THE CANCER LETTER INTERACTIVE

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

Vol. 27 No. 41
Nov. 9, 2001

Appeals Court Overturns FDA Approval Of Generic Paclitaxel, A Setback For Ivax

A federal appeals court earlier this week overturned the FDA approval of generic paclitaxel, citing the agency's failure to provide documentation supporting its decision to approve the Ivax Corp. version of the widely used cancer drug.

The Nov. 6 ruling by the U.S. Court of Appeals for the District of Columbia appears to be a setback for the Miami-based Ivax and other players in the market for the generic version of the Bristol-Myers Squibb drug Taxol.

It is unclear whether the court's decision to oust the generics will benefit Bristol, but it appears to be a victory for American BioScience

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In Brief:

Henderson Heads HHS Preparedness Office; NCI Awards $22M Southern Cohort Study

DONALD HENDERSON was named director of the Office of Public Health Preparedness by HHS Secretary Tommy Thompson. The newly created office will coordinate national response to public health emergencies. Henderson was founding director of the Center for Civilian Biodefense Studies at the Johns Hopkins Bloomberg School of Public Health. He directed the World Health Organization's global smallpox eradication campaign from 1966 to 1977 and iniated the 1974 WHO global program of immunization. In his new position, Henderson will work with all agencies within the department to enhance the response to the anthrax attacks. Secretary Thompson had named Henderson chairman of a new national advisory council on public health preparedness, a position he will continue to hold. The council is charged with recommending improvements to the nation's public health infrastructure to better prepare it for bioterrorism attacks. Among his awards, Henderson received the National Medal of Science in 1986. **Phillip Russell**, retired U.S. Army major general and director of the Army Medical Research Institute of Infectious Diseases, was appointed to HHS as a special advisor on vaccine development and production. Russell is an expert on virology. . . . **NCI AWARDED** a $22 million five-year grant for the Southern Community Cohort Study, which will determine why African Americans are more likely than other groups to develop cancer and to die from the disease. The study will enroll and follow 105,000 people—two-thirds of them African-Americans—in six southeastern states to identify genetic, environmental and lifestyle factors. The research team will be led by Vanderbilt-Ingram Cancer Center. . . .

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In Setback For Generics, Court Overturns FDA

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Inc., a small, privately-held company based in Santa Monica, CA. Bristol and ABI are involved in an unusual patent dispute over the size of vials used for branded Taxol.

In the decision earlier this week, Senior Circuit Judge Laurence Silberman wrote that in the absence of an "administrative record" supporting the FDA's decisions that cleared the way for Ivax to enter the paclitaxel market last year, the agency's action must be regarded as inappropriate.

"We frankly do not know what recourse is left to the FDA or other government agencies to take any steps that would affect the marketing of generic versions of Taxol," Silberman wrote. "But we are convinced that the FDA's order, in this case, was arbitrary and capricious and must be vacated."

The legal battle that culminated in the decision by the appeals court began in the summer of 2000, when ABI claimed that Bristol violated its patent. Whatever the merits of the ABI claims, the dispute between ABI and Bristol could have blocked Ivax and other generics from entering the market for as long as 30 months (**The Cancer Letter**, Oct. 20, 2000). The dispute over patent No. 6,096,331 is continuing.

Attorneys for the generics claim that Bristol was engaging in a last-minute maneuver to maintain exclusivity for branded Taxol. At the same time, the Federal Trade Commission initiated an investigation of Bristol. That investigation has not been concluded.

For a company trying to maintain exclusivity on a blockbuster drug, a protracted court battle over the fine points of a patent can be a remarkably attractive proposition. However, Bristol chose not to get involved in a dispute with ABI. After being notified about the claim, Bristol declined to notify FDA about the patent dispute.

Such certifications, which are entered in the "Orange Book," automatically entitle the companies to dispute the claims while the status quo is maintained. By declining to make the claim to the Orange Book, Bristol appeared to be passing up an opportunity to block Ivax and other generics from entering the paclitaxel market.

At this point ABI sued, obtaining a temporary restraining order that obligated Bristol to file a certification to the Orange Book. This seemed to be a terrific deal for Bristol: not only was the company prolonging its market exclusivity on Taxol, but it was under a court order to do so. Complying with the ruling of a California court, Bristol listed the patent in the Orange Book on Aug. 11, 2000.

However, Ivax, other generics and FTC entered the fray, prevailing on reversing the temporary restraining order, and forcing withdrawal of the Orange Book listing. The patent was "delisted" by FDA on Sept. 14, and with the ABI-Bristol dispute seemingly out of the way, on the following day the agency gave final approval to the Ivax version of paclitaxel.

At this point, ABI sued FDA in the federal court in the District of Columbia, and the case has bounced to the Court of Appeals twice. Both times the Court of Appeals demanded that FDA provide the administrative record supporting its decision to cross the patent out of the Orange Book.

The most recent decision said the agency merely maintains the Orange Book as a list of disputed patents, and lacks authority to decide which of these disputes have merit. Therefore, the agency acted improperly when it crossed out the ABI-Bristol patent dispute from the Orange Book.

"Indeed, it is not at all clear to us that the FDA, under its regulations, would be authorized to reject the obvious intent of an NDA holder even if it acted directly contrary to a court order," the ruling states. "Certainly, the FDA points us to no authority upon which it could rely to do so."

In a strongly worded press release, Ivax officials

THE CANCER LETTER

Member, Newsletter and Electronic Publishers Association

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

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Subscription $295 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd

said the company does not believe the appeals court decision will prevent the company from continuing to market its version of paclitaxel.

"Ivax believes the circuit court's decision to reverse the district court is incorrect and intends to seek reconsideration of the ruling," the company said. "The…decision appears to be based solely upon technical issues regarding the adequacy of the FDA's record in this matter."

Ivax has 45 days to ask the appeals court to reconsider the decision. Meanwhile, the company would be free to continue to market the drug.

The company said the district court in Los Angeles is considering the patent case, and that case may be resolved in a matter of weeks. "If the district court holds ABI's patent invalid, the decision of the DC Circuit would be effectively nullified," Ivax said in a statement.

"The underlying patent claim asserted by ABI is frivolous," said Neil Flanzraich, Ivax vice chairman and president. "The essence of ABI's patent is the claim that they invented the idea of putting Taxol in a bottle. If it were not for the thousands of cancer sufferers who have been compelled to pay exorbitant prices for this life preserving product, developed by the federal government at taxpayer expense, ABI's argument would be absurd."

In his statement, Flanzraich blasted the appeals court decision. "The circuit court refused to look at the substantial evidence of the chicanery between ABI and Bristol-Myers because it was in a court file and not in the FDA's files, but that honors form over substance," he said.

Bristol officials said they were uncertain about the impact of the appeals court decision on the company. "We are aware of the decision, but we believe it remains to be seen what the implications are," said company spokesman Nancy Goldfarb.

NCI Programs:

Advisors Suggest Consortia For Lung Cancer Research

NCI should support multi-institutional research consortia in lung cancer to further research in that disease, an advisory group formed to review the Institute's lung cancer research programs has concluded.

In a report submitted to NCI, the Lung Cancer Progress Review Group listed the funding of these research consortia as the highest priority need. The report also recommended research in new approaches to the study and treatment of nicotine addiction, and further research in spiral computed tomography scanning for early detection of lung cancer.

The Lung Cancer report is the seventh report completed by NCI Progress Review Groups under a review system established by former NCI Director Richard Klausner in 1997. PRGs have completed recommendations to NCI in breast, prostate, pancreatic, brain, and colorectal cancers, and leukemia, lymphoma, and myeloma.

Reviews are underway in gynecologic and kidney and bladder cancers. The report of the Gynecologic Cancers PRG is scheduled to be presented to the NCI Advisory Committee to the Director on Nov. 20. The Kidney-Bladder Cancer PRG has scheduled its "roundtable meeting," an invitation-only meeting that begins the PRG process, for Nov. 28-30. Also, an Esophageal Cancer PRG is to begin its work soon, said Cherie Nichols, director of the NCI Office of Science Planning and Assessment.

The recommendations of PRG reports have been implemented through various NCI funding mechanisms. The reports themselves serve as a method of prioritizing research, NCI officials said. Scientists may reference PRG reports in their grant applications. After a report is submitted, the Institute forms an "implementation group" to work with the advisory committee to identify high-priority needs, Nichols said.

All of the reports and further information about the PRG process is available at http://osp.nci.nih.gov/

Following are excerpts of the Report of the Lung Cancer Progress Review Group:

Lung cancer is the leading cause of cancer death for both men and women in the United States, killing more people than breast, prostate, colon, and pancreas cancers combined: Fully 85 percent of patients who develop lung cancer die from it. We are still largely ignorant of the molecular events underlying the development of lung cancer and the mechanisms of resistance to drug and radiation therapy; no agent has been found useful in the prevention of lung cancer; and the benefits of lung cancer screening and early detection are mired in controversy. With half of all lung cancers in the United States now diagnosed in former smokers, it is a sobering reality that tobacco control will ameliorate but not, in the foreseeable future, eliminate the problem of lung cancer. Yet we have funded lung cancer research far below the levels that characterize other common

malignancies and far out of proportion to its massive public health impact.

In October 2000, NCI convened the Lung Cancer Progress Review Group to identify high-priority areas of research that have the potential to reduce the great toll of this disease through advances in prevention, diagnosis, and treatment. The PRG's 30 members—expert clinicians, scientists, industry representatives, and consumer advocates—met in January 2001 to select topics for a Roundtable PRG meeting in April 2001. Eight topics were explored in detail in breakout group sessions. The breakout groups produced detailed reports on all eight topics, which are appended to the main PRG report. The main report of the Lung Cancer PRG highlights the overarching priorities identified by the eight Roundtable breakout groups that transcend their individual agendas. Those recommendations are:

—Foster the creation of scientifically integrated, multi-disciplinary, multi-institutional research consortia (Lung Cancer Consortia) organized around the problem of lung cancer rather than around specific research disciplines. The support and development of dedicated academic investigators who speak a common language across basic science, translational science, and clinical and population-based studies are key to the success of this initiative. The need for such organizations was articulated by most of the breakout groups, and they are the highest priority of the Lung Cancer PRG.

—Develop and expand new approaches to the biology and treatment of nicotine addiction and mount studies to explore the differential toxicity of various tobacco products, including so-called "safer" or low-tar cigarettes.

—Facilitate and hasten the evaluation of spiral computed tomography scanning as an effective means of detecting lung cancer early, reversing the current stage distribution at presentation, and reducing mortality from lung cancer.

—Elucidate the contributions of injury, inflammation, and infection to the genesis of lung cancer.

—Design, implement, and study "best practices" in lung cancer management.

—Facilitate and encourage training programs that emphasize multi-disciplinary scientific investigation and state-of-the-art clinical care.

Lung cancer presents a series of unique problems related to the virulence of the cancer itself and the response of the medical, scientific, and lay communities to its devastating impact on society. The lung defines our ability to breathe, and the loss of this capacity is one of the most frightening of all medical symptoms. Because it is a disease primarily of older patients who have smoked, lung cancer's negative impact on breathing compounds the concurrent effects of chronic smoking-related obstructive pulmonary disease and coronary artery disease.

Since peaking in 1984, the U.S. age-adjusted lung cancer incidence has decreased by more than 19 percent in men of all ages combined, with decreases since 1970 exceeding 40 percent among men less than age 55 years. Among women, rates continued to increase until recently and are now showing signs of leveling off. These trends largely reflect changes in smoking prevalence, which began to decline first among men and only later among women. Because 85 to 90 percent of lung cancer is attributable to smoking, lung cancer rates will continue to decline only if smoking prevalence declines further.

The scope of the problem, however, remains enormous:

Lung cancer is the leading cause of cancer death for both men and women and kills more patients than the next five most common cancers combined. Fully 85 percent of patients who develop lung cancer die from it.

In 2001, an estimated 169,500 Americans will be diagnosed with lung cancer. Lung cancer represents 13 percent of all incident cancers annually in the United States and 29 percent of all cancer deaths.

Although lung cancer mortality rates began to decline in 1990 for men (about 1.7 percent per year) and the 1-year relative survival rate for lung cancer overall has increased from 34 percent in 1975 to 41 percent in 1996, mortality rates for women continued to increase at least until 1998.

Since the 1980s, more women have died from lung cancer than from breast cancer-previously the major cause of cancer deaths in women.

Even patients with the earliest surgical stage (T1N0) have disseminated disease between 15 and 30 percent of the time.

Although the link to tobacco is the clearest etiologic relationship for a human cancer, the development of lung cancer in persons who have never smoked and in former smokers and the failure of the majority of heavy smokers to develop the disease are poorly understood. The complex inter-relationships among genetic, molecular, and other biologic processes in modulating the carcinogenic response to tobacco smoke need to be further explored.

Chemotherapy, surgery, and radiation therapy have had a modest effect on patient outcomes, but these are more often expressed as improvements in "time to progression" or short-term survival than as overall survival. The mechanisms of resistance to drug and radiation therapy are poorly understood.

Despite significant progress, the molecular events underlying the development of lung cancer are largely unknown.

No chemopreventive agent has been shown to be effective in the prevention of lung cancer, and there is often brisk debate about whether there are any proven means of diagnosing lung cancer early.

If the disease itself were not malignant enough, we

as scientists, clinicians, patients, and lay people have made the problem worse:

We have allowed a "blame the victim" mentality to permeate our dealings with those who contract the illness through their smoking behaviors, denying them, in the process, much of the social support we routinely provide for patients with other cancer diagnoses. This has hindered the development of effective, broadly based advocacy efforts.

We have allowed a pervasive sense of "therapeutic nihilism" to dominate the public and scientific discussion of lung cancer. The small (2 to 4 percent) changes in time to progression and survival that we frequently celebrate for patients with other cancers tend to be dismissed as irrelevant when we observe them in lung cancer trials.

Our health care system is poorly organized to deal with lung cancer, leaving surgeons, radiotherapists, medical oncologists, pulmonologists, diagnostic radiologists, and pathologists working in completely separate clinical settings. This has resulted in suboptimal patterns of referral and staging in most communities and many academic centers.

This "Balkanization" of the health care delivery system for patients with lung cancer results, in large measure, from the nature and content of the discipline-based training programs. For example, the emphasis on cardiac surgery in most cardiothoracic training programs over the past two decades has left us with only a few hundred "general" thoracic surgeons who are skilled in, and committed to, the unique issues surrounding surgery for lung cancer. The concepts of multi-disciplinary care and interdisciplinary respect are given insufficient attention in many, if not most, training programs. We have funded lung cancer research far below the levels that characterize other common malignancies and far out of proportion to its massive public health impact. Support for lung cancer research has been insufficient, given that lung cancer is the leading cause of cancer mortality. There are few non-NCI sources of funding, whether Federal or non-Federal, to buttress NCI spending on lung cancer.

There is no question that smoking has had an enormous negative impact on the health of the nation and that reducing tobacco use is one of our highest public health priorities. It is imperative that we enhance our understanding of smoking prevention and treatment, the effects of exposure to tobacco smoke, and tobacco-related carcinogenesis. On the other hand, even if we were to be successful in eradicating smoking today, we would still have decades of lung cancer to treat among former smokers. Therefore, it is also imperative that we continue to explore new treatment strategies and approaches to improve survival in patients who develop lung cancer. We must also continue to enhance our understanding of the biology of lung cancer so that these findings can be brought to bear on improving our diagnostic, preventive, and therapeutic approaches to lung cancer.

Top-Priority Recommendations

It is important to note that the following recommendations are all considered major priorities of the Lung Cancer PRG. The order in which they are presented does not represent a priority ranking.

Cross-Disciplinary Lung Cancer Consortia: Foster the creation of scientifically integrated, multi-disciplinary, multi-institutional research consortia organized around the problem of lung cancer rather than around specific research disciplines. The support and development of dedicated academic investigators who speak a common language across basic science, translational science, and clinical and population-based studies are key to the success of this initiative. The need for such organizations was articulated by most of the Roundtable breakout groups, and the formation of these groups is one of the highest priorities of the Lung Cancer PRG.

The Roundtable breakout groups all recognized the growing inability of lung cancer clinicians to participate meaningfully in translational and clinical research, given the fiscal constraints at most major medical centers. Furthermore, each area of research focus at NCI and the American Cancer Society currently has its own study group to advance knowledge within a discipline or to translate it to the clinical setting. The result is that lung cancer clinicians and researchers work in relative isolation and are dissipated across multiple research groups; no "critical mass" of scientific experts working together exists to conduct the large-scale research studies and clinical trials that are currently needed.

The PRG envisions the creation of formal, funded Lung Cancer Consortia using the existing Lung Cancer SPOREs as core or affiliate members. The membership of the LCC could also include other interested collaborators from NCI initiatives, such as the Director's Challenge, Early Detection Research Network, and Mouse Models Consortium, as well as other institutions at which the study, treatment, and prevention of lung cancer are a priority. The Lung Cancer SPOREs currently collaborate with one another on a variety of basic and translational research initiatives; the LCC would extend this focus to clinical, behavioral, and population-based research. In organization and activity, the LCC would closely resemble the former NCI-sponsored Lung Cancer Study Group, which was active from 1977 to 1988 and brought together thoracic surgeons, radiation and medical oncologists, pathologists, radiologists, pulmonologists, and basic scientists, all of whom contributed their expertise to the problem of lung cancer.

Tobacco Control: Develop and expand new approaches to the biology and treatment of nicotine addiction and mount studies to explore the differential toxicity of various tobacco and nicotine products, including cigarettes that purport to reduce tobacco toxin exposure (so-called "safer" or low-tar cigarettes).

Continue and systematically evaluate population-based tobacco control efforts currently in progress or planned. Expanding the use of existing guidelines and developing new approaches to both smoking cessation and relapse prevention are of the highest priority. The PRG also encourages the adoption and implementation of these guidelines in lung cancer prevention, screening, and treatment trials.

Early Detection: Facilitate and hasten the evaluation of spiral computed tomography scanning to detect lung cancer at an early stage, reverse the current stage distribution at presentation, and reduce mortality from lung cancer. This will necessitate creation of a comprehensive lung cancer infrastructure that includes sharing of specimens and clinical and epidemiologic data to further our understanding of the pathobiology of the small or early lesions detected by this technology.

Understanding of Lung Carcinogenesis: Elucidate the contributions of injury, inflammation, and infection to the genesis of lung cancer. Investigators of different disciplines need to work together to outline the specific cellular steps that underlie epithelial development in the airways during embryogenesis and during cell renewal in the normal adult lung. There is a need to study molecular mediators that drive the chronic pulmonary injury process and to develop the best model systems to study these interactions. NCI should bring together investigators from other institutes at NIH to address these emerging issues.

Outcomes: Design, implement, and study "best practices" in lung cancer management. The extent to which "best practices" (e.g., lobectomy as opposed to pneumonectomy; chemotherapy plus radiation for locally advanced disease) are employed is unclear. The extent to which existing guidelines (e.g., National Comprehensive Cancer Network) are in practice in the community at large is unknown. Expansion of the CanCORS program would allow a common data set on which to validate new measures of quality care and to evaluate novel programs of service delivery.

Training Programs: Facilitate and encourage training programs that emphasize multi-disciplinary science and clinical care. As noted earlier, discipline-based training programs rarely address true multi-disciplinary science and clinical care. Given the exigencies of discipline-based compensation, it is unlikely that the current training paradigms will change unless funding is specifically directed to address this problem.

Early and mid-career programs for training in lung cancer care and research need to be expanded and innovative designs encouraged through grant and contract mechanisms. As techniques for early detection and prevention are developed, it will be critical to educate primary care physicians, lung-oriented specialists, and other health care professionals.

Professional Societies:

Young Elected ACS President, Von Eschenbach Pres-Elect

Robert Young, president of Fox Chase Cancer Center in Philadelphia, was elected president of the American Cancer Society at the society's annual meeting Nov. 3, in Anaheim, Ca.

Young, a medical oncologist specializing in the treatment of lymphoma and ovarian cancer, also serves on the NCI Board of Scientific Advisors and is past-president of the Board of the National Comprehensive Cancer Network. He is past-president of the American Society of Clinical Oncology and past-president of the International Gynecologic Cancer Society. He is also a member of the American Society of Clinical Investigation.

Young succeeds Dileep Bal, chief of the Cancer Control Branch in the California Department of Health Services.

H. Fred Mickelson, of Newberg, Ore., was elected chairman of the board. Mickelson has been an ACS volunteer for more than 30 years, serving as chairman at the local and national levels, including chairman of the board of the California Division. He is a nationally certified arbitrator and mediator. Mickelson succeeds John Baity, a senior partner in the New York-based law firm of Milbank, Tweed, Hadley & McCloy.

Andrew von Eschenbach was elected president-elect of the society. He is professor of urology, special assistant for external affairs, and director of the Program Center–Genitourinary Cancer at the University of Texas M.D. Anderson Cancer Center in Houston. He has been an ACS volunteer for more than 20 years and is a member of the National Dialogue on Cancer.

Other officers elected were: Chairman-elect, David Zacks; Vice-chairman, Gary Streit; First vice-president, Mary Simmonds; Second vice-president, Ralph Vance. Lay officers include treasurer Jean McGill and secretary Thomas Burish.

The society elected four new members to its Board of Directors: Linda Jasper, elected by the Eastern Division; Laurie Storey-Manseau, elected by the New England Division; Donald Anthony, elected by the Ohio Division; and Elizabeth Terrell Hobgood Fontham, elected by the Mid-South Division.

Reginald Ho received the society's Humanitarian Award at the annual meeting for his dedication to the improvement of cancer control. Ho is an oncologist

and clinical professor of medicine at the Straub Clinic and Hospital in Honolulu. He served as ACS president in 1992-93.

ACS presented its Distinguished Service Awards recognizing major accomplishments in cancer to Donald Coffey and Irvin Fleming.

Coffey is professor of oncology, pathology, pharmacology, and molecular sciences, and director of the Research Laboratories of the Urology Department at Johns Hopkins University. He is president-elect of the National Coalition for Cancer Research.

Fleming is professor of surgical oncology at University of Tennessee College of Medicine and medical director of the Methodist Healthcare Cancer Center in Memphis. He was president of the society in 1993-94.

Funding Opportunities:

RFA Available

RFA-AT-02-001: The Placebo Effect in Clinical Practice

Letter of Intent Receipt Date: March 1, 2002

Application Receipt Date: April 11, 2002

National Center for Complementary and Alternative Medicine, John E. Fogarty International Center, National Heart, Lung, and Blood Institute, National Institute on Aging, National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Dental and Craniofacial Research, National Institute of Diabetes and Digestive and Kidney Diseases and National Institute of Mental Health invite applications for investigator-initiated research investigations on how placebos and placebo effects impact on clinical practice. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-AT-02-001.html.

Inquiries: Nancy Pearson, program officer, National Center for Complementary and Alternative Medicine, 6707 Democracy Blvd., Democracy 2, Rm 106, MSC 5475, Bethesda, MD 20892, phone 301-594-0519; fax 301-480-3621; e-mail pearsonn@mail.nih.gov.

Program Announcement

PA: Colorectal Cancer Screening in Primary Care Practice

The PA solicits exploratory/developmental research supporting efforts in primary care practice to develop the capability for gathering patient, provider, practice, and clinical data and/or conducting interventions to assess and enhance colorectal cancer screening delivery, utilization, and outcomes. Priority will be given to applications involving 10 or more physician practices; that have access to large, diverse, or underserved population groups; in which there are established referral linkages to specialty practices (i.e., gastroenterologists, surgeons, or diagnostic radiologists); and in which clinical sites have the ability to collect data electronically.

Examples of research aims are: 1. Developing interventions, mechanisms, or systems for monitoring the completion of and improving compliance with colorectal cancer screening and follow-up. 2. Evaluating screening utilization and the efficiency and effectiveness of screening delivery in community practice, including: (a) screening and compliance rates; (b) time to completion of recommended procedures; (c) procedure quality; (d) adverse events. 3. Determining the performance characteristics (i.e., sensitivity, specificity, and predictive value) of colorectal cancer screening tests as implemented in community practice. 4. Identifying factors that may influence performance characteristics for colorectal cancer screening procedures in community practice. 5. Piloting or refining theories that could inform future interventions to enhance colorectal cancer screening utilization that consider diverse populations and primary care settings. 6. Evaluating how risk for colorectal cancer is assessed in the primary care setting and proposing strategies to improve patient decision-making regarding colorectal cancer screening options. The PA is available at http://deainfo.nci.nih.gov/concepts/TPA-02-015.htm.

Inquiries: Carrie Klabunde, Applied Research Program, NCI, phone 301-402-3362; e-mail ck97b@nih.gov

Other Funding Notices

Pre-Application Meeting for the Cooperative Planning Grant for Cancer Disparities Research Partnership RFA CA-02-002

The Radiation Research Program of the Division of Cancer Treatment and Diagnosis will hold a pre-application informational meeting on Jan. 14, 2002, 9:00 a.m. – 1 p.m., Hyatt Regency Bethesda, MD, One Bethesda Metro Center, Wisconsin Ave. and Old Georgetown Rd., Bethesda, Maryland 20814.

The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/rfa-ca-02-002.html.

A transcript will be posted at http://www.nci.nih.gov/rrp/opps.htm.

Inquiries: Frank Govern, program scientist, Radiation Research Program, DCTD, NCI, NIH, Executive Plaza North, 6130 Executive Blvd., Rockville, MD 20892-7399; e-mail governfr@mail.nih.gov; voice 301-496-6111; fax 301-480-5785, or Rosemary Wong, program director, (same address as Govern), e-mail wongr@mail.nih.gov; voice 301-496-9360; fax 301-480-5785.

In Brief:

Detroit's "Dr. Vee" Honored For 50 Years In Medicine

(Continued from page 1)

VAINUTIS VAITKEVICIUS, interim president/CEO of the Barbara Ann Karmanos Cancer Institute, will be honored by friends, families, colleagues, and patients, at a gathering Nov. 16 in Dearborn, Mich., to celebrate his 50 years in medicine. Thirty-five years ago, "Dr. Vee," as he is known among colleagues and cancer survivors, began clinical trials that led to a multidisciplinary approach in the treatment of cancer. He "is a legend in the United States' war on cancer," said **Alan Rabson**, acting NCI director. "He is without a doubt one of our country's most ardent and insightful investigators." In 1995, when **Peter Karmanos Jr.** donated $15 million to form the Karmanos center, Vaitkevicius worked to unify Detroit cancer services—the Michigan Cancer Foundation, the Meyer L. Prentis Comprehensive Cancer Center of Metropolitan Detroit, the Detroit Medical Center, Harper Hospital and Wayne State University. . . . **JOHNS HOPKINS** scientists have been awarded over $2.1 million with the first distribution of funds from Johns Hopkins' share of Maryland's settlement with cigarette manufacturers. With money from the Cigarette Restitution Fund, Hopkins will conduct community-focused research in lung, breast, cervical, skin, colon, oral and prostate cancer. A full list of the first round of Johns Hopkins CRF Research Grants is posted at http://www.hopkinscancercenter.org/news/crfgrants.cfm. Hopkins will receive $2.25 million this year. The next distribution of $3 million for translational research grants is anticipated in 2002 and 2003. The CRF also provides Hopkins and the University of Maryland each an additional $1.5 million public health grant this year for the development of community-based cancer prevention and screening programs in collaboration with Sinai Hospital and the Baltimore City Health Department. . . . **SUSAN BRAUN** and the Susan B. Komen Foundation received the 2001 Frances Williams Preston Award for breast cancer awareness, outreach and advocacy, from the Vanderbilt-Ingram Cancer Center. The award is named for **Frances Williams Preston**, president and CEO of music rights organization BMI, and president of the board of the T.J. Martell Foundation for Leukemia, Cancer and AIDS Research. Braun has been president and CEO of the foundation since 1996. . . . **UNIVERSITY OF PITTSBURGH** has established the Center for Healthy Aging at its Graduate School of Public Health through a grant from the Centers of Disease Control and Prevention. It is one of only two CDC prevention centers to focus on aging and will serve as the regional hub of information and training for health professionals. Areas of emphasis include hypertension, diabetes, cholesterol management, osteoporosis and cancer screenings, proper immunizations, dementia, depression, exercise, nutrition, smoking cessation and social integration, said **Lewis Kuller**, professor and chairman, Department of Epidemiology, and principal investigator. The center will conduct a clinical trial to evaluate the efficacy of enhanced methods of delivering preventive medical care, and develop professional health education programs in geriatric preventive medicine. In addition to the GSPH, the following groups are involved in the center: UP School of Medicine, departments of geriatric medicine and psychiatry; UP School of Dental Medicine; UP School of Nursing, Center for Chronic Diseases; UP Cancer Institute; the Allegheny County Health Department; Pennsylvania Health Department; United Way; Area Agency on Aging; and other community health agencies. . . . **BARBARA McCLINTOCK**, a 1983 Nobel laureate for her genetic study of maize at the cellular level, will be the seventh scientist and first woman added to the National Library of Medicine Profiles in Science Web site (http://www.profiles.nlm.nih.gov). The National Library of Medicine is collaborating with the American Philosophical Society, the repository for the McClintock papers, on the project. . . . **JOANNE HAMBLETON**, director of nursing and patient services and assistant director of nursing at Fox Chase Cancer Center, was appointed vice president of nursing and patient services. . . . **PCN FOUNDATION INNOVATION AWARD** was presented to University of Pittsburgh School of Medicine researchers **Shi-Yuan Cheng**, assistant professor of pathology and **Xiao Xiao**, assistant professor of molecular genetics and biochemistry for brain cancer research. The award consists of a $150,000 grant to be divided over the next three years to fund a different individual investigator or team of investigators at UPCI each year. Cheng and Xiao will receive $40,000 for their study of gene therapy for gliomas. PCN is a corporate foundation based in Pittsburgh. . . . **CAROLYN OAKLEY** was appointed HHS regional representative for the Pacific Northwest. Oakley was the 36th district state representative in the Oregon House of Representatives.

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