THE CANCER LETTER

Vol. 23 No. 41
Oct. 24, 1997

Price $265 Per Year US
$285 Per Year Elsewhere

NCI Drops Protocol Review Requirement To Encourage Firms To List Trials On PDQ

NCI will no longer require industrial sponsors of clinical trials to submit full protocol documents for review before listing their trials on the Physicians Data Query database, an Institute official announced last week.

The policy change will make it easier for companies to voluntarily submit information about their trials to PDQ, the only government-funded, publicly accessible database of cancer clinical trials.

Susan Hubbard, director of NCI's International Cancer Information

(Continued to page 2)

In Brief

BMS Oncology Names New VP, Marketing; Hortobagyi Wins Freyer Medal; Perez Honored

FRANK PASQUALONE was named vice president, marketing, at the Bristol-Myers Squibb Oncology and Immunology Division. Pasqualone, the former senior director, franchise development, replaces **Timothy Whitten**, who was named vice president for marketing of Pravachol, a cholesterol-lowering drug. . . . **GABRIEL HORTOBAGYI** received the 1997 Sir Peter Freyer Medal from University College Hospital in Galway, Ireland. Hortobagyi, chairman of the Department of Breast Medical Oncology at MD Anderson Cancer Center, received the award in recognition of his contributions to breast research. . . . **CARLOS PEREZ** received the American College of Radiology Gold Medal in recognition of outstanding contributions to the field of radiology. Perez is the director of the Mallinckrodt Institute of Radiology at Washington University School of Medicine in St. Louis, MO. He received the award in recognition of his teaching style, leadership in clinical investigations, and his work on treating cancer patients with a combination of radiation, chemotherapy, and surgery. . . . **TUFTS UNIVERSITY** named an endowed professorship for **Louis Lasagna**, dean of Tufts Sackler School of Biomedical Sciences. **David Greenblatt**, professor and chairman of Tufts Department of Pharmacology and Experimental Therapeutics, will be the first to hold the professorship. . . . **THOMAS TRITTON** was named president of Haverford College in Philadelphia. Tritton, former provost of the University of Vermont, was previously the deputy director of the Vermont Comprehensive Cancer Center and professor of pharmacology at the University of Vermont.

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NCI Eases Method For Listing Industry-Funded Trials On PDQ

(Continued from page 1)

Center, said the Institute proposed the policy change to the PDQ Editorial Board in response to discussions with the Food and Drug Administration, cancer patient advocates, and pharmaceutical industry executives.

The decision reverses the policy for listing industry-sponsored trials that NCI Director Richard Klausner outlined earlier this year in a letter to Glaxo Wellcome Inc. NCI required companies to submit the full protocols for review by the PDQ Editorial Board "to control the quality of the information we provide and thereby to safeguard patients," Klausner wrote in a June 6 letter to Marna Doucette, project director for regulatory affairs at Glaxo, based in Research Triangle Park, NC.

NCI's review criteria included determining whether studies are "reasonable in design, based on rational scientific information, likely to yield useful information," and not unduly risky to patients, Klausner wrote.

Glaxo officials, who have been working with the National Action Plan on Breast Cancer in a project to encourage more firms to list their trials on PDQ, had proposed submitting "general protocol information consistent with the information listed in the PDQ database," Doucette wrote in a May 5 letter to Anne Thurn, of NCI.

The company was concerned about releasing proprietary information contained in protocols to the Editorial Board, Doucette wrote.

NCI decided to reverse the policy and seek the PDQ Editorial Board's concurrence with the decision following a meeting last August with members of the Action Plan and Glaxo, sources said. The advocates and the company pointed out that FDA reviews all clinical trials for safety, and a second review by PDQ would only result in two- to three-month delays for listing trials on the database, sources said.

"We learned that FDA review of protocols covers exactly the criteria we are interested in; therefore, we don't need a duplicate review," Hubbard said. "As long as FDA hasn't put the study on hold, we can list it."

Hubbard's announcement was made at an Oct. 15 meeting of Action Plan members, industry representatives, NCI and FDA staff members.

Companies that want to post cancer clinical trials that are not sponsored by NCI are welcome to submit any information about the trials to PDQ, Hubbard said. Over the next few months, NCI will work with companies to develop a list of the minimal information required. This could include the title of the study, target disease, eligibility criteria, and a phone number to call for information, Hubbard said. The information could be submitted electronically, she said.

The database, which also contains statements on cancer treatment, screening and prevention, is available through the NCI Cancer Information Service (1-800-4-CANCER) and on the Internet (http://cancernet.nci.nih.gov/.)

Information: A Two-Way Street

PDQ lists about 1,500 active studies, most of which are sponsored by NCI through the Institute's grantees, cooperative groups, and cancer centers. Only 113 studies listed in PDQ are funded solely by industry.

In recent years, an increasing number of companies have been funding trials in full, bypassing the NCI grantees. This has resulted in what patient advocates describe as a widening gap between the actual availability of clinical trials for cancer patients and those that are listed on PDQ.

While patients need more information about available trials, investigators need to accrue patients

THE CANCER LETTER
An Independent Newsletter
Member, Newsletter Publishers Association

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World Wide Web URL: http://www.cancerletter.com

Subscription $265 per year US, $285 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc.

Founded Dec. 21, 1973 by Jerry D. Boyd

more quickly to complete trials faster, said Kay Dickersin, co-chair of the Action Plan's Clinical Trials Working Group, a member of the National Cancer Advisory Board, and an epidemiologist at the University of Maryland School of Medicine. "This has been one of the Action Plan's priorities from the beginning," said Dickersin, who represents the National Breast Cancer Coalition on the NAPBC committee.

No one has a definitive number of how many clinical trials are sponsored by the industry. Robert DeLap, director of the FDA Division of Oncology Drug Products, estimates that the agency reviews and approves 3,000 to 4,000 clinical trials each year for oncologic drugs alone. This does not include biologics and devices, DeLap said at the meeting.

For the past year, NCI and FDA sought to educate companies about PDQ and encourage them to list their clinical trials. The project was funded last year through a $100,000 grant from the National Action Plan on Breast Cancer, administered by the Public Health Service's Office on Women's Health (**The Cancer Letter**, Oct. 11, 1996).

Staff from the FDA Cancer Liaison Office visited several companies to inform them about PDQ, assure executives that the agency encouraged them to list their trials, and surveyed 140 companies to gauge knowledge and use of PDQ.

FDA recently received a $70,000 grant from the Federal Coordinating Committee on Breast Cancer to continue the project in fiscal 1998.

"The Public Expects Information"

FDA officials said the project to list industry-sponsored clinical trials is part of the agency's effort to speed the approval of drugs for treating cancer. "We have just one goal: to educate those companies in cancer drug development about listing trials on PDQ," Sharon Smith-Holston, FDA deputy commissioner for external affairs, said to the Oct. 15 meeting to review the progress of the FDA-NCI project. "The idea is to speed recruitment of patients to trials."

Dropping in on the meeting for a few minutes, FDA Lead Deputy Commissioner Michael Friedman said the project also was important for providing better information to patients, investigators, and FDA. "We are talking about giving people the information they need to make better choices; we are talking about more effectively enrolling patients in clinical trials," Friedman said. "From the perspective of FDA's responsibilities, when we have data sets that are larger and can be more carefully analyzed, it serves the American public well, and it allows products to go on the market, and provides for reimbursement.

"It's hard to imagine anyone not being excited about this," Friedman said. "I could see this happening in many other therapeutic areas."

Larry Versteegh, vice president, regulatory and clinical development, at Procter & Gamble Pharmaceuticals, of Cincinnati, said companies were concerned about the possible unintended effects of providing more information to patients. "As patients get more informed and want more and more information, they may find out they are not quite eligible for some trials, so there develops pressure on the system," Versteegh said. "The clinical trial process may become less rigorous.

"There is also the general nuisance," Versteegh said. "Who is going to handle all the requests that come to companies? Investigators may not want to be flooded with phone calls."

"As an agency, we are past that," Friedman responded. "We have heard from patient groups and Congressional advocates that it is clear the public expects a lot of information. The question is how to manage it, not whether or not to do it."

Advocacy organizations can help companies recruit patients to trials, if patients are informed and involved, Dickersin said. Informed patients also are able to better educate others about trials, and perhaps dispel inaccurate information, she said.

Industry representatives at the meeting said they were interested in listing their trials on PDQ as long as the program was voluntary and they did not have to submit the full protocol.

"The reality is that if you set up a trial at 30 sites, the competition knows about it whether or not the trial is listed in PDQ," said George Gill, vice president of medical affairs for Ligand Pharmaceuticals, of San Diego, CA. "As a small company, we would like to have our trials listed on PDQ and the study sites listed, because we don't have the staff to respond directly" to patient inquiries.

NCI and FDA should ensure that companies are aware of the database, Gill said. "We need a way to make [listing a trial on PDQ] as automatic as possible," he said. A PDQ voluntary submission form could be included in the documents companies file with FDA, he said.

Gill suggested that the Pharmaceutical Research

and Manufacturers of America (PhRMA), which represents about 100 pharmaceutical companies, endorse the NCI-FDA effort to list industry trials on PDQ. "The imprimatur of PhRMA would be enormously valuable," he said. "It would disarm the substantial amount of resistance within companies."

Versteegh, who serves as chairman of the PhRMA regulatory affairs committee, said his committee could recommend that the PhRMA board make a statement about PDQ. "As long as the program is voluntary," he said.

Versteegh suggested that FDA write a letter to drug sponsors encouraging the submission of trials to PDQ.

Douglas Jones, director of regulatory affairs for Glaxo Wellcome, suggested NCI market PDQ aggressively at scientific meetings. "Educate people about the new system," said Jones, who has worked with NCI over the past year to develop a model PDQ submission form. "People may have been aware of PDQ, and found their early experience was not the best," Jones said.

Hubbard said NCI has tried to enhance PDQ in recent years, but now realizes that the 13-year-old database needs an overhaul.

"We have decided not to tweak PDQ at the edges anymore, and we are in a planning mode for a complete redesign of PDQ," Hubbard said. "PDQ is the system we've got, but we have a lot of technology we didn't have when PDQ was developed."

NCI is planning to hold a meeting, sometime in December, to find out what PDQ users would like to see in a redesigned database. The meeting would include patients, nurses, physicians, industry representatives, and others, she said.

PDQ Listing Is Not An Ad

Industry executives said they were concerned that the FDA Division of Drug Marketing, Advertising, and Communication would determine that PDQ listings or PDQ links to company web sites are a promotional activity. Under FDA regulations, drugs not approved for marketing cannot be promoted.

Two FDA officials dispelled that concern:

—"It can't possibly be a problem," said Robert Temple, FDA associate director for medical policy and director of the Office of Drug Evaluation I. "It is not a promotional activity."

—"A pharmaceutical company web page can link back to the PDQ site," said Norm Drezin, deputy director of DDMAC. "That's no different from a company handing out a scientific article. It's not a problem."

To Submit A Trial…

"Okay, if we have trial to submit tomorrow, what do we do?" asked Ronald Garutti, vice president, clinical research and regulatory affairs for Shering-Plough Health Care Products, of Liberty Corner, NJ.

Call the NCI International Cancer Information Center at tel: 301-496-7406, and ask for the protocol coordinator, Hubbard said.

"Who is the protocol coordinator?" came the next question from the industry executives.

"It changes every day. Ask for the coordinator of the day," Hubbard said. "If you have any problems, call me at 301-496-9096."

Sensing the executives' need for a name and a face to put on the protocol coordinator, ICIC staff member Kevin Davis volunteered to take all company calls. That number again: 301-496-7406.

Companies can send the entire protocol, which NCI will send to a contractor, who will excerpt the key information for the PDQ listing for the company's approval. "Or, suggest the way you would like to submit information," Hubbard said. "You decide what goes in the data fields."

NCI and Glaxo expect to develop a model electronic template for PDQ trial submission in a few weeks, Hubbard said.

Jane Reese-Coulbourne, a clinical trials consultant and member of the National Action Plan Steering Committee who served as moderator for the meeting, said it is likely that a small group of patient advocates, industry representatives, and NCI and FDA staff will meet to work out final details for company PDQ submissions, including an efficient process for FDA to inform NCI about trial approvals.

Clinical Trials

NCI Removes Brooklyn Site From PLCO Screening Trial

Citing insurmountable "compliance and [patient] retention problems," NCI has removed the Cancer Institute of Brooklyn from the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial, officials said.

"All NCI clinical studies are carefully and regularly reviewed for participant safety, data

quality, and scientific merit," NCI said in a statement. "NCI closed the Brooklyn site following the recommendation of an independent data monitoring committee that determined that it was not possible for the Cancer Institute of Brooklyn to overcome compliance and retention problems that affected the quality and scientific validity of its study data."

NCI said the Cancer Institute of Brooklyn, located at Maimonides Medical Center, was not recruiting properly, had problems retaining patients, and had poor follow-up. The site randomized about 7,000 volunteers to the trial, NCI said.

The medical center declined to comment.

Data from the Brooklyn site will not be used in analyses of the PLCO study and volunteers from the the Brooklyn site will no longer be screened through PLCO, NCI said.

NCI said medical care given to patients at the Cancer Institute of Brooklyn and its collaborating institution is not under question.

The PLCO study includes nine centers in Denver, Washington, Honolulu, Detroit, Minneapolis, St. Louis, Pittsburgh, Salt Lake City, and Marshfield, WI. The study is designed to enroll 148,000 participants. About 85,000 people have volunteed at the nine sites so far, NCI said.

New Journal Scrutinizes Alternative Medicine Claims

Prometheus Books has founded a peer-reviewed journal devoted solely to evaluation of claims made by practitioners of alternative medicine.

The journal, Scientific Review of Alternative Medicine, will consider alternative medicine claims on their merits, said editor Wallace Sampson, an oncologist and clinical professor of Medicine at Stanford University.

"[The journal] will simply seek justified answers to two questions: `Is it True?' and `Does this treatment work?'" Sampson said.

Articles in the first issue include reviews of hydrazine sulfate, chelation therapy, homeopathy, therapeutic touch, as well as claims of "quantum healing."

The journal has the endorsement of the Council for Scientific Medicine, a panel of 50 scientists and physicians that includes five Nobel laureates. Additional information is available from Prometheus Books, 59 John Glenn Dr., Amherst, NY, 14228-2197, tel. 800/421-0351.

Cancer Survivorship

NCI Offers Training Program For Health Professionals

NCI has created a training program to educate health professionals on the issues facing cancer survivors and how to help cancer patients deal with those issues.

"The Cancer Journey: Issues for Survivors," was developed by the NCI Office of Cancer Survivorship through a grant from Ortho Biotech Inc., and with support from the National Coalition for Cancer Survivorship.

"As treatment becomes increasingly effective in the coming years, we will need joint initiatives like this training program to renew our commitment to improve the quality of life of those who develop cancer," NCI Director Richard Klausner said last week at a ceremony to introduce the program.

"The Cancer Journey" covers psychosocial, physiological, end-of-life, employment, insurance, financial, and legal issues of survivorship.

The training program includes a 30-minute video in which 11 survivors talk about the issues they have faced in surviving cancer. The survivors were honored at the Oct. 8 premier of the video at NCI.

The program includes a leader's guide suggesting ways to design a program to educate staff on survivorship, and a manual of reference materials on the issues most relevant to cancer survivors.

For more information on "The Cancer Journey: Issues for Survivors," contact the Cancer Information Service at 1-800-4-CANCER.

Cancer Meetings Listed Through August 1998

October

50th Annual symposium of Fundamental Cancer Research: Molecular Determinants of Cancer Metastasis—Oct. 28-31, Houston, TX. Contact Conference Services, M.D. Anderson Cancer Center, tel: 713/792-2222, fax: 713/794-1742, email: meetings@utmdacc.uth.tmc.edu.

November

American Society of Clinical Oncology Fall Education Conference—Nov. 7-9, Orlando, FL. Contact ASCO, tel: 703/299-1000, fax: 703/299-1044.

Chemotherapy Foundation Symposium XV:

Innovative Cancer Therapy for Tomorrow —Nov. 12-14, New York City. Contact Jaclyn Silverman, Mount Sinai Medical Center, Division of Neoplastic Diseases, tel: 212/241-6772, fax: 212/996-5787, email: J_silverman@smtplink.msmm.edu.

New Frontiers in Oncology: 13th National Congress of SIT—Nov. 13-15, Trieste, Italy. Contact Guido Tuveri, Oncology Department, Ospedale Maggiore, Via Pieta 19, 34100 Trieste, Italy, tel: 0039 40 399-2423, fax: 0039 40 399-2490.

Bone Marrow Transplantation for the Treatment of Autoimmune Disease—Nov. 13-15, Worcester, MA. Contact University of Massachusetts Medical Center, tel: 508/856-1671, fax: 508/856-6838, website: www.ummed.edu/dept/Continuing Education/worctrns.htm.

Commission on Cancer: Second Annual Conference—Nov. 14-15, Chicago. Contact American College of Surgeons, Elaine Fulton, tel: 312/664-4050 ext. 401, email: efulton@facs.org.

Oncology Nursing Society Annual Fall Institute—Nov 14-16, Washington, DC. Contact ONS, tel: 412/921-7373.

Asia Pacific Cancer Conference & Hong Kong International Cancer Congress—Nov. 16-19, Wanchai, Hong Kong. Contact Dept. of Surgery, University of Hong Kong Medical Center, Queen Mary Hospital, Hong Kong, tel: 852-2818-0232, fax: 852-2818-1186, email: mededcon@hkucc.hku.hk.

Workshop on the Quality of Health Information on the Internet—Nov. 17, Bethesda, MD. Contact Health Improvement Institute, tel: 301/657-0404, email: hii@mcman.com.

Melanoma: Lymphatic Mapping/Sentinel Lymph Node Biopsy in Clinical and Pathological Staging—Nov. 19, Philadelphia. Contact Kathy Smith, Fox Chase Cancer Center, tel: 215/728-5358, fax: 215/214-8908.

Human Diet and Endocrine Modulation: Estrogenic and Androgenic Effects—Nov. 19-21, Fairfax, VA. Contact ILSI, tel: 202/659-3859.

First European Conference on the Economics of Cancer—Nov. 19-21, Brussels, Belgium. Contact Mr. Ian, EORTC, ave E Mounier 83 b 11, 1200 Brussels, Belgium, tel: 32-2-774-1611, fax: 32-2-772-3545.

Controversies in Oncology—Nov. 20-21, New York. Contact Jean Campbell, Memorial Sloan-Kettering Cancer Center, tel: 212/639-8961, fax: 212/717-3311.

6th International Conference on Gene Therapy of Cancer—Nov. 20-22, San Diego, CA. Contact Cass Jones, tel: 619/565-9921, fax: 619/565-9954.

December

San Antonio Breast Cancer Symposium—Dec. 3-6, San Antonio. Contact Lois Dunnington, CTRC, tel: 210/616-5912, fax: 210/616-5981.

American Brachytherapy Society Meeting— Dec. 7-9, Phoenix. Contact ABS, tel: 215/574-3158, fax: 215/923-1737, email: abs@acr.org.

DNA Methylation, Imprinting, and the Epigenetics of Cancer—Dec. 12-16, Las Croabas, Puerto Rico. Contact AACR Special Conference Registration, tel: 215/440-9300, fax: 215/440-9313.

American Society for Cell Biology Annual Meeting—Dec. 13-17, Washington. Contact American Society for Cell Biology, tel: 301/530-7153, fax 301/530-7139, email: ascbinfo@ascb.org.

January 1998

AACR Conference: Molecular Mechanisms of Apoptosis Regulation—Jan 9-13, Indian Wells, CA. Contact AACR, tel: 215/440-9300, fax: 215/440-9313.

Gene Therapy for Hematopoietic Stem Cells in Genetic Disease and Cancer—Jan 10-15, Lake Tahoe, NV. Contact Keystone Symposia, tel: 970/262-1230, fax: 970/262-1525.

15th Annual Symposium of the Society of Gynecologic Nurse Oncologists—Jan. 17-21, Seattle, WA. Contact L. Winkelman, tel: 708/301-7868.

Synthetic Non-viral Gene Delivery Systems—Jan. 19-25, Keystone, CO. Contact Keystone Symposia, tel: 970-262-1230, fax: 970/262-1525.

Molecular and Cellular Biology of Gene Therapy— Jan. 19-25, Keystone, CO. Contact Keystone Symposia, tel: 970-262-1230, fax: 970/262-1525.

AACR Conference: Angiogenesis and Cancer—Jan 24-28, Orlando, FL. Contact AACR, tel: 215/440-9300, fax: 215/440-9313.

T Lymphocyte Activation, Differentiation, and Death— Jan. 26-Feb. 1, Keystone, CO. Contact Keystone Symposia, tel: 970-262-1230, fax: 970/262-1525.

Integrating Complementary Therapies for Cancer Care—Jan 29-20, Atlanta, GA. Contact CambridgeHealth Resources, tel: 617/630-1330.

February

International Congress on Anti-Cancer Treatment—Feb 3-6, Paris. Contact Edith Ben Brahim, Service d'Oncologie Médicale Pitié-Salpêtrière, tel: (33-1) 42 16 04 76, fax (33-1) 42 16 04 77, email: edith.benbrahim@psl.ap-hop-paris.fr.

Clinical Hematology and Oncology: 1998—Feb. 16-19, La Jolla, CA. Contact Laurie REgis, Scripps Clinic, tel: 619/554-8556, fax 619/554-6310.

AACR Conference: Innovative Molecular Biology Approaches to the Prevention, Diagnosis, and Therapy of Cancer—Feb. 16-19, Maui. Contact AACR, tel: 215/440-9300, fax: 215/440-9313.

Advances in Oncology Nursing—Feb. 20-21, Houston, TX. Contact Office of Conference Services, M.D. Anderson Cancer Center, tel: 713/792-2222, fax: 713/794-1742, email: meetings@utmdacc.uth.tmc.edu.

Breast and Prostate Cancer—**Feb. 21-26, Copper Mountain, CO. Contact Keystone Symposia, tel: 970/262-1230, fax: 970/262-1525.**

Motility and Metastasis—Feb. 21-26, Copper Mountain, CO. Contact Keystone Symposia, tel: 970/262-1230, fax: 970/262-1525.

Adjuvant Therapy of Primary Breast Cancer—Feb. 25-28, St. Gallen, Switzerland. Contact Beatrice Nair, Haus 09, Kantonsspital, CH-9007, St. Gallen, Switzerland, fax: 41-71-245-6805, email: mccs@ms1.kssg.ch.

15th Annual International Breast Cancer Conference—Feb. 26-28, Orlando, FL. Contact Lois Osman, Miami Cancer Conference Inc., tel: 305/447-3804.

Joint Cancer Conference of the Florida Universities—Feb. 26-28, Orlando, FL. Contact Continuing Education Office, University of South Florida, tel: 813/974-4296 or 800/852-5362, fax: 813/974-3217.

March

National Comprehensive Cancer Network Third Annual Conference: Practice Guidelines and Outcomes Data in Oncology—March 1-4, Fort Lauderdale. Contact NCCN Conference, c/o PRR Inc., tel: 516/424-8900 x300.

International Symposium on Drug Resistance in Leukemia and Lymphoma—March 4-7, Amsterdam. Contact VU Conference Service, De Boelelaan 1105, 1081 HV Amsterdam, The Netherlands, tel: 31-20-444-5790, fax: 31-20-444-5825.

Supportive Care in Cancer 10th International Symposium —March 14-17, San Antonio. Contact conference secretary, Imedex USA, tel: 770/751-7332, fax: 770/751-7334, email: imedex@aol.com.

Breast Cancer, Sexuality, Intimacy, and Communication—March 21, San Francisco. Contact Pamela Priest Naeve, Northern California Cancer Center, tel: 510/429-2500, fax: 510/429-2550.

American Association for Cancer Research Annual Meeting—March 28-April 1, New Orleans. Contact AACR, tel: 215/440-9300, fax: 215/440-9313.

Diagnosis of Lymphoproliferative Disorders—March 30-April 3, Maui. Contact Laurie Regis, Scripps Clinic, tel: 619/554-8556, fax: 619/554-6310.

April

The Nuclear Matrix: Involvement in Genomic Organization, Function, and Regulation—April 4-9, Copper Mountain, CO. Contact Keystone Symposia, tel: 970/262-1230, fax: 970/262-1525.

May

American Radium Society Annual Meeting—May 2-6, Monte Carlo. Contact ARS, tel: 215/574-3158, fax: 215/923-1737, email: ars@acr.org.

American Brachytherapy Society Annual Meeting—May 30-June 4, Albuquerque, NM. Contact ABS, tel: 215/574-3158, fax: 215.923-1737, email: abs@acr.org.

American Society for Clinical Oncology Annual Meeting—May 16-19, Los Angeles. Contact ASCO, Dept. of Science and Education, tel: 703/299-0150.

June

11th Mediterranean Congress of Chemotherapy—June 7-12, Jerusalem. Contact Kenes, PO Box 50006, Tel Aviv 61500, Israel.

NCI-EORTC Symposium on New Drugs in Cancer Therapy—June 16-19, Amsterdam, The Netherlands. Contact EORTC, PO Box 7057, 1007, MB Amsterdam, The Netherlands, tel: 31-20-4442768, fax: 31-20-4442699, email: nddo@euronet.nl.

August

17th International Cancer Congress—Aug. 24-28, Rio de Janeiro. Contact Congrex do Brasil,

Av. Presidento Wilson, 164/9 andar, 20030-020, Rio de Janeiro, RJ-Brasil, tel: +55 21 509-4080, fax: +55 21 509-1492, email: congrex@ax.apc.org.

NCI Contract Awards

Title: Support and Management of the Project, "Effects of the Chernobyl Accident on Thyroid Cancer and Leukemia/Lymphoma." Contractor: The Trustees of Columbia University in the City of New York, New York, NY, $3,579,703.

Title: Facility for Preparing and Housing Virus Infected Mice, Genetically Manipulated Mice and Chimeric Mice. Contractor: Bioqual Inc., Rockville, MD, $744,748.

Title: Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trail Expansion for Minority Enrollment. Contractor: University of Alabama at Birmingham, Division of Preventive Medicine, Birmingham, AL, $7,680,568.

CRADA Opportunity:

NCI Seeks CRADA Partners To Develop Targeted Drugs

NCI has issued a call for Cooperative Research and Development Agreements with pharmaceutical or biotechnology companies or academic institutions to create and test new targeted drugs as therapeutics for cancer.

NCI is seeking collaborators to create, optimize and evaluate clinically "a variety of novel targeted drugs defined as a conjugated molecule consisting of a specific binding moiety, such as a monoclonal antibody, a receptor ligand or a similar construct, and a natural product or synthetic cytotoxic moiety which may include, but not be limited to the broad category of toxins and drugs," according to a notice in the Sept. 10 Federal Register.

"NCI can provide a variety of natural product cytotoxic drugs either in the unaltered state or chemically-modified (to facilitate conjugation) as starting substances for the creation of new targeted drug agents," the notice said. "In addition, a limited number of monoclonal antibodies which can be used in this drug development effort are available from the NCI. The NCI can also provide the chemical expertise to modify agents, as well as the resources to test newly constructed agents in an in vitro cell line screen.

"The successful CRADA collaborator will provide expertise and experience in the preparation of targeted drugs, and will prepare one or more targeted drug candidates using starting substances provided jointly by the NCI and the CRADA collaborator. For targeted drug candidates selected for clinical trials, the collaborator will also provide the necessary resources and expertise to perform tests to determine the drug candidate's physicochemical makeup, biological activity, stability and other characteristics necessary for filing an Investigational New Drug application with FDA. NCI will provide starting substances as well as consultation and expertise on drug preparation and development. Also, the NCI may elect to provide resources for preclinical and/or clinical evaluation, subject to future review and approval."

Inquiries: Thomas Stackhouse, Office of Technology Development, NCI-Frederick Cancer Research and Development Center, PO Box B, Frederick, MD 21702-1201, tel: 301/846-5465, fax: 301/846-6820.

ORI Rules St. Jude Researcher Falsified Authorship Of Papers

The HHS Office of Research Integrity has made a final finding of scientific misconduct in the following case:

—David Shapiro, St. Jude Children's Research Hospital: Based upon a report from St. Jude Children's Research Hospital as well as information obtained by ORI during its oversight review, ORI found that Shapiro, former faculty member, St. Jude Children's Research Hospital, engaged in scientific misconduct by falsifying the authorship of five publications listed in his biographical sketches in several NIH grant applications, including applications submitted to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of General Medical Sciences, the National Institute of Diabetes and Digestive and Kidney Diseases, and the National Cancer Institute.

Shapiro entered into an agreement with ORI in which he agreed to exclude himself from serving in any advisory capacity to the Public Health Service for three years; from contracting or subcontracting with the U.S. government and from involvement in, nonprocurement transactions for a period of two years. Any institution that submits an application for PHS support for a research project on which Shapiro's participation is proposed must submit a plan for supervision of his duties, ORI said.