PO Box 9905 Washington DC 20016 Telephone 202-362-1809

SmithKline Seeks FDA Action Against Homeopathic Smoking-Cessation Gum

To put its smoking cessation drugs on the market, SmithKline Beecham conducted clinical trials, filed a New Drug Application with FDA, and compiled a label with claims, content, and dosage.

The makers of CigArrest, a homeopathic smoking cessation gum, took a radically different road to the market. They commissioned a lab to prepare a tincture out of ingredients described in the 200-year-old Homeopathic Pharmacopeia, developed a gum flavor, and hired television celebrity and lung cancer survivor Morton Downey Jr. as a spokesman.

Once they emerged from the development pipeline, CigArrest gum (Continued to page 2)

In Brief:

THE

Candlelight Vigil At Lincoln Memorial Planned For Night Before Cancer March

THE MARCH: Coming Together to Conquer Cancer has scheduled a candlelight vigil on Sept. 25 at the Lincoln Memorial, with corresponding vigils in every state capital, said Ellen Stovall, president of The March. Stovall and other march organizers announced details of the event during a broadcast of The Group Room, a nationally syndicated radio program for cancer patients and health care professionals. The candlelight vigil will be held the night before The March, an event designed to promote increased funding for cancer research, to be held Sept. 26 in Washington. Organizers said those who cannot participate in the Washington event can plan a local vigil. "This has to be a communitydriven event," Stovall said on the program, broadcast March 1. "Washington is our nation's community-that's where the focal point of our government is. But every community has a center, a town hall, a park, a support group. A small gathering of candle-lighting the evening before [the march] is a wonderful testimony to shining the light on cancer." Local events can be registered as official The March events by calling 800/THE-MARCH, or by visiting the website at www.themarch.org. . . . UNIVERSITY OF CALIFORNIA Board of Regents has approved \$33 million in financing for the construction of a clinical cancer center at the UC San Francisco Mount Zion Medical Center. The university said the new 88,000-square-foot building will house a radiation therapy center, a patient-oriented breast care center, mammography, chemotherapy, and physician offices. The facility has a (Continued to page 8)

Vol. 24 No. 9 March 6, 1998

© Copyright 1998 The Cancer Letter Inc. All rights reserved. Price \$275 Per Year US \$295 Per Year Elsewhere

In Congress:

HHS Hasn't Identified Another Source For NIH Increase If Tobacco Bill Not Passed: Shalala ... Page 4

Professional Societies: FASEB Urges Increase Of 15% For NIH, Double In Five Years ... Page 5

Funding Opportunities: NKCA Offers Young Researcher Award ... Page 6

Program Announcements ... Page 6

As Alternative Market Grows, **Drug Companies Fight Back**

(Continued from page 1)

and the SmithKline gum Nicorette and patch NicoDerm ended up in the same place: the shelves of your neighborhood drug store.

This outcome has prompted SmithKline Beecham Consumer Healthcare to cast away the industry tradition of not acknowledging competition from alternative remedies. Last month, the company filed a "citizen petition" requesting that FDA force CigArrest to go through the NDA process to comply with labeling requirements that apply to over-thecounter drugs.

"By capturing a share of the over-the-counter market, purveyors of alternative remedies have caused alarm among the pharmaceutical companies," said Barrie Cassileth, a psychosocial oncologist and author of the recently published book, The Alternative Medicine Handbook. "After demanding parity with mainstream medicine, they are about to find out that the marketplace entails an obligation to support their claims with data."

Competing pharmaceutical companies are not known to treat each other with collegiality. Seeking FDA action against a competitor is a time-honored strategy.

There are two ways to trigger regulatory action. One approach is to have a lawyer write a letter



Publishers Association World Wide Web: http:// www.cancerletter.com

Editor & Publisher: Kirsten Boyd Goldberg Editor: Paul Goldberg Staff Writer: Catherine Fiore

Editorial: 202-362-1809 Fax: 202-362-1681 PO Box 9905, Washington DC 20016

E-mail: kirsten@cancerletter.com or paul@cancerletter.com

Customer Service: 800-513-7042 PO Box 40724, Nashville TN 37204-0724

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

alleging transgressions by a competitor. The second, less subtle, strategy is to file a citizen petition demanding FDA action.

FDA has 180 days to respond to petitions, though the process usually takes longer. After receiving the response, the filer acquires standing to sue the agency.

"Calling your product homeopathic has become a growing loophole for manufacturers who seek to skirt drug safety and efficacy requirements of FDA," said Michael Petty, an attorney with the Washington law firm of Fox, Bennett & Turner, which filed the SmithKline petition.

Gary Kehoe, president of GumTech International Inc. of Phoenix, the manufacturer and distributor of CigArrest, said his company's growing sales were the motivation for SmithKline's petition. "If it wasn't selling well, they wouldn't be filing a citizen petition," Kehoe said.

GumTech markets the product in a venture with More Direct Response, a company based in Carlsbad, CA.

"We have hundreds of testimonials from people that love it, and they believe in it," said Kehoe, formerly a developer of gum flavors with LifeSavers Inc. "If I thought in any way that it wasn't an effective product, obviously we would work on the formulation. But it's totally the opposite of that. Every bit of response we'd gotten back-excluding SmithKlein Beecham's-has been very positive."

Challenge To (And From) Drug Companies

The SmithKline petition appears to be the second of two recent actions in which pharmaceutical companies challenge the purveyors of alternative remedies, say Washington attorneys who practice FDA law.

In a similar case last year, a lawyer for Merck & Co. urged FDA to take action against the maker of the dietary supplement Cholestin that claims to lower serum cholesterol. Merck argues that Cholestin contains the same active ingredient as its drug Mevacor. FDA action in that case is pending.

These challenges by SmithKline and Merck may be the beginning of escalating competition between allopathic medicine and alternative remedies, Washington lawyers say. "In time you will find that pharmaceutical companies are going to protect their markets from the makers of dietary supplements and alternative remedies by filing false advertising claims and seeking injunctive relief and damages," predicted an attorney who spoke on condition that his name would not be used.

The dietary supplements market, which does not necessarily require companies to renounce evidencebased medicine, may be especially alluring for drug companies, industry observers say. "My sense is that many pharmaceutical companies are having an internal debate about whether to get into the dietary supplements market or to squash it," said a Washington attorney who represents drug companies and dietary supplement manufacturers.

By filing a citizen petition against CigArrest, SmithKline used a strategy tested in battles with generics, said Steven Lieberman, an attorney with the Washington firm of Rothwell, Figg, Ernst & Kurz.

"Citizen petitions have been used increasingly by pharmaceutical companies over the past several years to erect additional road blocks in the way of competitors," Lieberman said. "So, it's not terribly surprising that SmithKline Beecham would pull this arrow out of its quiver."

Skeptics Cheer

Several critics of alternative medicine said they are delighted by the prospect of pharmaceutical companies getting into the business of scrutinizing health claims by manufacturers of dietary supplements and alternative medicines.

"It would be great to have an ally, especially one who has the money and a motivation to scrutinize the claims made by alternativists and place the truth before the public," said Saul Green, a basic scientist who frequently publishes evaluations of scientific claims made by proponents of alternative medicine. "If drug companies join the scientists in *demonstrating that reality and fairy tales are not one* and the same, medical consumers will be well served."

While even some supporters acknowledge that the principles of homeopathy run counter to the laws of physics, the federal law clearly protects the homeopaths.

That's because in 1938, Sen. Royal Copeland, a homeopathic physician, convinced Congress to "grandfather" the entire homeopathic pharmacopeia, in effect exempting it from legal requirements that apply to drugs.

Active ingredients in homeopathic remedies are so heavily diluted that not even a molecule remains in the final product. Water "remembers" those ingredients, homeopaths say. Further, homeopaths claim that a higher dilution of the ingredient is *more potent* than a lower dilution.

This principle produces great mirth among skeptics. "Homeopathy is the ultimate dilution," offered Victor Herbert, a nutrition scientist and lawyer who battles alternative therapists in scientific journals, in courts, and on talk shows.

"Homeopathy is best summarized in a joke," said Green. "Have you heard about a patient who forgot to take a homeopathic remedy and died of an overdose?"

The botanical ingredients listed on the CigArrest label include Lobella inflata, Cinchona officianalis, Daphne Indica, Plantago major, Calcarea phosphorica and Nux vomica. The first of the ingredients, Lobella inflata, is present in three concentrations, labeled 6X, 12X, and 30X.

"The range between 6X and 30X is not trivial," said Robert Park, professor of physics at the University of Maryland, director of the Washington office of the American Physical Society, and a student of alternative medicine. "At 6X concentration, a good analytical chemist would be able to detect about 1 part per million. At 12X, the most modern analytical techniques wouldn't be able to identify any active ingredient. And if you were to make a 30X solution, the patient would have to drink 386,000 gallons of the water-alcohol solution to get one molecule of the active ingredient.

"If this leaves you feeling dizzy, the standard homeopathic remedy for dizziness is crude oil at a dilution of 30C. That concentration would mean that there is not one molecule of the active ingredient in the galaxy, which is just as well, because I wouldn't want to drink crude oil," Park said. "It's hard to get it across to people just how wild this is."

Kehoe said all three potencies of *Lobella inflata* are present in the gum. "Each potency has different physiological effects on the body," he said. "Therefore each entity is a separate entity in the product. They refer to this as harmonization, or concordant potencies, and it's a standard procedure for homeopathy.

"Anyone that's schooled in homeopathic medicine would understand that," he said.

The citizen petition is a head-spinning case study of what happens when an arcane, esoteric discipline is scrutinized in accordance with the principle of FDA regulation.

Given homeopathy's privileged status under US

law, SmithKline found itself in the curious situation of having to argue that CigArrest is *not* a true homeopathic drug. To begin with, Aspartame, an artificial sweetener, is included as an inactive ingredient. This contradicts claims that homeopathic drugs are natural substances.

Menthol, a drug with active homeopathic uses, pops up among inactive ingredients, also a potential breech of tradition, the petition notes. "In addition, CigArrest does not list a dosage for menthol," the document states.

The use of gum can be a problem, too, SmithKline lawyers say. The Homeopathic Pharmacopeia of the United States lists only "solutions, powders, tablets or globules."

In another assault, the petition provided the English names for botanical substances on the CigArrest label. *Lobelia* is Indian tobacco, SmithKline said. *Nux vomica* is poison nut, a substance that contains strychnine. Digging deeper, the petition states that in 1972, FDA ruled that smoking cessation drugs containing *Lobelia* would have to file NDAs to get on the market.

The case of CigArrest offers FDA the opportunity to adopt meaningful regulations in homeopathy, the petition states. "Reason would dictate that FDA would either: (1) have safety concerns over the use of this product, or (2) have to admit that `active' ingredient levels in CigArrest are so miniscule that true medical efficiacy for this product is virtually impossible."

200 Years of Homeopathy

Kehoe said the petition against his product is part of a broader assault on homeopathy.

"Homeopathy has been practiced for 200 years that I know of," he said. "I think it's a great approach to—if you will—stimulate your own immune system to help combat various ailments."

The tincture for CigArrest was prepared at a homeopathic laboratory, Kehoe said. "We went to a very good lab and said, we would like to do a nonnicotine smoking cessation formula," he said. "It was their job to use their resources to put this formula together. This formula has been scrutinized by the best homeopathic minds in the country, and there has not been any negative response from the homeopathic community."

The gum is good, too, Kehoe said. "I find when I chew CigArrest, I get relaxed from it," he said. "I find myself chewing it when I am in meetings, or at the end of the day, when I am tense."

The principal claim made by CigArrest is that, unlike nicotine gum and patch, it does not contain nicotine. "You know nicotine is addictive, so why trade one nicotine addiction for another," the company says in its television commercial. "CigArrest can help you quit smoking without nicotine naturally!"

The CigArrest package includes the following claims: "Reduces Irritability; Reduces Tobacco Cravings, Relieves Nervous Tension; Helps Detoxify."

The company's web site displays the logos of the American Cancer Society and the American Lung Association.

Both ACS and ALA said the link—and the use of the logos—were unauthorized, and do not imply endorsement.

"We are going to send them a letter demanding that they cease and desist using our name and logo on their web site," said William Dalton, an ACS attorney. "Failure to do so will result in legal action."

ACS receives \$1 million a year from SmithKline Beecham in a marketing arrangement that allows the company to use the society's logo. The American Lung Association has a similar arrangement with Johnson & Johnson, the sponsor of the Nicotrol patch.

In Congress:

No Other Source Of NIH Funds Besides Tobacco: Shalala

The \$1.15 billion increase for NIH proposed in the President's fiscal 1999 budget proposal is dependent on Congress passing comprehensive, bipartisan tobacco legislation this year, HHS Secretary Donna Shalala said at a Congressional hearing earlier this week.

"Obviously the tobacco legislation will need to be passed, and we are working very hard to make sure that happens," Shalala said at hearing of the House Appropriations Subcommittee on Labor, HHS, and Education on March 3. "There should be no reason in this Congress that we can't pass bipartisan tobacco legislation."

The increase for NIH is a priority for the Administration, Shalala said. However, an alternate source for the funds has not been identified, she said.

Members of the subcommittee questioned where the NIH increase would come from if tobacco

legislation is not passed during the current Congressional session.

"We believe we can get comprehensive legislation that will be bipartisan," Shalala said. "There are bills up here that are acceptable, and we have outlined in some detail what the elements of those bills would have to be in order for us to support them. We will work very closely with this bipartisan effort in Congress to pass legislation.

"We are committed though, to the NIH increase as a priority of the President, and like any other priority of the President, we will work with Congress to identify revenue sources to pay for those increases," Shalala said. "So we believe that the revenue source that we have identified, part of a comprehensive piece of tobacco legislation, can be passed this year with very strong bipartisan support."

Shalala said that at least one bill introduced in the Senate meets all of the Administration's guidelines.

The Healthy Kids Act (S. 1638), sponsored by Sen. Kent Conrad (D-ND), would provide 21 percent of revenues from increased cigarette prices and penalties imposed on manufacturers to health research at NIH. The bill could provide revenues of up to \$82 billion over five years, Conrad said (**The Cancer Letter**, Feb. 20).

However, Republicans have criticized the bill, written by the Senate Democratic Task Force on Tobacco, as being overly partisan.

One of the Administration's goals is to see bipartisan tobacco legislation crafted, Shalala said.

In a related development, Sen. Connie Mack (R-FL) said any comprehensive tobacco legislation passed by Congress needs to include significant *funding for biomedical research*, including research on smoking-related illnesses.

"I encourage my colleagues to take this monumental opportunity to 'get even' in the most constructive way I know—by forcing Big Tobacco to pick up the tab for finding cures to the very diseases they have caused," Mack said in testimony to the Senate Commerce Committee. "For there to be comprehensive tobacco legislation without significant medical research funding would be a tragedy."

Mack, a key supporter of increased funding for NIH, said he is willing to work with members of the Committee to draft legislation that would include biomedical research funding. Mack is a member of the Senate Appropriation Subcommittee on Labor, HHS, and Education.

"The Senate has indicated unprecedented support for a significant commitment to NIH," Mack said. "Tobacco companies should at the very least pay for research into new methods of treatment and cures for the horrible diseases the industry has inflicted upon our citizens."

"Now is the time for America to take this opportunity to win the war against teen smoking, and at the same time, win the war against the diseases which plague our society," he said. "We have the knowledge, we have the technology, and, most importantly, we have the support of the American people."

<u>Professional Societies:</u> FASEB Urges 15% Increase For NIH, Double In 5 Years

The Federation of American Societies for Experimental Biology has recommended an appropriation of \$15.69 billion for NIH in fiscal 1999, a 15 percent increase over the current fiscal year.

The funding recommendation, published in the FASEB report "Federal Funding for Biomedical and Related Life Sciences Research, FY 1999" released last month, also supports a doubling of the NIH budget in the next five years.

"With additional resources, NIH will be able to capitalize on past discoveries and accelerate its progress in the fight against disease," the report said. "This investment will enable NIH to fund more topquality scientists, provide sufficient support so that scientists can spend more time in the laboratory, raise stipends for trainees to ensure that the best and brightest students are able to become the scientists of tomorrow, modernize the research infrastructure, and provide the state-of-the-art equipment needed to continue the progress we have made."

In addition to funding recommendations, the report outlines policy issues and recommendations for the Institutes.

"FASEB endorses NIH's ongoing program of reviews, experiments, and evaluations to refine merit-review procedures, funding strategies, and management practices," the report said. "FASEB also supports the allocation of sufficient funds for the research management and support activities at NIH to insure the proper stewardship of critical science programs."

The federation recommended that NIH set priorities in research funding that would balance the emphasis on specific diseases with their potential for scientific opportunity. FASEB supports a system where research priorities are set by NIH alone, with input from Congress, the public, and scientific advisory boards.

The report outlines several recommendations for the review system for investigator-initiated grants. FASEB recommendations include reviewing study sections and Initial Review Groups, expanding the responsibilities of scientific administrators, developing mechanisms to identify first-time R01 applicants as new investigators required to submit less preliminary data, and investigating the financial impact of significantly expanding the payline for first-time applicants.

The report also recommends an expansion of advanced technology and instrumentation at NIH to include study sections and programs to focus on technology, collaborative programs with scientists, and cooperative programs with other agencies.

FASEB recommends spending \$155 million in FY 1999 to fund the shared biomedical technologies resource program, \$80 million in FY 1999 to support shared instrumentation, and \$150 million each year to develop technology for translational research linking protein biology and genomics.

The report recommends an increase in the number of positions in the predoctoral MD-PhD program and the postdoctoral Mentored Clinical Scientist Development Award, and at least a 25 percent raise in stipends for pre- and postdoctoral trainees and fellows.

The full text of the report, which includes recommendations for the National Science Foundation, the Department of Agriculture, the Department of Energy, the Department of Veterans Affairs, and NASA, is available at www.faseb.org/ opa, or from the FASEB Office of Public Affairs at 301/571-0657.

<u>Funding Opportunities:</u> Young Researcher Award Honors Eugene Schonfeld

The National Kidney Cancer Association has established the Eugene P. Schonfeld Medical Research Award for basic research in renal cancer.

The award, formerly the Young Researcher

Award, was renamed in honor of the association's late founder and president.

The association will award \$60,000 over two years to a young MD or PhD less than five years past a postdoctoral degree. Candidates should have access to a lab.

Focus should be on theory, originality, technical approach, and potential for new contributions.

Deadline is April 1. Funds will be available by July 19. Contact NKCA, 1234 Sherman Ave., Suite 203, Evanston, IL 60202, tel: 847/332-1051.

Program Announcements

PAR-98-023

Title: Small Grants Program for Cancer Epidemiology Deadlines: May 15, Sept. 15

The NCI Division of Cancer Control and Population Sciences invites Small Grant applications relating to cancer epidemiology with a primary focus on etiologic cancer research. The short-term awards are intended to provide support for pilot projects, testing of new techniques, or development of innovative or high-risk projects. Total budget may not exceed \$100,000 in direct costs. Direct costs in any one year must not exceed \$50,000. Investigations may include:

—Planning a complex epidemiologic investigation;

—Developing or validating a laboratory or statistical procedure that has the potential for improving the quality of cancer epidemiologic research;

—Obtaining support to study a question relevant to cancer epidemiology in special situations, such as the availability of special personnel for limited time periods, rapidly evolving research or limited access to an important resource;

—Analyzing previously collected data for epidemiologic purposes, such as combining data from several studies to examine consistency or strength of observed associations;

—Resolving methodologic problems, such asdocumenting the accuracy of a customary procedure in preparation for use in epidemiologic research, or evaluating the effect of cancer diagnosis and/or treatment on risk factor estimates derived from case-control studies;

—Investigations of urgent or emergent issues in cancer epidemiology.

Contact A. R. Patel, DCCPS, NCI, 6130 Executive Boulevard, Suite 535, MSC 7395, Bethesda, MD 20892-7395, tel: 301/496-9600, fax: 301/402-4279, email: patela@epndce.nci.nih.gov.

PA-98-027

Title: Cancer Survivorship Studies In Established Epidemiologic Cohorts

The NCI Division of Cancer Control and Population

Sciences invites investigator-initiated grant applications (R01s) and applications for competing supplements to existing NIH-funded research project grants (R01s, P01s) or cooperative agreements (U01s) for innovative, interdisciplinary research using existing epidemiologic study populations to address issues related to long-term survivorship of cancer, particularly in the areas of specific health or lifestyle outcomes and their modulation by common risk factors or other exposures.

Total project period may not exceed five years. Competing supplements may not extend beyond the funding period of the parent grant; the parent grant must have at least one year remaining in its project period after award of the supplement.

The original project may be a retrospective epidemiologic study (e.g., case-control study of etiologic or risk factors) or a prospective study or demonstration project in which incident cancer cases have been identified. For either approach, the number of cases and duration of potential follow-up must be sufficient to provide a clear picture of the survivorship experience from time of diagnosis and to address specific questions about late effects and long-term consequences in cases surviving more than two years from completion of therapy.

Applications should address specific issues in any of the following areas:

1) Physiologic function and/or medical diagnoses, including but not limited to: competing causes of mortality; comorbid medical conditions, modulation of medical outcomes by epidemiologic or molecular risk factors.

2) Reproduction and sexuality, including but not limited to: post-treatment fertility, complications of pregnancy, occurrence and consequences of early menopause, medical/surgical interventions for sexual dysfunction.

3) Second cancers, including premalignant and predisposing conditions.

4) Other areas: psychosocial issues (including quality of life); career, employment, and economic impact.

Applications should represent collaborative efforts between investigators skilled in clinical and/or preventive oncology and colleagues with expertise in cancer epidemiology. R01 applications based on completed epidemiologic studies should, if possible, include the Principal Investigator of the original epidemiologic studies as a collaborator in the proposed research.

Inquiries: Susan Nayfield, NCI DCCPS, 6130 Executive Blvd Suite 535-MSC 7395, Bethesda MD 20892-7395, tel: 301-594-7344, fax: 301-435-5477, email: nayfiels@epndce.nci.nih.gov

PA-98-028

Title: Diet, Lifestyle And Cancer In U.S. Special Populations

The NCI Division of Cancer Control and Population

Sciences invites P01 and R01 grant applications for epidemiologic studies to elucidate causes of cancer and means of prevention in African Americans, American Indians, Alaska Natives, Asian and Pacific Islanders, Native Hawaiians, Hispanics, rural, older, low income and low-literacy groups. These groups experience unusually high cancer incidence and mortality for some cancer sites.

Applicants requesting budgets greater than \$500,000 in direct costs are required to contact program staff prior to submitting applications.

Innovative approaches that involve interdisciplinary collaborations of basic, behavioral or clinical researchers with epidemiologists are encouraged. Whenever possible, studies should make cost-efficient use of existing resources, such as population-based cancer registries or specimen repositories.

The initiative permits a wide range of epidemiologic investigations of cancer in US special populations. The areas of research listed below are not intended to be allinclusive, but are designed to give the applicant some direction for the types of research that the NCI is interested in stimulating to enhance knowledge about the etiology of various cancers and means for their prevention.

1. Cross-cultural studies of cancers with striking ethnic disparities in incidence rates, among groups residing in the same or different geographic areas, to identify more specifically the etiologic factors and to study their relationships with biomarkers of exposure.

2. Analytic studies of specific cancer sites to determine the impact of age-specific changes in exposure over time, due to waves of migration within the US as well as from other countries, and/or secular changes in lifestyle, occupation and environment.

3. Studies of ethnic differences in the histologic and cytologic parameters of *particular cancers* that may reflect differences in exposures or susceptibility.

4. Studies addressing methodological issues related to the heterogeneity of ethnic groups, especially dietary and genetic parameters.

5. Molecular epidemiologic studies exploring differences in genetic predisposition to cancer due to variations in carcinogen metabolism, DNA repair activities, response to tumor promoters, measures of immune function, chromosome sensitivity to mutagens, or other factors.

6. Development and validation of instruments for assessing diet and lifestyle factors such as smoking, alcohol intake and exercise and their role in the risk of cancer among understudied special populations.

7. Studies among Hispanics with special consideration given to the assessment of Hispanic ethnicity within the study population.

8. Feasibility studies to establish cohorts of Native Americans for elucidating causes of illness and assessing influence of lifestyle changes on disease risk.

9. Studies exploring culturally sensitive and

socioeconomically sensitive, appropriately tailored approaches for dietary modification, monitoring compliance via appropriate means, to assess cancer risk in U. S. special populations.

10. Studies of motivational and behavioral strategies, including use of adjuncts, on diet modification and other lifestyle changes.

Inquiries: A.R. Patel, DCCPS, NCI, 6130 Executive Blvd Ste 535-MSC 7395, Bethesda MD 20892-7395, tel: 301-496-9600, fax: 301-402-4279, email: Patela@epndce.nci.nih.gov.

PA-98-029

Title: Molecular And Cellular Biology Of Metastatic Tumor Cells

NCI invites R21 exploratory/developmental grant applications to study the molecular and cellular biology of metastatic tumor cells. This initiative is designed to promote collaborations and facilitate scientific interchange between investigators, one with experience in the biology of metastasis and the other in a more basic scientific discipline such as molecular or cellular biology, or biochemistry. Prospective Principal Investigators need to identify a research collaborator.

Direct costs per year must not exceed \$75,000. Total project period may not exceed two years and is not renewable.

The scope of the research may encompass the application of any aspect of molecular and cellular biology and biochemistry to the investigation of metastasis biology. Applications should be for preliminary data gathering or pilot feasibility studies, and should be founded on the combined research experience of the Principal Investigator and his/her collaborator.

Inquiries: Suresh Mohla, Cancer Biology Branch, NCI, EPN Rm 505, Bethesda MD 20892, tel: 301-496-7028, fax: 301-402-1037, email: sm82e@nih.gov.

Breast, Prostate Cancer PAs

This notice is to remind the scientific community of the jointly sponsored (announced by NIA, NCI, NINR, & NIMH) "Aging Women and Breast Cancer" Program Announcement (see PA-96-034 available at http:// www.nih.gov/grants/guide/pa-files/PA-96-034.html) and the jointly sponsored (announced by NIA, NCI, & NIEHS) "Aging, Race, and Ethnicity in Prostate Cancer" Program Announcement (see PA-97-019 available at http:// www.nih.gov/grants/guide/pa-files/PA-97-019.html)

Inquiries: (For either announcement) Rosemary Yancik, Geriatrics Program, National Institute on Aging, 7201 Wisconsin Ave. Suite 3E327, Bethesda MD 20892-9205, tel: 301-496-5278, fax: 301-402-1784, email: YancikR@exmur.nia.nih.gov

In Brief: Cleveland Clinic Wins GM Grant

(Continued from page 1)

projected cost of \$42.5 million, \$10 million of which will be raised through private fund-raising efforts. The Mount Zion center is part of a \$338.4 million capital construction and debt restructuring bond package for UCSF Stanford Health Care. The plan includes a \$47 million financing for an ambulatory care center at Stanford University. . . . **CLEVELAND CLINIC FOUNDATION** was granted \$350,000 from the General Motors Foundation for research into the genetic tendencies associated with prostate cancer, and the study of a new radiation delivery system used to treat prostate cancer. General Motors said it could grant up to \$650,000 in 1999 and 2000 to continue the studies. Research will be conducted under the direction of the Cleveland Clinic Taussig Cancer Center. . . . JAMES BARTHEL was named gastroenterology section chief and medical director of the endoscopy clinic at H. Lee Moffitt Cancer Center and Research Institute. Barthel, former director of the University Hospital Endoscopy Center at the University of Missouri School of Medicine, was also named associate professor of medicine in the department of internal medicine, digestive diseases, and nutrition at the University of South Florida School of Medicine. . . . VIRGINIA TROTTER BETTS, immediate past president of the American Nurses Association, was named senior advisor on nursing policy and senior health policy advisor at the Department of Health and Human Services. Betts, former president and CEO of HealthFutures, is on leave from Vanderbilt University. . . . GEORGE HITCHINGS, a 1988 winner of the Nobel Prize in Medicine, died Feb. 27 at his home in Chapel Hill, NC. He was 92. Hitchings won the Nobel Prize for research that led to the creation of drugs to treat leukemia, gout, malaria, and immune system disorders, and that eventually made organ transplants possible. He was the chief researcher and biochemist at Burroughs Wellcome in Research Triangle Park, NC, where he worked with Gertrude Elion. Hitchings and Elion are considered pioneers in the field of chemotherapeutics.... CORRECTION: An article in the Feb. 27 issue of The Cancer Letter incorrectly listed President Clinton's proposed funding for grants to improve minority health. The budget proposes spending \$150 million on 30 grants.