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ETTER

## BMS Control Of Billion-Dollar Taxol Market Facing Court Challeges By Competitors

As Bristol-Myers Squibb generates about \$1 billion a year in sales of Taxol, competitors are launching new attacks on the fortifications that protect Bristol's control of the market for the drug.

The broadening of the drug's indications is giving competitors incentives to throw greater resources into the battle.

At this point, Bristol's control over the market for Taxol is facing challenges from two directions:

—A newcomer into the paclitaxel market, Mylan Pharmaceuticals (Continued to page 2)

#### In Brief:

THE

### Moffitt Cancer Center Awarded Core Grant; Biotech Industry Honors Jeffords, Bliley

H. LEE MOFFITT Cancer Center & Research Institute has been awarded a cancer center core grant by NCI. The center, at the Univ. of South Florida in Tampa, opened in 1986. John Ruckdeschel is the chief executive officer and director.... SEN. JAMES JEFFORDS, (R.-Vt.), and REP. TOM BLILEY, (R.-Va.) have been named "outstanding legislators of the year" by the Biotechnology Industry Organization. They were recognized for their efforts in passing the FDA Modernization Act.... ONCOLOGY NURSING SOCIETY awards presented at the society's annual congress this month: Kathi Mooney, professor of parentchild and adult nursing at the Univ. of Utah College of Nursing, received the ONS/Roche Laboratories distinguished service award. Frances Marcus Lewis, professor of family and child nursing at the Univ. of Washington School of Nursing, received the ONS/Bristol-Myers Squibb Oncology Div. distinguished researcher award. Harold Freeman, chairman of the President's Cancer Panel and director of the Dept. of Surgery at Harlem Hospital, received the ONS annual public service award. Phylip Pritchard, chief executive of the Federation of European Cancer Societies, received the first ONS international award for contributions to cancer care. . . . ROSWELL PARK Cancer Institute dedicated its new diagnostic and treatment center and 133 bed inpatient tower May 22. The facility is the centerpiece of the \$241.5 million modernization project at RPCI, the largest health related project ever undertaken by New York state. David Hohn is RPCI president and CEO. (Continued to page 8)

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## Competitors Challenge Bristol Control Of Taxol Market

### (Continued from page 1)

Inc. of Morgantown, WV, earlier this month mounted a court challenge to the validity of Bristol's use patents for Taxol. The claim was made in response to a patent infringement suit filed by BMS against Mylan in the US District Court for the District of New Jersey.

—Miami-based Baker Norton Pharmaceuticals last month filed a suit against FDA, seeking reversal of the agency's decision to keep the company's paclitaxel off the market for the next six years. Last December, Baker Norton, a subsidiary of IVAX Corp., received a "tentative" FDA approval to start marketing its paclitaxel for Kaposi's sarcoma after Aug. 4, 2004, following expiration of the BMS orphan drug exclusivity for the indication. That decision was "arbitrary, capricious, [and] contrary to law," the suit states.

Bristol's market exclusivity for Taxol expired in December 1996. While the active ingredient in Taxol was never patented, Bristol has accumulated patents for formulation of the drug and use patents for its administration. In the case of the Kaposi's sarcoma indication, Taxol is also protected by an orphan drug designation.

Steven Tighe, a senior analyst with Merrill Lynch who first described the Bristol strategy for



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Subscription \$275 per year US, \$295 elsewhere. ISSN 0096-3917. Published 48 times a year by The Cancer Letter Inc. Other than "fair use" as specified by U.S. copyright law, none of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, mechanical, photocopying, facsimile, or otherwise) without prior written permission of the publisher. Violators risk criminal penalties and \$100,000 damages. **Founded Dec. 21, 1973 by Jerry D. Boyd**  maintaining control of the market nearly a year ago, said the defenses erected by BMS are holding up (**The Cancer Letter**, July 4, 1997). "The execution of Bristol's patent defense has gone completely in accordance with our predictions, both in Europe and in the US," Tighe said.

#### The Mylan Claims

In its suit against BMS, Mylan claims that two Bristol patents covering the administration of Taxol (No. 5,641,803 and 5,670,537) are invalid and unenforceable. The '803 patent covers infusion of paclitaxel, and the '537 patent covers premedication.

The Mylan case is centered around a claim that BMS obtained the two patents despite the fact that the dosage and administration were disclosed in a 1989 paper that reported the results of a phase II trial of Taxol in refractory ovarian cancer. (William McGuire *et al*, "Taxol: A Unique Antineoplastic Agent With Significant Activity in Advanced Ovarian Epithelial Neoplasms," *Annals of Internal Medicine* 111(4):273-279.

According to Mylan's suit, BMS relied on the paper in its dealings with FDA, but did not acknowledge it in dealings with the U.S. Patent and Trademark Office. "Bristol did not inform the PTO about the prior public use and prior invention by Dr. McGuire, even though Bristol was relying on that work in support of both its... 24-hour infusion NDA and its... 3 hour infusion NDA," the complaint states.

The Mylan suit claims that the patents were obtained "through fraud on PTO," and that Bristol's efforts to keep competitors off the market constitute a violation of anti-trust laws. "With the specific intent to obtain monopoly power, Bristol has engaged in exclusionary, unfair and anticompetitive acts..., and has thereby achieved a dangerous probability of success that it will obtain a monopoly in the market for paclitaxel in the US," the complaint states.

Mylan is represented by the Washington law firm of Rothwell, Figg, Ernst & Kurz. [The law firm also represents **The Cancer Letter** in corporate matters unrelated to the pharmaceutical industry.]

### The IVAX Challenge

In its suit against FDA, IVAX claimed that the agency acted improperly when it declined to break Bristol's exclusivity for the KS indication under the Orphan Drug Act. The FDA regulations indicate that orphan drug exclusivity can be broken if one drug is materially different or more efficacious than another. The IVAX challenge rests on the definition of the word "drug." IVAX claims that the agency acted improperly when it determined that Paxene was essentially the same drug as Taxol. Since Taxol was protected by seven-year exclusivity under the Orphan Drug Act, the agency denied market clearance to Paxene.

The IVAX suit claims that a broader definition of "drug" should have been applied. The agency should have looked beyond the active ingredient and considered the entire finished product, which would include the drug's formulation.

"Because... human testing can be performed only with a finished product (and not merely an active ingredient), the market exclusivity and other relevant provisions of the Orphan Drug Act must be read as using the term `drug' to mean a finished drug product," the document states.

IVAX claims that its paclitaxel, Paxene, is "clinically superior" to Taxol for the following reasons:

—"Paxene has less severe side effects than Taxol, including a significantly reduced occurrence of severe arthralgia/myalgia.,

—"Paxene, unlike Taxol, is indicated for thirdline as well as second-line treatment of Kaposi's sarcoma; and,

—"The safety and efficacy of Paxene are not diminished when it is co-administered with protease inhibitors."

Taxol and Paxene were never compared in sideby-side trials. (**The Cancer Letter**, Sept. 26, 1997).

"The effect of FDA's decision is to grant a private pharmaceutical manufacturer, Bristol, a broad and highly lucrative monopoly on a naturallyoccurring and unpatentable compound, paclitaxel, which was developed and tested at taxpayers' expense," the complaint states.

#### Strain on Producers of Bulk Paclitaxel

The durability of Bristol's defenses has been bad news for NaPro Biotherapeutics Inc. and Hauser Pharmaceuticals Inc., two companies that provide bulk paclitaxel to pharmaceutical companies.

In recent months Hauser watched its European paclitaxel business evaporate as a Netherlands court revoked approval for Yewtaxan, a drug produced by Yew Tree Pharmaceuticals. On April 22, the District Court of Utrecht, Netherlands, ruled that the dossier submitted by Yew Tree did not meet the regulatory requirements since it relied on previously published data as opposed to original research.

Hauser's US client, Immunex Corp., is also tied up in litigation with Bristol. Typically, FDA allows at least 30 months for companies to resolve patent disputes. Immunex has the approval to market its generic paclitaxel in Canada.

Last month, IVAX parted ways with its supplier NaPro. The split left NaPro looking for another development partner while IVAX is working on finding another source of the bulk agent.

Thus, instead of enjoying a cash windfall that would have followed approval of the IVAX drug, NaPro has laid off about 40 percent of its employees, closed its manufacturing plant in British Columbia and stopped construction of a commercial scale manufacturing plant in Boulder, CO, the company said in its 10-K filing with the Securities and Exchange Commission.

NaPro said that its production of bulk paclitaxel has been geared to use in clinical trials and other research and development. "Accordingly, NaPro has generated only limited revenue from such activities and has incurred significant losses, including losses of approximately \$4.1 million, \$6.8 million and \$15.5 million for the years ended Dec.31, 1995, 1996 and 1997, respectively," the company said in its filing.

Under the agreement that ended the NaPro-IVAX partnership, IVAX received a royalty-free, limited, non-exclusive license to one of NaPro's pending patents, and NaPro received \$6 million in cash. NaPro will continue to supply bulk paclitaxel to IVAX for the next 12 months.

### Food & Drug Administration: FDA Oncology Division Director Delap Promoted

Robert Delap, director of the Food and Drug Administration Division of Oncology Drug Products, has been appointed deputy director in the agency's Office of Drug Evaluation V.

Delap was one of five FDA officials recently selected for deputy director positions in the Office of Drug Evaluation.

In his new position, Delap will be responsible for policy issues related to implementation of the Prescription Drug User Fee Act, as well as oversight and policy relating to three FDA divisions dealing with over-the-counter drugs, dermatologic and dental drugs, analgesics, anti-inflamatory drugs, and opthamalogic drugs. Delap was named director of the oncology in 1995. He joined FDA in 1993 as a medical officer in the division.

Robert Justice, deputy director of the oncology division since 1995, is serving as acting division director.

### <u>NIH AIDS Research:</u> Neal Nathanson Selected For Office Of AIDS Research

Neal Nathanson was appointed director of the NIH Office of AIDS Research, the Institutes said.

Nathanson, vice dean for research and research training at the University of Pennsylvania Medical Center, is an expert in viral pathogenesis and serves on the NIH AIDS Vaccine Research Committee.

"Dr. Nathanson brings a powerful scientific intellect, great compassion, and long administrative experience to the task of leading the NIH AIDS research program at this critical time," NIH Director Harold Varmus said. "He will have a central role in our continuing efforts to develop an effective vaccine, improve treatments for HIV disease, and prevent transmission of HIV."

The previous OAR director, William Paul, returned last November to the Laboratory of Immunology at the National Institute of Allergy and Infectious Diseases. Jack Whitescarver has been serving as OAR acting director.

The OAR, in the Office of the Director of NIH, is responsible for coordinating the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program.

OAR conducted the first comprehensive evaluation of the NIH AIDS research program. The final report, known as the "Levine Report," provided a blueprint for restructuring the program. In implementing a key recommendation of that report, the OAR has made HIV vaccine development a high priority, restructuring the program, and providing increased resources.

"The recruitment of Dr. Nathanson to serve as OAR director will further enhance our deep commitment to vaccine research," Varmus said.

Nathanson received BS and MD degrees from Harvard University. He received clinical training in internal medicine at the University of Chicago and postdoctoral training in virology at Johns Hopkins University. Nathanson spent two years at the Centers for Disease Control where he headed the Polio Surveillance Unit. Later he joined the faculty of the Johns Hopkins School of Hygiene and Public Health, where he became professor and head of the Division of Infectious Diseases in the Department of Epidemiology. He moved to the University of Pennsylvania Medical Center where he chaired the Department of Microbiology for 15 years, finally serving for two years as vice dean for research.

Nathanson is known for his contributions to the field of viral epidemiology as the author of the definitive papers on the epidemiology of polio.

## <u>Letter to the Editors:</u> Scientists, Media Should Not Overstate "Breakthroughs"

To the Editors:

The New York Times failed recently to live up to its motto "All the News That's Fit to Print" with a front-page story written by veteran science reporter Gina Kolata. The story hailed a breakthrough advance in the discovery of two normal human proteins called angiostatin and endostatin that cured cancer in mice and could, as the Times reported, "cure cancer in two years."

In the days that have followed since this story appeared, we have learned several interesting facts. First, that three of the scientists quoted, including Judah Folkman of Boston, the discoverer of these human proteins, feel they were misquoted or quoted out of context (however, the Times stands behind the story). Second, that EntreMed, the company developing the proteins as potential drugs, experienced a quadrupling of its stock within 24 hours of the Times story. Third, that Kolata signed, then later rescinded, a book deal on angiogenesis that might have brought her a hefty profit. As the author of a recently published book on Dolly, the cloned sheep, Kolata is no stranger to book deals. Understandably, cancer patients across the country were devastated to later learn that this "cure" would not be available for use for several more years.

While it is important for scientists and physicians conducting cancer research to share their findings with the public—as important as it is for the public to understand the science—this story created a cancer of its own. The New York Times failed miserably in determining what was fit to print in this field of biomedical research and how to present the information responsibly. Simply put, the story overstated and hyped the reality of this research and omitted important information.

Angiostatin and endostatin are members of a class of potential drugs that work by blocking tumorinduced angiogenesis, that is, the formation of a network of new blood vessels required for the nourishment and growth of a cancer. Without such angiogenesis, cancers cannot grow much larger than the head of a pin. The hypothesis being considered is that if we create drugs to block angiogenesis, the major threat of cancer could be eliminated. If this proves true, the disease would be relegated to a clinical problem that could readily be kept in check, not unlike the way we treat asthma or diabetes. New blood vessel formation is only rarely needed during adult life (e.g., at times of wound healing), so the long-term use of a drug blocking angiogenesis could potentially be quite safe.

The Times article has left us with a "good newsbad news" scenario. The good news is that this approach to cancer treatment is scientifically valid. There are more than 12 different drugs in development that block angiogenesis in laboratory research and more than six of these drugs are already in clinical trials in patients with cancer. Even an old drug, thalidomide, works by blocking angiogenesis. The fact that there are so many different drugs that are structurally dissimilar yet all target the same essential mechanism of cancer growth markedly increases the odds that at least one of these drugs will prove to be useful in the clinic and will then become part of standard cancer treatment. However until the game is over, it is too early to know whether the winning run will be Folkman's drug or someone else's.

The bad news is that what has happened since Kolata's story was printed may severely impact the *public's trust of not only* journalists, but of the scientific community. It is important for the public to know that this story was not generated by a formal announcement such as a press release, a publication in a peer-reviewed journal, or a formal presentation. Furthermore, no new information was provided by this report as Folkman had already published his findings last November in the journal Nature. The public didn't hear about this peer-reviewed article when it was released. It was only after this story received such prominent placement in The New York Times that other news organizations ran with the story. In other words, the Times created the news.

The public needs to know that curing cancer in mice is not proof that the same drug will cure patients

with cancer. We've known how to cure cancer in mice for at least 30 years, and most drugs that have cured cancer in mice have unfortunately failed in the clinic. Despite this, mice provide the best predictive tool that we have for identifying potentially useful anticancer drugs. Would that we had a better predictor!

Is there a moral to this story? At least once every five to 10 years, the media is filled with premature stories of breakthroughs in cancer treatment such as interferon and interleukin 2. While these agents subsequently proved to be useful drugs with limited indications, they were not the overall cancer cures they were hailed to be by the media. Writers and editors have a responsibility to the public to present information as accurately as possible. Miracle "breakthroughs" need to be looked at scrupulously before they are published, with independent checking of sources when claims appear to be extraordinary. Those of us in the scientific community have a responsibility as well. We need to ensure that we don't overstate our discoveries and that we balance our enthusiasm with reality.

I'm personally quite optimistic about the prospects of angiogenesis inhibitors becoming a major component of cancer treatment. However, cures can't happen in the press. Cures come from laboratory and clinical research, and only research can cure cancer.

> Sydney Salmon Regents Professor of Medicine Director, Arizona Cancer Center

### <u>Funding Opportunities:</u> NCI RAID Program Info Available On Website

The new NCI Rapid Access to Intervention Development program has established a website with information about submitting requests for preclinical development resources: http://epnws1.ncifcrf. gov:2345/dis3d/raidfin.html.

RAID plans to make available to academic investigators the preclinical development contract resources of NCI's Developmental Therapeutics Program (**The Cancer Letter**, April 24). According to a recent NCI notice in the NIH Guide to Grants and Contracts, the goal of RAID is the "rapid movement of novel molecules and concepts from the laboratory to the clinic for proof-of-principle clinical trials. RAID will assist investigators who submit successful requests by providing any (or all) of the pre-clinical developmental requirements for clinical translation. These include, for example, production, bulk supply, GMP manufacturing, formulation, and toxicology. Suitable types of agents for RAID include small molecules, biologics, or vaccines. For more detailed information, visit the web site."

Requests for RAID resources are to be submitted as described in the web site. Written requests will be evaluated by a panel of NCI staff and outside experts from academia and industry.

The first deadline is Aug. 1. Thereafter, there will be two receipt dates per year, Feb. 1 and Aug. 1, with all materials submitted directly to: RAID, Developmental Therapeutics Program, NCI, 6130 Executive Blvd Suite 843, Bethesda, MD 20892; or for express/courier service, Rockville, MD 20852, tel: 301/496-8720, fax: 301/402-0831, email: sausville@ dtpax2.ncifcrf.gov.

## NCI Offers Extra Funds To Centers For Cancer Control

NCI is requesting competing supplemental applications from NCI-designated cancer centers funded through P30 Cancer Center Support Grants, according to a recent notice.

"This supplemental initiative is intended to assist cancer centers in building a research capability in cancer control and population sciences research through provision of developmental funds for innovative pilot research projects having potential, ultimately, to compete for R01 support," according to a notice in the NIH Guide to Grants and Contracts.

"The initiative is part of a continuing effort to stimulate and strengthen research in cancer control and population sciences in NCI-designated cancer centers as an important component of the broad research portfolio of the program as a whole. NCIdesignated cancer centers possess the infrastructure, organization, leadership, and integrated multidisciplinary research objectives that enable them to build and incorporate new programs in emerging areas of cancer research. NCI staff will contact the current grantees directly regarding application procedures and format."

Inquiries: Kim Pham, Cancer Centers Branch, NCI, 6130 Executive Blvd Rm 502, Rockville, MD 20892-9904, tel: 301/496-8531, fax: 301/402-0181, email: pp64n@nih.gov.

# **RFAs Available**

**RFA CA-98-020** Title: **Community Clinical Oncology Program** Letter of Intent Receipt Date: July 28 Application Receipt Date: Aug. 25

The NCI Div. of Cancer Prevention invites applications from domestic institutions for cooperative agreements to the Community Clinical Oncology Program. Applicants for new and currently funded CCOPs and research bases are invited to respond to this RFA.

Using the national resource of highly trained oncologists in community practice, the CCOP: 1) provides support for expanding the clinical research effort in the community setting; 2) stimulates quality care in the community through participation in protocol studies; 3) fosters the growth and development of a scientifically viable community cancer network able to work closely with NCI-supported clinical cooperative groups and cancer centers; 4) supports development of and community participation in cancer prevention and control intervention research, which includes chemoprevention, biomarkers and early detection, symptom management, rehabilitation, and continuing care research; 5) involves primary care providers and other specialists in cancer prevention and control clinical trials; and 6) increases the involvement of minority and underserved populations in clinical research. Combining the expertise of community physicians and other health care professionals with NCIapproved cancer treatment and prevention and control clinical trials provides the opportunity for the transfer of the latest research findings to the community level.

This issuance of the CCOP RFA seeks to build on the strength and demonstrated success of the CCOP over the past 15 years by: 1) continuing the program as a vehicle for supporting community participation in cancer treatment and prevention and control clinical trials through research bases (clinical cooperative groups and cancer centers supported by NCI); 2) expanding and strengthening the cancer prevention and control research effort; 3) utilizing the CCOP network for conducting NCIassisted cancer prevention and control research; and 4) evaluating on a continuing basis CCOP performance and its impact in the community.

Applications may be submitted from domestic institutions for cooperative agreements to continue the CCOP. New applicants and currently funded programs are eligible as described below. Foreign institutions are not eligible.

An applicant may be a hospital, a clinic, a group of practicing physicians, a health maintenance organization, or a consortium of hospitals and/or clinics and/or physicians and/or HMOs that agree to work together with a principal investigator and a single administrative focus.

A university, Veterans Administration hospital, or military treatment facility may be included in an application as a member of a consortium led by a community institution, but may not be the applicant organization or the major contributor to accrual. An unfunded, nonuniversity clinical trials cooperative group member is eligible to apply.

Funded Cooperative Group Outreach Program (CGOP) participants are eligible to apply, but should state in the application that CGOP support will be relinquished if a CCOP award is received.

Institutions not eligible to apply as the CCOP applicant organization include:

a. A comprehensive, consortial, or clinical cancer center holding an NCI cancer center support (CORE) grant;

b. A university hospital that is the major teaching institution for that university;

c. A university hospital clinical trials cooperative group member funded by the Div. of Cancer Treatment and Diagnosis, NCI.

Research Base Applicants may be an NCI funded clinical trials cooperative oncology group; an NCI funded clinical center, consortium, or comprehensive cancer center.

Cooperative groups must participate in both cancer treatment and prevention and control clinical trials; cancer centers as CCOP research bases may participate in both cancer treatment and prevention and control studies or cancer prevention and control research only.

The funding instrument to be used for this program will be the cooperative agreement (U10). The total project period may not exceed 3 years for new applicants, and no more than 5 years for applicants currently supported under this program. Currently supported applicants may be funded for 3, 4, or 5 years depending upon priority score/ percentile, review committee recommendations, and programmatic considerations. The anticipated award date is June 1, 1999.

It is anticipated that up to \$4.4 million in total costs per year for 5 years will be committed to fund applications submitted in response to this RFA. Approximately two research base awards and 12 CCOP awards will be made.

Inquiries: Lori Minasian, Div. of Cancer Prevention, NCI, 6130 Executive Blvd Rm 300-D, MSC-7340, Bethesda, MD 20892-7340. Tel: 301/496-8541, email: Im145a@nih.gov.

#### RFA CA-98-017

Title: Regional Variation in Breast Cancer Rates in the U.S.

Letter of Intent Receipt Date: June 30

Application Receipt Date: Aug. 25

The NCI Division of Cancer Control and Population Sciences the Division of Extramural Research and Training of the National Institute of Environmental Health Sciences invite grant applications for interdisciplinary epidemiologic studies to better understand determinants of regional variations in breast cancer incidence and mortality rates in the U.S. Studies are to be designed to take known risk factors into consideration and to utilize biological markers or indicators, e.g., of exogenous exposures, individual susceptibility to environmental factors, intrinsic physiological processes or risk-related behavior, for elucidating the role of geographic-specific elements in the natural history and progression of breast cancer.

The program will use the cooperative agreement (U01). Total project period may not exceed 4 years. The earliest feasible start date will be April 1, 1999. The average award is expected to be approximately \$500,000 total (direct plus indirect) costs per year.

The purpose of this RFA is to stimulate innovative epidemiologic studies that include assessment of markers or indicators of exposures, susceptibility or other factors relevant to human breast carcinogenesis. Major consideration will be directed to studies, including those that are transitional (from laboratory-based to populationbased), that incorporate validation of utilizable markers, e.g., hormone-related, in human populations. Collaborations among multiple disciplines and research institutions are particularly encouraged, and research designs can make use of existing resources, such as specimen repositories. Supplementary research to expand an ongoing investigation (i.e., parent study) may be proposed, contingent upon the continuation of the parent study for at least two years. There is special interest in understudied populations, particularly those subgroups with unusually high breast cancer incidence and mortality rates, and in study populations of contrasting risk.

Investigators are encouraged to involve appropriate community/advocacy groups interested in breast cancer research. These groups could be comprised, for example, of breast cancer survivors, health care professionals involved in breast cancer care or women at high risk of the disease. The type and degree of participation by the group members could vary depending upon the proposed research activities; e.g., members could serve as advisors to the investigative team or assist in research implementation such as informing and recruiting eligible study participants in the community.

Studies responding to this initiative may propose, for example, research in areas listed below, but are not limited to:

—Evaluation of joint effects of environmental factors, intrinsic host characteristics or susceptibility, and behavioral patterns;

—Assessment of mechanisms by which exogenous exposures, e.g., occupational, could act in initiation and progression of breast cancer. This may include the evaluation of such exposures on hormonal or metabolic pathways, consideration of the timing of exposures during critical windows of development, and modulation of risk due to environmental exposures by genetic factors; —Comparison of populations with substantial regional differences in breast cancer incidence or mortality rates using parameters such as, for example: 1) hostspecific factors related to health (e.g., comorbidity), socioeconomic status (e.g., income, residence in the inner city or rural geographic areas); 2) tumor-specific characteristics (e.g., histology types, tumor aggressiveness in susceptible subpopulations); or 3) related to medical care utilization;

—Improvement and validation of methodology, e.g., for detecting steroid hormones, their metabolites, and xenohormones in biologic media, for use in large population studies;

—Application of computer technology, e.g., geographic information systems, and development of innovative statistical methods for improving estimates of historical environmental exposures;

—Investigation of environmental interaction and modulation of age-related markers of hormone activity related to normal and malignant breast physiology.

Inquiries: Kumiko Iwamoto, Division of Cancer Control and Population Sciences, NCI, 6130 Executive Blvd Suite 535, MSC 7395, Bethesda, MD 20892-7395, tel: 301/496-9600, fax: 301/402-4279, email: ki6n@nih.gov.

Gwen Collman, Chemical Exposures and Molecular Biology Branch, National Institutes of Environmental Health Sciences, PO Box 12233, Research Triangle Park, NC 27709, tel: 919/541-5980, fax: 919/541-4937, email: collman@niehs.nih.gov.

## <u>HHS News:</u> Skin Cancer Awareness Campaign Begun By HHS

The Department of Health and Human Services has begun a national, multi-year skin cancer awareness initiative.

The "Choose Your Cover" campaign is designed to educate people to protect themselves from the sun's ultraviolet rays. HHS released public service announcements targeted to 18-25 year olds. The initiative will also reach 9-18 year olds. The five-year campaign will expand to reach other age groups.

In addition, the initiative will be adopted by Girl Power!, the Department's national public education campaign to help encourage and empower 9-14 year old girls to make the most of their lives.

The initiative will be conducted by the Centers for Disease Control and Prevention. CDC has produced a "Choose Your Cover" web site: www.cdc.gov/ChooseYourCover.

## In Brief: Hutchinson Symposium On Clinical Research Planned

(Continued from page 1)

... FRED HUTCHINSON Cancer Research Center has scheduled a symposium, "Clinical Cancer Research in the Coming Decade," for June 5, in conjunction with opening the E. Donnall Thomas building. Speakers include NCI Director Richard Klausner; Univ. of Washington's Leroy Hood; David Botstein and Ronald Levy of Stanford Univ.; Arthur Nienhuis of St. Jude Children's Research Center; Michael Kastan of Johns Hopkins Hospital; Earnest Beutler of Scripps Research Institute; and Amy Langer of the National Alliance of Breast Cancer Organizations. . . . JESSIE AU, professor of pharmacy and medicine at Ohio State Univ. and deputy director of the Comprehensive Cancer Center-Arthur G. James Cancer Hospital and Research Institute from 1994-1997, was selected as a distinguished university professor at OSU.... **MEMORIAL SLOAN-Kettering Cancer Center** appointments and awards: Raju Chaganti, chief of the cytogenetics service, was named to the NIH mammalian genetics study section. Ethan **Dmitrovsky**, genitourinary oncology service, has joined the editorial advisory board if the Journal of the National Cancer Institute. William Fair, vice chairman for academic affairs, Dept. of Surgery, received the Ferdinand C. Valentine award from the New York Academy of Medicine. Diana Godfrey, director, Breast Examination Center of Harlem, was honored at the "Unsung Heroes" awards reception of the National Black Leadership Initiative on Cancer. Randy Gross, special surveillance breast program, received the Paula Major award from the Society of Gynecologic Nurse Oncologists. Vinod Prasad, special fellow, Dept. of Pediatrics, received a merit award from the American Society of Hematology.... JEFFERSON CANCER Network formed the Jefferson Oncology Group, a cooperative program among network members to enhance clinical and translational cancer research, including clinical trial development. Walter Curran, clinical director of Thomas Jefferson University Kimmel Cancer Center, said 20,000 patients are diagnosed with cancer each year in the network, which includes 14 hospitals and cancer centers in the Philadelphia area. Curran said the cooperative group will compete for funding from NCI and the American Cancer Society.