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Judge Rules First Amendment Protects Distribution Of Off-Label Use Information

FDA will not restrict the dissemination of peer reviewed materials on the use of drugs for off-label indications.

And that's how it shall remain—at least for the next three months.

A federal judge July 30 ruled that the First Amendment protection applies to the content of continuing medical education programs as well as to the distribution of reprints from textbooks or peer reviewed journals.

However, critics of FDA policies have only a limited cause for celebration. The ruling by Judge Royce Lamberth of the U.S. District Court for the District of Columbia applies, in part, to a 1996 agency

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In Brief:

Arkansas, Iowa Appoint Center Directors; Broder Moves To Gene Sequencing Venture

BART BARLOGIE has been appointed director of the Arkansas Cancer Research Center. Barlogie, who has been director of research, replaces Kent Westbrook, who with James Suen founded the center 14 years ago. Harry Ward, chancellor of the Univ. of Arkansas for Medical Sciences, announced the appointment. Westbrook will continue as a special advisor to the ACRC Foundation board and as professor of surgical oncology. . . . **GEORGE WEINER**, associate professor in the Dept. of Internal Medicine, has been named interim director of the Univ. of Iowa Cancer Center. He steps in for Robert Wallace who has resigned. Weiner had served as deputy director of the center for the past two years. . . . ***SAMUEL BRODER***, former senior vice president, research and development, for IVX Bioscience Inc., of Miami, has moved to **Celera Genomics Corp.**, the Rockville, MD, joint venture between Perkin-Elmer Corp. and The Institute for Genomic Research. The company is headed by **J. Craig Venter**, who earlier this year announced the joint venture's plans to sequence the human genome in three years. Broder's position is "executive vice president for medical stuff," Broder said to **The Cancer Letter**. "I will be doing a range of things. We are just beginning to build a group." . . . **SUBIR NAG** has been installed as president of the American Brachytherapy Society. Nag is chief of brachytherapy and professor of clinical radiology at the Comprehensive Cancer Center/Arthur G. James

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Off-Label Drug Use Information Ruled "Commercial Speech"

(Continued from page 1)

guidance document that will be superceded by the FDA Modernization Act no later than Nov. 21.

"Judge Lamberth's decision is important, because it makes clear something FDA wasn't ready to accept before, and that is that the agency is fully subject to First Amendment limits," said Richard Samp, chief counsel of the Washington Legal Foundation, a public interest law and policy center that brought the suit against FDA four years ago.

WLF filed the suit on behalf of physician supporters who claimed that they were denied access to peer-reviewed materials distributed by pharmaceutical companies. The suit is especially relevant to oncology, a specialty where off-label use of drugs is frequent.

In the past, pharmaceutical companies sought to distribute reprints of articles from peer-reviewed oncology journals, chapters from widely accepted textbooks, or even entire textbooks to oncologists, but were stopped by FDA from doing so. FDA has also restricted the content of some continuing medical education programs.

Throughout this long-running controversy, the agency's policy of restricting such flow of information has been opposed by oncology professional societies, several patient groups, and pharmaceutical companies.

The Lamberth ruling, a summary judgment, clearly comes down on the side of the agency's critics on this issue. The ruling rejected the agency's argument that its 1996 Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data as well as an earlier guidance document on continuing medical education regulate "conduct" rather than "speech," and classified distribution of peer-reviewed materials by drug companies as "commercial speech," which is protected under the Constitution.

"Commercial speech" differs from academic speech in that under some circumstances it can be restricted by the government to protect consumers from misleading and deceptive sales practices. However, in the case of the FDA guidance documents on reprints and CME, the government did not satisfy the criteria for limiting "commercial speech" on the part of drug companies.

Ironically, Lamberth's ruling strikes down a document that spells out policies that are nearly defunct. In November, these policies will be superceded by FDAMA, a law that aims to expand the number of labeled indications.

Under FDAMA, manufacturers will be allowed to distribute information on off-label uses of drugs to physicians. However, these sponsors would then have to submit supplemental applications for these uses of the drugs or promise to file an application within six months of dissemination of information. Since FDAMA does not cover CME, the ruling is likely to remain in effect in that area of exchange of information on off-label use of drugs.

Will Lamberth's First Amendment ruling be used to ram through the walls of FDAMA?

It appears that the answer is yes. Sources said that later this week, FDA is expected to file a motion arguing that the ruling should be amended to state that it would not apply to FDAMA. This motion is expected to be countered by the WLF.

"The decision clearly will survive the effective date of FDAMA because the decision is based on the Constitution, and federal laws are trumped by the Constitution," Samp said to **The Cancer Letter**. "If FDA takes any enforcement action that contradicts the ruling, I will move to hold them in contempt of court."

In oncology, the implementation of FDAMA is expected to produce a tidal wave of Supplemental New Drug Applications. Still, some uses of drugs

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Founded Dec. 21, 1973 by Jerry D. Boyd

would not get on the label simply because the cost of seeking approval would not be recovered through sales, industry observers say.

The Law Until Nov. 21

Lamberth's ruling bans the agency from enforcing its policies on reprints and CME. Thus, at least for the next three months, FDA will be prohibited from:

—Limiting dissemination or redistribution to physicians or other medical professionals of any "article concerning prescription drugs or medical devices previously published in a bona fide peer-reviewed journal, regardless of whether such article includes a significant or exclusive focus on uses of drugs or medical devices other than those approved by FDA and regardless of whether such article reports the original FDA study on which FDA approval of the drug or device in question was based."

—Limiting dissemination or redistribution to physicians or other medical professionals of any "reference textbook (including any medical textbook or compendium) or any portion thereof published by a bona fide independent publisher and otherwise generally available for sale in bookstores or other distribution channels where similar books are normally available, regardless of whether such reference textbook or portion thereof includes a significant or exclusive focus on uses of drugs or medical devices other than those approved by FDA."

—"Suggesting content or speakers to an independent program provider in connection with a continuing medical education seminar or other symposium, regardless of whether uses of drugs and medical devices other than those approved by FDA are to be discussed." CME is not covered by *FDAMA*.

The ruling defines a "bona fide peer-reviewed journal" as a "journal that uses experts to objectively review and select, reject, or provide comments about proposed articles." Reviewers should be independent from the journal and should have a demonstrated expertise in the subject of the article.

A "bona fide independent publisher" is defined as a publisher that has "no common ownership or other corporate affiliation with a pharmaceutical or medical device manufacturer and whose principal business is the publication and distribution of books through normal distribution channels."

To be protected, a CME program provider should be independent from a pharmaceutical manufacturer, and should be accredited by organizations pertinent to the subject covered by the seminars.

Protected "Commercial Speech"

The WLF suit argued that FDA's 1996 regulations violate scientific and academic speech, which is subject to the highest level of Constitutional protection.

Countering the plaintiff's claims, FDA said it is using it broad powers to regulate "conduct" rather than speech, and that at the most its guidance documents are intended to regulate "commercial speech," which is not entitled to the same level of Constitutional protection as scientific and academic self-expression.

Lamberth rejected the FDA contention that the agency is regulating conduct rather than speech, but agreed that distribution of peer-reviewed materials constituted "commercial speech," which can be subject of government restriction.

The judge pointed out that distribution of materials on off-label use of drugs can have adverse consequences. Since drug companies are likely to disseminate only materials that support off label use of their drugs, "physicians could be led to believe that a certain drug is safe and effective because a manufacturer has found, and aggressively promoted, 'the one' article that supports use of their drug, even if there exists considerable evidence to the contrary," the ruling states.

However, even as "commercial speech," dissemination of information on off-label use of drugs is subject to constitutional protection, the judge ruled. The FDA guidance documents did not meet

The Cancer Letter Takes Annual Publication Break

The Cancer Letter will take its annual summer publication break for the next two weeks. The next issue, Vol. 24 No. 33, will have the publication date of Sept. 4.

The editorial office will be closed Aug. 17-21. The customer service office, at 800-513-7042, remains open.

The Cancer Letter is published weekly, 48 times a year, with publication breaks generally scheduled for the last two weeks of August and December.

the criteria for legitimately limiting commercial speech because the restrictions it spelled out were "considerably more extensive then necessary to further the substantial government interest in encouraging manufacturers to get new uses on-label," the ruling states.

It would be less burdensome to obligate the drug sponsors to make a full disclosure of the fact that indications covered in peer-reviewed materials are not on the drug's label, Lamberth wrote.

"This determination is based in large part upon the fact that there exist less-burdensome alternatives to this restriction on commercial speech," the ruling states. "The most obvious alternative is full, complete, and unambiguous disclosure by the manufacturer. Full disclosure not only addresses all of the concerns advanced by FDA, but it addresses them more effectively. It is less restrictive on speech, while at the same time deals more precisely with concerns of FDA and Congress."

Manufacturers would still have incentives to get more indications on the label, the judge wrote. Sponsors would need full approval of an indication before they are allowed to distribute internally produced marketing materials, initiate person-to-person contact with physicians, become involved in seminars, or market directly to consumers.

"The fact that these adequate incentives still exist to get off-label treatments on-label is central to this court's finding that the First Amendment is violated by the Guideline Documents," the ruling states. "Were manufacturers permitted to engage in all forms of marketing off-label treatments, a different result might be compelled."

Also, the judge noted that in some cases, off-label indications constitute the most effective treatment available.

"Through the government's well-intentioned efforts to prevent misleading information from being communicated, a great deal of truthful information will also be embargoed," the ruling states. "In this case, the truthful information may be life-saving information, or information that makes life with a debilitating condition more comfortable."

The FDAMA Drama

WLF last month laid out its emerging challenge of FDAMA regulations that cover off-label use of drugs.

FDAMA allows for exemptions to be granted in cases where a sponsor finds it "economically prohibitive... to incur costs necessary for the submission of a SNDA" or when it's unethical to conduct studies necessary for an SNDA.

Specifically, WLF is prepared to challenge the FDA proposed regulations for granting exemptions under FDAMA. In recently published rules for implementation of the law, FDA said exemptions from the SNDA filing requirement would be "rare."

Excerpted text of the WLF comment on proposed regulation follows:

"WLF is particularly alarmed by FDA's repeated statements in its notice of proposed rule that such exemptions will 'rarely' be granted.... The word 'rare' appears nowhere [in the FDAMA legislative language], nor can any such congressional intent be discerned from the statutory language.

"While FDA may be aware of some secret congressional intent to which WLF is not privy, WLF respectfully suggests that FDA—in discerning congressional intent—ought to be guided by what Congress wrote in its statute. Moreover, it is implausible that Congress would have gone to the trouble of creating an exemption from the 'supplemental application' requirement if it did not believe that the need for an exemption would arise in a fair number of circumstances.

"WLF also believes that FDA has departed from congressional intent in its definition of what constitutes 'economically prohibitive' circumstances.

"The proposed regulations state that a manufacturer seeking an exemption must 'at a minimum' provide evidence 'demonstrating that the estimated cost of the studies needed for the approval and the new use would exceed the estimated total revenue from the drug or device less the cost of goods sold, and marketing, and administrative expenses attributable to the product.'

"Under that definition, manufacturers would almost never be able to demonstrate 'economically prohibitive' circumstances. If the 'estimated total revenue from the drug or device'—including revenue already being derived from on-label uses—is to be taken into account, then the costs of needed studies are highly unlikely to exceed a manufacturer's expected profit.

"Yet no economically rational manufacturer will go to the expense of undertaking the studies necessary to supple a supplemental application unless it is likely to recoup those costs through increased sales directly attributable to the new use. A course

of action is 'economically prohibitive' whenever it inevitably will result in a net loss, not simply in those circumstances in which the action will drive a company into bankruptcy.

"FDA's interpretation of `economically prohibitive' is unfaithful not only to the statutory language, but also to the purposes underlying FDAMA. Congress was concerned that truthful information regarding off-label uses was not reaching doctors because manufacturers were prohibited from disseminating that information, yet lacked the economic incentive to seek the supplemental approval necessary to permit such dissemination.

"FDA's crabbed definition of 'economically prohibitive' would mean that doctors would continue to be denied access to valuable information about off-label uses of approved products—because no manufacturer will incur the expenses associated with a supplemental application unless it has reason to believe that it will generate a net profit thereby."

In Congress:

Senate Passes Bill For DOD Medical Research Funding

The Senate has passed an appropriations bill for the Dept. of Defense that would provide $250 million as a lump sum for medical research.

The bill includes language that, at a minimum, would provide $40 million for peer reviewed prostate cancer research and $135 million for breast cancer research.

The bill is expected to go to a conference committee next month, where it will be reconciled with the House bill for DOD appropriations. The House bill would provide $10 million for prostate cancer research, $135 million for breast cancer research, and $25 million for a breast cancer treatment program for military personnel.

Congress is on recess until the first week of September.

"We're not pleased with where we are," Jay Hedlund, president of the National Prostate Cancer Coalition, said to **The Cancer Letter**. "The DOD prostate cancer research program has been at a startup level for two years. Our position is that we need to get $60 million of peer review money just to maintain the program at the current level, or else the program will be constricting and send a terrible message to the research community."

In The States:

Georgia Requires Coverage Of Routine Care For Children

A Georgia law that requires insurance coverage of routine medical costs such as doctor visits, blood tests and x-rays when children diagnosed with cancer are treated on phase II and phase III clinical trials became effective July 1.

The law is not expected to increase healthcare costs. The law does not ask health plans to pay for experimental drugs or the administrative costs of managing a study.

Called "Callaway's Law" in memory of a Georgia boy who died of leukemia 20 years ago, the new law is part of a growing trend among states requiring health plans to offer cancer patients access to research therapies through coverage of clinical trials.

Rhode Island has had a law for all cancer patients since 1991; Maryland passed a comprehensive law for all patients, all phases of trials this year, effective in January 1999 (**The Cancer Letter**, July 3).

Other states, such as Colorado and New York, have proposed similar bills.

The Georgia bill was brought to the legislature in January by members of CURE Childhood Cancer, a 23-year-old Atlanta-based non-profit group that funds laboratory research and patient/family support program.

• • •

The Maryland legislature has passed a bill that provides payment by the state for breast cancer screening, diagnosis and treatment for low income women.

The bill, whose chief sponsor was Delegate Shirley Nathan-Pulliam, will provide payment for those services for women whose family income is less than 250 percent of the proverty level. That will include this year those whose income is $40,000 a year or less.

The bill was approved unanimously. The budget for the first year is $2.6 million.

The new law requires the Dept. of Health and Mental Hygiene to establish a breast cancer program to provide screening mammograms and clinical breast examinations to specified low income women age 40-49 on at least a biennial basis and for women age 50 years and older on an annual basis.

The law also requires payment for diagnosis and

treatment for individuals who are identified as being in need.

The program will be available only to women who meet the income requirements and who either are uninsured or whose insurance does not cover breast examinations and mammography screening.

Claudia Baquet, associate dean for policy and planning of the Univ. of Maryland School of Medicine, led the effort to get the measure enacted into law. She formerly was associate director of the NCI Division of Cancer Prevention & Control and head of the Cancer Control Science Program.

HHS News:

Shalala To Form Committee To Advise On Genetic Testing

Health and Human Services Secretary Donna Shalala has announced that HHS will create an Advisory Committee on Genetic Testing to help the epartment formulate policies on the development, validation and regulationof genetic tests.

The committee will focus especially on tests measuring DNA.

"Researchers continue to develop new and exciting genetic tests that can help us treat and prevent disease," Shalala said in an Aug. 7 statement. "However, we need to ensure that test results are accurate and medically valid and that this information remains confidential. This new advisory commission creates the mechanism that will help us make sure that patients are protected throughout the process."

The decision to establish the committee was in response to the recommendation of two advisory groups commissioned for the Human Genome Project by NIH and the Department of Energy: the Task Force on Genetic Testing and the Joint NIH/DOE Committee to Evaluate the Ethical, Legal, and Social Implications Program of the Human Genome Project.

The committee will address Department-wide policy issues raised by genetic testing, HHS said. It will have overlapping membership with the Clinical Laboratory Improvement Advisory Committee and the Medical Devices Advisory Committee. The committee's recommendations will be submitted to the Secretary through the Assistant Secretary for Health, who also will be responsible for coordinating common agenda issues among the three advisory committees. Committee members are to be appointed by the end of the year, HHS said.

Cancer Meetings Scheduled

September

Colon Cancer Prevention: Dietary Modulation of Cellular and Molecular Mechanisms—Sept. 3-4, Washington, DC. Contact American Institute for Cancer Research, tel: 800/843-8114, email: research@aicr.org, website: www.aicr.org.

Sentinel Lymph Node Mapping in Breast Cancer and Melanoma—Sept. 10-11 and Dec. 10-11, Fox Chase Cancer Center, Philadelphia. Contact Kathy Smith, FCCC, 7701 Burholme Ave., Philadelphia 19111, phone 215-728-5358, fax 215-214-8908.

3rd International Symposium on In Utero Stem Cell Transplantation and Gene Therapy—Sept. 11-14, Portland, OR. Contact Kimberly Higgins, DVA Medical Center (151B), 1000 Locust St., Reno, NV 89520, phone 702-328-1232.

Cancer Genetics: Understanding the Role of Genes in Cancer—Sept. 14-15, Washington DC. Contact Cambridge Healthtech Institute, 1037 Chestnut St., Newton Upper Falls, MA 02464, phone 617-630-1300, fax 617-630-1325.

New Cancer Strategies—Sept. 14-15, Washington DC. Contact Cambridge Healthtech Institute, address and phone above.

Association of Community Cancer Centers 15th National Oncology Economics Conference—Sept. 16-19, Seattle. Contact ACCC, David Walls, 301/984-9496.

4th Annual Jaffar Oncology Conference: Strategies for Cure: Breast Cancer—Sept. 18, Dearborn, Michigan. Contact Gayle Blakely, Providence Hospital Cancer Center, 22301 Foster Winter Dr., Southfield, MI 48075, phone 248/424-3183, fax 248/424-2919.

State of the Art Management of Pancreatic Carcinoma—Sept. 18, Chicago. Contact Denise Marshall, Education Coordinating, Lurie Cancer Center, Northwestern Univ., phone 312-908-5258, fax 312-908-1372, Email d-marshall4@nwu.edu.

Cellular Targets of Viral Carcinogenesis—Sept. 24-28, Dana Point, CA. Contact Special Conference Registration, AACR, Public Ledger Bldg, Suite 826, 150 S. Independence Mall West, Philadelphia 19106-3483, phone 215/440-9300, fax 215/440-9313.

Tumor Suppressor Genes—Sept. 26-30, Victoria, Canada. Contact AACR, 215/440-9300, fax: 215/440-9313.

European Breast Cancer Conference—Sept. 29-Oct. 3, Florence, Italy. Contact FECS Conference Unit, Avenue E. Mounier 83, B-1200 Brussels, Belgium, tel: 32 (2) 775-0206, fax: 32 (2) 775-0200.

October

International Society for Pediatric Oncology—Oct. 4-8, Yokohama, Japan. Contact Imedex, PO Box 3283, 5203 DG's-Hertogenbosch, Netherlands, fax: 31-

73-41-47-66.

President's Cancer Panel: Decision Making Based on *Quality* of Care—Oct. 6, Buffalo, NY. Contact Maureen Wilson, tel: 301/496-1148, fax: 301/402-1508, email: prescan@nih.gov.

Cancer Survivorship throughout the Lifespan—Oct. 8-10, Atlantic City, NJ. Contact Nancy Petrucci, tel: 212/366-6565, fax: 212/366-6581, email: npetrucci@pgi.com.

Gene Regulation and Cancer—Oct. 14-18, Hot Springs, VA. Contact AACR, Public Ledger Bldg. Suite 826, 150 S. Independence Mall West, Philadelphia 19106-3483, phone 215/440-9300, fax 215/440-9313.

Radioimmunodetection and Radioimmunotherapy of Cancer—Oct. 15-17, Belleville, NJ. Contact Lois Gillespie, Garden State Cancer Center, tel: 973/844-7000, fax: 973/844-7020, email: gscancer@worldnet.att.net.

Educational Forum on Lymphoma for Patients—Oct. 17-18, Houston. Contact Lymphoma Research Foundation of America, 8800 Venice Blvd. #207, Los Angeles 90034, phone 310-204-7040, fax 310-204-7043, Email LRFA@aol.com.

Southwest Oncology Group Clinical Trials Training Course and Group Meeting—Oct. 20-24, San Antonio, TX. Contact Kimberly Jacobs, tel: 210/677-8808.

Systematic Reviews: Evidence for Action—Oct. 22-26, Baltimore. 6th International Cochrane Colloquium. Contact Courtesy Associates, 2000 L St. NW Suite 710, Washington DC 20036, phone 202-973-8685, fax 202-331-0111, Email kgillesp@courtesyassoc.com.

Lung Cancer: News from the Cutting Edge—Oct. 23, Fox Chase Cancer Center. Contact Kathy Smith, FCCC, 7701 Burholme Ave., Philadelphia 19111, phone 215-728-5358, fax 215-214-8908.

American Society for Therapeutic Radiation and Oncology Annual Meeting—Oct. 25-28, Phoenix, AZ. Contact ASTRO, tel: 703/648-8900.

American College of Surgeons Clinical Congress—Oct. 25-30, Orlando, FL. Contact ACOS Communications Dept., tel: 312/664-4050 ext. 409.

November

American Association for Cancer Education 32nd Annual Meeting—Nov. 5-8, Portland, OR. First meeting with the International Network of Cancer Educators. Contact Virginia Krawiec, MPA, PO Box 601, Snellville, GA 30078-0601, phone 404-329-7612, fax 404-321-4669, Email gkrawiec@cancer.org.

Endogenous Sources of Mutations—Nov. 11-15, Fort Myers, FL. Contact AACR, phone 215/440-9300, fax 215/440-9313.

Chemotherapy Foundation Symposium: Innovative Cancer Therapy for Tomorrow—Nov. 11-13, New York. Contact Jaclyn Silverman, Box 1178, Mount Sinai School of Medicine, One Gustave Levy Place, New York, NY 10029, phone 212-241-6772, fax 212-996-5787.

Hereditary Predisposition to Common Cancers—Nov. 12-13, New York. Contact Jean Campbell, Memorial Sloan-Kettering Cancer Center, tel: 212/639-8961, fax: 212/717-3311.

Society for Neuro-Oncology Annual Meeting—Nov. 12-15, San Francisco. Contact Jan Esenwein, M.D. Anderson Cancer Center, tel: 713/745-2344, fax: 713-794-4999.

Cancer Prevention: Novel Nutrient and Pharmaceutical Developments—Nov. 13-14, New York. 3rd Stranag Cancer Prevention Center conference. Contact Jenifer Schmitz, Shandwick, phone 212-591-9756, Email jschmitz@shandwick.com.

President's Cancer Panel: Issues in Environmental Carcinogenesis—Nov. 17, Tucson, AZ. Contact Maureen Wilson, tel: 301/496-1148, fax: 301/402-1508, email: prescan@nih.gov.

Commission on Cancer 3rd Annual Conference—Nov. 18-19, Chicago. Contact Elaine Fulton, American College of Surgeons, 633 N. Saint Clair St., Chicago, IL 60611, phone 312/202-5401, e-mail efulton@facs.org.

State of the Knowledge Conference on Nurse Sensitive Outcomes—Nov. 20-22, Pittsburgh. Contact ONS, 501 Holiday Dr. Bldg #4, 3rd floor, Pittsburgh, PA 15220-2749.

December

New Research Approaches in the Prevention and Cure of Prostate Cancer—Dec. 2-6, Indian Wells, CA. Contact AACR, Public Ledger Bldg. Suite 826, 150 S. Independence Mall West, Philadelphia 19106-3843.

Sentinel Lymph Node Mapping in Breast Cancer and Melanoma—Dec. 10-11, Philadelphia. Contact Kathy Smith, phone 215-728-5358, fax 215-214-8908.

American Society for Cell Biology Annual Meeting—Dec. 12-16, San Francisco, CA. Contact ASCB, tel: 301-530-7153, fax: 301-530-7139, email: scbainfo@ascb.org.

Meetings In Early 1999

Joint Cancer Congress of the Florida Universities—Jan. 28-30, Walt Disney World. Contact Div. of CME, Univ. of Miami School of Medicine, PO Box 016960 (D23-3), Miami, FL 33101, phone 305-243-6716, or 1-800-U-OF-M, fax 305-243-5613.

9th International Congress on Anticancer Treatment—Feb. 2-5, Paris. Contact SOMPS, Prof. D. Khayat, Hopital de la Salpetriere, 47 Bd de l'Hopital, 75651 Paris Cedex 13, France.

Making a Difference, Optimizing Pharmacotherapy of the Oncology Patient—March 16-20, Orlando. Contact Kirk Berendes, phone 813-261-0062, Email kberendes@cortex-comm.com.

Funding Opportunities:

RFA available

RFA CA-98-018

Title: **Interdisciplinary studies in the genetic epidemiology of cancer**

Letter of Intent Receipt Date: Oct. 20, 1998

Application Receipt Date: Nov. 17, 1998

The NCI Epidemiology and Genetics Program, Div. of Cancer Control and Population Sciences, and the National Institute on Aging invite investigator initiated cooperative agreement applications for collaborative and interdisciplinary genetic epidemiology investigations designed to identify and evaluate the interactions of genetic and epidemiologic risk factors leading to cancer susceptibility in individuals, families and populations, and factors influencing the rate of increase with age in cancer susceptibility. The special feature of this RFA is to solicit the submission of multisite, cooperative research applications by multidisciplinary teams of investigators wishing to collaborate within the common theme of the genetic epidemiology of cancer.

Approximately $5 million per year in total costs for five years will be committed by NCI. The expected number of awards is three to four. NIA will commit up to $500,000 per year for five years in total costs for the support of research on aging relevant issues within funded projects.

Inquiries: Daniela Seminara, Div. of Cancer Control and Population Sciences, NCI, 6130 Executive Boulevard, Room 535, MSC 7395, Bethesda, MD 20892-7395, phone 301-496-9600, fax 301-402-4279, email ds79k@nih.gov.

Program Announcements

PA-98-094

Title: **Cerebral radiobiology and neuroimaging of brain tumors**

The National Institute of Neurological Disorders and Stroke and NCI invite applications for support of research that will increase knowledge of the genetic, molecular, cellular, and physiological mechanisms of radiation induced cell injury and recovery, and the sensitizing and protective mechanisms in the central nervous system under radiation treatment conditions for brain tumors.

The intent of this PA is to encourage investigator initiated applications to study tumor and normal brain cell injury and repair mechanisms induced by brain tumor radiotherapy including stereotactic radiosurgery procedures such as the gamma knife, altered fractionation and/or radioenhancing agents, using state of the art neurobiological and neuroimaging approaches.

Inquiries: Francis Mahoney, Div. of Cancer Treatment and Diagnosis, NCI, 6130 Executive Boulevard, Room 800, Rockville, MD 20852, phone 301-496-9360, fax 301-480-5785, email FM43q@NIH.GOV.

PA-98-095

Title: **Genetic regulation of susceptibility to tobacco related carcinogenesis**

The NCI Chemical and Physical Carcinogenesis and Genetics Branches, Div. Cancer Biology, and Div. of Cancer Control and Population Sciences, and the National Institute of Environmental Health Sciences invite investigator initiated grant applications for multidisciplinary research on genetic regulation of susceptibility to tobacco related carcinogenesis.

The goal of this initiative is to stimulate the investigation, at the basic experimental level, of the mechanism of differential genetic susceptibility to tobacco related carcinogenesis in the context of lung cancer and other tobacco related cancers.

Inquiries: Harold Seifried, Div. of Cancer Biology, NCI, 6006 Executive Boulevard, Room 220, Bethesda, MD 20892, phone 301-496-5471, fax 301-496-1040, Email hs41s@nih.gov; or Susan Nayfield, Div. of Cancer Control and Population Sciences, NCI, Executive Plaza North, Room 214, Rockville, MD 20892, phone 301-594-7344, fax 301-402-4079, Email sn15c@nih.gov.

PA-98-096

Title: **Therapeutic modulation of angiogenesis in disease**

Letter of Intent Receipt Dates: Oct. 15; June 15

Application Receipt Dates: Nov. 19; July 20

This PA reflects the interests of NCI, the National Heart, Lung, and Blood Institute, and the National Eye Institute to encourage the translation of basic knowledge of the angiogenic process into therapeutic applications. It may also promote new collaborations between basic and clinical scientists currently engaged in this area of research to design novel therapeutic approaches to disease. This PA is for new grant applications focusing on vascular biology in disease pathogenesis and treatment.

Inquiries: Colette Freeman, Div. of Cancer Biology, NCI, 6130 Executive Boulevard, Room 505, Bethesda, MD 20892-7385, phone 301-496-7028, fax 301-402-1037, email cf33a@nih.gov.

In Brief:

Doris Duke Awards Announced

(Continued from page 1)

Cancer Hospital and Research Institute. . . . **FIRST DORIS DUKE** clinical scientist awards have been announced. Fourteen scientists received $100,000 each for three years. Cancer research grants went to Howard Kaufman, Albert Einstein; Edmund Waller, Emory Univ.; James Brooks, Stanford; and Jennifer Griggs, Rochester School of Medicine. Other awards were in AIDS, cardiovascular disease, and sickle cell and other blood disorders.