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Taxol Patents Reveal Bristol Strategy To Safeguard Market Against Competitors

Bristol-Myers Squibb last week received a broad patent for the methods of administration of Taxol, the drug that may contribute nearly $1 billion to the company's revenues.

The issuance of the patent, which covers commonly used methods of infusion of the drug, revealed a key aspect of the company's unusual strategy for safeguarding its market share of the drug.

By obtaining patents, BMS will be able to make use of an FDA procedure that blocks the efforts by generic competitors to obtain FDA approval for marketing their versions of the drug for 30 months or until

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In Brief

HHS Names Deputy HCFA Administrator; M.D. Anderson's Error-Free Record Honored

NANCY-ANN MIN DEPARLE was named deputy administrator of the Health Care Financing Administration by HHS Secretary **Donna Shalala** this week. Her appointment is effective July 7. **President Clinton** said he intends to nominate DeParle to be administrator of HCFA following the resignation of **Bruce Vladeck** later this year. DeParle is associate director for health and personnel, Office of Management and Budget. . . . **BARBARA ANN KARMANOS CANCER INSTITUTE** received a $500,000 contribution from Comerica Inc., a Detroit-based bank holding company. The contribution will be paid over the next five years to the Institute's Cancer Care and Cure Campaign. . . . **M. D. ANDERSON CANCER CENTER** received an award for achieving error-free medication dispensing from Automated Healthcare Inc., a subsidiary of McKesson Health Systems. The center dispensed three million doses with zero errors over the past two years. The award was presented last week to **Roger Anderson**, head of the division of pharmacy at M.D. Anderson. . . . **CLINICAL TRIALS** being conducted at M. D. Anderson Cancer Center that are open for enrollment now are posted on the center's web site at www.mdanderson.org. The site lists over175 trials which can be viewed by cancer type, physician name, or treatment agent. Study summaries are also available on the site. . . . **GERALD DODD** was awarded the Mucio Athayde Cancer Prize by the International Union Against Cancer at their annual meeting in Vienna last week. Dodd received the award in recognition of his contributions to the development

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BMS Strategy Could Block Taxol Competitors For Years

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the claims are resolved. If Bristol's patents withstand court challenges, the company would be able to hamper the efforts of the generics for the 20-year duration of the patents.

The deployment of use patents is just one aspect of the BMS strategy. The others are:

—The use of the Orphan Drug Act to counter the efforts of companies filing New Drug Applications for their versions of Taxol (**The Cancer Letter**, April 18).

—The use of the Cooperative Research and Development Agreement with NCI to maintain a leadership position in research on the drug (**Cancer Economics**, December 1996).

While this unusual three-element strategy was apparently known to only a tight circle of top level BMS officials, the issuance of the patent revealed all of its interlocking aspects. Steven Tighe, first vice president at Merrill Lynch & Co., was the first to catch on to its significance.

"We do not believe that Taxol is as exposed as many may believe," Tighe wrote in a report dated June 24, the day BMS announced the issuance of the use patent and the day following the recommendation by the FDA Oncologic Drugs Advisory Committee that Taxol should be approved for the treatment of Kaposi's sarcoma.

"We believe generic competitors in particular stand a slim chance of getting a product on the market in the near term," Tighe wrote. "NDA filers are more likely to make it, but there may be some entry barriers that will not be easy to overcome."

Based on the issuance of the patent, Tighe raised the BMS rating from "accumulate" to "buy," and a lot of people did just that, leading to a one-day 11.5 percent jump in the value of BMS shares, to 85 3/16 on June 24. The shares settled at 81 3/16 on July 1.

"It's an unusual combination of protections," said Steven Lieberman, an attorney with the Washington law firm of Rothwell, Figg, Ernst & Kurz, who represents both generics and branded drug companies in patent issues. "I've seen people use two of the three in various combinations, but it's unusual to see all three combined at once.

"I would expect that companies out there which want to provide Taxol-based remedies would be looking carefully if there is a way to break the exclusivity that Bristol is seeking to maintain," Lieberman said.

As its strategy became apparent, BMS remained tight-lipped. "The improvements in the administration of Taxol in the treatment of cancer were discovered during the course of BMS-sponsored clinical trials," said Patrick Donohue, a company spokesman.

"It is chief among our responsibilities as a research-based company to plan and manage our entire product portfolio," Donohue said. "We cannot comment beyond that, except to point out that BMS believes it is very important that research on Taxol continue because the full potential of the drug has not yet been realized."

Bruce Ross, a former BMS executive who oversaw the development of Taxol, said he was unaware of the strategy the company used to protect its market share of the drug. "If the net result of all this is that Bristol would continue to pay for a lot of research on Taxol, then I think everybody wins," Ross said to **The Cancer Letter**.

Bruce Chabner, former director of the NCI Division of Cancer Treatment who oversaw the development of the drug by the Institute and later defended the cooperative agreement at congressional hearings, said he, too, was unaware of the development of the Bristol strategy.

"There is no way they could monitor practice, but it would be a major hindrance to other

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companies," said Chabner, chief of hematology and oncology and clinical director of the Massachusetts General Hospital Cancer Center. "Other companies would not be able advertise or promote their version of the drug."

According to a Merril Lynch estimate, Taxol generated $813 million in sales for BMS last year, and would generate $987 million in the current year.

The Use Patents

Taxol itself is not patentable. However, patents issued to Bristol or licensed by the company now claim infusions over the periods of three, six, 24 and 96 hours.

According to patent documents, the recent patent, No. 5,641,803, includes the following claims:

Claim 1: A method for reducing hematologic toxicity in a cancer patient undergoing Taxol treatment comprising parenterally administering to said patient an antineoplastically effective amount of about 135-175 mg/m^2 Taxol over a period of about three hours.

Claim 2: A method for reducing both hematologic toxicity and neurotoxicity in a cancer patient undergoing Taxol treatment comprising parenterally administering to said patient an antineoplastically effective amount of about 135 mg/m^2 Taxol over a period of about three hours.

Claim 3: The method of claim 2, wherein said patient is suffering from solid tumors or leukemias.

Claim 4: A method for reducing hematologic toxicity in patients suffering from ovarian cancer and undergoing Taxol treatment for such cancer comprising parenterally administering an antineoplastically effective amount of about 135-175 mg/m^2 Taxol over a period of about three hours.

Claim 5: A method for reducing both hematologic toxicity and neurotoxicity in a patient suffering from ovarian cancer and undergoing Taxol treatment comprising parenterally administering to said patient an antineoplastically effective amount of about 135 mg/m^2 Taxol over a duration of about three hours.

Claim 6: The method of claim 1, wherein said patient is suffering from solid tumors or leukemias.

Earlier this year, BMS obtained a related patent, No. 5,621,001. That patent, which attracted no attention either from the press or the financial community, made two claims:

*Claim 1***.** A method for reducing peripheral neurotoxicity symptoms in patients suffering from ovarian cancer and undergoing Taxol therapy comprising reducing peripheral neurotoxicity symptoms in said patients while maintaining an antitumor effect by administering about 135 mg/m^2 over a period of about 24 hours.

Claim 2. The method of claim 1 wherein the administration of Taxol is repeated at least once, about 21 days after the preceding administration.

Last year, BMS licensed three additional use patents from NCI. These include:

—Taxol treatment of breast cancer, which includes 96-hour infusion of the drug (No. 5,496,846).

—Treatment of Taxol side effects with G-CSF (No. 4,496,804).

—Combination therapy using signal transduction inhibitors with paclitaxel and other taxane analogs (No. 5,565,478).

The licensing of these patents, which was an element of the extension of the Taxol development CRADA, was estimated to bring the Institute $30 million in royalties, research support and patient enrollment costs.

Typically, CRADAs are extended annually.

Welcome To A Maze

While the financial community, FDA cognoscenti and aficionados of strategy are taking their hats off to Bristol, payers and more than a few physicians are wondering how soon they would be able to get a less expensive version of Taxol.

"If it's the best thing for a patient, I am going to use it," said Peter Eisenberg, an oncologist in Marin County, California.

"If I have an opportunity to save some money and still provide good care, that's what I am going to do," said Eisenberg, who operates a clinical training program for drug company officials and advises pharmaceutical companies including Rhone-Poulenc Rorer, the sponsor of the drug Taxotere.

It would be unwise to bet that a sales rep would soon show up in Eisenberg's office with an offer of a Taxol-like drug that costs less. The reason for that are the separate mazes BMS constructed for companies that would be filing Abbreviated New Drug Applications and companies taking the New Drug Application route to approval.

"[BMS] has created a multi-faceted maze that contains a number of one-way corridors and dead ends," Tighe wrote in the Merril Lynch report. "The question is whether the maze contains an exit.

"For generic filers, the answer may be no for a couple of years if [BMS} triggers patent litigation, or longer if [BMS] patents hold up in court. For NDA filers, it's too early to predict, due to lack of information."

If a generic company applies to produce its version of Taxol, it would have to demonstrate that its drug is identical to the pioneer drug and that it has identical labeling.

However, FDA would automatically put a 30-month hold on the application after ascertaining that potential patent infringement issues exist between the generic and the pioneer.

To proceed, the generic would have to challenge the BMS use and process patents in court, an undertaking that would be both expensive and risky. "If the [BMS patents] prove to be valid, we will not see generic Taxol for the life of the patents," Merrill Lynch analyst Tighe wrote.

Patent protection in the US extends for 20 years from the filing date.

Companies that file New Drug Applications would have to conduct their own clinical trials of the drug, a route taken by IVAX Corp. of Miami. IVAX has applied for an NDA for its version of paclitaxel for the treatment of Kaposi's sarcoma and is conducting trials in breast and ovarian cancers.

At least for now, BMS has beaten IVAX to the door at FDA, obtaining the ODAC recommendation for approval of Taxol for that indication. Whenever FDA grants full approval for the drug, it would automatically grant Taxol the Orphan Drug designation, which entails seven years of exclusivity for that indication.

No date has been set for the ODAC review of the IVAX KS indication.

Co-exclusivity under the Orphan Drug Act is possible in the cases where one sponsor is unable to supply sufficient quantities of the drug to meet the patients' need (an unlikely argument in the case of the BMS Taxol), or in case another sponsor's drug has a distinct molecular structure.

Assuming that IVAX or another player succeeds at obtaining FDA approval of an NDA, these competitors would still have to contend with the menace of the BMS use patents.

While competitors would be allowed to conduct head-to-head trials against Taxol for the purpose of getting FDA approval, using comparative data in marketing could constitute an infringement of the BMS use patents.

Thus, if the use patents hold up, a potential competitor may have to face the unenviable challenge of convincing physicians to switch from Taxol to another drug without the benefit of referring to comparative data.

And that--as far as the BMS maze-builders are concerned--is the catch.

Taxol Recommended For KS; ODAC Nixes 2 Other Drugs

An FDA advisory panel last week recommended marketing approval of Bristol-Myers Squibb's Taxol (paclitaxel) for the treatment of Kaposi's sarcoma.

The Oncologic Drugs Advisory Committee also recommended that the agency not provide marketing approval for Ilex Oncology's Zyrkamine (mitoguazone dihydrochloride) for non-Hodgkin's lymphoma and Janssen Pharmaceutica's Liazal (liarozole fumerate) for prostate cancer.

ODAC voted to recommend full FDA approval of Taxol for the secondary treatment of AIDS-related Kaposi's sarcoma patients.

"The data does present reliable evidence of efficacy," said Donald Abrams, director of the AIDS Activities Division at San Francisco General Hospital, who served as a consultant to FDA on the review. "I've never seen dramatic improvements like those shown."

Data From Two Phase II Trials Presented

BMS presented results from two phase II trials. The first was a study of 29 patients conducted at NCI, and the second was a study of 56 patients conducted at the University of Southern California and Harvard Medical School.

The studies showed response rates of 59% and 69%, with high efficacy in patents who received prior systemic therapy, anthracyclines, or who were resistant or intolerant to prior therapy. Of the 85 patients enrolled in the studies, 59 had received prior systemic therapy, and 38 had prior anthracyclines.

"Prolonged therapy with Taxol was tolerated in these immunosuppressed, heavily pretreated patients with advanced stage Kaposi's sarcoma," the company said in its presentation. "The safety profile was comparable to that of patients with previously treated carcinomas of the ovary and of the breast."

The company recommended a dosage of 135 mg/m^2 every three weeks.

FDA raised concerns over sample size, lack of

comparative arms, inadequate controls in follow-up, and lack of pharmacokinetic and drug interaction data.

FDA also questioned the recommended 135 mg/m^2 dosage, raising concerns over toxicity. Reports showed that 17% of the patients died within 30 days of beginning the Taxol regimen. BMS said the deaths can not be specifically linked to therapy.

ODAC voted to recommend full approval of the drug based on consistency of data and strong evidence of efficacy in tumor reduction.

Committee members who voted against recommending full approval said Taxol should go through FDA's accelerated approval, which would require a phase IV trial while the drug is being marketed.

Bristol said it has begun a phase III randomized trial in conjunction with the Eastern Cooperative Oncology Group to study the effects of Taxol in combination with protease inhibitors for the treatment of Kaposi's sarcoma, and a separate phase III trial of Taxol in combination with Sequus Pharmaceutical's Doxil (liposomal doxirubicin).

BMS was issued a patent last week for the infusion of paclitaxel in doses between 135 and 175 mg/m^2, for the treatment of breast and ovarian cancer.

Small Study Cited For Zyrkamine

Zyrkamine, a polyamine inhibitor indicated for AIDS-related NHL, was submitted to FDA by Ilex in October. Data submitted reported results from two phase II studies on 90 patients who had failed standard therapy or who relapsed after remission.

The committee voted unanimously against recommendation of Zyrkamine based on the small number of patients in the study, and the uncertain efficacy of the drug.

Liazal Not Proven, ODAC Says

Liazal, by Johnson & Johnson's subsidiary Janssen Pharmaceutica, was also voted against unanimously.

The company presented results from three trials of Liazal as a treatment for prostate cancer in patients who relapse after first-line therapy. The drug is an oral therapeutic to inhibit production of retinoic acid.

ODAC said the drug's efficacy was not proven in Janssen's presentation. The committee also said the studies showed Liazal to be inferior to Pharmacia & Upjohn's prednisone and Schering AG's cyproterone acetate.

Cancer Prevention

BCPT Completes Enrollment Of 13,000 After Five Years

The Breast Cancer Prevention Trial completed the enrollment of 13,000 women, five years after the trial began, NCI and the National Surgical Adjuvant Breast and Bowel Project said last week.

The 13,000th woman joined the study on May 20.

The study, the first large randomized trial to assess whether a five-year course of tamoxifen can prevent breast cancer in women at increased risk, should produce results within two to three years, NSABP said.

"Reaching this point in the study represents an achievement of unprecedented dimension," said NSABP Chairman Norman Wolmark. "Everyone recognizes that breast cancer is a major health problem for women, and the 13,000 women who have entered this trial are doing something positive and productive about it. The contribution they have made in the fight against this disease is immeasurable."

NSABP, an NCI-funded clinical trials cooperative group, was selected in a competition to coordinate the study.

"Reaching this milestone is a tremendous accomplishment for the oncology community," said Leslie Ford, associate director for early detection and community oncology and NCI coordinator for the study. "Finding a way to prevent breast cancer is one of the most important research questions we have to answer. Each and every woman who has chosen to participate has my gratitude for their trust and conviction in seeing this study through."

Recruitment began in April 1992, enrolling women aged 35 and over with a 1.7% risk of breast cancer in the next five years. Women over 60 were enrolled based on age alone.

NSABP originally estimated that 16,000 participants would be needed to achieve the statistical power required. Last September, the cooperative group said the participants, on average, had a much greater underlying risk of breast cancer than anticipated, and only 13,000 would be needed.

Breast cancer risk was evaluated based on the following factors: the number of first-degree relatives (mother, daughter, or sisters) diagnosed with breast cancer, age at first menstrual period, age at first childbirth, number of breast biopsies, and the presence of lobular carcinoma in situ.

The participants represent each of three age groups about equally: Ages 35 to 49, ages 50 to 59, and age 60 and older. About 4 percent of the women are from a racial or ethnic minority group.

Participants have been randomized to daily doses of 20 milligrams of either tamoxifen (Nolvadex) or placebo for five years. Doses will be administered for the full five years unless early beneficial or adverse results are reported. Participants who complete five years of therapy will be followed for at least two more years.

Participant Advisory Board

Participants in the study are represented by a 16-member Participant Advisory Board. "I'm thrilled that we've reached our accrual goal because now we can get down to the business of finding out if tamoxifen will prevent breast cancer," Rici Rutkoff, co-chairman of the board, said in an NCI statement June 23.

Sandi Kanicki, the other co-chairman, said the study sparked her interest in health issues. "Since joining the trial I have become a real advocate for women's health, which will carry on long after the study is over. My five-year commitment to the study has become a life-long commitment."

Researchers also are conducting smaller studies within BCPT to assess the action of tamoxifen on blood lipid levels and bone density.

Zeneca Pharmaceuticals, of Wilmington, DE, provides both the tamoxifen and placebo pills for the study without charge.

NCI Clarifies Receipt Dates For AIDS-Related P01s

In a statement in the NIH Guide to Grants and Contracts earlier this week, NCI said it advises potential applicants for Program Project Grants (P01s) for AIDS-related research that the receipt dates are the same as for all Program Project Grant applications: February 1, June 1, and October 1.

These application receipt dates allow time for a site visit, if needed, prior to the review by the appropriate chartered Scientific Review Group. All P01 applications submitted on these dates have the same review and award schedule.

Inquiries: Referral Officer, NCI Division of Extramural Activities, 6130 Executive Boulevard, Room 636A - MSC 7407, Bethesda, MD 20892, tel: 301/496-3428, email: friedbet@dea.nci.nih.gov.

Letter to the Editors:

ASSIST Can't Reach Goals With Fewer Funds, ACS Says

To the Editors:

We wish to make it clear that the American Cancer Society does not concur with the recommendation of the Cancer Prevention Program Review Group to reduce the investment in large scale demonstration projects such as ASSIST [**The Cancer Letter**, June 20 and June 27]. As the national partners in ASSIST, our commitment to this project and its appropriate funding is unwavering.

ASSIST is the largest and most comprehensive tobacco control project ever sponsored by the federal government, with an annual budget of about $25 million. Yet, the total annual budget of ASSIST is only about .02 percent of the $100 billion in direct health care services and lost productivity that tobacco use costs this country each year. If ASSIST achieves its objectives, it will reach 91 million people, stop two million youths from becoming addicted to tobacco products and prevent nearly 1.2 million premature deaths. It cannot achieve those objectives with less funding.

While we understand and concur with the need for more research on individual behavior, we do not believe such research should be carried out at the expense of programs that are already making a difference. The American Cancer Society strongly supports the National Cancer Institute in its decision to extend ASSIST for another fiscal year.

John Seffrin
Chief Executive Officer
American Cancer Society

M.D. Anderson Honors Oncology Nurse Hossan

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and introduction of mammography as a screening and diagnostic tool. He is the former head of the American College of Radiology Breast Cancer Task Force, and is affiliated with St. Luke's Episcopal Hospital in Houston. . . . **BETSEY HOSSAN**, an oncology nurse specialist at M.D. Anderson Cancer Center, will receive the 1997 Ethel Fleming Arceneaux Outstanding Nurse-Oncologist Award. The award is presented annually to an M.D. Anderson nurse who demonstrates superior performance in all aspects of oncology nursing.

Grants Funding

NCI Restores Grant Paylines To Last Year's Levels

NCI has raised the "paylines" for most grant categories by releasing funds held in reserve, Institute Director Richard Klausner said.

The payline is the percentile ranking above which grants are considered in the range for funding. The payline is determined by the amount of money in the Institute's research project grants budget.

Last year, NCI set the payline for traditional investigator-initiated grants (R01s) at the 23rd percentile. For the first part of this fiscal year, the Institute held the R01 payline to the 22nd percentile by keeping some funds in reserve. Paylines for other grants also were held to levels below last year.

NCI officials said the paylines were held down because of an unexpected increase in grant applications. Earlier this year, Klausner said the Institute would restore the paylines to last year's levels (**The Cancer Letter**, March 14).

At a meeting of the National Cancer Advisory Board June 17, Klausner said the paylines have been restored. NCI plans to spend more than $1 billion, or about 45 percent of its budget, on research project grants this fiscal year.

The table below lists the current paylines (noted as percentages) or priority scores for the major grant mechanisms. The priority scores for the March funding round for Cancer Center Support Grants and the Community Clinical Oncology Program will be determined after additional review results are available, NCI said.

AHCPR Funds 12 Centers To Review Medical Practice

The HHS Agency for Health Care Policy and Research has awarded 12 five-year contracts to institutions in the U.S. and Canada to serve as Evidence-based Practice Centers.

The centers will review all the relevant scientific literature on medical topics assigned to them by AHCPR, and conduct additional analyses when appropriate.

The findings will be produced as "evidence reports" or technology assessments, which AHCPR will disseminate widely through the World Wide Web and as printed documents. The reports will serve as the scientific foundation for public- and private-sector organizations to develop strategies for improving the quality of health care services they provide and pay for. Technology assessments produced by the EPCs will give health plans and payers information they need to make informed decisions about covering new and changing medical devices and procedures, HHS said.

The centers will study topics within broad areas such as adult health, child and adolescent health, maternal health, geriatrics, rehabilitation, dental health, mental health and substance abuse, alternative care, and preventive care. The first set of topics, nominated by public- and private-sector organizations in response to a solicitation published by AHCPR in November 1996, will be announced this summer, HHS said.

To bring the broadest range of experts into the development of evidence reports and health

Paylines/Priority Scores For NCI Grants

	June 1997	March 1997	June 1996	June 1995
Traditional R01	23%	22%	23%	15%
Program Project P01	140	135	140	140
FIRST R29	30%	27%	30%	27%
Cancer Centers P30	197 to 212	(to be determined)	175 to 250	180 to 250
Clinical Groups U10	200/225	200/225	200/225	200/225
NRSA				
Individual F32/F33	164	164	41.10%	41.60%
Institutional T32	150	150	152	154
CCOPS U10	222	(to be determined)	172	229

Source: NCI Extramural Financial Data Branch

technology assessment, the centers are encouraged to collaborate with other organizations. Following are the centers and the organizations with which they will collaborate:

—Blue Cross/Blue Shield Technical Evaluation Center, Chicago. Collaborators include: Kaiser Permanente and, through members of the TEC Medical Advisory Panel, American College of Physicians; University of Washington, Massachusetts Institute of Technology; Wisconsin School of Medicine; University of Pittsburgh; and Johns Hopkins University.

—Duke University, Durham, NC. Subcontractor Health Economics Research Inc., Waltham, MA.

—ECRI, Plymouth Meeting, PA. Collaborators include Leonard Davis Institute and Philadelphia School of Pharmacy and Science.

—Johns Hopkins University, Baltimore, MD. Collaborators include University of Maryland and the Baltimore Cochrane Center.

—McMaster University, Hamilton, Ontario, Canada. Collaborators include Canadian Cochrane Center and St. Joseph Hospital.

—MetaWorks Inc., Boston, MA. Collaborators include Leonard Davis Institute and Philadelphia VA Medical Center.

—New England Medical Center, Boston, MA. Collaborators include the San Francisco Cochrane Center, Blue Cross/Blue Shield of Massachusetts; and the Tufts Managed Care Institute.

—Oregon Health Sciences University, Portland, OR. Collaborators include Northwest Kaiser Permanente and Northwest VA Medical Center.

—RAND Corp., Santa Monica, CA. Collaborators include the University of California, Los Angeles; University of California, San Diego; University of Southern California; Cedars Sinai; Value Health Sciences; and VA Medical Centers.

—Research Triangle Institute and University of North Carolina at Chapel Hill, NC. Collaborators include: Morehouse Medical Treatment Effectiveness Center, Morehouse School of Medicine; Urban Health Institute, Harlem Hospital Center; and Harvard School of Public Health, Center for Quality of Care Research and Education.

—University of California, San Francisco and Stanford University. Collaborators include the San Francisco Cochrane Center; Kaiser Permanente; and VA Medical Centers in San Francisco, Palo Alto, and Menlo Park.

—University of Texas, San Antonio. Collaborators include the San Antonio and San Francisco Cochrane Centers and American College of Physicians.

Funding Opportunities

Program Announcement

PAR-97-071

Title: **Interdisciplinary Training in Genetic Epidemiology of Cancer**

Application Receipt Dates: Sept. 15, 1997; Jan. 15, May 15; Sept. 15, 1998

The purpose of this Program Announcement is to stimulate the development of a diversity of comprehensive research training programs in the genetic epidemiology of cancer. A major goal of these programs is to provide students, new investigators and established researchers interested in diverse aspects of the genetic epidemiology of cancer with new research skills and a breadth of expertise that encompasses the many disciplines now merging into this expanding field. Therefore, a wide spectrum of research training, career, and education grant mechanisms will be used to further the goals of this PA.

A previous basic research initiative and other efforts have stimulated the expansion of the research base which is necessary to support research training programs in genetic epidemiology. A second goal of this PA is to build on the developing research base by promoting the development of the inter- and intra-institutional infrastructures necessary for providing training in the genetic epidemiology of cancer that would be accessible to interested investigators at different stages of career development.

This PA is intended primarily to solicit new applications. However, because it is critical to increase the number of comprehensively trained researchers in this area, and because the proposed training milieu could benefit from the experience of an existing program, competing supplemental applications to existing institutional National Research Service Award (T32) training grants in cancer genetics or epidemiology are encouraged to apply in order to expand their programs.

Existing institutional NRSA programs focused on the genetic epidemiology of other diseases are encouraged to submit new applications if they would like to expand their programs to include the genetic epidemiology of cancer. Funds will be provided from the following three budgets: National Research Service Awards Program (T32, F32, F33); Careers Program (K07, K08); and the Cancer Education Program (R25).

Contact Vincent Cairoli, NCI Division of Cancer Treatment, Diagnosis, and Centers, 6130 Executive Boulevard, Room 520, MSC 7390, Bethesda, MD 20892-7390, tel: 301/496-8580, fax: 301/402-4472, email: vc14z@nih.gov.