: SUGN) of South San Francisco said it has established a European affiliate, Sugen Europe AG, which is responsible for the European clinical development and franchise management of the Sugen cancer portfolio, and is expected to partner with a limited number of influential national pharmaceutical companies for local marketing and distribution in individual markets in Europe, company said.

Sugen Europe announced its first marketing and distribution agreement with Esteve SA, Spain's second largest pharmaceutical company.

Esteve is responsible for marketing, promotion and distribution of three products, SU101, SU5416 and SU6668 in Spain and Portugal. Sugen Europe will be responsible for the clinical and regulatory development of these products, and will supply finished product to Esteve.

Oncology Management:

Response Oncology Contracts To Provide High-Dose Chemo

(Continued from page 1)

where enrollees actually receive their care.

For additional information, contact Millie Perich at the Joint Commission; tel: 630/792-5932, or Jo Anne Sylvester, at the Commission on Cancer; tel: 312/202-5298 (email: jsylvester@facs.org).

• • •

Response Oncology Inc. (Nasdaq: ROIX) of Memphis, TN, said it has secured a national contract with **Intracorp**, a case management company, for high-dose chemotherapy.

Under the contract, Response Oncology will provide high-dose chemotherapy with peripheral stem cell transplantation at an agreed upon global case rate. The scope of care covered under the global case rate includes all professional services, pharmaceuticals, blood products and supplies used in the course of treament in the company's centers, as well as all related inpatient care for customers of Intracorp.

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